

European Commission



Draft Renewal Assessment Report prepared according to the Commission

Regulation (EU) N° 1107/2009

FLUFENACET

Volume 1

Rapporteur Member State: Poland

Co-Rapporteur Member State: France

Version History

When	What
August 1997	Initial assessment. Draft Assessment Report for first inclusion to Annex I. RMS: FR
April 2016	Draft Renewal Assessment Report prepared according to the Commission; Regulation (EU) N° 1107/2009; RMS: PL; Co-RMS: FR
May 2017	Revision according to the CoRMS comments

Table of content

1. <u>STATEMENT OF SUBJECT MATTER AND PURPOSE FOR WHICH THIS REPORT HAS BEEN PREPARED AND BACKGROUND INFORMATION ON THE APPLICATION</u>	8
1.1. CONTEXT IN WHICH THIS DRAFT ASSESSMENT REPORT WAS PREPARED	8
1.1.1. Purpose for which the draft assessment report was prepared.....	8
1.1.2. Arrangements between rapporteur Member State and co-rapporteur Member State	8
1.1.3. EU Regulatory history for use in Plant Protection Products	8
1.2.1. Name and address of applicant(s) for approval of the active substance	9
1.2.2. Producer or producers of the active substance.....	9
1.2.3. Information relating to the collective provision of dossiers	9
1.3. IDENTITY OF THE ACTIVE SUBSTANCE	9
1.3.1. Common name proposed or ISO- accepted and synonyms.....	9
1.3.2. Chemical name (IUPAC and CA nomenclature)	9
1.3.3. Producer's development code number	10
1.3.4. CAS, EEC and CIPAC numbers	10
1.3.5. Molecular and structural formula, molecular mass	10
1.3.6. Method of manufacture (synthesis pathway) of the active substance	10
1.3.7. Specification of purity of the active substance in g/kg.....	10
1.3.8. Identity and content of additives (such as stabilisers) and impurities.....	10
1.3.9. Analytical profile of batches	10
1.4. INFORMATION ON THE PLANT PROTECTION PRODUCT.....	11
1.4.1. Applicant	11
1.4.2. Producer of the plant protection product.....	11
1.4.3. Trade name or proposed trade name and producer's development code number of the plant protection product.....	11
1.4.4. detailed quantitative and qualitative information on the composition of the plant protection product	11
1.4.4.1. Composition of the plant protection product.....	12
1.4.4.2. Information on the active substances	12
1.4.4.3. Information on safeners, synergists and co-formulants.....	12
1.4.5. Type and code of the plant protection product	12
1.4.6. Function	12
1.4.7. Field of use envisaged	12
1.4.8. Effects on harmful organisms.....	12
1.5. DETAILED USES OF THE PLANT PROTECTION PRODUCT	13
1.5.2. Further information on representative uses	17
1.5.3. Details of other uses applied for to support the setting of MRLs for uses beyond the representative uses.....	17
1.5.4. Overview on authorizations in EU Member States.....	18
2. <u>SUMMARY OF ACTIVE SUBSTANCE HAZARD AND OF PRODUCT RISK ASSESSMENT</u>	30
2.1. IDENTITY	30
2.2. PHYSICAL AND CHEMICAL PROPERTIES	30
2.2.1. Summary of physical and chemical properties of the active substance ..	30
2.2.2. Summary of physical and chemical properties of the plant protection product	30
2.3. DATA ON APPLICATION AND EFFICACY	30

2.3.1. Summary of effectiveness	30
2.3.2. Summary of information on the development of resistance.....	31
2.3.3. Summary of adverse effects on treated crops.....	31
2.3.4. Summary of observations on other undesirable or unintended side-effects	31
2.4. FURTHER INFORMATION	31
2.4.1. Summary of methods and precautions concerning handling, storage, transport or fire	31
2.4.2. Summary of procedures for destruction or decontamination	32
2.4.3. Summary of emergency measures in case of an accident	32
2.5. METHODS OF ANALYSIS	33
2.5.1. Methods used for the generation of pre-authorisation data.....	33
2.5.2. Methods for post control and monitoring purposes	33
2.6. EFFECTS ON HUMAN AND ANIMAL HEALTH	34
2.6.1. Summary of absorption, distribution and excretion in mammals	34
2.6.2. Summary of acute toxicity	34
2.6.3. Summary of short-term toxicity	35
2.6.4. Summary of genotoxicity	36
2.6.5. Summary of long-term toxicity and carcinogenicity.....	38
2.6.6. Summary of reproductive toxicity.....	38
2.6.7. Summary of neurotoxicity.....	39
2.6.8. Summary of further toxicological studies on the active substance	40
2.6.9. Summary of toxicological data on impurities and metabolites	40
2.6.10. Summary of medical data and information	41
2.6.11. Toxicological end point for assessment of risk following long-term dietary exposure – ADI.....	42
2.6.12. Toxicological end point for assessment of risk following acute dietary exposure - ARfD (acute reference dose)	43
2.6.13. Toxicological end point for assessment of occupational, bystander and residents risks – AOEL	43
2.6.14. Summary of product exposure and risk assessment	43
2.7. RESIDUES	45
2.7.1. Summary of storage stability of residues.....	45
2.7.1.1. Plant matrices	45
2.7.1.2. Animal matrices	45
2.7.2. Summary of metabolism, distribution and expression of residues in plants, poultry, lactating ruminants, pigs and fish	45
2.7.2.1. Plant matrices	45
2.7.2.2. Animal matrices	46
2.7.3. Definition of the residue.....	47
2.7.4. Summary of residue trials in plants and identification of critical GAP....	48
2.7.5. Summary of feeding studies in poultry, ruminants, pigs and fish.....	49
2.7.6. Summary of effects of processing	50
2.7.7. Summary of residues in rotational crops	51
2.7.8. Summary of other studies.....	52
2.7.9. Estimation of the potential and actual exposure through diet and other sources.....	52
2.7.10. Proposed MRLs and compliance with existing MRLs	56
2.7.11. Proposed import tolerances and compliance with existing import tolerances.....	61
2.8. FATE AND BEHAVIOUR IN THE ENVIRONMENT	61
2.8.1. Summary of fate and behaviour in soil	64
2.8.2. Summary of fate and behaviour in water and sediment.....	103

2.8.3. Summary of fate and behaviour in air	112
2.8.4. Summary of monitoring data concerning fate and behaviour of the active substance, metabolites, degradation and reaction products	115
2.8.5. Definition of the residues in the environment requiring further assessment	118
2.8.6. Summary of exposure calculations and product assessment.....	119
2.9. EFFECTS ON NON-TARGET SPECIES	142
2.9.1. Summary of effects on birds and other terrestrial vertebrates.....	142
2.9.2. Summary of effects on aquatic organisms	144
2.9.3. Summary of effects on arthropods	149
2.9.4. Summary of effects on non-target soil meso- and macrofauna.....	151
2.9.5. Summary of effects on soil nitrogen transformation.....	153
2.9.6. Summary of effects on terrestrial non-target higher plants.....	153
2.9.7. Summary of effects on other terrestrial organisms (flora and fauna)....	154
2.9.8. Summary of effects on biological methods for sewage treatment	154
2.9.9. Summary of product exposure and risk assessment	154
2.10. CLASSIFICATION AND LABELLING	217
2.11. RELEVANCE OF METABOLITES IN GROUNDWATER	221
2.12. CONSIDERATION OF ISOMERIC COMPOSITION IN THE RISK ASSESSMENT	223
2.12.1. Identity and physical chemical properties	223
2.12.2. Methods of analysis.....	223
2.12.3. Mammalian toxicity	223
2.12.4. Operator, Worker, Bystander and Resident exposure	223
2.12.5. Residues and Consumer risk assessment	223
2.12.6. Environmental fate	223
2.12.7. Ecotoxicology	223
2.13. RESIDUE DEFINITIONS	224
2.13.1. Definition of residues for exposure/risk assessment	224
2.13.2. Definition of residues for monitoring	225
3. <u>PROPOSED DECISION WITH RESPECT TO THE APPLICATION</u>	227
3.1. BACKGROUND TO THE PROPOSED DECISION.....	227
3.1.1. Proposal on acceptability against the approval criteria – Article 4 and annex II of regulation (EC) No 1107/2009	227
3.1.2. Proposal – Candidate for substitution	252
3.1.3. Proposal – Low risk active substance.....	254
3.1.4. List of studies to be generated, still ongoing or available but not peer reviewed.....	255
3.1.5. Issues that could not be finalized	258
3.1.6. Critical areas of concern.....	259
3.1.7. Overview table of the concerns identified for each representative use considered	259
3.1.8. Area(s) where expert consultation is considered necessary	261
3.1.9. Critical issues on which the Co RMS did not agree with the assessment by the RMS	261
3.2. PROPOSED DECISION	262
3.3. RATIONAL FOR THE CONDITIONS AND RESTRICTIONS TO BE ASSOCIATED WITH THE APPROVAL OR AUTHORISATION(S), AS APPROPRIATE	262
3.3.1. Particular conditions proposed to be taken into account to manage the risks identified.....	262
APPENDIX 1. GUIDANCE DOCUMENTS USED IN THIS ASSESSEMENT.....	267
APPENDIX 2. REFERENCE LIST	275

APPENDIX 3. CONSUMER RISK ASSESSMENT.....	276
---	-----

Level 1

FLUFENACET

1. STATEMENT OF SUBJECT MATTER AND PURPOSE FOR WHICH THIS REPORT HAS BEEN PREPARED AND BACKGROUND INFORMATION ON THE APPLICATION

1.1. CONTEXT IN WHICH THIS DRAFT ASSESSMENT REPORT WAS PREPARED

1.1.1. Purpose for which the draft assessment report was prepared

This Draft Renewal Assessment Report (DRAR) is prepared for the renewal of the approval of the active substance Flufenacet. Flufenacet is part of the AIR3 renewal programme for active substances (Commission Implementing Regulation (EU) No 844/2012).

The dossier for the chemical active substance is supported by Diflufenican + Flufenacet SC 600 (200+400 g/L) Plant Protection Product dossier. Trade names for the formulation vary in different countries, but in most cases the name is Herold.

1.1.2. Arrangements between rapporteur Member State and co-rapporteur Member State

The evaluation was made by RMS Poland and reviewed by co-RMS France for all sections.

1.1.3. EU Regulatory history for use in Plant Protection Products

Flufenacet was originally included in Annex I of Directive 91/414/EEC on 01/01/2004, as notified in Directive 2003/84/EC dated 25 September 2003 wherein there is no specific provision under Part B which needs to be considered related to the metabolism and residue data.

The Monograph prepared by the Rapporteur Member State France in the context of the inclusion of flufenacet in Annex I of the Council Directive 91/414/EEC, the Review Report for flufenacet (7469/VI/98-Final – 3rd July 2003) and the EFSA's Reasoned Opinion on the review of existing maximum residue levels (MRLs) for flufenacet according to Article 12 of Regulation (EC) No 396/2005 (EFSA Journal 2012;10(4):2689) are considered to provide the relevant scientific information for the review of the active substance.

Flufenacet is a selective herbicide used in agriculture as foliar sprays in monocot and dicot crops. It was discovered by Bayer CropScience and developed for use in winter cereals in combination with partner, e.g. Diflufenican in various ratios to control mixed infestation of weeds like *Alopecurus sp.*, *Apera sp.*, *Lolium sp.* or *Poa sp.* as well as broad leaved weeds.

Flufenacet was first authorised in 1998. It has since become widely authorised in European countries including (not exhaustive list) Austria, Belgium, Czech Republic, Estonia, France, Germany, Greece, Ireland, Italy, Latvia, Lithuania, Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Switzerland, United Kingdom. Outside Europe it is authorised for some others uses in United States, Canada, Chile, Peru. Also, it is authorised in African countries such as Kenya, Tanzania and in Asia with China, Israel and India.

Authorisations for a range of different formulations have been achieved in Europe. These include (not exhaustive list) HEROLD SC, KOMPLET SC *etc.*

Apart from cereals, Flufenacet is also used in combination in numbers of crops across the world such as corn, potatoes, pulses, soybeans, tomatoes, asparagus and onions.

The active substance has not been evaluated under other relevant EU-legislations (e.g. biocides, flavourings, food additives, cosmetics).

1.2. APPLICANT INFORMATION

1.2.1. Name and address of applicant(s) for approval of the active substance

Bayer CropScience AG
R&D - Global Regulatory Affairs
Regulatory Affairs Small Molecules
Alfred-Nobel-Str. 50
D-40789 Monheim am Rhein
Germany

Person to contact: [REDACTED]
Telephone No.: [REDACTED]
Telefax No.: [REDACTED]
Email: [REDACTED]

1.2.2. Producer or producers of the active substance

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

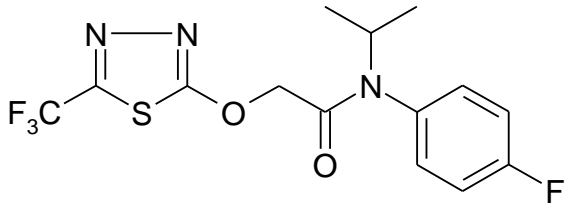
Person to contact: [REDACTED]
Telephone No.: [REDACTED]
Telefax No.: [REDACTED]
Email: [REDACTED]

1.2.3. Information relating to the collective provision of dossiers

Bayer CropScience AG is the only notifier for flufenacet.

1.3. IDENTITY OF THE ACTIVE SUBSTANCE

1.3.1. Common name proposed or ISO-accepted and synonyms	Flufenacet (ISO), no synonyms
1.3.2. Chemical name (IUPAC and CA nomenclature)	
IUPAC	4'-Fluoro- <i>N</i> -isopropyl-2-[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yloxy]acetanilide
CA	<i>N</i> -(4-Fluorophenyl)- <i>N</i> -(1-methylethyl)-2-[[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl]oxy]acetamide

1.3.3. Producer's development code number	FOE 5043 (applicant's code number) AE F133402 (applicant's code number)
1.3.4. CAS, EEC and CIPAC numbers	
CAS	142459-58-3
EC (EINECS/ELINCS)	Not allocated
CIPAC	588
EU index number	613-164-00-9
1.3.5. Molecular and structural formula, molecular mass	
Molecular formula	C ₁₄ H ₁₃ F ₄ N ₃ O ₂ S
Structural formula	
Molecular mass	363.34 g/mol
1.3.6. Method of manufacture (synthesis pathway) of the active substance	CONFIDENTIAL information - data provided separately in Volume 4
1.3.7. Specification of purity of the active substance in g/kg	970 g/kg 950 g/kg accepted in the initial DAR
1.3.8. Identity and content of additives (such as stabilisers) and impurities	
<i>1.3.8.1. Additives</i>	CONFIDENTIAL information - data provided separately in Volume 4
<i>1.3.8.2. Significant impurities</i>	CONFIDENTIAL information - data provided separately in Volume 4
<i>1.3.8.3. Relevant impurities</i>	The active substance as manufactured does not contain any impurities requiring toxicological / ecotoxicological relevance (e.g. nitrosamines, hexachlorobenzene, hydrazines, halogenated dibenzodioxins and halogenated dibenzofurans, polychlorinated biphenyls, oxygen analogs of organophosphates).
1.3.9. Analytical profile of batches	CONFIDENTIAL information - data provided separately in Volume 4

1.4. INFORMATION ON THE PLANT PROTECTION PRODUCT

1.4.1. Applicant	Bayer CropScience AG R&D - Global Regulatory Affairs Regulatory Affairs Small Molecules Alfred-Nobel-Str. 50 D-40789 Monheim am Rhein Germany Person to contact: [REDACTED] Telephone No.: [REDACTED] Telefax No.: [REDACTED] Email: [REDACTED]
1.4.2. Producer of the plant protection product	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] Contact: As applicant
1.4.3. Trade name or proposed trade name and producer's development code number of the plant protection product	Trade names: Herold SC 600 Fosburi Firebird Expert SC 600 Code numbers: 102000007948 UVP 05700094 FL07205 DFF+FFA SC 600 DFF+FFA SC 600 (200+400) Diflufenican + Flufenacet SC 600 (200+400 g/L)
1.4.4. detailed quantitative and qualitative information on the composition of the plant protection product	

1.4.4.1. Composition of the plant protection product	<p>Declared content in pure:</p> <p>-Diflufenican: 200 g/L</p> <p>-Flufenacet: 400 g/L</p> <p>FAO Limits:</p> <p>-Diflufenican: 188 - 212 g/L</p> <p>-Flufenacet: 380 - 420 g/L</p> <p>Technical content*:</p> <p>-Diflufenican: 206.2 g/L</p> <p>-Flufenacet: 412.4 g/L</p> <p>Technical content**:</p> <p>-Diflufenican: 16.63% w/w</p> <p>-Flufenacet: 33.26% w/w</p> <p>*Based on the minimum of content of the active for registration declared in the Annex II dossiers i.e. 970 g/kg for diflufenican based on dry active substance and 970 g/kg for flufenacet</p> <p>**Based on the density value from the specification $d = 1.24 \text{ g/cm}^3$</p>																								
1.4.4.2. Information on the active substances	<table border="1"> <thead> <tr> <th>Type</th><th>Name/Code Number</th></tr> </thead> <tbody> <tr> <td>ISO common name</td><td>Diflufenican</td></tr> <tr> <td>CAS No</td><td>83164-33-4</td></tr> <tr> <td>EC No</td><td>462</td></tr> <tr> <td>CIPAC No</td><td>616-032-00-9</td></tr> <tr> <td>Salt, ester anion or cation present</td><td>-</td></tr> </tbody> </table> <table border="1"> <thead> <tr> <th>Type</th><th>Name/Code Number</th></tr> </thead> <tbody> <tr> <td>ISO common name</td><td>Flufenacet</td></tr> <tr> <td>CAS No</td><td>142459-58-3</td></tr> <tr> <td>EC No</td><td>462</td></tr> <tr> <td>CIPAC No</td><td>613-164-00-9</td></tr> <tr> <td>Salt, ester anion or cation present</td><td>-</td></tr> </tbody> </table>	Type	Name/Code Number	ISO common name	Diflufenican	CAS No	83164-33-4	EC No	462	CIPAC No	616-032-00-9	Salt, ester anion or cation present	-	Type	Name/Code Number	ISO common name	Flufenacet	CAS No	142459-58-3	EC No	462	CIPAC No	613-164-00-9	Salt, ester anion or cation present	-
Type	Name/Code Number																								
ISO common name	Diflufenican																								
CAS No	83164-33-4																								
EC No	462																								
CIPAC No	616-032-00-9																								
Salt, ester anion or cation present	-																								
Type	Name/Code Number																								
ISO common name	Flufenacet																								
CAS No	142459-58-3																								
EC No	462																								
CIPAC No	613-164-00-9																								
Salt, ester anion or cation present	-																								
1.4.4.3. Information on safeners, synergists and co-formulants	<p>CONFIDENTIAL information - data provided separately in the Confidential Part.</p>																								
1.4.5. Type and code of the plant protection product	<p>Suspension Concentrate (SC)</p>																								
1.4.6. Function	<p>Herbicide</p>																								
1.4.7. Field of use envisaged	<p>Winter cereals</p>																								
1.4.8. Effects on harmful organisms	<p>Inhibits cell division and cell growth in susceptible weeds</p>																								

1.5. DETAILED USES OF THE PLANT PROTECTION PRODUCT

1.5.1. Details of representative uses

Summary of intended uses

PPP (product name/code)	HEROLD	Formulation type:	SC
active substance 1	SC	Conc. of as 1:	200
active substance 2	Diflufenican	Conc. of as 2:	400
safener	Flufenacet	Conc. of safener:	-
synergist	-	Conc. of synergist:	-
Applicant:	Bayer CropScience	professional use	<input checked="" type="checkbox"/>
Zone(s):	Northern Central and southern /EU	non professional use	<input type="checkbox"/>

Crop and/or situation (a)	Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Winter wheat, Winter barley, Winter rye	e.g. Germany	Herold SC	F	Annual dicot weeds, ALOMY, APESV, POAAN	SC	DFF: 200 g/L FFA: 400 g/L	Tractor mounted boom spraying	Post-emergence BBCH 10-13	1	-	DFF: 0.06 – 0.03 FFA: 0.12 – 0.06	200 – 400	DFF: 0.12 FFA: 0.24	n-a.	0.6 L/ha Autumn use only
Winter Wheat, Winter barley	e.g. France	Fosbury	F	Annual dicot weeds, GGGGG, GRA	SC	DFF: 200 g/L 400 g/L	Tractor mounted boom spraying	Post-emergence BBCH 11-13	1	-	DFF: 0.15 – 0.04 FFA: 0.3 – 0.08	80 – 400	DFF: 0.12 FFA: 0.24	n-a.	0.6 L/ha

Crop and/ or situation (a)	Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Winter wheat, Winter barley, Winter rye	e.g. Ireland	Firebird	F	ANTCO, AVEFA, CAPBP, CERSS, GALAP, GGGAN LAMAM, LAMSS, VERHE, VERSS	SC	DFF: 200 g/L FFA: 400 g/L	Tractor mounted boom spraying	Pre- emergence & Post- emergence BBCH 0-22	1	-	DFF: 0.015 – 0.03 FFA: 0.03 – 0.06	200 - 400	DFF: 0.06 FFA: 0.12	n-a.	0.3 L/ha
Wheat, Barley	e.g. Spain	Herold	F	Annual dicot weeds, ALOMY, APESV, POAAN	SC	DFF: 200 g/L FFA: 400 g/L	Tractor mounted boom spraying	Post- emergence BBCH 11-13	1	-	DFF: 0.02 – 0.04 FFA: 0.04 – 0.08	200 - 400	DFF: 0.08 FFA: 0.16	n-a.	0.4 L/ha (Approved in Spain : 0.4 L/ha-0.6 L/ha)

*The representative uses listed above derive from existing registrations or on-going re-registrations e.g. Sweden, United Kingdom.

Flufenacet

Volume 1 – Level 1

Remarks:	(1)	Diflufenican DFF		(h)	Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants
	(2)	Flufenacet FFA			- type of equipment used must be indicated
	(a)	For crops, Codex (or other, e.g. EU) classifications should be used; where relevant,		(i)	g/kg or g/l
	(b)	the use situation should be described (e.g. fumigation of a structure)			
	(b)	Outdoor or field use (F), glasshouse application (G) or indoor application(I)		(j)	Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	(c)	e.g. biting and suckling insects, soil born insects, foliar fungi, weeds			
	(d)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)			
	(e)	GCPF Codes - GIFAP Technical Monograph No 2, 1989		(k)	The minimum and maximum number of application possible under practical conditions of use must be provided
	(f)	All abbreviations used must be explained		(l)	PHI - minimum pre-harvest interval
	(g)	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench		(m)	Remarks may include: Extent of use/economic importance/restriction

1.5.2. Further information on representative uses

Please refer to the GAP table, see point 1.5.1.

1.5.3. Details of other uses applied for to support the setting of MRLs for uses beyond the representative uses

No other uses applied for to support the setting of MRLs beyond the representative uses.

1.5.4. Overview on authorizations in EU Member States

Country			APPLICATION DATA							Target (Weed, Pest, Fungi)
Tradename Composition	Tot. Cont.	FT	Location	Mode // Method	Timing from // Timing to // Period from // Period to	No. per season	Prod. Rate	A. I. Rates in kg/ha	PHI in days	
Crop										
Belgium										
HEROLD SC		SC								
	600 g/l									
flufenacet	400 g/l									
diflufenican	200 g/l									
Barley, winter			Field	Broadcast, overall // Spraying	BBCH11 - First leaf unfolded // BBCH13 - 3 leaves unfolded	1-1	0.6 - 0.6 l/ha	flufenacet: 0.240000 - 0.240000 diflufenican: 0.120000 - 0.120000	Annual broad-leaved plants Gramineae, annual grasses	
Wheat, winter			Field	Broadcast, overall // Spraying	BBCH11 - First leaf unfolded // BBCH13 - 3 leaves unfolded	1-1	0.6 - 0.6 l/ha	flufenacet: 0.240000 - 0.240000 diflufenican: 0.120000 - 0.120000	Annual broad-leaved plants Gramineae, annual grasses	
France										
ANTILOPE		SC								
	600 g/l									
flufenacet	400 g/l									
diflufenican	200 g/l									
Barley, winter			Field	Broadcast, overall // Spraying	BBCH11 - First leaf unfolded // BBCH13 - 3 leaves unfolded // FALL	1-1	0.6 - 0.6 l/ha	flufenacet: 0.240000 - 0.240000 diflufenican: 0.120000 - 0.120000	Gramineae Gramineae Dicotyledonous weed plants	
Wheat, soft			Field	Broadcast, overall // Spraying	BBCH11 - First leaf unfolded //	1-1	0.6 - 0.6 l/ha	flufenacet: 0.240000 -	Gramineae Gramineae	

Country			APPLICATION DATA							Target (Weed, Pest, Fungi)
Tradename Composition	Tot. Cont.	FT	Location	Mode // Method	Timing from // Timing to // Period from // Period to	No. per season	Prod. Rate	A. I. Rates in kg/ha	PHI in days	
Crop										
France										
ANTILOPE		SC			BBCH13 - 3 leaves unfolded // FALL			0.240000 diflufenican: 0.120000 - 0.120000		Dicotyledonous weed plants
FOSBURI		SC								
	600 g/l									
flufenacet	400 g/l									
diflufenican	200 g/l									
Barley, winter			Field	Broadcast, overall // Spraying	BBCH11 - First leaf unfolded // BBCH13 - 3 leaves unfolded // FALL	1-1	0.6 - 0.6 l/ha	flufenacet: 0.240000 - 0.240000 diflufenican: 0.120000 - 0.120000		Gramineae Dicotyledonous weed plants Gramineae
Wheat, soft			Field	Broadcast, overall // Spraying	BBCH11 - First leaf unfolded // BBCH13 - 3 leaves unfolded // FALL	1-1	0.6 - 0.6 l/ha	flufenacet: 0.240000 - 0.240000 diflufenican: 0.120000 - 0.120000		Gramineae Dicotyledonous weed plants Gramineae
Germany										
HEROLD SC		SC								
	600 g/l									
flufenacet	400 g/l									
diflufenican	200 g/l									
Triticale			Field	Broadcast, overall // Spraying	BBCH10 - First leaf through	1-1	- 0.5 l/ha	flufenacet: max. 0.200000		Alopecurus myosuroides HUDS.

Country			APPLICATION DATA							Target (Weed, Pest, Fungi)
Tradename Composition	Tot. Cont.	FT	Location	Mode // Method	Timing from // Timing to // Period from // Period to	No. per season	Prod. Rate	A. I. Rates in kg/ha	PHI in days	
Crop										
Germany										
HEROLD SC		SC								
						coleoptile // BBCH13 - 3 leaves unfolded // FALL // FALL			diflufenican: max. 0.100000	Apera spica-venti Poa annua Dicotyledonous weed plants
Spelt			Field	Broadcast, overall // Spraying	BBCH10 - First leaf through coleoptile // BBCH13 - 3 leaves unfolded // FALL // FALL	1-1	- 0.5 l/ha	flufenacet: max. 0.200000 diflufenican: max. 0.100000		Alopecurus myosuroides HUDS. Apera spica-venti Poa annua Dicotyledonous weed plants
			Field	Broadcast, overall // Spraying	BBCH10 - First leaf through coleoptile // BBCH13 - 3 leaves unfolded // FALL // FALL	1-1	- 0.6 l/ha	flufenacet: max. 0.240000 diflufenican: max. 0.120000		Alopecurus myosuroides HUDS. Apera spica-venti Poa annua Dicotyledonous weed plants
Wheat, winter			Field	Broadcast, overall // Spraying	BBCH10 - First leaf through coleoptile // BBCH13 - 3 leaves unfolded // FALL // FALL	1-1	- 0.5 l/ha	flufenacet: max. 0.200000 diflufenican: max. 0.100000		Alopecurus myosuroides HUDS. Apera spica-venti Poa annua Dicotyledonous weed plants
			Field	Broadcast, overall // Spraying	BBCH00 - Dry seed // BBCH09 - Emergence // FALL // FALL	1-1	- 0.6 l/ha	flufenacet: max. 0.240000 diflufenican: max. 0.120000		Alopecurus myosuroides HUDS. Apera spica-venti Poa annua Dicotyledonous weed plants
			Field	Broadcast, overall // Spraying	BBCH10 - First leaf through coleoptile // BBCH13 - 3 leaves unfolded //	1-1	- 0.6 l/ha	flufenacet: max. 0.240000 diflufenican: max. 0.120000		Alopecurus myosuroides HUDS. Apera spica-venti Poa annua Dicotyledonous weed

Country			APPLICATION DATA							Target (Weed, Pest, Fungi)
Tradename Composition	Tot. Cont.	FT	Location	Mode // Method	Timing from // Timing to // Period from // Period to	No. per season	Prod. Rate	A. I. Rates in kg/ha	PHI in days	
Crop										
Germany										
HEROLD SC		SC								
					FALL // FALL					plants
Barley, winter			Field	Broadcast, overall // Spraying	BBCH10 - First leaf through coleoptile // BBCH13 - 3 leaves unfolded // FALL // FALL	1-1	- 0.5 l/ha	flufenacet: max. 0.200000 diflufenican: max. 0.100000		Alopecurus myosuroides HUDS. Apera spica-venti Poa annua Dicotyledonous weed plants
			Field	Broadcast, overall // Spraying	BBCH00 - Dry seed // BBCH09 - Emergence // FALL // FALL	1-1	- 0.6 l/ha	flufenacet: max. 0.240000 diflufenican: max. 0.120000		Alopecurus myosuroides HUDS. Apera spica-venti Poa annua Dicotyledonous weed plants
			Field	Broadcast, overall // Spraying	BBCH10 - First leaf through coleoptile // BBCH13 - 3 leaves unfolded // FALL // FALL	1-1	- 0.6 l/ha	flufenacet: max. 0.240000 diflufenican: max. 0.120000		Alopecurus myosuroides HUDS. Apera spica-venti Poa annua Dicotyledonous weed plants
Rye, winter			Field	Broadcast, overall // Spraying	BBCH10 - First leaf through coleoptile // BBCH13 - 3 leaves unfolded // FALL // FALL	1-1	- 0.5 l/ha	flufenacet: max. 0.200000 diflufenican: max. 0.100000		Alopecurus myosuroides HUDS. Apera spica-venti Poa annua Dicotyledonous weed plants
			Field	Broadcast, overall // Spraying	BBCH00 - Dry seed // BBCH09 - Emergence // FALL // FALL	1-1	- 0.6 l/ha	flufenacet: max. 0.240000 diflufenican: max. 0.120000		Alopecurus myosuroides HUDS. Apera spica-venti Poa annua Dicotyledonous weed plants
			Field	Broadcast, overall // Spraying	BBCH10 - First leaf through	1-1	- 0.6 l/ha	flufenacet: max. 0.240000		Alopecurus myosuroides HUDS.

Country			APPLICATION DATA							Target (Weed, Pest, Fungi)
Tradename Composition	Tot. Cont.	FT	Location	Mode // Method	Timing from // Timing to // Period from // Period to	No. per season	Prod. Rate	A. I. Rates in kg/ha	PHI in days	
Crop										
Germany										
HEROLD SC	SC				coleoptile // BBCH13 - 3 leaves unfolded // FALL // FALL			diflufenican: max. 0.120000		Apera spica-venti Poa annua Dicotyledonous weed plants
Ireland										
FIREBIRD	SC									
	600 g/l									
flufenacet	400 g/l									
diflufenican	200 g/l									
Wheat, winter			Field	Broadcast, overall // Spraying	BBCH00 - Dry seed // BBCH22 - 2 tillers detectable // DEC	1-1	- 0.3 l/ha	flufenacet: max. 0.120000 diflufenican: max. 0.060000		Anthemis cotula Avena fatua Capsella bursa-pastoris Cerastium sp. Galium aparine Gramineae, annual grasses Lamium amplexicaule Lamium L. spec. Veronica hederifolia LINNAEUS Veronica L. spec. Viola tricolor ssp. tricolor
Barley, winter			Field	Broadcast, overall // Spraying	BBCH00 - Dry seed // BBCH23 - 3 tillers detectable // DEC	1-1	- 0.3 l/ha	flufenacet: max. 0.120000 diflufenican: max. 0.060000		Anthemis cotula Avena fatua Capsella bursa-pastoris Cerastium sp. Galium aparine Gramineae, annual grasses

Country		APPLICATION DATA						Target (Weed, Pest, Fungi)		
Tradename Composition	Tot. Cont. FT	Location	Mode // Method	Timing from // Timing to // Period from // Period to	No. per season	Prod. Rate	A. I. Rates in kg/ha		PHI in days	
Crop										
Ireland										
FIREBIRD	SC								Lamium amplexicaule Lamium L. spec. Veronica hederifolia LINNAEUS Veronica L. spec. Viola tricolor ssp. tricolor	
Netherlands										
HEROLD SC	SC									
	600 g/l									
flufenacet	400 g/l									
diflufenican	200 g/l									
Barley, winter		Field	Foliar // Spraying	BBCH11 - First leaf unfolded // BBCH12 - 2 leaves unfolded // SEP // FEB	1-1	0.6 - 0.6 l/ha	flufenacet: 0.240000 - 0.240000 diflufenican: 0.120000 - 0.120000		Annual broad-leaved plants Apera spica-venti Alopecurus myosuroides HUDS.	
Wheat, winter		Field	Soil // Spraying	B 00 (old Code) - Dry seed / Winter dormancy // SEP // FEB	1-1	0.6 - 0.6 l/ha	flufenacet: 0.240000 - 0.240000 diflufenican: 0.120000 - 0.120000		Annual broad-leaved plants Apera spica-venti Alopecurus myosuroides HUDS.	
		Field	Foliar // Spraying	B 11 (old Code) - First true leaf, leaf pair or whorl unfolded // B 12 (old Code) - 2 true leaves, leaf	1-1	0.6 - 0.6 l/ha	flufenacet: 0.240000 - 0.240000 diflufenican: 0.120000 - 0.120000		Annual broad-leaved plants Apera spica-venti Alopecurus myosuroides HUDS.	

Country			APPLICATION DATA							Target (Weed, Pest, Fungi)
Tradename Composition	Tot. Cont.	FT	Location	Mode // Method	Timing from // Timing to // Period from // Period to	No. per season	Prod. Rate	A. I. Rates in kg/ha	PHI in days	
Crop										
Netherlands										
HEROLD SC		SC	pairs or whorls unfolded // SEP // FEB							
Poland										
EXPERT 600 SC		SC								
	600 g/l									
flufenacet	400 g/l									
diflufenican	200 g/l									
Barley, winter			Field	Broadcast, overall // Spraying	Fall (autumn) treatment - at growing stage	1-1	0.25 - 0.35 l/ha	flufenacet: 0.100000 - 0.140000 diflufenican: 0.050000 - 0.070000	Viola arvensis Sinapis arvensis Stellaria media Apera spica-venti Myosotis arvensis (L.) HILL Raphanus raphanistrum L. Capsella bursa-pastoris Thlaspi arvense	
Rye			Field	Broadcast, overall // Spraying	Fall (autumn) treatment - at growing stage	1-1	0.25 - 0.35 l/ha	flufenacet: 0.100000 - 0.140000 diflufenican: 0.050000 - 0.070000	Viola arvensis Sinapis arvensis Stellaria media Apera spica-venti Myosotis arvensis (L.) HILL Raphanus raphanistrum L. Capsella bursa-pastoris Thlaspi arvense	
Wheat, winter			Field	Broadcast, overall //	Fall (autumn)	1-1	0.25 - 0.35 l/ha	flufenacet:	Viola arvensis	

Country			APPLICATION DATA							Target (Weed, Pest, Fungi)
Tradename Composition	Tot. Cont.	FT	Location	Mode // Method	Timing from // Timing to // Period from // Period to	No. per season	Prod. Rate	A. I. Rates in kg/ha	PHI in days	
Crop										
Poland										
EXPERT 600 SC	SC			Spraying	treatment - at growing stage			0.100000 - 0.140000 diflufenican: 0.050000 - 0.070000		Sinapis arvensis Stellaria media Apera spica-venti Myosotis arvensis (L.) HILL Raphanus raphanistrum L. Capsella bursa-pastoris Thlaspi arvense
Triticale, winter triticales			Field	Broadcast, overall // Spraying	Fall (autumn) treatment - at growing stage	1-1	0.25 - 0.35 l/ha	flufenacet: 0.100000 - 0.140000 diflufenican: 0.050000 - 0.070000		Viola arvensis Sinapis arvensis Stellaria media Apera spica-venti Myosotis arvensis (L.) HILL Raphanus raphanistrum L. Capsella bursa-pastoris Thlaspi arvense
Spain										
HEROLD	SC									
	600 g/l									
flufenacet	400 g/l									
diflufenican	200 g/l									
Barley			Field	Broadcast, overall // Spraying	BBCH11 - First leaf unfolded // BBCH13 - 3 leaves unfolded	1-	0.4 - 0.6 l/ha	flufenacet: 0.160000 - 0.240000 diflufenican: 0.080000 - 0.120000		Weed plants

Country			APPLICATION DATA							Target (Weed, Pest, Fungi)
Tradename Composition	Tot. Cont.	FT	Location	Mode // Method	Timing from // Timing to // Period from // Period to	No. per season	Prod. Rate	A. I. Rates in kg/ha	PHI in days	
Crop										
Spain										
HEROLD		SC								
Wheat, soft			Field	Broadcast, overall // Spraying	BBCH11 - First leaf unfolded // BBCH13 - 3 leaves unfolded	1-	0.4 - 0.6 l/ha	flufenacet: 0.160000 - 0.240000 diflufenican: 0.080000 - 0.120000		Weed plants
United Kingdom										
FIREBIRD		SC								
	600 g/l									
flufenacet	400 g/l									
diflufenican	200 g/l									
Wheat, winter			Field	Broadcast, overall // Spraying	BBCH00 - Dry seed // BBCH22 - 2 tillers detectable // MAR	1-2	- 0.3 l/ha	flufenacet: max. 0.120000 diflufenican: max. 0.060000		Anthemis cotula Avena fatua Capsella bursa-pastoris Cerastium sp. Galium aparine Gramineae, annual grasses Lamium amplexicaule Lamium L. spec. Veronica hederifolia LINNAEUS Veronica L. spec. Viola tricolor ssp. tricolor
Barley, winter			Field	Broadcast, overall // Spraying	BBCH00 - Dry seed // BBCH23 - 3 tillers detectable // MAR	1-2	- 0.3 l/ha	flufenacet: max. 0.120000 diflufenican: max. 0.060000		Anthemis cotula Avena fatua Capsella bursa-pastoris Cerastium sp. Galium aparine

Country			APPLICATION DATA							Target (Weed, Pest, Fungi)
Tradename Composition	Tot. Cont.	FT	Location	Mode // Method	Timing from // Timing to // Period from // Period to	No. per season	Prod. Rate	A. I. Rates in kg/ha	PHI in days	
Crop										
United Kingdom										
FIREBIRD		SC								Gramineae, annual grasses Lamium amplexicaule Lamium L. spec. Veronica hederifolia LINNAEUS Veronica L. spec. Viola tricolor ssp. tricolor
HEROLD		SC								
flufenacet	600 g/l									
diflufenican	400 g/l									
Wheat, winter	200 g/l		Field	Broadcast, overall // Spraying	BBCH00 - Dry seed // BBCH22 - 2 tillers detectable // MAR	1-2	- 0.3 l/ha	flufenacet: max. 0.120000 diflufenican: max. 0.060000		Anthemis cotula Avena fatua Capsella bursa-pastoris Cerastium sp. Galium aparine Gramineae, annual grasses Lamium amplexicaule Lamium L. spec. Veronica hederifolia LINNAEUS Veronica L. spec. Viola tricolor ssp. tricolor
Barley, winter			Field	Broadcast, overall // Spraying	BBCH00 - Dry seed // BBCH23 - 3 tillers detectable // MAR	1-2	- 0.3 l/ha	flufenacet: max. 0.120000 diflufenican: max. 0.060000		Anthemis cotula Avena fatua Capsella bursa-pastoris Cerastium sp. Galium aparine

Country		APPLICATION DATA						Target (Weed, Pest, Fungi)
Tradename Composition	Tot. Cont. FT	Location	Mode // Method	Timing from // Timing to // Period from // Period to	No. per season	Prod. Rate	A. I. Rates in kg/ha	
United Kingdom								

HEROLD

SC

Gramineae, annual
grasses
Lamium amplexicaule
Lamium L. spec.
Veronica hederifolia
LINNAEUS
Veronica L. spec.
Viola tricolor ssp.
tricolor

Level 2

FLUFENACET

2. SUMMARY OF ACTIVE SUBSTANCE HAZARD AND OF PRODUCT RISK ASSESSMENT

2.1. IDENTITY

The identity of flufenacet is summarized in Level 1, point 1.3.

Acceptable information has been submitted to establish both the identity of flufenacet and the representative plant protection product. This includes new data on the technical material.

The manufacturing process has changed to full industrial scale production. The minimum concentration of the active substance in technical flufenacet is set to 970 g/kg based on the new material accountability study. The minimum purity as specified for the first inclusion was 950 g/kg. Some adjustments in the specification for the impurities was introduced.

The active substance as manufactured does not contain any impurities requiring toxicological/ecotoxicological relevance (see Volume 4).

2.2. PHYSICAL AND CHEMICAL PROPERTIES

2.2.1. Summary of physical and chemical properties of the active substance

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

Flufenacet is an oxyacetamide herbicide. Its water solubility is 51 mg/L at pH 6.9 and is not pH dependent in the range of pH 4 - pH 9. Flufenacet has no dissociation constant in the pH-range of pH 1 - 12. Its vapor pressure is not determinable, because of isomerization to Flufenacet-*N*-isomer. The vapour pressure and volatility of Flufenacet-*N*-isomer are very low. Its log Pow of 3.5, not depending on the pH, requires particular consideration with respect to bioconcentration in aquatic organisms. Its flammability, explosive and oxidizing properties are not critical.

2.2.2. Summary of physical and chemical properties of the plant protection product

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

The appearance of the product is that of a whitish liquid with a musty odour. The product is not explosive and has no oxidizing properties. It has a self-ignition temperature of 445 °C. In aqueous solution, it has a pH value of 5.7. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE. Its technical characteristics are acceptable for a SC formulation.

2.3. DATA ON APPLICATION AND EFFICACY

2.3.1. Summary of effectiveness

Flufenacet contained in product HEROLD SC has been tested in field development trials which demonstrated efficacious activity.

2.3.2. Summary of information on the development of resistance

Flufenacet is grouped into the oxyacetamide chemical group. The mode of action is based on the inhibition of the biosynthesis of very long chain fatty acids (VLCFAs) resulting in inhibition of cell division and cell growth (HRAC group: K3). This group of herbicides is quite well known and has been applied commercially for decades without weed resistance development. Hence, no occurrence of resistant weeds has ever been reported during years of commercial application of the oxyacetamid mefenacet in rice, for instance.

2.3.3. Summary of adverse effects on treated crops

In case of difficult growth conditions, the crop may suffer from a treatment with Flufenacet. Selectivity is based on position so that if the crop seed are well covered with soil they might suffer damage in relation with its mode of action. The symptoms observed are yellowing and in more severe case thinning of the crop, recovery is generally good.

2.3.4. Summary of observations on other undesirable or unintended side-effects

Flufenacet being applied early in the growth cycle has no impact on the treated crops and as the active ingredient is tight to the soil no effect on the neighboring crop are to be expected.

2.4. FURTHER INFORMATION

2.4.1. Summary of methods and precautions concerning handling, storage, transport or fire

Precautions for safe handling

Advice on safe handling	Use only in area provided with appropriate exhaust ventilation. Avoid dust formation. For personal protection see section 8.
Advice on protection against fire and explosion	Take measures to prevent the buildup of electrostatic charge. Keep away from heat and sources of ignition. Dust may form explosive mixture in air.
Hygiene measures	Avoid contact with skin, eyes and clothing. Keep working clothes separately. Wash hands immediately after work, if necessary take a shower. Remove soiled clothing immediately and clean thoroughly before using again. Garments that cannot be cleaned must be destroyed (burnt).

Conditions for safe storage

Requirements for storage areas and containers	Keep containers tightly closed in a dry, cool and well-ventilated place. Store in original container. Store in a place accessible by authorized persons only. Keep away from direct sunlight.
Advice on common storage	Keep away from food, drink and animal feedingstuffs.

Transport information

UN number	3077
-----------	------

Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (FLUFENACET)
Transport hazard class(es)	9
Packing group	III
Environm. Hazardous Mark	YES
Hazard no.	90
Tunnel Code	E

Firefighting measures

Extinguishing media

Suitable: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable: High volume water jet

Special hazards arising from the substance or mixture: In the event of fire the following may be released: Hydrogen cyanide (hydrocyanic acid), Hydrogen fluoride, Carbon monoxide (CO), Nitrogen oxides (NOx), Sulphur oxides

2.4.2. Summary of procedures for destruction or decontamination

Product	In accordance with current regulations and, if necessary, after consultation with the site operator and/or with the responsible authority, the product may be taken to a waste disposal site or incineration plant.
Contaminated packaging	Not completely emptied packagings should be disposed of as hazardous waste.
Waste key for the unused product	020108 agrochemical waste containing dangerous substances.

2.4.3. Summary of emergency measures in case of an accident

General advice	Move out of dangerous area. Place and transport victim in stable position (lying sideways). Remove contaminated clothing immediately and dispose of safely.
Inhalation	Move to fresh air. Keep patient warm and at rest. Call a physician or poison control center immediately.
Skin contact	Wash off thoroughly with plenty of soap and water, if available with polyethyleneglycol 400, subsequently rinse with water. If symptoms persist, call a physician.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Get medical attention if irritation develops and persists.
Ingestion	Call a physician or poison control center immediately. Rinse mouth. Induce vomiting only, if: 1. patient is fully conscious, 2. medical aid is not readily available, 3. a significant amount (more than a mouthful) has been ingested and 4. time since ingestion is less than 1 hour. (Vomit should not get into the respiratory tract.)

2.5. METHODS OF ANALYSIS

2.5.1. Methods used for the generation of pre-authorisation data

The HPLC method for the determination of flufenacet in technical grade active substance has been completely validated by checking the parameters linearity, precision, accuracy, specificity and interference. The method was found to be valid and applicable.

In the original Annex II dossier the technique proposed for the determination of flufenacet residues in plant and animal matrices was GC-MS which was based on the conversion of the metabolites to 4-fluoro-*N*-methylethyl benzenamine moiety. The LOQ was 0.05 mg/kg kg and in animal matrices LOQs of 0.01 mg/kg (milk), 0.02 mg/kg (liver) and 0.05 mg/kg for eggs, kidney, muscle and fat were achieved. These analytical methods could be considered as acceptable during the renewal of flufenacet.

In this re-registration process new methods based on the HPLC-MS/MS technologies have been proposed for determination of flufenacet residues (determined as the common moiety 4-fluoro-*N*-isopropylaniline) in plant matrices with LOQ equal to 0.01 mg/kg and in animal matrices with LOQs of 0.01 mg/kg (milk), 0.02 mg/kg (liver) and 0.05 mg/kg for eggs, kidney, muscle and fat.

The procedure for extraction of residues from the matrices remains unchanged compared to old methods. All the new methods have been recognized as acceptable.

2.5.2. Methods for post control and monitoring purposes

In the original Annex II dossier the technique proposed for the determination of flufenacet residues in plant and animal matrices was GC-MS which was based on the conversion of the metabolites to 4-fluoro-*N*-methylethyl benzenamine moiety. The LOQ was 0.05 mg/kg kg and in animal matrices LOQs of 0.01 mg/kg (milk), 0.02 mg/kg (liver) and 0.05 mg/kg for eggs, kidney, muscle and fat were achieved. These analytical methods could be considered as acceptable during the renewal of flufenacet.

In this re-registration process new methods based on the HPLC-MS/MS technologies have been proposed for determination of flufenacet residues in plant matrices with LOQ equal to 0.01 mg/kg and in animal matrices with LOQs of 0.01 mg/kg (milk), 0.02 mg/kg (liver) and 0.05 mg/kg for eggs, kidney, muscle and fat. The procedure for extraction of residues from the matrices remains unchanged compared to old methods. The method for determination of flufenacet residues in soil was based on HPLC-MS/MS technique with LOQ equal to 0.01 mg/kg. The method for determination of flufenacet residues in drinking and surface water was based on HPLC-MS/MS technique with LOQ equal to 0.05 µg/L. The analytical method for the determination of flufenacet in air used the HPLC-UV technique with 230 nm wavelength. However the number of recovery per fortification level and method specificity and breakthrough is missing. Additionally the analytical method of Hellpointner, E.; 2000 can be considered as validated but not highly specific. A confirmatory method is required. Method of Kaussmann, M.; 2016, is considered to be applicable for the determination of flufenacet related residues in human and animal plasma. All methods (with exception of method for air) have been recognized as acceptable.

2.6. EFFECTS ON HUMAN AND ANIMAL HEALTH

2.6.1. Summary of absorption, distribution and excretion in mammals

The biokinetic and metabolism study on rats showed a high degree of absorption of radioactivity followed by fast elimination from the body. After oral administration of [fluorophenyl-UL-¹⁴C]FOE 5043 more than 87 % of the recovered radioactivity was excreted via urine and faeces within 72 hours in all dose groups tested. The plasma curve analysis after dosing of [fluorophenyl-UL-¹⁴C]- and [thiadiazole-2-¹⁴C]-labelled FOE 5043 revealed that only the fluorophenyl part of the molecule underwent enterohepatic circulation. Absorption commenced immediately after administration. The concentration in the different organs and tissues were relatively low and showed only slight differences with respect to dose and sex.

The identification rate ranged from 60 to 75 % of the recovered radioactivity in the experiments with [fluorophenyl-UL-¹⁴C]FOE 5043 and was 92% on average in the experiments with [thiadiazole-2-¹⁴C]FOE 5043. After application of [fluorophenyl-UL-¹⁴C]FOE 5043 all metabolites identified contained only the fluorophenyl moiety of the active ingredient, because the thiadiazole ring was cleaved off prior to further metabolism. This was confirmed by the results obtained after application of [thiadiazole-2-¹⁴C]FOE 5043. The major metabolites were the glucuronic acid of thiadone (M24), the oxalylacetic acid conjugate of thiadone (M26) and free thiadone (M09).

Glutathione conjugation appeared to be the major, and possibly the exclusive, metabolic pathway for [fluorophenyl-UL-¹⁴C]FOE 5043 in rats. Although the glutathione itself was not detected, the presence of a variety of glutathione-derived metabolites provided sufficient evidence for the glutathione pathway. Almost all metabolites identified were glutathione related compounds. The major metabolite in all dose groups was the N-acetylcysteine conjugate of fluorophenylacetanilide (M10).

For a better understanding of the biokinetic behaviour and metabolism of some FOE 5043 plant metabolites, the bioavailability of [fluorophenyl-UL-¹⁴C]FOE 5043-oxalate as well as [thiadiazole-2-¹⁴C]-N-glucoside was investigated after oral administration to rats. Both compounds were excreted unchanged with urine and faeces. Due to the extremely low residues in tissues and carcass, there should be no detectable residues in animal tissues neither from the acetamide moiety nor from the thiadiazole moiety of the molecule from dietary exposure of livestock to FOE 5043-derived crop residues.

An additional metabolism study with [thiadiazole-5-¹⁴C]flufenacet revealed an almost complete excretion of the radiolabel 48 hours after oral administration at a dose level of 1 mg/kg bw. The renal route was the predominant excretion route. Chromatographic profiling of the radioactive residues in the urine yielded a less polar metabolite at a portion of 6.5% of the dose. It was identified as thiadone. An additional very polar metabolite was identified as trifluoroacetate. It amounted to approx. 10% of the oral dose. This metabolite was also identified in the plasma. It can therefore be concluded that the trifluoroacetate metabolite is covered in toxicity studies of the parent substance flufenacet in the rat.

2.6.2. Summary of acute toxicity

Flufenacet was found to have a low to moderate order of acute toxicity when administered orally in mice and rats. Non-specific clinical signs of toxicity were observed on the day of dosing and included ataxia, labored breathing, decreased activity and, lacrimal, nasal, and perianal staining. All deaths occurred on days 0-5. The principal clinical signs in surviving animals resolved within a few days after dosing.

A low order of acute toxicity was demonstrated in acute dermal and inhalation toxicity studies. Clinical signs, but no mortalities, were seen at the limit dose, 2000 mg/kg, in the dermal toxicity study. Four-hour inhalation exposure to a liquid aerosol containing **flufenacet** at a concentration of 3,740 mg/m³ produced clinical symptoms, but no mortalities. Thus, by the routes of exposure relevant to workers, **flufenacet** has a low order of acute toxicity.

Eye and skin irritation studies also demonstrated favorable characteristics. **Flufenacet** is not irritating to skin and essentially non-irritating to eyes. The results of the dermal sensitization study revealed equivocal evidence of allergenic potential. **Both** maximization tests **were** positive; In Magnusson-Kligman test: at 50% challenge concentration the percentage of animals with a skin reaction at 48 and 72 hours was 55% and 60%. In total 13 animals, corresponding to 65%, of the animals showed a skin reaction. At 25% challenge concentration the percentage of animals with a skin reaction at 48 and 72 hours was 60% and 45%. In total 14 animals, corresponding to 70%, of the animals showed a skin reaction. More practice relevant Buehler test was negative **as well as the Local Lymph Node assay on mice. Furthermore, flufenacet does not show a phototoxic potential.**

Table 2.6.2-1 Summary of acute toxicity, irritancy, sensitisation studies and phototoxicity

Acute toxicity of Flufenacet	
Rat LD ₅₀ oral:	Males: 1617 mg/kg bw; Females: 589 mg/kg bw. Acute Tox 4, H302
Rat LD ₅₀ dermal:	>2000 mg/kg bw
Rat LC ₅₀ inhalation:	>3740 mg/m ³
Skin irritation:	Not irritating
Eye irritation:	Not irritating
Skin sensitization:	Skin Sens 1, H317
Phototoxicity	Not phototoxic

2.6.3. Summary of short-term toxicity

Short term oral toxicity of flufenacet was investigated in the rat (90-day toxicity study), in the mouse (90-day toxicity study) and in the dog (90-day and 1-year toxicity studies). In all three species, the main target organs were liver, thyroid, kidney, the hematopoietic and nervous systems indicated by changes in clinical chemistry, organ weights and/or histopathological findings. The comparative species differences in toxicological profile, find the rat and the mice similar in primary and secondary target organs, but a sensitivity of certain cell types was observed in the dog as evidenced by histopathological lesions of vacuoles in the brain after 90-day exposure. After 1-year exposure of flufenacet to dogs minimal to moderate vacuolization of the ciliary body epithelium and cystic vacuolization of the peripheral optic retina was observed and a minimal to moderate axonopathy was noted in the brain, spinal cord and sciatic nerve of dogs. Specialized testing such as computerized electrocardiograms, clinical neurological examinations, and quantitative electroencephalography revealed a number of compound-related effects.

Alterations in circulating serum thyroid hormones thyroxine (T₄) and triiodothyronine (T₃) were observed in each species and were considered indicative of hepatic interference. Primary haematological parameters affected by treatment in each species included changes in erythrocytes, platelets, haemoglobin, and haematocrit concentrations. Histopathological findings generally correlated with alterations in organ weights.

A decrease in body weight gain was observed at higher dose levels only in the 90-day rat study at 191/127 mg/kg bw/day in males/females. There were no meaningful body weight changes in mice and dogs. However, decreased terminal body weights were noted in the 1-year dog study at 62/27 mg/kg bw/day in males/females.

In a subacute dermal toxicity study in rats, findings included a decrease in thyroxine (T₄) and free thyroxine (FT₄) levels, an increase in liver weights, and histopathological findings of the liver. A high-dose recovery group treated similarly with flufenacet demonstrated a complete recovery from all responses to treatment by two weeks after the final application.

The liver was also the primary target organ after subacute (5x 6hours and 20x 6hours) inhalation exposure with secondary effects on the thyroid hormone levels. Increased liver weights with correlating clinical-

and histopathological findings were observed. The inhalation toxicity studies revealed also alterations in the nasal cavity and larynx, in kidney-, hematologic/spleen-, and thyroid-related endpoints.

Table 2.6.3-1 Summary of short-term toxicity

Study	Sex	NO(A)EL	LO(A)EL	Main findings seen at LO(A)EL
		mg/kg bw/day		
Rat 21-day dermal	M F	1000 1000	-- --	No adverse effects noted. T4 ↓, liver findings considered adaptive response to treatment.
Rat 1-week inhalation	M, F	~14 48 mg/m³	~66 225 mg/m³	T4 ↓ Liver: rel. weight ↑
Rat 4-week inhalation	M, F	~7 19 mg/m³	~81 220 mg/m³	HB ↓, HCT ↓, RETI ↑, HEINZ ↑, AP ↓, TG ↓, Liver: enzymes ↑, rel. weight ↑, spleen: weight ↑, histopathological changes in nasal cavity and larynx, spleen, testes, thyroid, liver
Rat 90-day feeding	M F	-- ^{a)} 7.2	6.0 29	HB ↓, T4 ↓, GLUC ↓, Liver: weight ↑, hepatocellular swelling, cell degeneration or necrosis; spleen: brown granular pigment accumulation within red pulp; kidney: mild renal proximal tubule injury
Mouse 90-day feeding	M F	18 25	64 91	T4 ↓ Liver: rel. weight ↑
Dog 90-day feeding	M F	1.7 1.7	7.2 6.9	ALAT ↓, LDH ↑, albumin ↓, globulin ↑, T4 ↓, GLUC ↓, Spleen: pigment, kidney: rel. weight ↑
Dog 1-year feeding	M F	1.3 1.1	28 27	Hb ↓, Hct ↓, MCV ↓, MCH ↓, MCHC ↓, CHOL ↑, GLUC ↓, T4/T3 ↓, ALAT ↓, AP ↑, albumin ↓, Liver, heart, kidney: abs. + rel. weight ↑ BW gain ↓, Haematology effect: alterations and compound related changes in hematologic endpoints, Neurology effects: abnormal behavior, postural abnormalities, optic nystagmus/strabismus/ placement Necropsy: ↑ increased relative heart weights; ↑ increased relative kidney weights ↑ increased relative and absolute liver weights ↑ increased relative adrenal weights ↑ increased relative thyroid compound-related changes were limited to the 800 and/or 1600 ppm dose levels in both males and females

2.6.4. Summary of genotoxicity

Mutagenicity studies with flufenacet were consistently negative. Point mutation assays in bacteria and mammalian cells revealed no evidence of mutagenic potential. In vitro and in vivo cytogenetic studies revealed no evidence of clastogenicity, and an unscheduled DNA synthesis assay using primary rat hepatocytes revealed no evidence of genotoxic activity. Thus, flufenacet is not mutagenic, clastogenic or genotoxic.

A new bacterial reverse mutation assay revealed no evidence of a mutagenic potential and thus, confirmed that flufenacet is not mutagenic. The conduct of an *in vivo* study in germ cells was not regarded necessary as there is no evidence of an effect on germ cells in other toxicological studies.

Photomutagenicity

For flufenacet there is no evidence of a photoreactivity potential and the Ultraviolet/visible molar extinction/absorption coefficient is smaller than 1000 L x mol⁻¹ x cm⁻¹. Therefore photomutagenicity testing is not required.

Table 2.6.4-1 Summary of genotoxicity testing

Study	Test system	Results	
		activation	non-activation
Bacterial reverse mutation assay	<i>S. typhimurium</i> TA98, TA100, TA1535, TA1537	negative	negative
Bacterial reverse mutation assay	<i>S. typhimurium</i> TA98, TA100, TA102, TA1535, TA1537	negative	negative
Mammalian cell gene mutation test (HGPRT)	Chinese hamster lung fibroblasts V79	negative	negative
Mammalian chromosome aberration test	Chinese hamster ovary cells CHO	negative	negative
Unscheduled DNA synthesis (UDS) assay	Primary rat hepatocytes	negative	negative
Micronucleus test	Mouse bone marrow	negative	

2.6.5. Summary of long-term toxicity and carcinogenicity

For rats the toxicological response could be broadly characterized as involving structural and/or functional alterations in liver-, kidney-, hematologic/spleen-, and thyroid-related endpoints. The liver was considered the primary target organ with increases in organ weight, cell size and number, and/or associated hepatic parameters. Hepatocytomegaly was exhibited in both species exposed to higher doses of FOE 5043.

The FOE 5043-induced liver changes would appear to be fundamentally adaptive in nature as the organism's principal metabolic organ responds to physiological need to clear, biotransformation, and excrete a xenobiotic.

The hematological profile of the rats and dogs indicated a mild anemia for animals at higher dose levels. Thyroid involvement was noted in both species by an increase in thyroid organ weights, and for dogs, a decrease in thyroxine (T₄ and triiodothyronine (T₃) levels. The lower levels of exposure used in the chronic rat study, as compared to the subchronic bioassay, suggested a dose >800 ppm (highest dose tested) was necessary for a broader and more significant toxicological response in this tissue. The thyroid organ changes resulting from exposure to FOE 5043 are likely to be a secondary effect in response to hepatic induction. Ophthalmological findings noted in the rat included cataracts and ocular scleral mineralization.

For dogs, eye effects included minimal to moderate vacuolization of the ciliary body epithelium and cystic vacuolization of the peripheral optic retina. In dogs, specialized testing such as computerized electrocardiograms, clinical neurological examinations, and quantitative electroencephalography revealed a number of compound-related effects. Renal pelvic epithelial hyperplasia was observed in the kidneys of rats and dogs. A minimal to moderate axonopathy was noted in the brain, spinal cord and sciatic nerve of dogs.

No evidence of an oncogenic potential of FOE 5043 was found in the long-term feeding studies in tested animals.

Table 2.6.5-1 Summary of long-term studies

Study	Sex	NOAEL	LOAEL	Main findings seen at LOAEL
		mg/kg bw/day		
Rat 2-year feeding	M	1.2*	19	BW gain ↓, structural and/or functional alterations in liver-, kidney-, haematopoietic-, and thyroid-related endpoints.
	F	1.5	24	
Mouse 20-month feeding	M	7.4	30	MetHB ↑
	F	9.4	77	Ocular cataracts ↑

2.6.6. Summary of reproductive toxicity

The reproductive toxicity of flufenacet was studied in a generational studies in rats and developmental toxicity studies in rats and rabbits.

Dietary levels up to and including 500 ppm (**premating: 37/41 mg/kg bw/day in males/females**), the highest dose tested, had no effect on reproduction when fed to rats over a period of 2 generations. In parental animals, there was a compound-related reduction in body weights for P generation females during the pre-mating phase. Other effects occurring in the P and F generation adults included increased absolute and relative liver weights and histopathological changes in the liver. The NOELs obtained for parental and reproductive toxicity were **100** and **500 ppm**, respectively.

In an oral developmental toxicity study in rats, developmental effects were observed at 125 mg/kg bw/day (highest dose tested) as demonstrated by decreased foetal body weights, and increased incidences of delayed ossification and skeletal variation. These effects were correlated with a reduction in body weight and food consumption in dams at 125 mg/kg bw/day. The NOEL for both maternal and developmental toxicity in the rat via oral administration was 25 mg/kg bw/day. However maternal NOEL in rabbits was 5 mg/kg bw/day via the same route of administration.

In an oral rabbit developmental toxicity study, developmental effects occurred at doses of 125 and 200 mg/kg bw/day. Effects included reduced foetal weights, and increased incidences of delayed ossification and skeletal variation. Maternal toxicity was characterized by clinical signs, reduced body weight gain during treatment, and an increase incidence of histopathological changes in the liver. The NOELs established in the rabbit for maternal and developmental toxicity by oral administration were 5 and 25 mg/kg bw/day, respectively.

Overall, it can be concluded that flufenacet is not a reproductive or developmental toxicant. The developmental effects observed were restricted to the higher dose levels which produced overt maternal toxicity.

The two-generation study with **flufenacet** revealed no evidence of reproductive toxicity. Dose levels including levels overtly toxic to parental animals had no effect on gonadal function, estrous cycles, mating behavior, conception, parturition, lactation, weaning, and the off-spring's ability to achieve adulthood and successfully reproduce. The study unequivocally demonstrated that **flufenacet** is not a reproductive toxin.

Teratology/embryotoxicity studies using rats and rabbits revealed no evidence of teratogenicity or embryotoxicity. At maternally toxic dose levels, reduced fetal bodyweights, and increased incidences of delayed ossification and skeletal variation were observed. Thus, **flufenacet** is not teratogenic or embryotoxic and it does not cause primary fetotoxicity.

Table 2.6.6-1 Summary of reproductive and developmental toxicity studies

Study	Sex	NOAEL	LOAEL	Main effects seen at LOAEL
	(mg/kg bw/d)			
Rat 2-generation feeding	M	7.4	37	BW ↓ in P females during pre-mating
	F	8.2	41	No reproductive effects.
Rat oral (gavage) developmental	Dam	25	125	Maternal: BW ↓, food consumption ↓
	Fetal	25	125	Fetal: BW ↓, delayed ossification and/or skeletal variation ↑ in some skeletal elements
Rabbit oral (gavage) developmental	Dam	5	25	Maternal: soft stool, BW gain ↓ during treatment, histopathological liver changes
	Fetal	25	125	Fetal: skeletal variation ↑

2.6.7. Summary of neurotoxicity

The neurotoxic potential of **flufenacet** has been thoroughly investigated and well characterized in studies using mice, rats and dogs. The neuropathological changes as assessed by both light and electron microscopy examinations appear to be metabolic lesions. In animals chronically exposed to high dose levels of **flufenacet**, similar lesions were observed in several high-oxygen demand tissues, the eye, brain and kidney. The data, taken collectively, demonstrate that these pathologic changes are due to limitations in glutathione interdependent pathways and antioxidant stress. Toxicokinetic data from the chronic dog study demonstrated saturation of metabolic pathways at the mid and high dose levels where these changes were observed. The pathological changes observed in the brain and spinal cord of **flufenacet**-treated animals primarily consisted of an increased incidence or exacerbation of a morphological change (i.e., axonal swelling) occurring spontaneously in untreated animals. Thus, prolonged exposure to high dose levels of **flufenacet** which saturate metabolic pathways causes a slight increase in the incidence of a normal morphologic change.

A developmental neurotoxicity study was conducted based on thyroid-related findings and therefore, the potential for affecting development of the nervous system. In this study flufenacet did not cause any neurotoxic effect in parental and offspring animals. Treatment-related findings consisted of reduced food consumption and a reduction in maternal body weights during gestation and in males at mid and high-dose. Body weights were also reduced in mid- and high-dose F1-offspring and secondary to the lower body weights the F1 offspring exhibited a delay in development (eye opening, preputial separation).

Table 2.6.7-1 Summary of neurotoxicity studies

Study	Sex	NOAEL (mg/kg bw/d)	LOAEL (mg/kg bw/d)	Main effects seen at LOAEL
Rat acute neuro-toxicity, oral	M F	75 50	200 75	Unspecific clinical signs (uncoordinated gait, decreased activity) NOEL neurotoxicity 450/150 mg/kg bw (males/females highest doses tested with survivors).
Rat 90-day neurotoxicity feeding	M F	7.3 8.4	38 43	Microscopic lesions in brain and spinal cord (increased incidence of swollen axons in the cerebellum-medulla oblongata)
Rat developmental neurotoxicity feeding	Dam Pup	1.7/3.0 (DG 6-21/DL 1-12)	8.3/15	Dam: BW ↓, food intake ↓ (gestation) Pup: BW/BWgain ↓, rel. food intake ↑, delayed development (eye opening, preputial separation)

2.6.8. Summary of further toxicological studies on the active substance

For registration of flufenacet in the United States (US), a developmental neurotoxicity study was conducted based on thyroid-related findings and therefore, the potential for affecting development of the nervous system. In this study dietary exposure to flufenacet did not cause any neurotoxic effect in parental and offspring animals. Treatment-related findings consisted of reduced food consumption and a reduction in maternal body weights during gestation and in males at the mid- and high-dose. Body weights were also reduced in mid- and high-dose F1-males and high-dose F1-females. F1 offspring of these dose groups exhibited also a delay in development (eye opening, preputial separation), for details please refer to supplemental dossier MCA 5.7.1.

Furthermore, the US EPA required a special comparative thyroid sensitivity assay with flufenacet in neonatal and adult (pregnant and lactating) female rats in order to investigate potential neonatal susceptibility to thyroid-related neurodevelopmental effects. Besides the range-finding study, two dietary studies were conducted to evaluate the effects of flufenacet on thyroid endpoints in pregnant and lactating rats and their offspring during fetal and post-natal development.

Dietary exposure to flufenacet during pregnancy from gestation day 6 to 20 revealed no adverse effects up to the top dose tested in dams and foetuses. Slight (non-statistical) decrease in T4 showed no compensatory thyroid response.

Dietary exposure to flufenacet during pregnancy and lactation from gestation day 6 to lactation/post-natal day 21 induced a slight decrease in maternal body weight gain resulting in lower body weight and decreases in T4 and T3 with thyroid follicular cell hypertrophy in two dams. In post-natal day (PND) 21 pups, the highest dose tested (500 ppm) reduced body weight and weight gain, with slightly lower T3 in males and females. Thus, these results support 16.7 mg/kg bw/day (100 ppm) flufenacet as a NOAEL and 84.2 mg/kg/day (500 ppm) as a LOAEL in the dam and offspring with dietary exposure during pregnancy / gestation and lactation.

Flufenacet administration once daily by gavage from PND 10 to 20 to male and female pups at 1.7 mg/kg bw/day had no effect on the thyroid or any other endpoint measured. Thus, 1.7 mg/kg bw/day is a NOAEL in pre-weaning rats.

2.6.9. Summary of toxicological data on impurities and metabolites

Toxicological studies conducted with FOE 5043-hydroxy, FOE 5043-(TDA)-sulfone and FOE-acetate are considered supportive to justify the limits of specified impurities.

During the previous EU review, the toxicological properties of the plant and/or soil metabolites (FOE-oxalate (M01), FOE-sulfonic acid (M02), FOE-thioglycolate sulfoxide (M04), and thiadone (M09)) were investigated in acute oral toxicity to rats and/or mutagenicity and/or their bioavailability in rats.

The genotoxic properties of several metabolites (FOE-oxalate (M01), FOE-sulfonic acid (M02), FOE-methylsulfone (M07), FOE 5043-trifluoroethanesulfonic acid (M44) and trifluoroacetate (TFA) (M45)) were further investigated in the recommended *in vitro* and if necessary *in vivo* genotoxicity assays. Overall, all metabolites are considered to be non-genotoxic.

In addition, TFA (M45) is of low acute toxicity with a LD50 above 2000 mg/kg bw without any evidence of acute effects based on clinical signs and necropsy findings. After repeated administration the liver was the target organ, with effects that were adaptive and reversible. Moreover, the 14-day mechanistic study showed that liver effects are related to peroxisome proliferation, a mode of action not relevant for humans. Furthermore, the developmental toxicity study in rats showed neither maternal nor developmental effects which are considered to be adverse up to the highest dose tested.

A toxicological assessment of several metabolites based on commonality assessments, structure similarity considerations, evaluation of genotoxicity and further toxicological studies as well as exposure calculations revealed that all plant metabolites are considered to be toxicologically adequately investigated and uncritical for human health.

2.6.10. Summary of medical data and information

In-company experience there were no unusual occurrences or complaints recorded. Medical assessment occupational medical surveillance of employees from the Flufenacet plant performed annually since 1997 as described above, not directly related to exposures, did not reveal any unwanted effects in the workers. During the production period since 1997 no accidents with Flufenacet occurred in the workers. No further consultations of the Medical Service due to work or contact with Flufenacet were required.

No human poisoning cases have been published; in animal experiment neurotoxicity has been observed, though only after repeated application of high doses. In humans the formation of methemoglobin and resulting cyanosis can be expected in severe cases.

Methemoglobin can very easily and quickly be measured with many hemoglobin analysers:

- 10% of methemoglobin will cause bluish-grey cyanosis, best seen on lips, fingertips, and earlobes, but spreading to all of the skin with increasing concentrations.
- 20% and more of methemoglobin will cause signs and symptoms as headache, nausea, vertigo, drowsiness, somnolence, shortness of breath, tachycardia.
- 60-80% of methemoglobin may be fatal.

Note: Due to the discoloration of the skin oxygen saturation cannot be measured with fingertip sensors.

Note: Due to a competition for metabolic enzymes alcohol greatly increases the formation of methemoglobin. Therefore any consumption of alcohol is strictly forbidden for 48 hours after the incident.

First Aid:

- Remove patient from exposure/terminate exposure.
- Thorough skin decontamination with copious amounts water and soap, if available with polyethyleneglykol 300 followed by water.

Note: Most formulations with this active ingredient can be decontaminated with water (and soap), so for formulations polyethyleneglykol 300 is not required.

- Flushing of the eyes with lukewarm water for 15 minutes
- Induction of vomiting should only be considered if a large amount has been swallowed, if the ingestion was less than one hour ago, and if the patient is fully conscious.
- Induced vomiting can remove maximum 50% of the ingested substance.

Note: Induction of vomiting is forbidden, if a formulation containing organic solvents has been ingested!

Treatment:

- Gastric lavage should be considered in cases of significant ingestions within the first (2) hour(s).
- The application of activated charcoal and sodium sulphate (or other cathartic) can be considered in significant ingestions.

As there is no antidote, treatment has to be symptomatic and supportive.

However:

- In case of proven methemoglobinemia:

The human organism is able to reduce methemoglobin to hemoglobin without further

intervention. However, this will take days and thus is not feasible in significant intoxications.

Therapy will aim at increasing oxygen transport and reversing the hemoglobin oxidation/reducing Fe^{+++} to Fe^{++} .

Methemoglobin should be measured before and during therapy (most hemoglobin analysers can measure methemoglobin).

- If *methemoglobin level is less than 20%*, administer 100% oxygen; additionally 1g of ascorbic acid (vitamin C) may be given orally or intravenously. The reducing effect of vitamin C is weak, but in these cases sufficient.
- If *methemoglobin level is greater than 20%* treat with 100% oxygen and administer a reducing agent: Methylene Blue or Toluidine Blue. These will be effective within 10-20 minutes. Additionally high doses (> 1g) of ascorbic acid/vitamin C intravenously can be considered.
 - **Methylene Blue:**
 - 1% solution (10 mg/mL) intravenously at 0.1-0.2 mL/kg body weight (1-2 mg/kg bw) during ca. 5 minutes.
 - A 60 kg person would thus receive 6 to 12 mL Methylene Blue 1% intravenously.
 - If required this dose may be repeated after 30 minutes.
 - The maximum daily dose is 7 mg/kg bw.
 - **Toluidine Blue:**
 - 3% solution (30 mg/ml) intravenously at 0.07 to 0.13 mL/kg bw (2-4 mg/kg bw).
 - A 60 kg person would thus receive about 4 to 8 mL Toluidine Blue 3% intravenously.
 - If required this dose may be repeated after 30 minutes.

Note: Both Methylene Blue and Toluidine Blue can cause methemoglobinemia themselves in case of overdose.

A known deficiency of G-6-PDH is a contraindication against both drugs.

Paravenous injection has to be avoided as it can cause severe tissue necrosis.

2.6.11. Toxicological end point for assessment of risk following long-term dietary exposure – ADI

At Annex I inclusion for flufenacet an ADI of 0.005 mg/kg bw/day was set based on an increased incidence of a spontaneous background lesion in the kidneys observed at the LOAEL of 1.2 mg/kg bw/day of the 2-year rat study by using a safety factor of 250. This finding was not considered as adverse. (Review Report for flufenacet 7469/VI/98- Final, 3 July 2013).

Flufenacet is not a reproductive or developmental toxicant and it is not mutagenic or carcinogenic. It does induce neurotoxicity, but only after prolonged, repeated exposures to high dose levels exceeding animal's capacity to rapidly metabolize and eliminate it. Clear threshold exists for all toxicological effects observed in studies with flufenacet. The more recently conducted studies in rats did not reveal lower NOAELs or more sensitive endpoints. **Therefore, the rationale for the establishment of the ADI has not changed.**

2.6.12. Toxicological end point for assessment of risk following acute dietary exposure - ARfD (acute reference dose)

At Annex I inclusion for flufenacet an ARfD of 0.017 mg/kg bw was set based on the NOEL of 1.7 mg/kg bw/day of the 90-day and 1-year toxicity studies in dog by using a safety factor of 100 (Review Report for flufenacet 7469/VI/98- Final, 3 July 2013). The maternal and developmental NOAEL of the DNT study is 20 ppm, corresponding to 1.7 mg/kg bw/day. Based on this the ARfD should be based on the 90d- and 1-y dog studies, as determined during the previous evaluation. Obviously the same rational as for the AOEL derivation was used for setting an ARfD.

2.6.13. Toxicological end point for assessment of occupational, bystander and residents risks – AOEL

At Annex I inclusion for flufenacet an AOEL of 0.017 mg/kg bw/day was set based on the NOEL of 1.7 mg/kg bw/day of the 90-day and 1-year toxicity studies in dogs by using a safety factor of 100 (Review Report for flufenacet 7469/VI/98- Final, 3 July 2013).

However, according to the monograph the AOEL was derived from the NOEL of 1.7/1.67 mg/kg bw/day established after 1 year exposure to flufenacet in the chronic rat study and derived from the 90-day dog study, respectively. The NOELs were based on minimal lower hemoglobin and thyroxin (T4) concentrations in rats and changes in clinical chemistry and higher relative kidney weight in dogs at the respective LOELs of 6.0 or 6.9 mg/kg bw/day. These findings observed at the LOELs were considered adaptive changes due to primary effects on the liver and resulting in secondary effects.

Due to the almost complete absorption of flufenacet from the gastrointestinal tract a correction for oral bioavailability is not needed.

Since no lower NOELs were determined in the more recently conducted studies, the systemic AOEL of 0.017 mg/kg bw/day is still considered to be a valid value for the protection of operators with regard to the exposure to flufenacet.

2.6.14. Summary of product exposure and risk assessment

Operators

Operator exposure estimates are calculated using both the German model (Lundehn *et al.*, 1992) and the UK-POEM (PSD, 1992). Exposure calculations are performed without and with protective equipment.

Consideration on estimation of operator exposure

- No unacceptable risk is anticipated with German model even when no PPE are worn during mixing loading and application. No unacceptable risk is anticipated for the operator if adequate work clothing is worn and, in addition, protective gloves during mixing/loading and application.
- UK POEM predicts acceptable exposure if gloves are worn during mixing loading.
- Additional PPE can be used to further reduce the exposure of the operator.

Bystander and resident exposure

Exposure scenarios associated with the product application are evaluated for bystanders and for residents (including children). Calculations are performed according to the German guideline published in 2008 (Martin *et al.*, 2008). The calculations showed that the situation with respect to bystander and resident exposure is favourable for the intended uses. Bystanders and residents will not be exposed to unacceptable levels of flufenacet during spray application in the fields.

Workers

The determination for worker re-entry is based on the recommendation provided in the EUROPOEM II report for worker exposure for four different harvesting scenarios with bare hands. Exposure of operators entering treated crops is within acceptable levels. Calculations reflect standard work clothing worn by

adult workers (shoes, socks, long-legged pants, and long sleeves) working with bare hands. No personal protective equipment is considered to mitigate the exposure.

2.7. RESIDUES

2.7.1. Summary of storage stability of residues

2.7.1.1. Plant matrices

In the EU review process (Directive 91/414/EEC) storage stability data were evaluated for flufenacet and five metabolites (FOE-oxalate, FOE-sulfonic acid, FOE-thioglycolate sulfoxide, FOE-methylsulfoxide, FOE-methylsulfone) in matrices of corn, soybean (up to 28 months) and turnips (20 months) covering the commodity groups of high water content, high oil content and high starch content.

In the supplementary dossier additional storage stability information is provided on wheat commodities (wheat forage, grain and straw) for flufenacet and the five metabolites for up to 21 months and for additional commodity groups of high protein content (dry bean seed) and high acid content (orange fruit) for up to 24 months (flufenacet, FOE-oxalate, FOE-sulfonic acid, FOE-thioglycolate sulfoxide).

No significant decrease of residues was observed for flufenacet and its metabolites after the tested periods. Thus the residues of flufenacet and its metabolites are stable in plant matrices under freezer storage conditions for at least as long as the storage periods lasted.

In addition, in some samples of supportive trials from three residue studies the requested temperature of -18°C was exceeded due to problems during the shipment of these samples. In order to address this deviation, a short-term storage stability study was conducted (tomato and wheat grain as representatives for two different commodity groups). Residues of flufenacet proved to be stable under the experimental conditions tested reflecting the conditions during shipment.

2.7.1.2. Animal matrices

Analysis of the goat matrices in feeding study (Monograph, France, 1997) showed, that FOE oxalate was stable in goat tissues and milk for 540 to 650 days. No additional studies were provided.

2.7.2. Summary of metabolism, distribution and expression of residues in plants, poultry, lactating ruminants, pigs and fish

2.7.2.1. Plant matrices

From the metabolism studies submitted for approval in the EU and USA a conclusion of a common metabolic pathway of flufenacet in plants was made. The initial metabolic reaction is a cleavage of the molecule into the thiadone and acetamide moiety by glutathione (GSH) conjugation of the acetamide part resulting in the transient glutathione conjugated FOE GSH (M22).

This transient glutathione conjugate is further metabolized by splitting off glycine and glutamine acid yielding the FOE cysteine conjugate (M23). All further metabolites can be considered as hydrolysis, oxidation and conjugation products of the FOE cysteine conjugate. However, the FOE oxalate (M01) most likely arose through direct oxidation of a transient primary alcohol hydrolysis product of Flufenacet (FOE alcohol, M03).

Due to the initial cleavage of the parent molecule caused by glutathione conjugation, trifluoromethyl thiadone (M09) was released. While this transient moiety was not observed, various conjugates were formed, the quantitatively most important being the corresponding *N*-glucoside (M 25). In soybeans, the malonylalanine conjugate (M34) predominated.

The additional studies with [fluorophenyl-UL-¹⁴C]flufenacet on potato (pre- and post-emergence application), wheat and corn (both post-emergence application) confirmed this metabolic pathway.

Additional plant metabolism studies with [thiadiazole-5-¹⁴C]flufenacet in potato (pre-emergence application), wheat (post-emergence application) and in the rotational crops wheat, turnip and Swiss chard disclosed an already known metabolite, a glycoside conjugate of FOE thiadone, probably THNG (M25), and a new metabolite, i.e. trifluoroacetate, TFA (denoted as the parent substance trifluoroacetic acid, since the counter cation depends from the surrounding medium, and therefore varies and is not defined). Trifluoroacetate proved to be the main residue component in all plant metabolism and confined rotational crop studies with the [thiadiazole-5-¹⁴C]-label.

The parent substance flufenacet did not occur in any crop. In order to find common major metabolites as potential marker substances for a residue analytical method all major metabolites of flufenacet in all investigated plants are compiled. However, no metabolite can be found that proved to be major in all crops and can be selected as marker substance. Therefore, a **common moiety method** was developed as alternative method on the basis of *N*-(4-fluorophenyl)-*N*-isopropyl amine. When summing up the metabolites with the common moiety the resulting sum represents the major portion of TRR in most of the examined raw agricultural commodities.

It can be concluded the common moiety approach seems to be an appropriate solution for deriving the residue definitions for enforcement and monitoring as well as for risk assessment purposes.

2.7.2.2. Animal matrices

In the goat Flufenacet is extensively metabolised. The first metabolic step is conjugation with glutathione. Further biodegradation follows the mercapturic acid (acetyl cysteine) pathway, with additional formation of cysteine (M23) or mercapturic acid (M10) conjugates.

In poultry metabolism of Flufenacet appeared to involve the mercapturic acid pathway resulting in a wide range of methylsulfinyl and methylsulfonyl containing metabolites produced from further metabolism of the cysteine and mercapturic acid conjugates of Flufenacet.

The metabolism studies performed with flufenacet indicate a wide range of metabolites are formed containing the *N*-fluorophenyl-*N*-isopropyl moiety. Therefore, EFSA concluded that for commodities of animal origin, it is desirable to include all metabolites containing the *N*-fluorophenyl-*N*-isopropyl moiety in the residue definition, both for enforcement and risk assessment.

In the EFSA reasoned opinion a detailed assessment is provided on the review of the existing maximum residue levels according to Art 12 of Regulation (EC) no. 396/2005 (2012). The general metabolic pathways in rodents and livestock were found to be comparable.

The metabolism of flufenacet in fish was investigated in the context of a bioconcentration study with bluegill sunfish. [Fluorophenyl-UL-¹⁴C]flufenacet was introduced into the inflowing water to aquaria with the fish to achieve a concentration of 100 µg/L. The principle metabolic pathway was the glutathionate conjugation of the acetanilide moiety of the molecule followed by further metabolic conversions as already observed in rat, goat, hen and plants. The residue levels in edible tissue and viscera were low as documented by the low bioconcentration factor of 68-71 for the whole body.

Since the parent compound degrades rapidly in plants and is not detectable in animal feeding items the metabolism study using [fluorophenyl-UL-¹⁴C]Flufenacet oxalate (M01) provides the most relevant information. Oral administration of this oxalate to ruminant and poultry showed its metabolic stability. Flufenacet oxalate is essentially not metabolised by the animal. This metabolic stability was confirmed by a bio-availability study of flufenacet oxalate in rats. The low residue levels in tissue, milk and eggs suggest that flufenacet oxalate is minimally absorbed and rapidly excreted. Following oral administration of radiolabeled flufenacet oxalate to three rats at a dose rate of approx. 1 mg/kg bw 19 – 37% of the dose was excreted with urine and 61 – 80% was excreted with faeces as unchanged flufenacet oxalate.

Another major plant metabolite in animal feeding items was detected as thiadone-*N*-glucoside (M25, THNG). This metabolite was observed after treatment of [thiadiazole-2-¹⁴C]Flufenacet to plants. Oral administration of radiolabelled M25 to a goat at an overdosed feeding rate indicated low residues in milk and edible organs and tissues. Free thiadone formed by de-conjugation was the main residue component in kidney, liver and muscle, but not in milk. However, the residue level of thiadone is negligible (< 0.01 mg/kg) if the overdose is transformed to a 1x feeding level.

New plant metabolism studies with [thiadiazole-5-¹⁴C]flufenacet in primary and succeeding plants revealed trifluoroacetate (M45) as a major metabolite in edible plant parts and in plant parts intended as feeding stuff for livestock animals. For a complete dietary risk assessment including residues in food of animal origin, a potential residue transfer of trifluoroacetate from feeding items to food of animal origin has been investigated. Therefore, metabolism studies on ¹⁴C-labelled trifluoroacetate in goat and hen were conducted indicating the metabolic stability and a low residue transfer of trifluoroacetate to milk, eggs and edible organs and tissues. The respective transfer factors were low and did not indicate any accumulation in milk, eggs and edible organs and tissues of livestock animals.

2.7.3. Definition of the residue

Flufenacet, a pre-and post-emergence herbicide with detectable residues in some crops shows a qualitatively similar metabolism in all examined crops. However the predominant metabolites vary widely depending on the crop and time of application.

Plant matrices

For monitoring purpose, the benefit of the inclusion of all the individual metabolites into a multi method and a subsequent need for revision of the residue definition is considered questionable since such a proposal is a negation of the “**marker compound**” concept. The high number of individual metabolites is not considered suitable for routine monitoring.

The presentation shown at the 9th European Pesticide Residue Workshop (Vienna (Austria), 27 June 2012) by a member of the EFSA Pesticides Unit suggests that it was noticed that possibilities for simplification of complex residue definitions are limited in some cases. The presentation addressed flufenacet as a case study where it was concluded that the complex residue definition (based on the *N*-fluorophenyl-*N*-isopropyl moiety) is needed.

The alternative method based on a common moiety determination by LC-MS/MS no longer requiring a derivatisation can be considered as a more appropriate approach.

This residue definition is applicable to all crops when application is made pre- and early post-emergence.

A specific residue definition for **rotational crops** is not considered necessary as metabolism in primary and rotational crops was found to be similar and very low residue levels are expected.

It seems unlikely that new metabolites not covered by the common moiety method would be generated during industrial processing and/or household preparation. The relevant residue definition for enforcement and risk assessment in **processed commodities** is therefore expected to be the same as for primary crops.

Animal matrices

For commodities of animal origin, similarly to plant origin products, a residue definition including all metabolites with the *N*-fluorophenyl-*N*-isopropyl moiety is expected to be the most appropriate, both for enforcement and risk assessment.

As concluded in the initial DAR and in the Reasoned opinion (EFSA 2012) flufenacet is considered as not fat soluble.

The proposed residue definitions are summarized in table 2.7.3-1.

Table 2.7.3-1 The proposed residue definitions for flufenacet

Matrices	Residue definition		Reference
Food of plant origin	Risk assessment Monitoring	Flufenacet including all metabolites containing the <i>N</i> -fluorophenyl- <i>N</i> -isopropyl moiety, expressed as flufenacet	Report of ECCO 73, Bruno Dujardin, Pesticides Unit, EFSA; 9 th European Pesticide Residue Workshop (Vienna (Austria), 27 June 2012 Reg. (EC) 1127/2014
Food of animal origin	Risk assessment Monitoring	Flufenacet including all metabolites containing the <i>N</i> -fluorophenyl- <i>N</i> -isopropyl moiety, expressed as flufenacet	

2.7.4. Summary of residue trials in plants and identification of critical GAP

During initial Annex I submission representative uses included cereals, corn, soybeans and sunflower while those for renewal of approval of flufenacet are limited to cereals only (see Table 2.7.4-1).

The use patterns involving an application rate of 240 g as/ha are considered to be the critical GAPs in the northern and southern climatic zones. The critical GAP for the northern zone corresponds to the GAP of the representative use in cereals supported with the Annex II dossier and taken into account for Annex I inclusion.

Table 2.7.4-1: Summary of the representative uses supporting the renewal of approval for flufenacet

Crop	Region*	Maximum Number of Applications	Growth stage at application	Maximum Rate flufenacet (g a.s./ha)	Minimum PHI (days)
Cereals (winter wheat, winter barley, winter rye)	EU-N	1	Early post-em. BBCH 10-13 (autumn use)	240	n.a.
Cereals (winter wheat, winter barley, winter rye)	EU-N	1	Pre-emergence; early post-emergence BBCH 00-22	120	n.a.
Cereals (wheat, barley)	EU-S	1	Early post-emergence BBCH 11-13	240	n.a.
Cereals (wheat, barley)	EU-S	1	Early post-emergence BBCH 11-13	160	n.a.

* EU-N northern Europe EU-S southern Europe

n.a. not applicable, the PHI is covered by the vegetation period of the crop from treatment to harvest.

In the EU review process (Directive 91/414/EEC) 17 trials on wheat, barley and rye, conducted in the northern European climatic zone were evaluated. The residue trials considered to grant Annex I inclusion of flufenacet support application of flufenacet to cereals at the rate of 240 g as/ha at pre- or early post emergence growth stages up to mid of tillering (BBCH 11 to 25) and were considered suitable to support the product Flufenacet WG 60.

The set of residue data on wheat, barley and rye conducted with the straight formulation WG 60 and evaluated for Annex I inclusion is considered appropriate to support the representative use for the mixed product 'flufenacet + diflufenican SC 600' at a rate of 240 g flufenacet/ha in northern Europe. The use pattern for both products involve the same application parameters and residue data obtained from trials using a WG formulation are considered appropriate to also support SC formulations. Both formulations types are known to produce comparable residues, particularly if the application is conducted early during the crop development. In all trials, residues have shown to be less than the LOQ for grain (< 0.05 mg/kg) and straw (< 0.1 mg/kg).

Nevertheless, 6 trials on wheat, barley and rye are reported for the northern region with WG and SC formulations at an application rate of 240 g flufenacet/ha which demonstrate that the residue behaviour of

flufenacet does not alter when applied in a mixture with diflufenican. Applications were performed early post-emergence during leaf development until mid of tillering (BBCH 13-25). Residues in grain and straw were always below the LOQ of 0.05 or 0.1 mg/kg, respectively.

No residue data for flufenacet from the southern region were evaluated for Annex I inclusion. With the present dossier 9 trials are submitted to support the use pattern at 240 g as/ha with early post-emergence application in southern Europe. The trials were already evaluated at a national level (evaluating member state France, product name FOSBURI). Flufenacet was applied at rates ranging from 220 – 254 g as/ha during leaf development until beginning of tillering (BBCH 13-21). The trials on wheat and barley were conducted over two growing seasons. Residues in grain ranged from < 0.01 to 0.05 mg/kg (median < 0.01 mg/kg), and in straw from 0.05 to 0.11 mg/kg (median 0.06 mg/kg).

The data sets from the northern and southern region are considered to represent the critical GAPs for flufenacet.

The data sets were recently reviewed by the RMS France and EFSA and the data set from southern Europe forms the basis for the new MRL proposal of 0.1 mg/kg as published with the EFSA Reasoned Opinion (EFSA Journal 2012;10(4):2689).

An overview on the supplementary residue data for the northern zone using mixed formulations, and for the southern climatic zone is given in Table 2.7.4-2. For both climatic regions residue data are reported also involving lower rates in support of supplementary representative GAPs at 120 g as/ha in the northern zone and 160 g as/ha in the southern zone.

Table 2.7.4-2: Summary of supplementary residue data on cereals supporting the representative GAPs for renewal of approval of flufenacet

Application rate flufenacet (g as/ha)	Region	Formulation	Crop	Sample material	n	Residue level (mg/kg) flufenacet		
						Min.	Max.	STM
240	EU-N	FFA+DFF WG 60 FFA+DFF SC 600	wheat, barley	grain	6	<0.05	<0.05	<0.05
				straw	6	<0.10	<0.10	<0.10
110-120	EU-N	FFA+FLT+DFF SC 360	Wheat, barley	grain	8	<0.01	0.022	<0.01
				straw	8	<0.05	<0.05	<0.05
220-254	EU-S	FFA+DFF SC 600	Wheat, barley	grain	9	<0.01	0.05	<0.01
				straw	9	<0.05	0.11	0.06
120-126	EU-S	FFA+FLT+DFF SC 360 FFA+DFF WG 70	Wheat, barley	grain	12	<0.01 <0.05	0.035/ <0.05	0.022
				straw	12	<0.05	0.069	<0.05

EU-N northern Europe

EU-S southern Europe

n: number of trials

FFA+DFF WG 60 containing 40% flufenacet and 20% diflufenican

FFA+ DFF SC600 containing 400 g/L flufenacet and 200 g/L diflufenican

FFA+FLT+DFF SC 360 containing 120 g/L flufenacet, 120 g/L flurtamone and 120 g/L diflufenican

FFA+DFF WG 70 containing 35% flufenacet and 35% diflufenican

The data set is considered as sufficient to cover the intended use.

2.7.5. Summary of feeding studies in poultry, ruminants, pigs and fish

During the EU peer review process and recently in the EFSA Reasoned Opinion on existing MRLs (2012) it was concluded that on the basis of the animal metabolism studies, after exposure to the maximum dietary burden (about 200 times lower than the dose level in the metabolism studies) residue levels in livestock commodities are expected to remain below the enforcement LOQ of 0.01 mg/kg in milk, 0.02 mg/kg in liver and 0.05 mg/kg in fat, eggs, kidney and muscle. Hence, no livestock feeding study is needed and MRLs and risk assessment values for the relevant commodities in ruminants, pigs and poultry can be established at the LOQ level. The representative uses on cereals supported in the present dossier are shown not to produce higher residues than those previously evaluated.

Taking into account the findings from the ruminant feeding study with the main plant metabolite FOE oxalate which was conducted for the US it was concluded that no detectable residues of FOE oxalate are to be expected in ruminant products.

In addition to the European methodology applied in the EU peer review process and by EFSA, the dietary burden was calculated according to the OECD guidance document (2013) taking into account the most recent feeding tables. Based on the feeding items cereals (including by-products) the dietary burden calculated for livestock was up to a maximum of 0.008 mg/kg bw/d (sheep - lamb). The conclusions drawn for Annex I inclusion and in the EFSA Reasoned Opinion on existing MRLs are considered to be still valid and no further data are considered necessary for this submission.

The metabolic pathway of flufenacet was similar in rats, poultry (laying hens), and ruminants (goat). Therefore, it can be expected that the metabolism in other farm animals does not differ, and thus for the active substance studies in pigs are not required.

The metabolism of flufenacet in fish was investigated in the context of a bioconcentration study with bluegill sunfish. [Fluorophenyl-UL-¹⁴C]flufenacet was introduced into the inflowing water to aquaria with the fish to achieve a concentration of 100 µg/L. The principle metabolic pathway was the glutathionate conjugation of the acetanilide moiety of the molecule followed by further metabolic conversions as already observed in rat, goat, hen and plants. The residue levels in edible tissue and viscera were low as documented by the low bioconcentration factor of 68-71 for the whole body.

No further data are considered necessary for this submission.

2.7.6. Summary of effects of processing

The relevant residues of flufenacet in raw agricultural commodities are determined by means of a common moiety method capturing the parent substance and all metabolites that contain the *N*-fluorophenyl-*N*-isopropyl functional group according to the residue definition in plants. This residue analytical method for risk assessment and enforcement involves a hydrolysis at conditions that are much harsher than those used to investigate the nature of processed residues. Therefore, a study on the nature of processed residues (high temperature hydrolysis according to OECD GL 507) can be omitted.

In the EU peer review process (Directive 91/414/EEC) processing studies on corn and soybean available from the US were reviewed although the residue levels did not exceed the threshold of 0.1 mg/kg. Supplementary processing data have been performed for wheat and barley. For wheat, the processed fractions resulting from milling, baking, production of wheat germs and starch were investigated. Concentration of residues was observed in some by-products, germs and bran (see Table 2.7.6-1). For barley, processed fractions from pearl barley processing and preparation of alcoholic beverages (malting, brewing, distillation) were investigated for flufenacet residues. Even though the crops were treated at an exaggerated rate (2N), no residues were determined in the raw agricultural commodity and thus processing factors were not calculated. No residues were determined in the processed fractions either, except for the by-products dried distiller's grain and pearl barley rub-off, for which the processing factors are considered to be indicative (see Table 2.7.6-2).

Table 2.7.6-1: Summary of processing factors for flufenacet in wheat processed fractions

Commodity	Report no 11-3401 Trial 11-3401-01 United Kingdom	Report no 11-3401 Trial 11-3401-02 The Netherlands	Report No 107840 Stilwell, Kansas (US)	Mean / Median processing factor*
Bran	4.4	5.2	2.1	4.4
Middlings	3.0	3.2	0.80	3.0
Shorts	4.4	5.3	0.89	4.4
White flour	0.1	< 0.8	0.44	0.3
White bread	0.5	0.8	--	0.7
Whole meal	1.1	1.3	--	1.2
Wholemeal bread	0.9	1.2	--	1.1
Wheat germ	1.2	1.6	1.3	1.3
Starch A	< 0.1	< 0.8	--	--
Gluten	1.0	1.2	--	1.1
Starch B	0.2	< 0.8	--	--
Gluten feed meal	0.6	< 0.8	--	--
Aspirated grain fractions	--	--	0.49	--

*The median is given in case more than 2 individual results are available; in case of two individual results > LOQ the mean value is calculated.

Table 2.7.6-2: Summary of processing factors for flufenacet in barley processed fractions

Commodity	Trial: 11-3400-01, Germany	Trial: 11-3400-02, Belgium
Processing into beer		
malt sprouts	n.c.	n.c.
brewer's malt	n.c.	n.c.
brewer's grain	n.c.	n.c.
hops draff	n.c.	n.c.
brewer's yeast	n.c.	n.c.
beer	n.c.	n.c.
Processing into distillers grain		
Distillers grain, fresh	n.c.	n.c.
Distillers grain dried	>1.2*	>1.3*
Processing into pearl barley		
pearl barley rub off	>1.8*	>2.1*
pearl barley	n.c.	n.c.

n.c. = not calculated because residues in the raw agricultural commodity and the processed fraction were < LOQ.

*In case residues in the processed fraction were >LOQ the LOQ of the RAC was used to calculate the transfer factor.

No further data are considered necessary for this submission.

2.7.7. Summary of residues in rotational crops

Metabolism in rotational crops was found to be very similar to primary crop metabolism. In the EU review process rotational crop metabolism studies using [fluorophenyl-UL-¹⁴C] and [thiadiazole-2-¹⁴C]flufenacet were evaluated and considered to be acceptable.

In order to complete the picture of all potential metabolic pathways in rotated crops a respective study was conducted with flufenacet radiolabelled in the C-5 position of the thiadiazole ring. Therefore, [thiadiazole-5-¹⁴C]flufenacet was applied to bare soil at a use rate of approximately 900 g as/ha and wheat (cereal crop), turnip (root crop) and Swiss chard (leafy crop) were sown 30 days (1st rotation), 142 days (2nd rotation) and 317 days (3rd rotation) after application. The crops were cultivated and harvested according to agricultural practice.

The total radioactive residues (TRR) increased in wheat from the 1st to the 2nd rotation and followed by a decrease at the 3rd rotation, whereas TRR continually decreased in turnip and Swiss chard from the 1st to the 3rd rotation. Extraction of harvested crops with acetonitrile/water (8/2, v/v) was almost complete amounting to more than 93% of TRR. Radio-HPLC and radio-TLC of the extracts revealed that more than 80% of TRR consisted of radiolabelled trifluoroacetate (TFA, M45) in all crops accompanied by minor amounts of FOE-thiadone-glycoside (M25) and trifluoroethane sulfonic acid (M44).

These results indicated an initial cleavage of the thiadiazole ring from the parent substance in soil. Lower portions of the split-off thiadiazole ring were taken up by rotated crops and conjugated as glycoside. The main metabolic pathway proceeded *via* complete degradation of the thiadiazole ring in soil to form TFA (M45). On a short-term period, a low amount of trifluoroethane sulfonic acid (M44) was also formed in soil. The major portion of TFA and a small amount of the sulfonic acid obviously were taken up by the rotated crops since their concentration in the crops was higher than in the soil.

In the Monograph and in the EFSA reasoned opinion on existing MRLs it was concluded that flufenacet residue levels in rotational crop commodities are not expected to exceed 0.01 mg/kg, provided flufenacet is applied in compliance with the GAPs that involve application rates ranging from 150 – 600 g as/ha.

Although according to the evaluation in the Monograph and by EFSA, no field rotational crop trials were deemed necessary four field rotational crop studies were conducted on request of UK CRD in order to investigate residue levels in cereal commodities in a scenario where winter cereals are grown after the preceding crop potato which also received an application of a flufenacet containing product at the maximum registered rate for potatoes. The trials are reported in the supplementary dossier.

Potatoes and cereals were both treated with one spray application of a flufenacet containing product (at the maximum rates which were 600 g as/ha for potatoes and 240 g as/ha for cereals). No residues were apparent in green material of cereals collected at growth stage BBCH 29 – 30 or grain and straw sampled at harvest (BBCH 89). The findings show that treatment of the preceding crop with a flufenacet containing product at the maximum field rate does not impact residue levels in/on cereals grown as succeeding crops. No uptake from the soil into the following crop has been observed. This scenario reflects a worst case rotation with regard to potential uptake from soil. Shorter plant back intervals (e.g. 30 days) were not investigated since the time for sowing spring cereals has already passed in case of failure of other spring crops (i.e. potatoes, maize) that may have received a treatment with a flufenacet containing product. The absence of residues in cereals when sown as following crop is considered to be representative for all other rotational crop situations where the preceding crop is treated with application rates up to 600 g as/ha.

The total residues of flufenacet were found to be less than the limit of quantification of 0.01 mg/kg in grain, 0.05 mg/kg in green material and 0.1 mg/kg in straw.

2.7.8. Summary of other studies

No other studies were conducted in support of the renewal of approval for flufenacet.

2.7.9. Estimation of the potential and actual exposure through diet and other sources

Flufenacet

The toxicological reference values (ADI, ARfD) as published in the Review Report (7469/VI/98-Final – 3rd July 2003) are taken into account to perform the dietary risk assessment (see Table 2.7.9-1).

Table 2.7.9-1: Toxicological endpoints for flufenacet

Endpoint	Value (mg/kg bw/day)	Study	Safety factor	Reference
Acceptable Daily Intake (ADI)	0.005	2 year rat study (LOEL)	250	Review Report (7469/VI/98-Final – 3 rd July 2003)
Acute Reference Dose (ARfD)	0.017	90 day, 1 year dog study	100	

Dietary Exposure Calculation

TMDI calculation

The Theoretical Maximum Daily Intake (TMDI) was calculated using the EFSA PRIMo rev. 2 and compared with the toxicological reference value. TMDI is based on the MRLs as established in Regulation (EU) 1127/2014 limited to the representative uses (wheat, rye, barley). Additionally MRLs for products of animal origin (swine, bovine, sheep, goat, poultry commodities, milk and birds eggs) established at the respective LOQ levels were considered. The total calculated intake values accounted up to 21.9 % of the ADI (WHO Cluster diet B). The PRIMo output template is included in the Appendix 3

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo.

It can be concluded that the supported uses of flufenacet do not result in a consumer exposure exceeding the toxicological reference value and therefore flufenacet is unlikely to pose a consumer health risk.

Acute Reference Dose (ARfD)

In order to evaluate the potential acute exposure to flufenacet residues through the diet, the National Estimated Short Term Intakes (NESTI)/International Estimated Short Term Intakes (IESTI) are estimated using the EFSA PRIMo model (revision 2).

According to the Review Report (7469/VI/98-Final – 3rd July 2003), an ARfD of 0.017 mg/kg bw/d was established based on the 90d and 1year dog study.

The acute consumer exposure was calculated for cereals limited to the representative uses (wheat, rye, barley) using the highest residue level found in cereal grain (0.05 mg/kg), products of bovine and poultry origin and cattle milk.

The results of the acute exposure calculations are compiled in Table 2.7.9-2. The PRIMo output template is included in the Appendix 3

Taking into account the ARfD of 0.017 mg/kg, the highest NESTI was estimated at **7.3% of ARfD** for children due to consumption of milk and **3.5% of ARfD** for adults due to consumption of poultry meat. It is concluded that the herein supported uses in cereals do not result in unacceptable health risks to European consumers.

Table 2.7.9-2: NESTI calculation for flufenacet according to the EFSA PRIMo model (rev 2)

Commodity	Input value (mg/kg)	Maximum food intake reported (g/kg bw/d)	Percentile	MS diet	Body weight (kg)	IESTI 1 (mg/kg bw/d)	% ARfD
Children							
Barley	0.05	1.77	97.5	UK 4-6 yrs.	20.5	0.0001	0.5
Rye	0.05	6.32	97.5	UK Infant	8.7	0.0003	1.9
Wheat	0.05	14.45	97.5	UK 4-6 yrs	20.5	0.0007	4.2
Meat (bovine)	0.05	12.78	95	DE	16.15	0.0006	3.8
Fat (bovine)	0.05	2.07	97.5	UK Infant	8.70	0.0001	0.6
Liver (bovine)	0.02	8.07	97.5	UK Infant	8.70	0.0002	0.9
Kidney (bovine)	0.05	3.77	97.5	UK Toddler	14.50	0.0002	1.1
Meat (poultry)	0.05	11.23	97.5	DE	16.15	0.0006	3.3
Fat (poultry)	0.05	-	-	-	-	-	-
Liver (poultry)	0.02	-	-	-	-	-	-
Kidney (poultry)	0.05	-	-	-	-	-	-
Milk (cattle)	0.01	124.22	97.5	UK Infant	8.70	0.0012	7.3
Eggs	0.05	12.41	97.5	UK Infant	8.7000	0.0006	3.7
Adults							
Barley	0.05	7.24	97.5	NL	63	0.0004	2.1

Commodity	Input value (mg/kg)	Maximum food intake reported (g/kg bw/d)	Percentile	MS diet	Body weight (kg)	IESTI 1 (mg/kg bw/d)	% ARfD
Rye	0.05	4.85	97.5	LT	70	0.0002	1.4
Wheat	0.05	7.82	97.5	UK vegetarian	66.7	0.0004	2.3
Meat (bovine)	0.05	5.95	97.5	NL	63.00	0.0003	1.8
Fat (bovine)	0.05	0.67	97.5	UK Adult	76.00	0.0000	0.2
Liver (bovine)	0.02	2.70	97.5	UK Adult	76.00	0.0001	0.3
Kidney (bovine)	0.05	1.70	97.5	UK Adult	76.00	0.0001	0.5
Meat (poultry)	0.05	11.75	97.5	UK	66.70	0.0006	3.5
Fat (poultry)	0.05	-	-	-	-	-	-
Liver (poultry)	0.02	4.44	97.5	NL	63.00	0.0001	0.5
Kidney (poultry)	0.05	-	-	-	-	-	-
Milk (cattle)	0.01	17.24	97.5	NL	63.00	0.0002	1.0
Eggs	0.05	3.79	97.5	UK Vegetarian	66.70	0.0002	1.1

Conclusion

Residues arising from the supported uses in cereals (wheat, barley, rye), following application consistent with good plant protection practice, do not result in unacceptable health risks to European consumer.

TFA

The toxicological reference values (ADI, ARfD) as proposed in the DRAR are taken into account to perform the dietary risk assessment (see Table 2.7.9-3).

Table 2.7.9-3 Toxicological endpoints for TFA

Endpoint	Value (mg/kg bw/day)	Study	Safety factor	Reference
Acceptable Daily Intake (ADI)	0.05	90 day rat study (NOAEL = 10 mg/kg bw/day)	200	EFSA, 2014
Acute Reference Dose (ARfD)	0.75	Rat developmental toxicity study Maternal NOAEL 75 mg/kg bw/d	100	Proposal CoRMS, 2017

TMDI calculation

In order to assess TFA residues that may arise from crops which are grown as rotational crops extrapolations were made as listed in the Table 2.7.9-4 below.

TFA residues in wheat grain were higher in cereals grown as rotational crops compared to directly treated cereals. The higher levels were used for the risk assessment as a worse case .

Table 2.7.9-4 TFA residue levels in plant products used for consumer risk assessment

Commodity	Cereal use rate 240 g as/ha TFA-Na (mg/kg)	Source of residue data
Wheat, barley, rye, oats grain	0.759	Wheat grain – from CRC study (2 nd rotation)
Maize grain	0.759	Wheat grain – from CRC study (2 nd rotation)
Peas, beans, lupins (dry)	0.759	Wheat grain – from CRC study (2 nd rotation)
Potatoes	0.050	Scenario 1: Turnip roots- from CRC study (1 st rotation)
Turnips, swedes	0.050	Scenario 1: Turnip roots- from CRC study (1 st rotation)

Sugar beet	0.050	Scenario 1: Turnip roots- from CRC study (1 st rotation)
Oil seeds	0.759	Wheat grain – from CRC study (2 nd rotation)

Anticipated TFA-Na residue levels in animal commodities used in consumer risk assessment are presented in Table 2.7.9-5

Table 2.7.9-5 Anticipated TFA-Na residue levels in animal commodities

	Milk	Muscle	Fat	Liver	Kidney
TFA-Na residue level (rate 240 g a.s./ha)	Milk and animal tissues of ruminant, bovine in mg/kg				
	0.034	0.115	0.030	0.182	0.319
	Eggs and animal tissues of poultry in mg/kg				
	0.077	0.141	0.021	0.174	0.307
	Animal tissues of pig in mg/kg; (Transfer factors from ruminants used)				
	-	0.088	0.023	0.140	0.246

The total calculated intake values accounted up to 23.7 % of the ADI (WHO Cluster diet B). The PRIMo output template is included in the Appendix 3.

The results indicate that given the multiple worst case assumptions considered the intended uses of flufenacet are not likely to cause unacceptable risks to human health as a result of long term exposure to TFA.

IESTI calculation

It was proposed by CoRMS to establish ARfD of 0.75 mg/kg bw/d based on the rat developmental toxicity study.

In order to evaluate the potential acute exposure to TFA residues through the diet, the National Estimated Short Term Intakes (NESTI)/International Estimated Short Term Intakes (IESTI) are estimated using the EFSA PRIMo model (revision 2).

The PRIMo output template is included in the Appendix 3. The highest short-term intake was estimated at 7.5% of ARfD for children due to consumption of scarole and 3.0% of ARfD for adults due to consumption of Chinese cabbage.

Conclusion

For an application rate of 240 g a.s./ha (highest use rate for the representative uses) the ADI exhaustion is 23.7% and the usage of the ARfD does not exceed 10% for any of the primary crops or those which may be grown in rotation. The predicted intake of the flufenacet from drinking water is negligible.

Estimation of TFA intake by means of drinking water

Different groundwater concentrations may be calculated for TFA according to different national requirements and models to be used. Therefore, the calculation of potential intakes of TFA by means of drinking water considers several quantities that need to be added to the amount taken up by food of plant and animal origin depending on the specific regional situation.

All calculations are made assuming an intake of 0.0267 L/kg bw/day (derived from the threshold of 0.02 µg/kg bw/d, 0.75 µg/L and an intake of 2 L/person/day as suggested in SANCO 221/2000 rev 10). In order to express the consumption of the ADI (which is expressed as mg TFA-Na/kg bw/d) also the drinking water concentrations are calculated as TFA-Na (see Table 2.7.9-6).

Table 2.7.9-6 Intake calculation for TFA by drinking water

TFA-H level in drinking water (µg/L)	Calculated daily intake (µg TFA-H/kg bw/d)	Calculated daily intake (µg TFA-Na/kg bw/d)	% of ADI (0.05 mg/kg bw/d)
0.75	0.02	0.02	0.05
10	0.27	0.32	0.64
20	0.53	0.64	1.27

Combined consumer exposure to TFA from food and drinking water will not exceed the toxicological reference value.

Estimation of FOE-oxalate (M01) and FOE-sulfonic acid (M02) intake by means of drinking water

FOE-oxalate (M01) and FOE-sulfonic acid (M02) are also metabolites which are prone to reach groundwater and therefore need to be considered in a consumer risk assessment taking into account all possible sources of intakes. Concentrations in groundwater for both metabolites are quite variable depending upon their degradation properties, the use pattern and application rates. Therefore, as a conservative approach, the risk assessments are performed using an upper limit concentration of 10 µg/L for both metabolites.

The following amounts for flufenacet metabolites by means of intake from drinking water and the corresponding ADI / ARfD usages are presented in Table 2.7.9-7.

Table 2.7.9-7 Upper limit intake of FOE oxalate and FOE sulfonic acid by drinking water

Metabolite	Intake [µg/kg bw/d] expressed as parent equivalent	Usage of ADI [%]	Usage of ARfD [%]
FOE oxalate (M01)	0.430	8.60	2.53
FOE sulfonic acid (M02)	0.352	7.04	2.07

Combined consumer exposure to FOE oxalate and FOE sulfonic acid from food and drinking water will not exceed the toxicological reference value.

2.7.10. Proposed MRLs and compliance with existing MRLs

Established EU MRLs for plant commodities

The EU MRLs for flufenacet in all types of small grain cereals (wheat, rye, triticale, barley, oats) were established in Commission Regulation (EU) No 1127/2014 of 20 October 2014 as recommended in the EFSA Reasoned Opinion on the review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (EFSA Journal 2012;10(4):2689), see Table 2.7.10-1.

Table 2.7.10-1 Existing EU MRLs for flufenacet in cereal grains (mg/kg)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Flufenacet (sum of all compounds containing the N fluorophenyl-N-isopropyl moiety expressed as flufenacet equivalent)
0500010	. Barley	0.1
0500020	. Buckwheat and other pseudo-cereals	0.05*
0500030	. Maize/corn	0.05*
0500040	. Common millet/proso millet	0.05*
0500050	. Oat	0.05*
0500060	. Rice	0.05*
0500070	. Rye	0.05*
0500080	. Sorghum	0.05*
0500090	. Wheat	0.1
0500990	. Others	0.05*

The residue data referred to in the EFSA evaluation are summarized in the table 2.7.10-2.

**Table 2.7.10-2 Overview of the residue trials data relevant for MRL setting as evaluated by EFSA
(EFSA Journal 2012;10(4):2689)**

Commodity	Residue region ^{a)}	Individual trial results for enforcement and risk assessment (mg/kg)	Median residue (mg/kg)	Highest residue (mg/kg)	MRL proposal (mg/kg)	Median CF ^{d)}	Comments
Wheat grain, Barley grain	NEU	23** x <0.05	0.05	0.05	0.05*	1	Combined dataset on barley (8), rye (3) and wheat (13) supporting the GAP for all small grain cereals
	SEU	Barley: 3 x <0.01; <0.05 Wheat: 2 x <0.01; 0.01; <0.05; 0.05	0.01	0.05	0.1	1	Combined dataset on barley (4) and wheat (5)
Oats grain, rye grain	NEU	24** x 0.05	0.05 ^{b)}	0.05	0.05*	1	Extrapolation from northern GAPs on barley and wheat is possible
Barley straw; wheat straw	NEU	<0.01; 0.011; 18**x <0.1 ^{c)}	0.1	0.1	0.1	1	Combined dataset on barley (8), rye (3) and wheat (9) ^{c)}
	SEU	Barley: <0.05; 2x 0.06; 0.11 Wheat: 3x <0.05; 0.09; < 0.10	0.06	0.11	0.2	1	Combined dataset on barley (4) and wheat (5)
Oats straw, rye straw	NEU	<0.01; 0.011; 18** x <0.1 ^{c)}	0.1	0.1	0.1	1	Combined dataset on barley (8), rye (3) and wheat (9) ^{c)}

* indicates the MRL is set at the LOQ

** one trial was erroneously harvested before sampling of grain and straw

^{a)} NEU = northern Europe, SEU = southern Europe

^{b)} in EFSA Table 0.01 mg/kg

^{c)} according to applicant's information 23 x < 0.1 mg/kg for the critical GAP of 240 g as/ha (combined dataset on barley (8), rye (3) and wheat (12)) corresponding to the data set for wheat and barley grain in northern Europe

^{d)} conversion factor from for enforcement to risk assessment residue definition

In the tables 2.7.10-3 and 2.7.10-4 MRL calculations for cereal grain are performed for the critical GAP (southern Europe) using the EU methodologies and the OECD MRL calculator.

For both methodologies used the proposed MRL results in 0.1 mg/kg and is in line with the proposal in the EFSA document.

No calculations are performed for the critical GAP from the northern region since residues in cereal grain were less than the LOQ (0.05 mg/kg) in all trials.

Table 2.7.10-3: Calculation of MRL proposal for flufenacet according to EU guideline 7039/VI/95 of 22 July 1997 based on the data set from southern Europe

No.	Crop	Days after application	Residue value (mg/kg)	Plot No. ¹ / Study No.	No. of applic.	FL-Type	Product	Country
1	Wheat, winter	153	<0.01	09-2052-02 / 09-2052MAN	1	SC 600	Flufenacet & Diflufenican SC 600	France
2	Wheat, winter	220	<0.01	09-2052-04 / 09-2052MAN	1	SC 600	Flufenacet & Diflufenican SC 600	France
3	Barley, winter	148	<0.05	0570-00 / RA-2144/00	1	SC 600	Flufenacet & Diflufenican SC 600	Spain
4	Barley, winter	203	<0.01	09-2048-03 / 09-2048MAN	1	SC 600	Flufenacet & Diflufenican SC 600	France
5	Wheat, winter	196	0.05	09-2052-03 / 09-2052MAN	1	SC 600	Flufenacet & Diflufenican SC 600	France
6	Wheat, winter	209	0.01	09-2052-01 / 09-2052MAN	1	SC 600	Flufenacet & Diflufenican SC 600	France
7	Barley, winter	197	<0.01	09-2048-01 / 09-2048MAN	1	SC 600	Flufenacet & Diflufenican SC 600	France
8	Wheat, winter	196	<0.05	0567-00 / RA-2144/00	1	SC 600	Flufenacet & Diflufenican SC 600	France
9	Barley, winter	188	<0.01	09-2048-02 / 09-2048MAN	1	SC 600	Flufenacet & Diflufenican SC 600	France

¹ as given in the Tier 1 summaries**Results (Wheat, winter; Barley, winter)**

Method I (Weinmann/Nolting) (all values)	R	0.023
	s	0.020
	k	3.032
	$R_{\max} = R + k \cdot s$	0.084
Method II (Wilkenning) (75 % quantile)	R (0.75)	0.050
	$R_{\text{ber}} = 2 \cdot R(0.75)$	0.100

STMR: <0.01;<0.01;<0.01;<0.01;<0.01;0.01;<0.05;<0.05;0.05

Table 2.7.10-4: Calculation of MRL proposal for flufenacet according to OECD Calculator based on the data set from southern Europe

No.	Crop	Days after application	Residue value (mg/kg)	Plot No. ¹ / Study No.	No. of applic.	FL-Type	Product	Country
1	Wheat, winter	153	<0.01	09-2052-02 / 09-2052MAN	1	SC 600	Flufenacet & Diflufenican SC 600	France
2	Wheat, winter	220	<0.01	09-2052-04 / 09-2052MAN	1	SC 600	Flufenacet & Diflufenican SC 600	France
3	Barley, winter	148	<0.05	0570-00 / RA-2144/00	1	SC 600	Flufenacet & Diflufenican SC 600	Spain
4	Barley, winter	203	<0.01	09-2048-03 / 09-2048MAN	1	SC 600	Flufenacet & Diflufenican SC 600	France
5	Wheat, winter	196	0.05	09-2052-03 / 09-2052MAN	1	SC 600	Flufenacet & Diflufenican SC 600	France
6	Wheat, winter	209	0.01	09-2052-01 / 09-2052MAN	1	SC 600	Flufenacet & Diflufenican SC 600	France
7	Barley, winter	197	<0.01	09-2048-01 / 09-2048MAN	1	SC 600	Flufenacet & Diflufenican SC 600	France
8	Wheat, winter	196	<0.05	0567-00 / RA-2144/00	1	SC 600	Flufenacet & Diflufenican SC 600	France
9	Barley, winter	188	<0.01	09-2048-02 / 09-2048MAN	1	SC 600	Flufenacet & Diflufenican SC 600	France

¹ as given in the Tier 1 summaries

FL - formulation

Results (Wheat, winter; Barley, winter)

Total number of data (n)	9	Standard deviation (SD)	0.020
Lowest residue	0.01	Percentage of censored data	78
Highest residue	0.05	Number of non-censored data	2
Median residue	0.000	Correction factor for censoring (CF)	0.481
Mean	0.023		

Proposed MRL estimate

Highest residue	0.05
Mean + 4 SD	0.103
CF x 3 mean	0.034
Unrounded MRL	0.103
Rounded MRL	0.1

MRL calculation presented considers only those trials which were performed according to the critical GAP (i.e. 240 g as/ha). For lower application rates where residues were apparently covered by the existing MRLs no separate calculations would be necessary since no new MRLs need to be proposed.

The existing MRLs (Commission Regulation (EU) No 1127/2014 of 20 October 2014) for cereal grain are considered sufficient to cover the residues in cereal grain after GAP compliant use.

Established EU MRLs for animal commodities

According to animal metabolism and livestock feeding studies residues in animal matrices, milk and eggs are unlikely to occur. The representative uses supported correspond to the frame which was evaluated by EFSA when reviewing the MRLs.

MRLs for animal commodities have been set up in Commission Regulation (EU) No 1127/2014 of 20 October 2014 at LOQ for the individual matrices (see Table 2.7.10-5). It is considered to be appropriate for the representative uses of flufenacet and MRLs do not need to be modified.

Table 2.7.10-5 Existing EU MRLs for flufenacet in products of animal origin (mg/kg)

Products	Flufenacet (sum of all compounds containing the N fluorophenyl-N-isopropyl moiety expressed as flufenacet equivalent)
Products of animal origin	Meat: 0.05* Fat: 0.05* Liver: 0.02* Kidney: 0.05* Milk: 0.01* Eggs: 0.05*

*- LOQ

2.7.11. Proposed import tolerances and compliance with existing import tolerances

There are no relevant import tolerances established at EU level; and no CXLs are set.

2.8. FATE AND BEHAVIOUR IN THE ENVIRONMENT

For the purpose of the current evaluation, aimed on the renewal of the approval of Flufenacet in the EU, the Applicant provided a Dossier consisting of, in section B.8. – Environmental Fate and Behaviour, old studies, already evaluated for the previous approval for use of Flufenacet in the EU, and new studies, updating the dataset for Flufenacet in the following areas:

- Degradation in soil examined in laboratory (25 studies);
- Degradation in soil examined under field conditions (1 study);
- Soil sorption and mobility in soil of Flufenacet and its metabolites (11 studies);
- Fate and behaviour of Flufenacet the aquatic environment (7 studies);
- Fate and behaviour of Flufenacet and its degradation products in air – no new studies submitted;
- Monitoring data for Flufenacet and its degradation products (3 reports);
- Modelling exposure assessment (6 study reports).

All submitted studies, old and new, were evaluated according to the current valid test guidelines and summarised in the documents Vol 3 B.8._CA and Vol 3 B.8._CP of the Renewal Assessment Report under the relevant data points, with exception of those considered not valid and/or being superseded by the newly submitted studies. In such cases, the studies were cited in the Renewal Assessment Report, but not summarised. Instead, for each of them the extended rationale for its non-inclusion into the Assessment Report was provided.

For all studies submitted for the first evaluation of Flufenacet, considered then valid and summarised in either Draft Assessment Report or Addenda to it, unless in course of the current evaluation they were found not valid, new summaries were provided to meet the current requirements.

For the present evaluation the Applicant proposed the revised representative GAP, limiting the intended uses to those aimed on suppression of the annual weeds in cereals, pre-emergence and early post emergence (range of BBCH 00-22) in autumn and at early spring.

It shall be noted that, unlike for the previous assessment, the Applicant proposed the representative formulation codenamed DFF+FFA SC 600, containing 400 g/L Flufenacet and 200 g/L Diflufenican. The proposed trade names are Herold SC (to be used in both North- and South European countries), Fosburi (to be used only in NE climatic zone) and Firebird (to be used in SE climatic zone). This representative formulation was already evaluated for the purpose of the authorisation of Diflufenican in the EU (RMS – UK).

That new representative GAP, used in the evaluation in the area of environmental fate and behaviour, including the environmental exposure assessment, is presented below in the table 2.8-1. For clarity reasons the application rates for the second active substance of the EU-representative formulation – Diflufenican, were not reported in this table.

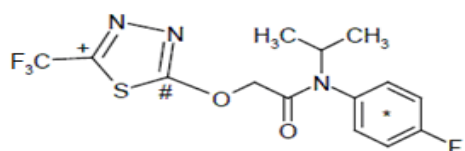
Table 2.8.-1: The proposed updated representative GAP for Flufenacet.

Region	Crop	Product name	Data on application						
			Type of application	Number of Applic.	Interval between applications	Application time		Application rate - flufenacet [g/ha]	Spray volume [L/ha]
						Period	Crop's growth stage (BBCH)		
North EU	Cereals (winter wheat, winter barley, winter rye)	Herold SC (400 g/L flufenacet + 200 g/L diflufenican)	Foliar spraying	1	Not applicable – single application	Early post-emergence, Autumn only;	10-13	240	200 – 400
South EU	Cereals (wheat, winter barley)	Fosburi (400 g/L flufenacet + 200 g/L diflufenican)	Foliar spraying	1	Not applicable – single application	Early post-emergence	11-13	240	80 – 400
North EU	Cereals (winter wheat, winter barley, winter rye)	Firebird (400 g/L flufenacet + 200 g/L diflufenican)	Foliar spraying	1	Not applicable – single application	Pre-emergence and early post-emergence	00-22	120	200 – 400
South EU	Cereals (wheat, barley)	Herold SC (400 g/L flufenacet + 200 g/L diflufenican)	Foliar spraying	1	Not applicable – single application	Early post-emergence	11-13	160	200 – 400

Fulfilling the data requirement set in the Article 8 point 5 of the Regulation (EC) 1107/2009, the Applicant submitted the report presenting the results of the search of the scientific peer-reviewed open literature. This report, covering the results of the search performed for all sections, was submitted by the Applicant as a separate part of the Dossier – Document MCA, Section 9: Literature data. The Report was summarised and evaluated in Vol. 3 B.8._CA – Environmental Fate and Behaviour under the point B.8.6. – Open literature review. In this summary also the results of the repeated literature search performed by the RMS – Poland, were presented. All publications that were found relevant for the present assessment were summarised under the relevant points within either section Vol. 3 B.8._CA or section Vol. 3 B.8._CP of the Renewal Assessment Report.

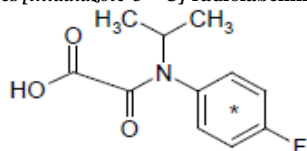
In the current assessment the environmental fate and behaviour of the active substance – Flufenacet, was examined using a compound radiolabelled in either phenyl ring (one radiolabelling position) or in thiadiazole moiety (two different radiolabelling positions). The radiolabelled compounds were used also in examination of the fate and behaviour in the environment of the degradation products of Flufenacet. All radiolabelled structures used to examine the environmental fate and behaviour of Flufenacet are presented below on Fig. 2.8.-1.

In the documentation submitted by the Applicant following code names and alternative names for Flufenacet were used: fluthiamid, fluthiamide and FOE 5043.



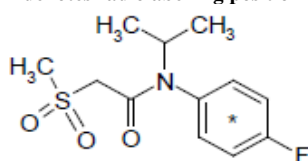
Flufenacet radiolabelled in phenyl and thiadiazole moieties;

* denotes [phenyl-UL-¹⁴C] radiolabelling position,
denotes [thiadiazole-2-¹⁴C] radiolabelling position;
+ denotes [thiadiazole-5-¹⁴C] radiolabelling position;



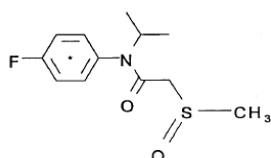
FOE Oxalate (M1);

* denotes radiolabelling position



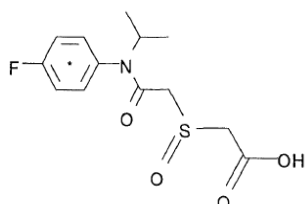
FOE Methylsulfone (M7; BCS-CO62475);

* denotes radiolabelling position



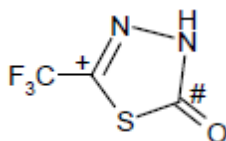
FOE Methylsulfoxide

* denotes radiolabelling position



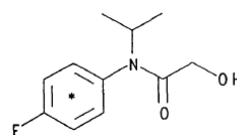
FOE Thioglycolate sulfoxide

* denotes radiolabelling position



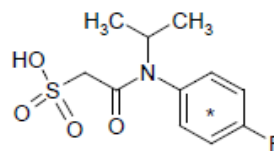
FOE-Thiadione (M9; Thiadione);

denotes [thiadiazole-2-¹⁴C] radiolabelling position;
+ denotes [thiadiazole-5-¹⁴C] radiolabelling position;



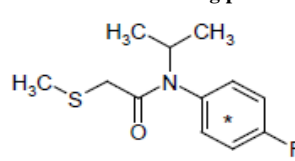
FOE Alcohol;

* denotes radiolabelling position



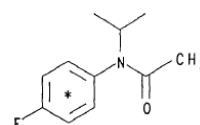
FOE Sulfonic acid (M2);

* denotes radiolabelling position



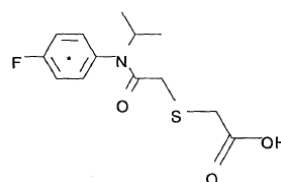
FOE Methylsulfide (M5);

* denotes radiolabelling position



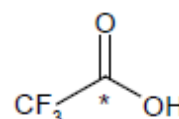
FOE Amine acetate

* denotes radiolabelling position



FOE Thioglycolate sulfide

* denotes radiolabelling position



Trifluoroacetic acid (M45, TFA, BCS-AZ6567);

* denotes radiolabelling position

Figure 2.8.-1: Radiolabelled forms of Flufenacet and its metabolites used in environmental fate and behaviour studies (all structures copied from the documentation provided by the Applicant).

2.8.1. Summary of fate and behaviour in soil

I) Persistence in soil:

The results of the examination of the persistence of Flufenacet in soil are presented below.

1) Degradation in soil under aerobic conditions:

The route of degradation of the acetanilide herbicide Flufenacet in aerobic soil was extensively examined in eight agricultural soils – seven originating from the EU and one from US. The test compound – Flufenacet, was radiolabelled in one of the following three following positions:

- uniformly in phenyl ring – compound tested on four soils,
- position C2 in thiadiazole moiety – test performed on one soil,
- position C5 in thiadiazole moiety – examined in four soils.

These data were presented in five unpublished studies submitted specifically for the purpose of this assessment. Additionally the data relevant for determining transformation pattern of Flufenacet in aerobic soil, relevant for regulatory purposes, were found in one scientific paper, examining the degradation of Flufenacet radiolabelled uniformly in phenyl ring in two US soils. That study was based on a non-GLP regulatory study, conceived as a bridging study for laboratory and field experiments on the degradation of Flufenacet in soil. That study was verified by RMS and found acceptable. Therefore the results of the literature study based on it were included into evaluation.

The key results of the examination of transformation of Flufenacet are presented in the tabularised form below (tables 2.8.1.-1 – 2.8.1.-4), separately for the compound radiolabelled in phenyl ring and in thiadiazole moiety.

Table 2.8.1.-1: The levels of mineralisation and NER fraction formed, and identified degradation products in experiments with [Phenyl-U-¹⁴C] Flufenacet.

Study	Soil		Level of mineralisation [% AR]:		Level of NER [% AR]:			Identified degradation products
	Name	Type (USDA)	After ~100 days	at the study's end	Max.	After ~100 days	at the study's end	
Kelley <i>et al</i> ; 1995	BBA 2.2	Loamy sand	12.6 DAT 100	14.2 DAT 120	42.3 DAT 120	37.3 DAT 100	42.3 DAT 120	FOE Sulfonic acid; FOE Oxalate; FOE TGS; FOE Methylsulfoxide; FOE Methylsulfone
	Laacherhof	Silt loam	20.8 DAT 100	23.8 DAT 120	37.1 DAT 120	29.9 DAT 100	37.1 DAT 120	FOE Sulfonic acid; FOE Oxalate; FOE TGS; FOE Methylsulfoxide; FOE Methylsulfone
	Hofchen im Tal	Silt loam	10.2 DAT 100	12.0 DAT 120	58.0 DAT 120	56.2 DAT 100	58.0 DAT 120	FOE Sulfonic acid; FOE Oxalate; FOE TGS; FOE Methylsulfoxide; FOE Methylsulfone
Pangilinan & Smith; 1994	Howe	Sandy loam	2.7 DAT 91	5.9 DAT 365	17.7 DAT 271	16.3 DAT 91	16.5 DAT 365	FOE Sulfonic acid; FOE Oxalate; FOE Alcohol; FOE TGS; FOE Methylsulfoxide; FOE Chloroacetanilide;
Bloomberg <i>et al</i> ; 2002	Fresno	Sandy loam	14.1 ¹⁾ DAT 88	14.1 ¹⁾ DAT 88	41.6 ²⁾ DAT 88	41.6 ²⁾ DAT 88	41.6 ²⁾ DAT 88	FOE Sulfonic acid; FOE Oxalate; FOE Alcohol;
	Chualar	Sandy loam	5.8 ¹⁾ DAT 88	5.8 ¹⁾ DAT 88	46.4 ²⁾ DAT 19	31.6 ²⁾ DAT 88	31.6 ²⁾ DAT 88	FOE Sulfonic acid; FOE Oxalate; FOE Alcohol;

Footnotes to the table:

- 1) Value estimated as a difference between the reported “total AR recovered” and the theoretical 100% AR;
- 2) The value is the sum of NER fraction in topsoil (0-3 cm) and subsoil (3-13 cm) for the given tie point; as in the subsoil the detected radioactivity was not further examined, but considered to represent NER fraction, in fact that value may be an overestimate;

Table 2.8.1.-2: Concentrations and classification of soil degradation products identified in experiments with [Phenyl-U-¹⁴C] Flufenacet

Degradation product	Maximum [% AR] in soil, detected on:						Classification according to SANCO/221/2000	Justification ¹⁾
	BBA 2.2	Laacherhof	Hofchen im Tal	Howe	Fresno	Chualar		
FOE Sulfonic acid	25.4 DAT 100	26.3 DAT 100	13.5 DAT 100	7.7 DAT 180	2.4 DAT 88	1.3 DAT 88	major/relevant for GW assessment	> 10% AR
FOE Oxalate	6.6 DAT 28	15.6 DAT 28	10.0 DAT 28	26.5 DAT 365	13.0 DAT 46	7.6 DAT 88	major/relevant for GW assessment	>10% AR
FOE Alcohol	n. d.	n. d.	n. d.	2.1 DAT 44, DAT 65	8.1 DAT 88	21.2 DAT 88	major/relevant for GW assessment	>10% AR
FOE TGS	3.3 DAT 56	5.5 DAT 28	1.9 DAT 28	3.7 DAT 180	n. d. ²⁾	n. d. ²⁾	minor/not relevant for GW assessment	Not meeting any of the criteria
FOE Methyl-sulfoxide	1.1 DAT 28, DAT 56	3.5 DAT 56	1.5 DAT 56	0.6 DAT 28	n. d. ²⁾	n. d. ²⁾	minor/not relevant for GW assessment	Not meeting any of the criteria
FOE Methyl-sulfone	6.6 DAT 100	4.3 DAT 120	5.6 DAT 120	n. d.	n. d. ²⁾	n. d. ²⁾	major/relevant for GW assessment	>5% AR at study end, increasing
FOE Chloroacet-anilide	n. d. ²⁾	n. d. ²⁾	n. d. ²⁾	5.1 DAT 44	n. d. ²⁾	n. d. ²⁾	minor/not relevant for GW assessment	Not meeting any of the criteria

Footnotes to the table:

1) Justification based on the criteria set by the Guideline SANCO/221/2000, listed under the point 4 on page 6:

“As a minimum, degradation products must be characterized and identified by the notifiers to the extent that it is technically feasible and their relevance must be assessed, if one of the following conditions applies:

- a) *Metabolites, which account for more than 10% of the amount of active substance added in soil at any time during the studies; or*
- b) *which account for more than 5% of the amount of active substance added in soil in at least two sequential measurements during the studies; or*
- c) *for which at the end of soil degradation studies the maximum of formation is not yet reached.*

2) Compound not detected in that soil.

Table 2.8.1.-3: The levels of mineralisation and NER fraction formed, and identified degradation products in experiments with [Thiadiazole-¹⁴C] Flufenacet.

Study/ radiolabelling position	Soil		Level of mineralisation [% AR]:		Level of NER [% AR]:			Identified degradation products
	Name	Type (USDA)	after ~100 days	at the study's end	Max.	after ~100 days	at the study's end	
Pangilinan & Smith; 1994a [Thiadiazole-2- ¹⁴ C]	Howe	Sandy loam	31.9 DAT 90	50.9 DAT 368	6.9 DAT 270	6.2 DAT 90	6.5 DAT 368	FOE Thiadone
Hein; 2012 [Thiadiazole-5- ¹⁴ C]	Hoefchen am Hohenseh 4a	Silt loam	5.7 DAT 120	5.7 DAT 120	13.5 DAT 60	12.5 DAT 120	12.5 DAT 120	FOE Thiadone; FOE Trifluoroethane-sulfonic acid; Trifluoroacetic acid (TFA)
Hein; 2012a [Thiadiazole-5- ¹⁴ C]	Laacherhof AXXa	Loamy sand	5.6 DAT 121	5.6 DAT 121	18.6 DAT 63	17.2 DAT 121	17.2 DAT 121	FOE Thiadone; FOE 5043-Trifluoroethane-sulfonic acid; Trifluoroacetic acid (TFA)
	Dollendorf II	Clay loam	6.5 DAT 121	6.5 DAT 121	11.5 DAT 63	10.6 DAT 121	10.6 DAT 121	FOE Thiadone; FOE 5043-Trifluoroethane-sulfonic acid; Trifluoroacetic acid (TFA)
	Laacherhof Wurmwiiese	Loam	4.6 DAT 121	4.6 DAT 121	18.6 DAT 35, DAT 63	17.2 DAT 121	17.2 DAT 121	FOE Thiadone; FOE 5043-Trifluoroethane-sulfonic acid; Trifluoroacetic acid (TFA)

Table 2.8.1.-4: Concentrations and classification of soil degradation products identified in experiments with [Thiadiazole-¹⁴C] Flufenacet

Degradation product	Maximum [% AR] in soil, detected on:					Classification according to SANCO/221/2000	Justification ¹⁾
	Howe	Hoefchen am Hohenseh 4a	Laacherhof AXXa	Dollendorf II	Laacherhof Wurmweise		
FOE Thiadone	3.9 DAT 7	5.8 DAT 10	2.8 DAT 7	5.6 DAT 10	4.6 DAT	major/relevant for GW assessment	> 5% AR at two consecutive time points
FOE 5043-Trifluoroethane-sulfonic acid	n. d. ²⁾	6.0 DAT 14	4.4 DAT 10	3.4 DAT 10	1.9 DAT 10	major/relevant for GW assessment	> 5% AR at two consecutive time points
TFA (Trifluoroacetic acid)	n. d. ²⁾	77.7 DAT 87	74.1 DAT 121	81.5 DAT 91	74.8 DAT 91	major/relevant for GW assessment	> 10% AR

Footnotes to the table:

1) Justification based on the criteria set by the Guideline SANCO/221/2000, listed under the point 4 on page 6:

“As a minimum, degradation products must be characterized and identified by the notifiers to the extent that it is technically feasible and their relevance must be assessed, if one of the following conditions applies:

- a) Metabolites, which account for more than 10% of the amount of active substance added in soil at any time during the studies; or*
- b) which account for more than 5% of the amount of active substance added in soil in at least two sequential measurements during the studies; or*
- c) for which at the end of soil degradation studies the maximum of formation is not yet reached.*

2) Compound not detected in that soil.

The transformation pattern of Flufenacet in soil was examined only on biologically viable soil. That was due to the fact that, on the basis of available results it was assumed that all transformation processes were predominantly or solely biologically-mediated. It was postulated that the initial step of the degradation was the cleavage of the test item on bridging oxygen of the thiadiazole heterocycle. The further sequence for the thiadiazole moiety is presented below:

- tautomerisation of keto-enol functional group, resulting in formation of FOE Thiadone,
- hydrolytical opening of thiadiazole ring and further oxidation resulting in formation of either FOE 5043-Trifluoroethanesulfonic acid or Trifluoroacetic acid (TFA), or else simple products of mineralisation and NER fraction – ultimate transformation products;
- further transformation of FOE 5043-Trifluoroethanesulfonic acid or Trifluoroacetic acid (TFA) to the simple products of mineralisation and NER fraction – ultimate transformation products.

In case of the moiety containing fluorophenyl ring next postulated step was the formation of the transient FOE Cysteine- or FOE Glutathione conjugates, undergoing subsequent quick transformation to FOE Methylsulfoxide, FOE Alcohol and FOE Chloroacetanilide. As possible side-processes were postulated direct formation of FOE Chloroacetanilide and FOE Alcohol. It shall be noted that FOE Chloroacetanilide may be not only a genuine degradation product, but also, and possibly to greater extent, analytical artefact. However, as the issue was not satisfactorily clarified, the RMS's proposal is to consider FOE Chloroacetanilide a genuine degradation product.

Additionally, as in course of evaluation FOE Alcohol was identified to be a potentially major degradation product, the additional assessment was performed to determine whether, in absence of data for that compound, the exposure assessment for FOE Alcohol may be considered to be covered by that for its immediate degradate – FOE Oxalate.

The Applicant in course of the discussion on the nature of FOE Alcohol made a following statement (the text is copied directly from the Applicant's e-mail; the “outdoor soil metabolism study” refers to the cited study by Shadrack and Kasper [1995]):

We cannot reconstruct what the reason for the accumulation or artificial formation of FOE alcohol (aka FOE hydroxy) was in that outdoor soil metabolism study, but we have several other laboratory studies, as well as EU and US field studies, which demonstrate, that FOE alcohol is a minor, transient metabolite, not accumulating at all, but rather being further oxidized quickly to FOE oxalate.

RMS having analysed the results provided by the study by Shadrack and Kasper [1995], reproduced in the publication by Bloomberg et al. [2002], noted that the compound was formed in greater amounts in Chualar soil, having lower OC content and slightly lower microbial activity of the two soils used in the experiment. Taking into account the fact that FOE Alcohol was also detected only in the study by Pangilinan and Smith [1994], performed on another soil having low OC content and microbial activity, but not in the study by Kelley et al [1995], all that may indicate that FOE Alcohol is indeed a transient, fast degrading compound, that would appear in higher amounts and for longer only in weak soils.

To further demonstrate that it was possible to cover the exposure assessment for FOE Alcohol with that for its immediate degradate – FOE Oxalate, RMS performed the comparative analysis by means of QSAR calculations, carried out with EPI Suite ver. 4.10 (September 2010) tool. The results of that assessment indicate that the properties of both compounds relevant for their environmental fate and behaviour are comparable. Therefore the exposure assessment performed for FOE Oxalate may be considered as covering that for FOE Alcohol.

Metabolic pathway of flufenacet in soil:

Flufenacet (1-(4-fluorophenyl)-N-isopropyl-3-methyl-2-oxo-2-(2,2,2-trifluoroethoxy)propanamide) is degraded via several pathways:

- Pathway 1:** Flufenacet is converted to FOE-thiadione (ASM, AASM), which then yields FOE 5043-trifluoroethanesulfonic acid (ASM, AASM) and trifluoroacetic acid (ASM, AASM).
- Pathway 2:** Flufenacet is converted to FOE alcohol (ASM, AASM), which then yields FOE oxalate (ASM, AASM).
- Pathway 3:** Flufenacet is converted to FOE cysteine conjugate (proposed intermediate), which then yields FOE thioglycolate sulfide (AASM), FOE thioglycolate sulfoxide (ASM), and FOE sulfonic acid (ASM, AASM).
- Pathway 4:** Flufenacet is converted to FOE methylsulfide (ASM), which then yields FOE methylsulfone (ASM).
- Pathway 5:** Flufenacet is converted to FOE chloroacetanilide (ASM).

The final products of the degradation are CO_2 and NER.

Legend: ASM = aerobic soil metabolism; AASM = anaerobic soil metabolism.
Remark: Flufenacet is stable to photolysis.

The degradation kinetics of Flufenacet in aerobic soil under laboratory conditions was extensively examined by the Applicant and its results presented in 26 study reports, of which 24 were found by the RMS acceptable and relevant for the current assessment. Additionally two literature studies were identified by the RMS which also provided the data on the degradation kinetics of Flufenacet in aerobic soils. These reports were found by the RMS relevant as supplementary source of data, however not suitable for deriving the regulatory endpoints.

a) Kinetic endpoints determined for Flufenacet:

The persistence (best-fit) kinetic endpoints obtained for Flufenacet are presented below in the table 2.8.1.-7. The modelling endpoints are given in the table 2.8.1.-8.

Table 2.8.1.-7: The persistence kinetic endpoints determined for Flufenacet in aerobic soil.

Soil		Soil properties		Incubation conditions	Kinetic model	Evaluation of the fit		Kinetic parameters		Kinetic endpoints	
Soil name	Soil type (USDA)	OC	pH			χ^2 error	Visual fit ¹⁾ /R ²	Param.	Value	DT ₅₀ [days]	DT ₉₀ [days]
BBA 2.2; [Phenyl-U- ¹⁴ C] label	Loamy sand	2.58	6.2 ²⁾	20°C; 40% MWHC	SFO	8.53	A/ 0.974	<i>k</i>	0.0217	31.9	106.1
Laacherhof; [Phenyl-U- ¹⁴ C] label	Silt loam	0.9	6.2 ²⁾	20°C; 40% MWHC	SFO	11.0	G/0.978	<i>k</i>	0.0411	16.9	56
Höfchen im Tal; [Phenyl-U- ¹⁴ C] label	Silt loam	2.40	6.2 ²⁾	20°C; 40% MWHC	SFO	5.47	G/ 0.990	<i>k</i>	0.0339	20.4	67.9
Howe, Indiana; [Phenyl-U- ¹⁴ C] label	Sandy loam	0.35	6.2 ³⁾	21°C; 75% of 1/3 bar	SFO	2.36	G/ 0.981	<i>k</i>	0.0215	32.2	107.0
Laacherhof AXXa; [Phenyl-U- ¹⁴ C] label	Sandy loam	1.41	6.1 ⁴⁾	20°C; 50% MWHC	SFO	11.23	A/ 0.975	<i>k</i>	0.0943	7.35	24.4
Hoefchen Am Hohenseh 4a; [Thiadiazole-5- ¹⁴ C] label	Silt loam	2.5	6.7 ⁴⁾	19.1°C; 55% MWHC	SFO	4.88	G/ 0.995	<i>k</i>	0.0438	15.8	52.6
Laacherhof AXXa; [Thiadiazole-5- ¹⁴ C] label	Loamy sand	2.4	6.1 ⁴⁾	19.9°C; 55% MWHC	SFO	3.03	G/ 0.997	<i>k</i>	0.0349	19.85	65.9
Dollendorf II; [Thiadiazole-5- ¹⁴ C] label	Clay loam	5.3	7.2 ⁴⁾	19.9°C; 55% MWHC	SFO	4.67	G/ 0.994	<i>k</i>	0.0425	16.3	54.2
Laacherhof Wurmwiese; [Thiadiazole-5- ¹⁴ C] label	Loam	2.2	5.4 ⁴⁾	19.9°C; 55% MWHC	SFO	4.27	G/ 0.994	<i>k</i>	0.0465	14.9	49.5
Howe, Indiana; [Thiadiazole-2- ¹⁴ C] label	Sandy loam	0.35	6.2 ³⁾	21°C; 75% of 1/3 bar	SFO	2.80	A/ 0.940	<i>k</i>	0.0120	57.6	191.42

Footnotes to the table:

- 1) The abbreviations used to describe the visual fit: G. – good, A. – acceptable, P. – poor;
- 2) Declared to be measured in CaCl₂/Water;
- 3) Measured in distilled water;
- 4) Measured in CaCl₂

The DT₅₀ = **57.6 days** value, determined in Howe, Indiana Sandy loam soil treated with [Thiadiazole-2-¹⁴C] Flufenacet was identified as appropriate input parameter for soil exposure assessment.

Table 2.8.1.-8: The modelling kinetic endpoints determined for Flufenacet in aerobic soil.

Soil		Soil properties		Incubation conditions	Kinetic model	Evaluation of the fit		Kinetic parameters		Kinetic endpoints	
Soil name	Soil type (USDA)	OC	pH			χ^2 error	Visual fit ¹⁾ /R ²	Param.	Value	DT ₅₀ [days]	DT ₉₀ [days]
BBA 2.2; [Phenyl-U- ¹⁴ C] label	Loamy sand	2.58	6.2 ²⁾	20°C; 40% MWHC	SFO	8.53	A/ 0.974	<i>k</i>	0.0217	31.9	106.1
Laacherhof; [Phenyl-U- ¹⁴ C] label	Silt loam	0.9	6.2 ²⁾	20°C; 40% MWHC	SFO	11.0	G/0.978	<i>k</i>	0.0500	13.86	45.92
Höfchen im Tal; [Phenyl-U- ¹⁴ C] label	Silt loam	2.40	6.2 ²⁾	20°C; 40% MWHC	SFO	5.47	G/ 0.990	<i>k</i>	0.0339	20.44	67.9
Howe, Indiana; [Phenyl-U- ¹⁴ C] label	Sandy loam	0.35	6.2 ³⁾	21°C; 75% of 1/3 bar	SFO	2.36	G/ 0.981	<i>k</i>	0.0332	20.90	69.44
Laacherhof AXXa; [Phenyl-U- ¹⁴ C] label	Sandy loam	1.41	6.1 ⁴⁾	20°C; 50% MWHC	SFO	11.23	A/ 0.975	<i>k</i>	0.0985	7.04	23.37
Hoefchen Am Hohenseh 4a; [Thiadiazole-5- ¹⁴ C] label	Silt loam	2.5	6.7 ⁴⁾	19.1°C; 55% MWHC	SFO	4.88	G/ 0.995	<i>k</i>	0.0451	15.36	51.02
Laacherhof AXXa; [Thiadiazole-5- ¹⁴ C] label	Loamy sand	2.4	6.1 ⁴⁾	19.9°C; 55% MWHC	SFO	3.03	G/ 0.997	<i>k</i>	0.0356	19.45	64.58
Dollendorf II; [Thiadiazole-5- ¹⁴ C] label	Clay loam	5.3	7.2 ⁴⁾	19.9°C; 55% MWHC	SFO	4.67	G/ 0.994	<i>k</i>	0.0447	15.49	51.52
Laacherhof Wurmwielse; [Thiadiazole-5- ¹⁴ C] label	Loam	2.2	5.4 ⁴⁾	19.9°C; 55% MWHC	SFO	4.27	G/ 0.994	<i>k</i>	0.0474	14.61	48.51
Howe, Indiana; [Thiadiazole-2- ¹⁴ C] label	Sandy loam	0.35	6.2 ³⁾	21°C; 75% of 1/3 bar	SFO	2.80	A/ 0.940	<i>k</i>	0.0185	37.40	124.23
Geometric mean (n = 10)									0.0387	17.89	59.42
Median (n = 10)									0.0402	17.47	58.05

Footnotes to the table:

1) The abbreviations used to describe the visual fit: G. – good, A. – acceptable, P. – poor;

2) Declared to be measured in CaCl₂/Water;

3) Measured in distilled water;

4) Measured in CaCl₂

For GW and SW model exposure assessment the **geomean DT₅₀ = 17.89 days** and **geomean *k* = 0.0387 [days⁻¹]** are the kinetic endpoints recommended as input parameters.

b) Kinetic endpoints determined for FOE Sulfonic acid:

The degradation kinetics of FOE Sulfonic acid in aerobic soil was examined in seventeen trials on the same number of the test soils. The experiments were performed in two variants – four trials on soils treated with Flufenacet (active substance) and the remaining thirteen trials on soils treated with FOE Sulfonic acid.

The performed kinetic analysis resulted in a data base consisting of twelve reliable kinetic endpoints, all determined in trials in which the test soils were treated with FOE Sulfonic acid. In case of the experiments on soils treated with Flufenacet it was not possible to obtain reliable kinetic endpoints characterising degradation of FOE Sulfonic acid in soil because decline of that compound was not observed. As a result, the default values – DT₅₀ = 1000 days and DT₉₀ > 1000 days, were proposed for these trials. These values, due to their nature and uncertainty related to them, were not used either as input parameters in soil exposure assessment or to calculate normalised mean values used subsequently in GW/SW exposure assessment. They are however provided in the table presenting the persistence endpoints, as with them are associated reliable kinetic formation fractions for FOE Sulfonic acid, recommended to be used in GW exposure assessment. RMS however decided not to provide them in the table presenting the kinetic endpoints recommended for modelling.

In case of the kinetic analysis of the data obtained in Laacherhof IIIA Silt loam soil in the study by [Hellpointner; 1996], it was not possible to obtain a reliable kinetic fit and hence kinetic endpoints. For that reason the trial was removed from both summary table presenting persistence and modelling endpoints.

The persistence (best-fit) kinetic endpoints obtained for FOE Sulfonic acid are presented below in the table 2.8.1.-9. The modelling endpoints are given in the table 2.8.1.-10.

Table 2.8.1.-9: The persistence kinetic endpoints determined for FOE Sulfonic acid in aerobic soil.

Soil		Soil properties		Incubation conditions	Kinetic model	Evaluation of the fit		Kinetic parameters		Kinetic endpoints		
Soil name	Soil type (USDA)	OC	pH ¹⁾			χ^2 error	Vis. fit ²⁾	Par.	Value	DT ₅₀ [days]	DT ₉₀ [days]	Kinetic formation fraction ff
BBA 2.2	Loamy sand	2.58	6.2 ^{a)}	20 ⁰ C; 40% MWHC	SFO	15.4	G	k	n. d. ³⁾	1000	>1000	0.257
Laacherhof	Silt loam	0.9	7.3 ^{a)}	20 ⁰ C; 40% MWHC	SFO	8.42	G	k	n. d. ³⁾	1000	>1000	0.272
Höfchen im Tal	Silt loam	2.40	5.8 ^{a)}	20 ⁰ C; 40% MWHC	SFO	6.56	G	k	n. d. ³⁾	1000	>1000	0.143
Howe, Indiana;	Sandy loam	0.35	6.2 ^{b)}	21 ⁰ C; 75% of 1/3 bar	SFO	6.28	G	k	n. d. ³⁾	1000	>1000	0.108
BBA 2.1	Sand	0.57	5.3 ^{c)}	20 ± 2 ⁰ C; 75% of 1/3 bar	SFO	1.78	G	k	2.18 E-3	318	1060	n. a. ⁴⁾
BBA 2.2	Loamy sand	2.48	6.3 ^{c)}	20 ± 2 ⁰ C; 75% of 1/3 bar	SFO	1.88	G	k	3.28 E-3	211	701	n. a. ⁴⁾
Laacherhof AXXa	Sandy loam	1.47	6.3 ^{c)}	20 ± 2 ⁰ C; 40% MWHC	SFO	3.05	G	k	0.0111	62.31	206.99	n. a. ⁴⁾
Laacherhof AIII	Silt loam	0.88	6.8 ^{c)}	20 ± 2 ⁰ C; 40% MWHC	SFO	3.03	G	k	0.0115	60.26	200.18	n. a. ⁴⁾
Laacherhof AXXa	Loamy sand	1.7	6.2 ^{c)}	19.6 ⁰ C; 55% MWHC	SFO	1.28	G	k	9.45 E-3	73.38	243.77	n. a. ⁴⁾
Dollendorf II	Loam	4.6	7.0 ^{c)}	19.6 ⁰ C; 55% MWHC	SFO	5.59	G	k	0.1033	6.71	22.30	n. a. ⁴⁾
Hoefchen Am Hohenseh 4a;	Silt loam	2.0	6.1 ^{c)}	19.6 ⁰ C; 55% MWHC	SFO	7.68	G	k	0.0242	28.58	94.95	n. a. ⁴⁾
Wurm-wiese	Sandy loam	1.8	5.0 ^{c)}	19.6 ⁰ C; 55% MWHC	SFO	3.66	G	k	0.0139	49.77	165.32	n. a. ⁴⁾
Hanscheider Hof	Loam	2.8	5.6 ^{c)}	19.9 ⁰ C; 55% MWHC	SFO	3.25	G	k	0.02539	27.30	90.70	n. a. ⁴⁾
Frankenforst	Silt loam	1.8	6.8 ^{c)}	19.9 ⁰ C; 55% MWHC	SFO	6.41	G	k	0.03181	21.79	72.39	n. a. ⁴⁾
LUFA 2.3	Sandy loam	1.1	6.8 ^{c)}	19.9 ⁰ C; 55% MWHC	SFO	1.45	G	k	0.0108	63.87	212.16	n. a. ⁴⁾
LUFA 6S	Clay	1.9	7.0 ^{c)}	19.9 ⁰ C; 55% MWHC	SFO	6.49	G	k	0.01838	37.71	125.28	n. a. ⁴⁾
Arithmetic mean for ff (n = 4)											0.195	

Footnotes to the table:

- 1) Measured in:
 - CaCl₂/water for values marked a);
 - distilled water for results marked b);
 - 0.01M CaCl₂ for results marked c);
- 2) The abbreviations used to describe the visual fit: G. – good, A. – acceptable, P. – poor;
- 3) Value not determined – the decline phase not reached;
- 4) Value not available – the test compound applied as parent.

The DT₅₀ = **318 days** value, determined in BBA 2.1 Sand soil treated with FOE Sulfonic acid was identified as appropriate input parameter for soil exposure assessment.

Table 2.8.1.-10: The modelling kinetic endpoints determined for FOE Sulfonic acid in aerobic soil.

Soil		Soil properties		Incubation conditions	Kinetic model	Evaluation of the fit		Kinetic parameters		Kinetic endpoints		
Soil name	Soil type (USDA)	OC	pH ¹⁾			χ^2 error	Vis. fit ²⁾	Par.	Value	DT ₅₀ [days]	DT ₉₀ [days]	Kinetic formation fraction ff
BBA 2.2	Loamy sand	2.58	6.2 ^{a)}	20 ⁰ C; 40% MWHC	SFO	15.4	G	k	n. d. ³⁾	n. d. ³⁾	n. d. ³⁾	0.257
Laacherhof	Silt loam	0.9	7.3 ^{a)}	20 ⁰ C; 40% MWHC	SFO	8.42	G	k	n. d. ³⁾	n. d. ³⁾	n. d. ³⁾	0.272
Höfchen im Tal	Silt loam	2.40	5.8 ^{a)}	20 ⁰ C; 40% MWHC	SFO	6.56	G	k	n. d. ³⁾	n. d. ³⁾	n. d. ³⁾	0.143
Howe, Indiana;	Sandy loam	0.35	6.2 ^{b)}	21 ⁰ C; 75% of 1/3 bar	SFO	6.28	G	k	n. d. ³⁾	n. d. ³⁾	n. d. ³⁾	0.108
BBA 2.1	Sand	0.57	5.3 ^{c)}	20 ± 2 ⁰ C; 75% of 1/3 bar	SFO	1.78	G	k	2.66 E-3	260.76	869.2	n. a. ⁴⁾
BBA 2.2	Loamy sand	2.48	6.3 ^{c)}	20 ± 2 ⁰ C; 75% of 1/3 bar	SFO	1.88	G	k	3.28 E-3	211.00	701	n. a. ⁴⁾
Laacherhof AXXa	Sandy loam	1.47	6.3 ^{c)}	20 ± 2 ⁰ C; 40% MWHC	SFO	3.05	G	k	0.0139	49.85	165.59	n. a. ⁴⁾
Laacherhof AIII	Silt loam	0.88	6.8 ^{c)}	20 ± 2 ⁰ C; 40% MWHC	SFO	3.03	G	k	0.0172	40.37	134.12	n. a. ⁴⁾
Laacherhof AXXa	Loamy sand	1.7	6.2 ^{c)}	19.6 ⁰ C; 55% MWHC	SFO	1.28	G	k	9.84 E-3	70.44	234.02	n. a. ⁴⁾
Dollendorf II	Loam	4.6	7.0 ^{c)}	19.6 ⁰ C; 55% MWHC	SFO	5.59	G	k	0.1109	6.25	20.77	n. a. ⁴⁾
Hoefchen Am Hohenseh 4a;	Silt loam	2.0	6.1 ^{c)}	19.6 ⁰ C; 55% MWHC	SFO	7.68	G	k	0.0269	25.79	85.68	n. a. ⁴⁾
Wurm-wiese	Sandy loam	1.8	5.0 ^{c)}	19.6 ⁰ C; 55% MWHC	SFO	3.66	G	k	0.0145	47.78	158.71	n. a. ⁴⁾
Hanscheider Hof	Loam	2.8	5.6 ^{c)}	19.9 ⁰ C; 55% MWHC	SFO	3.25	G	k	0.0256	27.03	89.79	n. a. ⁴⁾
Frankenforst	Silt loam	1.8	6.8 ^{c)}	19.9 ⁰ C; 55% MWHC	SFO	6.41	G	k	0.0321	21.57	70.68	n. a. ⁴⁾
LUFA 2.3	Sandy loam	1.1	6.8 ^{c)}	19.9 ⁰ C; 55% MWHC	SFO	1.45	G	k	0.0110	63.23	210.04	n. a. ⁴⁾
LUFA 6S	Clay	1.9	7.0 ^{c)}	19.9 ⁰ C; 55% MWHC	SFO	6.49	G	k	0.02158	32.11	106.60	n. a. ⁴⁾
Geometric mean (n = 12)									0.0154	45.11	149.74	----
Median (n = 12)									0.0159	44.08	146.42	----
Arithmetic mean for ff (n = 4)												0.195

Footnotes to the table:

- 1) Measured in:
 - CaCl₂/water for values marked a);
 - distilled water for results marked b);
 - (0.01M) CaCl₂ for results marked c);
- 2) The abbreviations used to describe the visual fit: G. – good, A. – acceptable, P. – poor;
- 3) Value not determined – the decline phase not reached;
- 4) Value not available – the test compound applied as parent.

For GW and SW model exposure assessment the **geomean DT₅₀ = 45.11 days** and **geomean k = 0.0154 [days⁻¹]** are the kinetic endpoints recommended as input parameters. The corresponding recommended ff value is **ff = 0.195** (arithmetic mean) for Flufenacet as a precursor.

c) Kinetic endpoints determined for FOE Oxalate:

The degradation kinetics of FOE Oxalate in aerobic soil was examined in four trials on the same number of the test soils. The experiments were performed on soils treated with Flufenacet (active substance).

The performed kinetic analysis resulted in a data base consisting of three reliable kinetic endpoints. In case of the experiment in Howe, Indiana, Sandy loam soil it was not possible to obtain reliable kinetic endpoints characterising degradation of FOE Oxalate because the decline of that compound was not observed. As a result, the default values – DT₅₀ = 1000 days and DT₉₀ > 1000 days, were proposed for that trial. These values, due to their nature and uncertainty related to them, were not used either as input parameters in soil exposure assessment or to calculate normalised mean values used subsequently in GW/SW exposure assessment. They are however provided in the table presenting the persistence endpoints, as with them are associated reliable kinetic formation fraction for FOE

Oxalate, recommended to be used in GW exposure assessment. RMS however decided not to provide them in the table presenting the kinetic endpoints recommended for modelling.

The persistence (best-fit) kinetic endpoints obtained for FOE Oxalate are presented below in the table 2.8.1.-11. The modelling endpoints are given in the table 2.8.1.-12.

Table 2.8.1.-11: The persistence kinetic endpoints determined for FOE Oxalate in aerobic soil.

Soil		Soil properties		Incubation conditions	Kinetic model	Evaluation of the fit		Kinetic parameters		Kinetic endpoints		
Soil name	Soil type (USDA)	OC	pH ¹⁾			χ^2 error	Vis. fit ²⁾	Par.	Value	DT ₅₀ [days]	DT ₉₀ [days]	Kinetic formation fraction ff
BBA 2.2	Loamy sand	2.58	6.2 ^{a)}	20°C; 40% MWHC	SFO	25.2	A	k	0.1011	6.9	22.8	0.448
Laacherhof	Silt loam	0.9	7.3 ^{a)}	20°C; 40% MWHC	SFO	12.7	G	k	0.0366	18.9	62.9	0.422
Höfchen im Tal	Silt loam	2.40	5.8 ^{a)}	20°C; 40% MWHC	SFO	10.5	G	k	0.0530	13.09	43.48	0.350
Howe, Indiana;	Sandy loam	0.35	6.2 ^{b)}	21°C; 75% of 1/3 bar	SFO	3.99	G	k	n. d. ³⁾	1000	>1000	0.484
Arithmetic mean for ff (n = 4)												0.426

Footnotes to the table:

- 1) Measured in:
- CaCl₂/water for values marked a);
- distilled water for results marked b);
- 2) The abbreviations used to describe the visual fit: G. – good, A. – acceptable, P. – poor;
- 3) Value not determined – the decline phase not reached;

The DT₅₀ = **18.9 days** value, determined in Laacherhof Silt loam soil was identified as appropriate input parameter for soil exposure assessment.

Table 2.8.1.-12: The modelling kinetic endpoints determined for FOE Oxalate in aerobic soil.

Soil		Soil properties		Incubation conditions	Kinetic model	Evaluation of the fit		Kinetic parameters		Kinetic endpoints		
Soil name	Soil type (USDA)	OC	pH ¹⁾			χ^2 error	Vis. fit ²⁾	Par.	Value	DT ₅₀ [days]	DT ₉₀ [days]	Kinetic formation fraction ff
BBA 2.2	Loamy sand	2.58	6.2 ^{a)}	20°C; 40% MWHC	SFO	25.2	A	k	0.1011	6.7	22.8	0.448
Laacherhof	Silt loam	0.9	7.3 ^{a)}	20°C; 40% MWHC	SFO	12.7	G	k	0.0447	15.5	51.58	0.422
Höfchen im Tal	Silt loam	2.40	5.8 ^{a)}	20°C; 40% MWHC	SFO	10.5	G	k	0.0530	13.09	43.48	0.350
Howe, Indiana;	Sandy loam	0.35	6.2 ^{b)}	21°C; 75% of 1/3 bar	SFO	3.99	G	k	n. d. ³⁾	n. d. ³⁾	n. d. ³⁾	0.484
Geometric mean (n = 3)									0.0639	11.08	37.12	----
Arithmetic mean for ff (n = 4)												0.426

Footnotes to the table:

- 1) Measured in:
- CaCl₂/water for values marked a);
- distilled water for results marked b);
- 2) The abbreviations used to describe the visual fit: G. – good, A. – acceptable, P. – poor;
- 3) Value not determined – the decline phase not reached;

For GW and SW model exposure assessment the **geomean DT₅₀ = 11.08 days** and **geomean k = 0.0639 [days⁻¹]** are the kinetic endpoints recommended as input parameters. The corresponding recommended ff value is **ff = 0.426** (arithmetic mean) for Flufenacet as a precursor.

d) Kinetic endpoints determined for FOE Methylsulfone:

The degradation kinetics of FOE Methylsulfone in aerobic soil was examined in eleven trials using the same number of the test soils. The experiments were performed in two variants – three trials on soils treated with Flufenacet (active substance) and the remaining eight trials on soils treated with FOE Methylsulfone.

The performed kinetic analysis resulted in a data base consisting of nine reliable kinetic endpoints, one with soil treated with Flufenacet as a precursor of FOE Methylsulfone and remaining eight with soils treated with FOE

Methylsulfone. In case of two trials on soils treated with Flufenacet – BBA 2.2 Loamy sand soil and Hoefchen im Tal Silt loam soil, it was not possible to obtain reliable kinetic endpoints characterising degradation of FOE Methylsulfone in soil, because decline of that compound was not observed. As a result, the default values – $DT_{50} = 1000$ days and $DT_{90} > 1000$ days, were proposed for these trials. These values, due to their nature and uncertainty related to them, were not used either as input parameters in soil exposure assessment or to calculate normalised mean values used subsequently in GW/SW exposure assessment. They are however provided in the table presenting the persistence endpoints, as with them are associated reliable kinetic formation fractions for FOE Methylsulfone, recommended to be used in GW exposure assessment. RMS however decided not to provide them in the table presenting the kinetic endpoints recommended for modelling.

The persistence (best-fit) kinetic endpoints obtained for FOE Methylsulfone are presented below in the table 2.8.1.-13. The modelling endpoints are given in the table 2.8.1.-14.

Table 2.8.1.-13: The persistence kinetic endpoints determined for FOE Methylsulfone in aerobic soil.

Soil		Soil properties		Incubation conditions	Kinetic model	Evaluation of the fit		Kinetic parameters		Kinetic endpoints		
Soil name	Soil type (USDA)	OC	pH ¹⁾			χ^2 error	Vis. fit ²⁾	Par.	Value	DT_{50} [days]	DT_{90} [days]	Kinetic formation fraction ff
BBA 2.2	Loamy sand	2.58	6.2 ^{a)}	20 ⁰ C; 40% MWHC	SFO	28.5	G	k	n. d. ³⁾	1000	>1000	0.061
Laacherhof	Silt loam	0.9	7.3 ^{a)}	20 ⁰ C; 40% MWHC	SFO	14.4	G	k	3.99 E-3	174	576	0.096
Hoefchen im Tal	Silt loam	2.40	5.8 ^{a)}	20 ⁰ C; 40% MWHC	SFO	17.3	G	k	n. d. ³⁾	1000	>1000	0.052
Laacherhof AXXa	Loamy sand	1.7	6.2 ^{b)}	19.6 ⁰ C; 55% MWHC	SFO	3.37	G	k	1.61 E-2	43.14	143.32	n. a. ⁴⁾
Dollendorf II	Loam	4.6	7.0 ^{b)}	19.6 ⁰ C; 55% MWHC	SFO	3.04	G	k	2.98 E-2	23.30	77.41	n. a. ⁴⁾
Hoefchen Am Hohenseh 4a;	Silt loam	2.0	6.1 ^{b)}	19.6 ⁰ C; 55% MWHC	SFO	3.58	G	k	1.58 E-2	43.84	145.64	n. a. ⁴⁾
Wurm-wiese	Sandy loam	1.8	5.0 ^{b)}	19.6 ⁰ C; 55% MWHC	SFO	3.32	G	k	7.21 E-3	96.13	319.32	n. a. ⁴⁾
Hanscheider Hof	Loam	2.8	5.6 ^{b)}	19.9 ⁰ C; 55% MWHC	SFO	2.11	G	k	8.40 E-3	82.53	274.14	n. a. ⁴⁾
Frankenforst	Silt loam	1.8	6.8 ^{b)}	19.9 ⁰ C; 55% MWHC	SFO	2.88	G	k	0.01083	63.98	212.53	n. a. ⁴⁾
LUFA 2.3	Sandy loam	1.1	6.8 ^{b)}	19.9 ⁰ C; 55% MWHC	SFO	2.10	G	k	4.72 E-3	146.78	487.60	n. a. ⁴⁾
LUFA 6S	Clay	1.9	7.0 ^{b)}	19.9 ⁰ C; 55% MWHC	SFO	1.70	G	k	4.25 E-3	163.06	541.68	n. a. ⁴⁾
Arithmetic mean for ff (n = 3)												0.070

Footnotes to the table:

- 1) Measured in:
- CaCl₂/water for values marked a);
- (0.01M) CaCl₂ for results marked b);
- 2) The abbreviations used to describe the visual fit: G. – good, A. – acceptable, P. – poor;
- 3) Value not determined – the decline phase not reached;
- 4) Value not available – the test compound applied as parent.

The $DT_{50} = 174$ days value, determined in Laacherhof Silt loam soil was identified as appropriate input parameter for soil exposure assessment.

Table 2.8.1.-14: The modelling kinetic endpoints determined for FOE Methylsulfone in aerobic soil.

Soil		Soil properties		Incubation conditions	Kinetic model	Evaluation of the fit		Kinetic parameters		Kinetic endpoints		
Soil name	Soil type (USDA)	OC	pH ¹⁾			χ^2 error	Vis. fit ²⁾	Par.	Value	DT ₅₀ [days]	DT ₉₀ [days]	Kinetic formation fraction ff
BBA 2.2	Loamy sand	2.58	6.2 ^{a)}	20 ⁰ C; 40% MWHC	SFO	28.5	G	k	n. d. ³⁾	n. d. ³⁾	n. d. ³⁾	0.061
Laacherhof	Silt loam	0.9	7.3 ^{a)}	20 ⁰ C; 40% MWHC	SFO	14.4	G	k	4.86 E-3	142.68	472.32	0.096
Höfchen im Tal	Silt loam	2.40	5.8 ^{a)}	20 ⁰ C; 40% MWHC	SFO	17.3	G	k	n. d. ³⁾	n. d. ³⁾	n. d. ³⁾	0.052
Laacherhof AXXa	Loamy sand	1.7	6.2 ^{b)}	19.6 ⁰ C; 55% MWHC	SFO	3.37	G	k	1.66 E-2	41.85	139.00	n. a. ⁴⁾
Dollendorf II	Loam	4.6	7.0 ^{b)}	19.6 ⁰ C; 55% MWHC	SFO	3.04	G	k	3.07 E-2	22.60	75.09	n. a. ⁴⁾
Hoefchen Am Hohenseh 4a;	Silt loam	2.0	6.1 ^{b)}	19.6 ⁰ C; 55% MWHC	SFO	3.58	G	k	1.63 E-2	42.52	141.23	n. a. ⁴⁾
Wurm-wiese	Sandy loam	1.8	5.0 ^{b)}	19.6 ⁰ C; 55% MWHC	SFO	3.32	G	k	7.43 E-3	93.25	309.74	n. a. ⁴⁾
Hanscheider Hof	Loam	2.8	5.6 ^{b)}	19.9 ⁰ C; 55% MWHC	SFO	2.11	G	k	8.48 E-3	81.70	271.40	n. a. ⁴⁾
Frankenforst	Silt loam	1.8	6.8 ^{b)}	19.9 ⁰ C; 55% MWHC	SFO	2.88	G	k	1.09 E-2	63.34	210.40	n. a. ⁴⁾
LUFA 2.3	Sandy loam	1.1	6.8 ^{b)}	19.9 ⁰ C; 55% MWHC	SFO	2.10	G	k	4.77 E-3	145.31	482.72	n. a. ⁴⁾
LUFA 6S	Clay	1.9	7.0 ^{b)}	19.9 ⁰ C; 55% MWHC	SFO	1.70	G	k	4.99 E-3	138.83	461.19	n. a. ⁴⁾
Geometric mean (n = 9)									9.55 E-3	72.57	240.99	----
Median (n = 9)									8.48 E-3	81.70	271.40	----
Arithmetic mean for ff (n = 3)												0.070

Footnotes to the table:

- 1) Measured in:
- CaCl₂/water for values marked a);
- (0.01M) CaCl₂ for results marked b);
- 2) The abbreviations used to describe the visual fit: G. – good, A. – acceptable, P. – poor;
- 3) Value not determined – the decline phase not reached;
- 4) Value not available – the test compound applied as parent.

For GW and SW model exposure assessment the **median DT₅₀ = 81.70 days** and **median k = 0.00848 [days⁻¹]** are the kinetic endpoints recommended as input parameters. The corresponding recommended ff value is **ff = 0.070** (arithmetic mean) for Flufenacet as a precursor.

e) Kinetic endpoints determined for FOE Thiadone:

The degradation kinetics of FOE Thiadone in aerobic soil was examined in eight trials using the equal number of the test soils. The experiments were performed in two variants – five trials using soils treated with Flufenacet (active substance) and the remaining eight trials using soils treated with FOE Methylsulfone.

The performed kinetic analysis resulted in a data base consisting of eight reliable kinetic endpoints, four with soil treated with Flufenacet as a precursor of FOE Thiadone and three with soils treated with FOE Thiadone. In case of one trial on soil treated with Flufenacet – Howe, Indiana Sandy loam soil, it was not possible to obtain reliable fit for FOE Thiadone in combination with the parent compound. Such fit however was obtained when the data were kinetically analysed for FOE Thiadone alone using the top-down approach. That solution however implied that no reliable value for kinetic formation fraction in that trial could be obtained and reported. RMS decided not to report the default value ff = 1.00, proposed by the Applicant. The persistence (best-fit) kinetic endpoints obtained for FOE Thiadone are presented below in the table 2.8.1.-15. The modelling endpoints are given in the table 2.8.1.-16.

Table 2.8.1.-15: The persistence kinetic endpoints determined for FOE Thiadone in aerobic soil.

Soil		Soil properties		Incubation conditions	Kinetic model	Evaluation of the fit		Kinetic parameters		Kinetic endpoints		
Soil name	Soil type (USDA)	OC	pH			χ^2 error	Vis. fit ¹⁾	Par.	Value	DT ₅₀ [days]	DT ₉₀ [days]	Kinetic formation fraction ff
Hoefchen Am Hohenseh 4a;	Silt loam	2.5	6.7 ²⁾	19.1 ⁰ C; 55% MWHC	SFO	16.42	G	k	0.6110	1.13	3.77	0.913
Laacherhof AXxa;	Loamy sand	2.4	6.1 ²⁾	19.9 ⁰ C; 55% MWHC	SFO	15.65	G	k	0.5087	1.36	4.53	0.524
Dollendorf II;	Clay loam	5.3	7.2 ²⁾	19.9 ⁰ C; 55% MWHC	SFO	16.36	G	k	0.2438	2.84	9.45	0.438
Laacherhof Wurm-wiese;	Loam	2.2	5.4 ²⁾	19.9 ⁰ C; 55% MWHC	SFO	14.73	G	k	0.3490	1.99	6.60	0.404
Howe, Indiana;	Sandy loam	0.35	6.2 ³⁾	21 ⁰ C; 75% of 1/3 bar	SFO	4.95	G	k	0.0435	15.9	52.9	n. d. ⁵⁾
Iowa	Loamy sand	1.91	7.2 ⁴⁾	20 ⁰ C; 75% of 1/3 bar	SFO	6.72	A	k	0.3494	1.98	6.59	n. d. ⁶⁾
Indiana	Sandy loam	1.28	6.5 ⁴⁾	20 ⁰ C; 75% of 1/3 bar	SFO	5.67	A	k	0.4945	1.40	4.66	n. d. ⁶⁾
Nebraska	Silt loam	1.66	7.7 ⁴⁾	20 ⁰ C; 75% of 1/3 bar	SFO	3.71	A	k	0.2363	2.93	9.74	n. d. ⁶⁾
Arithmetic mean for ff (n = 3)												0.570

Footnotes to the table:

- 1) The abbreviations used to describe the visual fit: G. – good, A. – acceptable, P. – poor;
- 2) Measured in 0.01M CaCl₂;
- 3) Measured in distilled water;
- 4) Medium for measuring pH not given;
- 5) Value not available – kinetic endpoints determined using the top-down approach;
- 6) Value not available – the test compound applied as parent.

The DT₅₀ = **15.9 days** value, determined in Howe, Indiana Sandy loam soil was identified as appropriate input parameter for soil exposure assessment.

Table 2.8.1.-16: The modelling kinetic endpoints determined for FOE Thiadone in aerobic soil.

Soil		Soil properties		Incubation conditions	Kinetic model	Evaluation of the fit		Kinetic parameters		Kinetic endpoints		
Soil name	Soil type (USDA)	OC	pH			χ^2 error	Vis. fit ¹⁾	Par.	Value	DT ₅₀ [days]	DT ₉₀ [days]	Kinetic formation fraction ff
Hoefchen Am Hohenseh 4a;	Silt loam	2.5	6.7 ²⁾	19.1 ⁰ C; 55% MWHC	SFO	16.42	G	k	0.6301	1.10	3.66	0.913
Laacherhof AXxa;	Loamy sand	2.4	6.1 ²⁾	19.9 ⁰ C; 55% MWHC	SFO	15.65	G	k	0.5212	1.33	4.44	0.524
Dollendorf II;	Clay loam	5.3	7.2 ²⁾	19.9 ⁰ C; 55% MWHC	SFO	16.36	G	k	0.2567	2.70	8.98	0.438
Laacherhof Wurm-wiese;	Loam	2.2	5.4 ²⁾	19.9 ⁰ C; 55% MWHC	SFO	14.73	G	k	0.3555	1.95	6.47	0.404
Howe, Indiana;	Sandy loam	0.35	6.2 ³⁾	21 ⁰ C; 75% of 1/3 bar	SFO	4.95	G	k	0.0672	10.32	34.33	n. d. ⁵⁾
Iowa	Loamy sand	1.91	7.2 ⁴⁾	20 ⁰ C; 75% of 1/3 bar	SFO	6.72	A	k	0.5458	1.27	4.22	n. d. ⁶⁾
Indiana	Sandy loam	1.28	6.5 ⁴⁾	20 ⁰ C; 75% of 1/3 bar	SFO	5.67	A	k	0.7702	0.90	2.98	n. d. ⁶⁾
Nebraska	Silt loam	1.66	7.7 ⁴⁾	20 ⁰ C; 75% of 1/3 bar	SFO	3.71	A	k	0.3027	2.29	7.60	n. d. ⁶⁾
Geometric mean (n = 8)									0.3557	1.95	6.48	----
Median (n = 8)									0.4384	1.64	5.46	----
Arithmetic mean for ff (n = 3)												0.570

Footnotes to the table:

- 1) The abbreviations used to describe the visual fit: G. – good, A. – acceptable, P. – poor;
- 2) Measured in 0.01M CaCl₂;
- 3) Measured in distilled water;
- 4) Medium for measuring pH not given;
- 5) Value not available – kinetic endpoints determined using the top-down approach;
- 6) Value not available – the test compound applied as parent.

For GW and SW model exposure assessment the **geomean $DT_{50} = 1.95$ days** and **geomean $k = 0.3557$ [days⁻¹]** are the kinetic endpoints recommended as input parameters. The corresponding recommended ff value is **$ff = 0.570$** (arithmetic mean) for Flufenacet as a precursor.

f) Kinetic endpoints determined for FOE 5043-Trifluoroethanesulfonic acid (TFESA):

The degradation kinetics of FOE 5043-Trifluoroethanesulfonic acid (TFESA) in aerobic soil was examined in four trials using the equal number of the test soils. The experiments were performed with soils treated with Flufenacet (active substance).

The performed kinetic analysis resulted in a data base consisting of four reliable kinetic endpoints. In case of two trials – on the Dollendorf II Clay loam soil and Laacherhof Wurm-wiese Loam soil it was not possible to obtain reliable kinetic fits for the whole transformation scheme, therefore the top-down approach was used. RMS however decided to keep the determined values of kinetic formation fraction ff . The persistence (best-fit) kinetic endpoints obtained for FOE 5043-Trifluoroethanesulfonic acid (TFESA) are presented below in the table 2.8.1.-17. The modelling endpoints are given in the table 2.8.1.-18.

Table 2.8.1.-17: The persistence kinetic endpoints determined for FOE 5043-Trifluoroethanesulfonic acid in aerobic soil.

Soil		Soil properties		Incubation conditions	Kinetic model	Evaluation of the fit		Kinetic parameters		Kinetic endpoints		
Soil name	Soil type (USDA)	OC	pH ¹⁾			χ^2 error	Vis. fit ²⁾	Par.	Value	DT_{50} [days]	DT_{90} [days]	Kinetic formation fraction ff
Hoefchen Am Hohenseh 4a;	Silt loam	2.5	6.7	19.1°C; 55% MWHC	SFO	5.85	G	k	0.0761	9.10	30.23	0.264
Laacherhof AXXa;	Loamy sand	2.4	6.1	19.9°C; 55% MWHC	SFO	18.25	G	k	0.1548	4.48	14.87	0.534
Dollendorf II;	Clay loam	5.3	7.2	19.9°C; 55% MWHC	SFO	4.31	G	k	0.0331	20.9	69.5	0.422
Laacherhof Wurm-wiese;	Loam	2.2	5.4	19.9°C; 55% MWHC	SFO	12.3	G	k	0.3090	2.24	7.45	0.655
Arithmetic mean for ff (n = 3)											0.469	

Footnotes to the table:

1) Measured in 0.01M CaCl₂;

2) The abbreviations used to describe the visual fit: G. – good, A. – acceptable, P. – poor;

The **$DT_{50} = 20.9$ days** value, determined in Dollendorf II Clay loam soil was identified as appropriate input parameter for soil exposure assessment.

Table 2.8.1.-18: The modelling kinetic endpoints determined for FOE 5043-Trifluoroethanesulfonic acid in aerobic soil.

Soil		Soil properties		Incubation conditions	Kinetic model	Evaluation of the fit		Kinetic parameters		Kinetic endpoints		
Soil name	Soil type (USDA)	OC	pH ¹⁾			χ^2 error	Vis. fit ²⁾	Par.	Value	DT ₅₀ [days]	DT ₉₀ [days]	Kinetic formation fraction <i>ff</i>
Hoefchen Am Hohenseh 4a;	Silt loam	2.5	6.7	19.1°C; 55% MWHC	SFO	5.85	G	<i>k</i>	0.0785	8.83	29.32	0.264
Laacherhof AXa;	Loamy sand	2.4	6.1	19.9°C; 55% MWHC	SFO	18.25	G	<i>k</i>	0.1579	4.39	14.57	0.534
Dollendorf II;	Clay loam	5.3	7.2	19.9°C; 55% MWHC	SFO	4.31	G	<i>k</i>	0.0349	19.87	66.01	0.422
Laacherhof Wurm-wiese;	Loam	2.2	5.4	19.9°C; 55% MWHC	SFO	12.3	G	<i>k</i>	0.3165	2.19	7.30	0.655
Geometric mean (n = 4)									0.1082	6.41	21.30	----
									Arithmetic mean for <i>ff</i> (n = 3)			0.469

Footnotes to the table:1) Measured in 0.01M CaCl₂;

2) The abbreviations used to describe the visual fit: G. – good, A. – acceptable, P. – poor;

For GW and SW model exposure assessment the **geomean DT₅₀ = 6.41 days** and **geomean *k* = 0.1082 [days⁻¹]** are the kinetic endpoints recommended as input parameters. The corresponding recommended *ff* value is ***ff* = 0.469** (arithmetic mean) for FOE Thiadone as a precursor.

g) Kinetic endpoints determined for Trifluoroacetic acid (TFA):

The degradation kinetics of Trifluoroacetic acid (TFA) in aerobic soil was examined in eight trials using the equal number of the test soils. The experiments were performed in two variants – four trials with soils treated with Flufenacet (active substance) and the remaining four trials with soils treated with TFA.

Due to the high persistence of the test compound – TFA, in none of the test soils it was possible to obtain the reliable kinetic endpoints. For that reason the default values were proposed.

Due to the difference between the modelling tools, for the persistence endpoints two sets of the default values were provided. For trials on test soils treated with Flufenacet as precursor of TFA, where the analysis performed by the Applicant was accepted, the default kinetic endpoints were: **DT₅₀ = 1000 days** and **DT₉₀ > 1000 days**. In case however of the trials with TFA applied as parent compound, for which RMS had to repeat the kinetic analysis, the kinetic endpoints were: **DT₅₀ = 10000 days** and **DT₉₀ > 10000 days** – the values returned by the applied tool. RMS considers these defaults to be representative for the persistence of TFA in soil, as that indicated the results of the examination of the fate of TFA in environment presented in the open-source literature.

However for modelling the recommended input value is **DT₅₀ = 1000 days**, because of the constraints of the current modelling tools. It shall be noted that due to the nature of the determined endpoint – a default value, its normalisation was not performed as not necessary.

For TFA a set for two kinetic formation fraction values were determined – one for formation of TFA from Flufenacet and the second for its formation from FOE Thiadone.

The persistence (best-fit) kinetic endpoints obtained for TFA Thiadone are presented below in the table 2.8.1.-19. The modelling endpoints are given in the table 2.8.1.-20.

Table 2.8.1.-19: The persistence kinetic endpoints determined for Trifluoroacetic acid (TFA) in aerobic soil.

Soil		Soil properties		Incubation conditions	Kinetic model	Evaluation of the fit		Kinetic parameters		Kinetic endpoints		
Soil name	Soil type (USDA)	OC	pH ¹⁾			χ^2 error	Vis. fit ¹⁾	Par.	Value	DT ₅₀ [days]	DT ₉₀ [days]	Kinetic formation fraction $ff^{4)}$
Hoefchen Am Hohenseh 4a;	Silt loam	2.5	6.7	19.1 ⁰ C; 55% MWHC	SFO	10.49	G	k	n. d. ³⁾	1000	>1000	$ff_1 = 0.087$ $ff_2 = 0.736$
Laacherhof AXx;	Loamy sand	2.4	6.1	19.9 ⁰ C; 55% MWHC	SFO	10.34	G	k	n. d. ³⁾	1000	>1000	$ff_1 = 0.476$ $ff_2 = 0.466$
Dollendorf II;	Clay loam	5.3	7.2	19.9 ⁰ C; 55% MWHC	SFO	9.45	G	k	n. d. ³⁾	1000	>1000	$ff_1 = 0.562$ $ff_2 = 0.578$
Laacherhof Wurm-wiese;	Loam	2.2	5.4	19.9 ⁰ C; 55% MWHC	SFO	9.44	G	k	n. d. ³⁾	1000	>1000	$ff_1 = 0.596$ $ff_2 = 0.345$
Hanscheider Hof	Loam	2.8	5.6	19.9 ⁰ C; 55% MWHC	SFO	4.95	G	k	n. d. ³⁾	10000	>10000	n. d. ³⁾
Frankenforst	Silt loam	1.8	6.8	19.9 ⁰ C; 55% MWHC	SFO	6.72	A	k	n. d. ³⁾	10000	>10000	n. d. ³⁾
LUFA 2.3	Sandy loam	1.1	6.8	19.9 ⁰ C; 55% MWHC	SFO	5.67	A	k	n. d. ³⁾	10000	>10000	n. d. ³⁾
LUFA 6S	Clay	1.9	7.0	19.9 ⁰ C; 55% MWHC	SFO	3.71	A	k	n. d. ³⁾	10000	>10000	n. d. ³⁾
Arithmetic mean for ff (n = 4)												$ff_1 = 0.430$ $ff_2 = 0.531$

Footnotes to the table:

- 1) Measured in 0.01M CaCl₂;
- 2) The abbreviations used to describe the visual fit: G. – good, A. – acceptable, P. – poor;
- 3) n. d. – not determined
- 4) ff_1 – kinetic formation fraction for formation of TFA from Flufenacet; ff_2 – kinetic formation fraction for formation of TFA from FOE Thiadone.

The default **DT₅₀ = 10000 days** value was identified as appropriate input parameter for soil exposure assessment.

Table 2.8.1.-20: The modelling kinetic endpoints determined for Trifluoroacetic acid (TFA) in aerobic soil.

Soil		Soil properties		Incubation conditions	Kinetic model	Evaluation of the fit		Kinetic parameters		Kinetic endpoints		
Soil name	Soil type (USDA)	OC	pH ¹⁾			χ^2 error	Vis. fit ¹⁾	Par.	Value	DT ₅₀ [days]	DT ₉₀ [days]	Kinetic formation fraction $ff^{4)}$
Hoefchen Am Hohenseh 4a;	Silt loam	2.5	6.7	19.1 ⁰ C; 55% MWHC	SFO	10.49	G	k	n. d. ³⁾	1000	>1000	$ff_1 = 0.087$ $ff_2 = 0.736$
Laacherhof AXx;	Loamy sand	2.4	6.1	19.9 ⁰ C; 55% MWHC	SFO	10.34	G	k	n. d. ³⁾	1000	>1000	$ff_1 = 0.476$ $ff_2 = 0.466$
Dollendorf II;	Clay loam	5.3	7.2	19.9 ⁰ C; 55% MWHC	SFO	9.45	G	k	n. d. ³⁾	1000	>1000	$ff_1 = 0.562$ $ff_2 = 0.578$
Laacherhof Wurm-wiese;	Loam	2.2	5.4	19.9 ⁰ C; 55% MWHC	SFO	9.44	G	k	n. d. ³⁾	1000	>1000	$ff_1 = 0.596$ $ff_2 = 0.345$
Hanscheider Hof	Loam	2.8	5.6	19.9 ⁰ C; 55% MWHC	SFO	4.95	G	k	n. d. ³⁾	1000	>1000	n. d. ³⁾
Frankenforst	Silt loam	1.8	6.8	19.9 ⁰ C; 55% MWHC	SFO	6.72	A	k	n. d. ³⁾	1000	>1000	n. d. ³⁾
LUFA 2.3	Sandy loam	1.1	6.8	19.9 ⁰ C; 55% MWHC	SFO	5.67	A	k	n. d. ³⁾	1000	>1000	n. d. ³⁾
LUFA 6S	Clay	1.9	7.0	19.9 ⁰ C; 55% MWHC	SFO	3.71	A	k	n. d. ³⁾	1000	>1000	n. d. ³⁾
Geometric mean (n = 8)										1000	>1000	---
Arithmetic mean for ff (n = 4)												$ff_1 = 0.430$ $ff_2 = 0.531$

Footnotes to the table:

- 1) Measured in 0.01M CaCl₂;
- 2) The abbreviations used to describe the visual fit: G. – good, A. – acceptable, P. – poor;
- 3) n. d. – not determined
- 4) ff_1 – kinetic formation fraction for formation of TFA from Flufenacet; ff_2 – kinetic formation fraction for formation of TFA from FOE Thiadone.

For GW and SW model exposure assessment the default $DT_{50} = 1000$ days is a kinetic endpoint recommended as input parameter. The corresponding recommended ff values are $ff_1 = 0.430$ (arithmetic mean) for Flufenacet as a precursor and $ff_2 = 0.531$ (arithmetic mean) for FOE Thiadone as a precursor.

The kinetic endpoints identified by RMS as appropriate to be used in model exposure assessment for soil, groundwater and surface water compartments are summarised below in the table 2.8.1.-21. For completeness also the maximum concentrations observed in soils are provided.

Table 2.8.1.-21: The kinetic endpoints determined in laboratory studies on aerobic soils, recommended to be used in model exposure assessment for soil, groundwater and surface water compartments.

Compound	Compartment	Recommended endpoints					
		Maximum observed in soil		Kinetic formation fraction - ff		Persistence in soil – DT_{50} value	
		Observed soil maximum [%]	Remark	ff	Remark	DT_{50} [days]	Remark
Flufenacet	Soil	Not applicable	Not applicable – parent compound	----	Not applicable – parent compound	57.6	Longest not normalised lab value
	Groundwater			----		17.89	Normalised lab geomean value
	Surface Water			----		17.89	Normalised lab geomean value
FOE Sulfonic acid	Soil	26.5	Recommended for simple modelling ¹⁾	0.195	Precursor: flufenacet; to be used in complex modelling ²⁾	318	Longest not normalised lab value
	Groundwater	----	Not applicable	0.195	Precursor: flufenacet;	45.11	Normalised lab geomean value
	Surface Water	26.5	To be used in calculations at Steps 1 and 2	0.195	Precursor: flufenacet; to be used in Step 3-4 assessment	45.11	Normalised lab geomean value
FOE Oxalate	Soil	26.3	Recommended for simple modelling ¹⁾	0.426	Precursor: flufenacet; to be used in complex modelling ²⁾	18.9	Longest not normalised lab value
	Groundwater	----	Not applicable	0.426	Precursor: flufenacet;	11.08	Normalised lab geomean value
	Surface Water	26.3	To be used in calculations at Steps 1 and 2	0.426	Precursor: flufenacet; to be used in Step 3-4 assessment	11.08	Normalised lab geomean value
FOE Methylsulfone	Soil	6.6	Recommended for simple modelling ¹⁾	0.070	Precursor: flufenacet; to be used in complex modelling ²⁾	174	Longest not normalised lab value
	Groundwater	----	Not applicable	0.070	Precursor: flufenacet;	81.70	Normalised lab median value
	Surface Water	6.6	To be used in calculations at Steps 1 and 2	0.070	Precursor: flufenacet; to be used in Step 3-4 assessment	81.70	Normalised lab median value
FOE Thiadone	Soil	5.8	Recommended for simple modelling ¹⁾	0.570	Precursor: flufenacet; to be used in complex modelling ²⁾	15.9	Longest not normalised lab value
	Groundwater	----	Not applicable	0.570	Precursor: flufenacet;	1.95	Normalised lab geomean value
	Surface Water	5.8	To be used in calculations at Steps 1 and 2	0.570	Precursor: flufenacet; to be used in Step 3-4 assessment	1.95	Normalised lab geomean value
FOE 5043-Trifluoroethane-sulfonic acid	Soil	6.0	Recommended for simple modelling ¹⁾	0.469	Precursor: Thiadone; to be used in complex modelling ²⁾	20.9	Longest not normalised lab value
	Groundwater	----	Not applicable	0.469	Precursor: Thiadone;	6.41	Normalised lab geomean value
	Surface Water	6.0	To be used in calculations at Steps 1 and 2	0.469	Precursor: Thiadone; to be used in Step 3-4 assessment	6.41	Normalised lab geomean value
Trifluoroacetic acid (TFA)	Soil	81.5	Recommended for simple modelling ¹⁾	0.430	Precursor: flufenacet; to be used in complex modelling ²⁾	10000	Longest lab value (default)
				0.531	Precursor: Thiadone; to be used in complex modelling ²⁾		
	Groundwater	----	Not applicable	0.430	Precursor: flufenacet;	1000	FOCUS default for non-degrading compounds
				0.531	Precursor: Thiadone;		
	Surface Water	81.5	To be used in calculations at Steps 1 and 2	0.430	Precursor: flufenacet; to be used in Step 3-4 assessment	1000	FOCUS default for non-degrading compounds
				0.531	Precursor: Thiadone; to be used in Step 3-4 assessment		

Footnotes to the table:

- 1) By the term "simple modelling" are understood calculations performed using simple models with metabolites applied as parent;
- 2) The term "complex models" concerns calculations performed using more sophisticated tools, e.g. ESCAPE, in which metabolites are calculated as formed from their precursor (parent compound or preceding degradation product).

Additionally the results of the determination of the rate of degradation of Flufenacet in aerobic soils incubated under controlled (laboratory) conditions were provided by two literature studies. The key results of these two studies are provided below in the table 2.8.1.-22. These results shall be considered as indicative and for that reason were not used to derive the regulatory endpoints.

Table 2.8.1.-22: The key results of the relevant publications examining the rate of degradation of Flufenacet in aerobic soils.

Study	Test soil	Key soil properties			Incubation conditions		Fortification level [µg a. s./g soil]	Kinetic endpoints – DT ₅₀ [days]		Method of calculation
		Soil type (USDA)	pH	OC [%]	T [°C]	Soil moisture		T=25°C; FC	T=20°C; FC	
<i>Gupta, Gajbhiye, Agnihotri [2001]</i>	Sandy loam	Sandy loam	7.1	0.34	25	FC	1	9.3	13.4	1 st order, linear regression, r =0.99
							10	13.0	20.4	1 st order, linear regression, r =0.99
<i>Gupta, Gajbhiye, [2002]</i>	Dehli sandy loam	US Loamy sand	7.69	0.50	25	FC	1	10.1	15.8	1 st order, linear regression, r =0.99
							10	13.0	20.4	1 st order, linear regression, r =0.99
	Ranchi sandy loam	US Sandy clay loam	5.54	0.04	25	FC	1	10.5	16.5	1 st order, linear regression, r =0.99
							10	21.3	33.4	1 st order, linear regression, r =0.99
	Nagpur clayey soil	US Clay	8.25	0.40	25	FC	1	31.0	48.6	1 st order, linear regression, r =0.99
							10	29.2	45.8	1 st order, linear regression, r =0.94

2) Degradation in soil under anaerobic conditions:

The route of degradation of the acetanilide herbicide Flufenacet in anaerobic soil was examined in three soils – one from the US and two European. The test compound – Flufenacet, was radiolabelled in one of the following two positions:

- uniformly in phenyl ring – compound tested on one US soil,
- in position C5 of Thiadiazole moiety – examined in two EU soils.

The experiments performed to determine the transformation pattern of Flufenacet in soil under anaerobic conditions consisted of two phases – aerobic preincubation phase and anaerobic incubation phase. RMS decided to present the key results of the experiments taking into account both phases. In case of aerobic preincubation phase the results are given for the terminal time point of that phase.

The key results for the examination of transformation of Flufenacet in anaerobic soils in the area of formation of terminal degradation products – mineralisation expressed as CO₂ and NER fraction, are presented below in the table 2.8.1.-23. To differentiate the results obtained for aerobic phase from those for anaerobic phase the former were shaded light grey. It shall be noted that under anaerobic conditions mineralisation, if occurred at all, was minimal. No other volatile compounds were identified during either aerobic or anaerobic phases. The level of NER formed under anaerobic conditions (net formation) was comparable to that observed in aerobic soils.

Table 2.8.1.-23: The levels of the terminal degradation products – CO₂ and NER fraction formed in soil during examination of the transformation pattern of Flufenacet in soil under anaerobic conditions.

Study/ radiolabelling position	Soil		Results obtained for aerobic phase		Results obtained for anaerobic phase ¹⁾					
	Name	Type (USDA)	CO ₂ [%AR] – end of phase	NER [%AR] – end of phase	Mineralisation level – CO ₂ formed [% AR]			NER level [% AR]		
					Beginning of phase	Max.	Net anaero- bic ²⁾	Beginning of phase	Max.	Net anaero- bic ³⁾
Pangilinan & Smith [1994]/ ¹⁴ C-phenyl	Howe	Sandy loam	1.4 (DAT 30)	8.4 (DAT 30)	1.4 (DAT 30 DAF 0)	1.8 (DAT 210 DAF 180)	0.4	8.4 (DAT 30 DAF 0)	32.6 (DAT 210 DAF 180)	24.2 (DAT 210 DAF 180)
Heinemann [2012]/ ¹⁴ C-5- Thiadiazole	HH ⁴⁾	Silt loam	1.6 (DAT 15)	16.9 (DAT 15)	1.6 (DAT 15 DAF 0)	1.7 (DAT 105 DAF 90)	0.1	10.2 (DAT 15 DAF 0)	24.5 (DAT 135 DAF 120)	14.3 (DAT 135 DAF 120)
	DD ⁵⁾	Loam	1.9 (DAT 15)	10.1 (DAT 15)	1.8 (DAT 15 DAF 0)	1.9 (DAT 105 DAF 90)	<0.1 ⁶⁾	8.6 (DAT 15 DAF 0)	31.6 (DAT 135 DAF 120)	23.0 (DAT 135 DAF 120)

Footnotes to the table:

- 1) In case of Howe soil the results for the beginning of anaerobic phase are the same as those for the end of aerobic phase. In case of soils HH and DD they are different, because there were available the results obtained immediately after generating the anaerobic conditions;
- 2) “Net anaerobic” is a difference between the total amount of CO₂ formed and that determined in aerobic traps for volatiles;
- 3) “Net anaerobic” is a difference between maximum determined level of NER and that measured at the beginning of anaerobic phase;
- 4) HH stands for *Hoefchen am Hohenseh 4a* soil;
- 5) DD stands for *Dollendorf II* soil;
- 6) At the time point where maximum CO₂ level of 2.0% AR was recorded, the amount recovered for aerobic volatile traps was 1.9% AR and from anaerobic volatile traps <0.1 AR. The slightly higher total amount may be due to either rounding or losses during extraction. In that soil the level of mineralization, expressed as recovered CO₂ in anaerobic phase was <0.1% AR;

The examination of the extracted fraction enabled the identification of one new degradate, not identified in aerobic soils – FOE Thioglycolate. All other identified degradation products were those already found in aerobic soils. On that basis it can be stated that the transformation pattern of Flufenacet in soil under anaerobic conditions would not differ significantly from that determined in aerobic soils. The key results of the profiling of degradation products in anaerobic soils are presented below in table 2.8.1.-24. To differentiate the results obtained for aerobic phase from those for anaerobic phase the former were shaded light grey.

Table 2.8.1.-24: The results of the profiling of Flufenacet and its degradation products.

Study/ radiolabelling position	Soil		Results obtained for aerobic phase		Results obtained for anaerobic phase ¹⁾				
	Name	Type (USDA)	Identified compound	Amount [% AR] at the end of phase	Identified compound	Amount [% AR] measured at:			Anaerobic metabolite (yes/no)
Pangilinan & Smith [1994]/ ¹⁴ C-phenyl	Howe	Sandy loam	Flufenacet	69.0 (DAT 30)	Flufenacet	69.0 (DAT 30/ DAF 0)	39.0 ⁶⁾ (DAT 210/ DAF 180)	N/A ⁸⁾	N/A ⁸⁾
			FOE Oxalate	11.2 (DAT 30)	FOE Oxalate	11.2 (DAT 30/ DAF 0)	14.5 (DAT 60/ DAF 30)	3.3 (DAT 60/ DAF 30)	Yes
			FOE Sulfonic acid	6.6 (DAT 30)	FOE Sulfonic acid	6.6 (DAT 30/ DAF 0)	6.6 (DAT 30/ DAF 0)	0.0	No
			FOE Alcohol	0.0 (DAT 30)	FOE Alcohol	0.0 (DAT 30/ DAF 0)	1.4 (DAT 153/ DAF 123)	1.4 (DAT 153/ DAF 123)	Yes
			FOE TGS ³⁾	2.6 (DAT 30)	FOE TGS ³⁾	2.6 (DAT 30/ DAF 0)	2.6 (DAT 30/ DAF 0)	0.0	No
					FOE Thioglycolate	0.0 (DAT 30/ DAF 0)	1.7 (DAT 60/ DAF 30)	1.7 (DAT 60/ DAF 30)	Yes
Heinemann [2012]/ ¹⁴ C-5- Thiadiazole	HH ⁴⁾	Silt loam	Flufenacet	30.8 (DAT 15)	Flufenacet	42.8 (DAT 15/ DASF 0)	6.4 ⁶⁾ (DAT 135/ DASF 120)	N/A ⁸⁾	N/A ⁸⁾
			FOE Thiadone	5.9 (DAT 15)	FOE Thiadone	4.8 (DAT 15/ DASF 0)	13.6 (DAT 77/ DASF 62)	8.8 (DAT 77/ DASF 62)	Yes
			FOE 5043- Trifluoroethane- sulfonic acid	2.5 (DAT 15)	FOE 5043- Trifluoroethane- sulfonic acid	5.1 (DAT 15/ DASF 0)	4.2 ⁷⁾ (DAT 48/ DASF 33)	4.2 ⁷⁾ (DAT 48/ DASF 33)	Yes
			Trifluoroacetic acid	37.5 (DAT 15)	Trifluoroacetic acid	31.4 (DAT 15/ DASF 0)	47.9 (DAT 135/ DASF 120)	16.5 (DAT 135/ DASF 120)	Yes
	DD ⁵⁾	Loam	Flufenacet	44.2 (DAT 15)	Flufenacet	35.4 (DAT 15/ DASF 0)	3.1 ⁶⁾ (DAT 135/ DASF 120)	N/A ⁸⁾	N/A ⁸⁾
			FOE Thiadone	4.3 (DAT 15)	FOE Thiadone	7.1 (DAT 15/ DASF 0)	12.4 (DAT 21/ DASF 6)	5.3 (DAT 21/ DASF 6)	Yes
			FOE 5043- Trifluoroethane- sulfonic acid	6.0 (DAT 15)	FOE 5043- Trifluoroethane- sulfonic acid	3.2 (DAT 15/ DASF 0)	3.2 (DAT 15/ DASF 0)	0.0	No
			Trifluoroacetic acid	28.0 (DAT 15)	Trifluoroacetic acid	40.4 (DAT 15/ DASF 0)	53.2 (DAT 105/ DASF 90)	12.8 (DAT 105/ DASF 90)	Yes

Footnotes to the table:

- 1) In case of Howe soil the results for the beginning of anaerobic phase are the same as those for the end of aerobic phase. In case of soils HH and DD they are different, because were available the results obtained immediately after generating the anaerobic conditions;
- 2) "Net anaerobic" is a difference between the maximum amount determined in anaerobic phase and that at its beginning;
- 3) FOE TGS – FOE Thioglycolate sulfoxide;
- 4) HH stands for *Hoefchen am Hohenseh 4a* soil;
- 5) DD stands for *Dollendorf II* soil;
- 6) Flufenacet is the active substance, therefore not forming in soil. For that reason its concentration at the end of incubation period is given to show the level of decline;
- 7) In that soil the concentrations of FOE Trifluoroethane sulfonic acid initially decreased, to increase afterwards reaching maximum on the indicated time point. It was assumed that this maximum can be attributed totally to the amount of that compound formed under anaerobic conditions;
- 8) N/A – not applicable (parent compound);

The results of the determination of transformation pathway of Flufenacet in anaerobic soil demonstrated that it would not significantly differ, qualitatively and quantitatively, from that observed in aerobic soil.

The degradation products that may require further consideration for the risk assessment are the same as identified during examination of the degradation pattern of Flufenacet in aerobic soil: FOE Oxalate, FOE Thiadone and Trifluoroacetic acid. The proposed whole transformation pattern determined during examination of degradation of Flufenacet in anaerobic soil, is presented below on figure 2.8.1.-2.

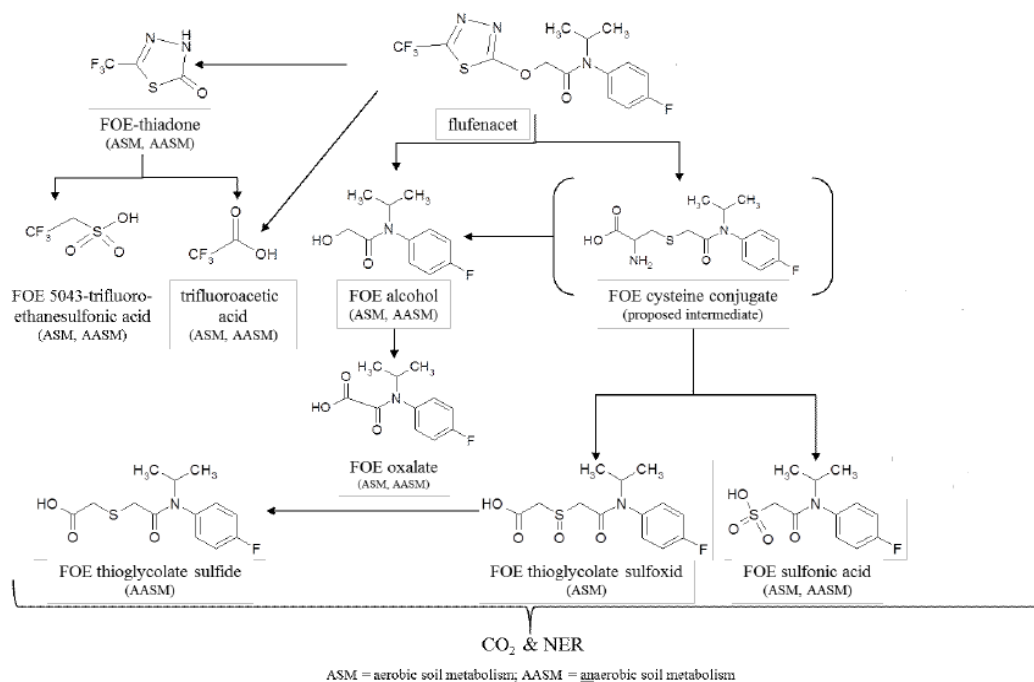


Figure 2.8.1-2: The proposed degradation scheme for Flufenacet in anaerobic soil, including initial aerobic stage. **ASM** stands for transformation under aerobic conditions and **AASM** for that under anaerobic conditions (scheme copied from the Applicant's documentation, modified by the RMS).

The determination of the kinetic parameters of the process of degradation of Flufenacet in anaerobic soil was performed for the results obtained in two studies, on three soils using the test compound radiolabelled in two different positions:

- uniformly in phenyl ring (one test soil);
- in C5 position of thiadiazole moiety (two test soils).

The conclusions and key results are presented below, individually for each test soil.

- The conclusions and key results obtained for Sandy loam (Howe) soil treated with Phenyl-U-¹⁴C] Flufenacet (study by [Pangilinan and Smith; 1995]):

The kinetic analysis of the data for Flufenacet and its major degradation products – FOE Oxalate and FOE Sulfonic acid, obtained for Sandy loam (Howe) soil incubated under anaerobic conditions demonstrated that:

- The degradation of Flufenacet in that soil was most adequately described by DFOP kinetic model. Therefore that model should be considered as providing the kinetic endpoints describing the persistence of Flufenacet in anaerobic sandy loam soil;
- DFOP kinetic model – its slow phase, should be also considered as providing the kinetic endpoints appropriate for modelling. That conclusion is drawn by the RMS and is different from the Applicant's proposal – to consider the SFO kinetic model as a source of the kinetic endpoints appropriate for modelling. That conclusion is based on the fact that DFOP fit was superior to SFO both when the fitting was performed for the parent compound alone and for the parent and degradation products.
- It was not possible to obtain the reliable kinetic fit for either of the degradation products – FOE Oxalate and FOE Sulfonic acid kinetically examined together with parent. Slightly better results were obtained when the data for these two compounds were fitted alone using the top-down approach. In both cases SFO was identified as returning visually and statistically reliable fits with reliable parameters. RMS however is of the opinion that the kinetic endpoints derived from those fits should be considered indicative with regard to the persistence of both compounds in anaerobic sandy loam soil and cannot be further used to derive any modelling endpoints. It shall be also noted that it was not possible to derive reliable kinetic formation fractions for either FOE Oxalate or FOE Sulfonic acid.

The proposed set of the kinetic endpoints derived from that study is following:

- Flufenacet, persistence endpoints: $DT_{50} = 229.63$ days, $DT_{90} = 895.64$ days, DFOP model ($k_1 = 0.9976$ [days⁻¹], $k_2 = 2.416 \times 10^{-3}$ [days⁻¹], $g = 0.1291$);

- Flufenacet, modelling endpoints not normalised: $k = 2.416 \text{ E-3 } [\text{days}^{-1}]$, $\text{DT}_{50} = 286.90 \text{ days}$, $\text{DT}_{90} = 953.06 \text{ days}$, SFO (slow phase DFOP);
 - Flufenacet, modelling endpoints normalized for temperature: $k = 2.205 \text{ E-3 } [\text{days}^{-1}]$, $\text{DT}_{50} = 314.35 \text{ days}$, $\text{DT}_{90} = 1044.26 \text{ days}$, SFO (slow phase DFOP);
 - FOE Oxalate, persistence endpoints (indicative): $\text{DT}_{50} = 311 \text{ days}$, $\text{DT}_{90} = 1030 \text{ days}$, SFO model – top-down approach ($k = 0.002233 [\text{days}^{-1}]$);
 - FOE Sulfonic acid, persistence endpoints (indicative): $\text{DT}_{50} = 352 \text{ days}$, $\text{DT}_{90} = 1170 \text{ days}$, SFO model – top-down approach ($k_I = 0.001986 [\text{days}^{-1}]$).
- The conclusions and key results obtained for Silt loam (Hoefchen am Hohenseh 4a) soil treated with [Thiadiazole-5- ^{14}C]Flufenacet (study by [Heinemann; 2012]):

The kinetic analysis of the data for Flufenacet and its major degradation products – FOE Thiadone, FOE-5043 Trifluoroethanesulfonic acid and Trifluoroacetic acid, obtained for Silt loam (Hoefchen am Hohenseh 4 a) soil incubated under anaerobic conditions demonstrated that:

- The degradation of Flufenacet in that soil was most adequately described by DFOP kinetic model. Therefore that model should be considered as providing the kinetic endpoints describing the persistence of Flufenacet in anaerobic Silt loam soil;
- DFOP kinetic model – its slow phase, should be also considered as providing the kinetic endpoints appropriate for modelling.
- It was possible to obtain reliable kinetic fit and kinetic endpoints for FOE Thiadone;
- Although it was possible to obtain reliable kinetic fit for Trifluoroacetic acid, the reliable kinetic parameters describing degradation of that compound could not be derived due to the fact that the decline phase was not reached. Therefore RMS proposed to use the default DT_{50} and DT_{90} values instead of those calculated by the model;
- It was not possible to obtain the reliable kinetic fit for FOE 5043-Trifluoroethanesulfonic acid, therefore for that compound no reliable kinetic endpoints are available. RMS attributed that to the low concentrations of the compound recorded in the test system and their significant scattering, what may indicate that the compound of concern is transient and rapidly degrades in anaerobic silt loam soil.

The proposed set of the kinetic endpoints derived from that study is following:

- Flufenacet, persistence endpoints: $\text{DT}_{50} = 22.66 \text{ days}$, $\text{DT}_{90} = 156.90 \text{ days}$, DFOP model ($k_I = 0.1214 [\text{days}^{-1}]$, $k_2 = 0.01162 [\text{days}^{-1}]$, $g = 0.3810$);
 - Flufenacet, modelling endpoints: $k = 0.01162 [\text{days}^{-1}]$, $\text{DT}_{50} = 59.65 \text{ days}$, $\text{DT}_{90} = 198.16 \text{ days}$, SFO (slow phase DFOP), normalisation was not required as the experiment was carried out at $T = 20^\circ\text{C}$ and the correction for soil moisture was not necessary (soil was permanently flooded);
 - FOE Thiadone, persistence and modelling endpoints: $\text{DT}_{50} = 97.04 \text{ days}$, $\text{DT}_{90} = 322.30 \text{ days}$, $ff = 0.425$ (from parent compound), SFO model ($k = 0.0071 [\text{days}^{-1}]$);
 - Trifluoroacetic acid persistence endpoints (indicative): $\text{DT}_{50} = 1000 \text{ days}$, $\text{DT}_{90} > 1000 \text{ days}$, $ff = 0.575$ (from parent compound), SFO model;
 - FOE 5043-Trifluoroethanesulfonic acid: it was not possible to derive reliable kinetic endpoints.
- The conclusions and key results obtained for Loam (Dollendorf II) soil treated with [Thiadiazole-5- ^{14}C] Flufenacet (study by [Heinemann; 2012]):

The kinetic analysis of the data for Flufenacet and its major degradation products – FOE Thiadone, FOE-5043 Trifluoroethanesulfonic acid and Trifluoroacetic acid, obtained for Loam (Dollendorf II) soil incubated under anaerobic conditions demonstrated that:

- The degradation of Flufenacet in that soil was most adequately described by DFOP kinetic model. Therefore that model should be considered as providing the kinetic endpoints describing the persistence of Flufenacet in anaerobic Silt loam soil;
- DFOP kinetic model – its slow phase, should be also considered as providing the kinetic endpoints appropriate for modelling.
- It was possible to obtain reliable kinetic fit and kinetic endpoints for FOE Thiadone;
- Although it was possible to obtain reliable kinetic fit for Trifluoroacetic acid, the reliable kinetic parameters describing degradation of that compound could not be derived due to the fact that the well pronounced decline phase was not reached. Therefore RMS proposed to use the default DT_{50} and DT_{90} values instead of those calculated by the model;
- It was not possible to obtain the reliable kinetic fit for FOE 5043-Trifluoroethanesulfonic acid, therefore for that compound no reliable kinetic endpoints are available. RMS attributed that to the low concentrations of the compound recorded in the test system and their significant scattering, what may indicate that the compound of concern is transient and rapidly degrades in anaerobic silt loam soil.

The proposed set of the kinetic endpoints derived from that study is following:

- Flufenacet, persistence endpoints: $DT_{50} = 13.51$ days, $DT_{90} = 110.02$ days, DFOP model ($k_1 = 0.4756$ [days⁻¹], $k_2 = 0.0167$ [days⁻¹], $g = 0.3745$);
- Flufenacet, modelling endpoints not normalised: $k = 0.0167$ [days⁻¹], $DT_{50} = 41.51$ days, $DT_{90} = 137.88$ days, SFO (slow phase DFOP), normalisation was not required as the experiment was carried out at $T = 20^\circ\text{C}$ and the correction for soil moisture was not necessary (soil was permanently flooded);
- FOE Thiadone, persistence and modelling endpoints: $DT_{50} = 97.04$ days, $DT_{90} = 322.30$ days, $ff = 0.425$ (from parent compound), SFO model ($k = 0.0071$ [days⁻¹]);
- Trifluoroacetic acid persistence endpoints (indicative): $DT_{50} = 1000$ days, $DT_{90} > 1000$ days, $ff = 0.575$ (from parent compound), SFO model;
- FOE 5043-Trifluoroethanesulfonic acid: it was not possible to derive reliable kinetic endpoints.

Additionally the results of the determination of the rate of degradation of Flufenacet in anaerobic soils incubated under controlled (laboratory) conditions were provided by two literature studies, also providing the results for aerobic soils. Below, in the table B.8.1.1.3_CA-25 are given the key results obtained in these two studies. As already indicated, these results may be considered only as indicative and were not used to derive the regulatory endpoints.

Table 2.8.1.-25: The key results of the relevant publications examining the rate of degradation of Flufenacet in anaerobic (submerged) soils.

Study	Test soil	Key soil properties			Incubation conditions		Fortification level [µg a. s./g soil]	Kinetic endpoints – DT_{50} [days]		Method of calculation
		Soil type (USDA)	pH	OC [%]	T [°C]	Soil moisture		T=25°C; FC	T=20°C; FC	
<i>Gupta, Gajbhiye, Agnihotri [2001]</i>	Sandy loam	Sandy loam	7.1	0.34	25	FC	10	22.5	35.3	1 st order, linear regression, r=0.99
<i>Gupta, Gajbhiye, [2002]</i>	Dehli sandy loam	US Loamy sand	7.69	0.50	25	FC	10	22.3	35.0	1 st order, linear regression, r=0.99
	Ranchi sandy loam	US Sandy clay loam	5.54	0.04	25	FC	10	24.1	37.8	1 st order, linear regression, r=0.99
	Nagpur clayey soil	US Clay	8.25	0.40	25	FC	10	30.1	47.2	1 st order, linear regression, r=0.93

3) Photodegradation on the soil surface:

The soil photolysis of Flufenacet was examined in one soil – US Sandy loam, using the test compound radiolabelled in one position – uniformly at phenyl ring. The experiment was performed using soil that was demonstrated to be biologically viable throughout the whole irradiation/incubation period. Samples were irradiated with artificial light (Xenon lamp) continuously for 10.25 days, corresponding to 30 days of natural summer sunlight (conditions relevant for Phoenix, Arizona, USA). The key results of the examination are presented below in the table 2.8.1.-26.

Table 2.8.1.-26: The key results obtained for Flufenacet in soil photolysis study

Parameter		Results obtained for:	
		Irradiated sample	Dark control
Terminal transformation products	Mineralisation (CO ₂) at the end of the study	0.2% AR; DAT ²⁾ 10.25; 30 th DNS ³⁾	0.1% AR; DAT ²⁾ 10.25; 30 th DNS ³⁾
	Max. NER level	3.2% AR; DAT ²⁾ 10.25; 30 th DNS ³⁾	4.4% AR; DAT ²⁾ 10.25; 30 th DNS ³⁾
Identified compounds	Flufenacet – amount at study's end	91.2 AR; DAT ²⁾ 10.25; 30 th DNS ³⁾	87.2 AR; DAT ²⁾ 10.25; 30 th DNS ³⁾
	FOE Oxalate – max. amount	0.6% AR; DAT ²⁾ 10.25; 30 th DNS ³⁾	4.6% AR; DAT ²⁾ 10.25; 30 th DNS ³⁾
	FOE Sulfonic acid – max. amount	0.4% AR; DAT ²⁾ 5.13; 15 th DNS ³⁾	2.2% AR; DAT ²⁾ 10.25; 30 th DNS ³⁾
	FOE Methylsulfoxide – max. amount	0.7% AR; DAT ²⁾ 10.25; 30 th DNS ³⁾	0.6% AR; DAT ²⁾ 10.25; 30 th DNS ³⁾
	FOE Alcohol – max. amount	1.0% AR; DAT ²⁾ 10.25; 30 th DNS ³⁾	0.4% AR; DAT ²⁾ 10.25; 30 th DNS ³⁾
	FOE N-isomer ¹⁾ – max. amount	1.8% AR; DAT ²⁾ 5.13; 15 th DNS ³⁾	0.3% AR; DAT ²⁾ 2.75; 8 th DNS ³⁾
Kinetics of the process	rate constant k [days ⁻¹]	0.0076	0.0124
	DT ₅₀ [days]	90.72	55.90

Footnotes to the table:

- 1) N-isomer of Flufenacet (for the structural formula, please refer to the table in Appendix 1- List of Evaluated Compounds in the Vol. 3 B.8_CA);
 2) DAT stands for Days After Treatment, the real sampling point in the experiment;
 3) DNS – Days of Natural Sunlight, the sampling point related to the natural summer day sunlight conditions in Tucson Arizona, USA

On the basis of these results it was stated that Flufenacet is not prone to photolytical degradation on the soil surface, therefore soil photolysis will not be a relevant degradation mechanism of Flufenacet in soil. Additionally the potential of photodegradation of FOE Thiadone on soil surface was examined. Although it was demonstrated that the process might contribute to transformation of FOE Thiadone in soil, its relevance is estimated to be minimal, also because FOE Thiadone is not expected to occur on the soil surface in significant, if any, amounts.

The photolysis of Flufenacet on the soil surface was examined in one experiment using one soil. Its results were kinetically examined, in line with the recommendations given by FOCUS [2006], by the RMS. The final set of the kinetic endpoints obtained for Flufenacet as a result of that examination is presented below in the table 2.8.1.-27.

Table 2.8.1.-27: The definitive set of the kinetic endpoints obtained for Flufenacet in the study examining soil photolysis of that compound.

Determined parameter	Results obtained for:		
	Dark control samples	Irradiated samples	
		Values not corrected (Suntest days)	Values corrected for summer sunlight intensity (Natural sunlight days) ¹⁾
Rate constant k [days ⁻¹]	0.0124	0.076	0.0026
DT ₅₀ [days]	55.90	90.72	265.67
DT ₉₀ [days]	185.68	301.36	882.55
Kinetic model	SFO	SFO	SFO

Footnotes to the table:

- 1) values calculated for conditions representative for summer sunny day in Phoenix, AZ, USA – longitude: 33° 27' N

On their basis it can be stated that Flufenacet is not expected to degrade in soil via its photolysis on the soil surface.

The conclusion drawn by the RMS from the study on the basis of the results presented above was following: “The results clearly demonstrate that the degradation of Flufenacet was slower in irradiated samples than in the dark control. On that basis it can be stated that Flufenacet is not prone to the photolysis on the soil surface, hence soil photolysis will not be a relevant mechanism of degradation of Flufenacet in soil.”

None of the degradation products of Flufenacet requiring further assessment were formed in that study, so the kinetic analysis for them was not performed. However, for one the major soil degradation product of Flufenacet – FOE Thiadone the photodegradation of that compound on the soil surface was examined in a separate study. The results were kinetically examined by the RMS and the definitive data set is presented below in the table 2.8.1.-28.

Table 2.8.1.-28: The definitive set of the kinetic endpoints obtained for FOE Thiadone in the study examining its photolysis on the soil surface.

Determined parameter	Results obtained for:	
	Dark control samples	Irradiated samples
Rate constant k [days ⁻¹]	0.1612	0.2120
DT ₅₀ [days]	4.30	3.27
DT ₉₀ [days]	14.29	10.86
Kinetic model	SFO	SFO

The results demonstrate that photolysis on the soil surface might contribute to degradation of FOE Thiadone in soil. The net rate constant of the photolysis will be:

$$k_{\text{photolysis}} = k_{\text{irrad}} - k_{\text{dark control}} = 0.2120 - 0.1612 = 0.0508 \text{ [days}^{-1}\text{]}.$$

The resulting kinetic endpoints calculated using that value are: **DT₅₀ = 13.64 days** and **DT₉₀ = 45.33 days**.

At the same time it shall be pointed out however that the probability that that compound would be found on the soil surface in any substantial amounts is minimal. For that reason the process should be considered to have minimal relevance in the overall transformation of Flufenacet in soil.

4) Soil persistence under realistic – field, conditions:

The dissipation of Flufenacet in soil under field conditions was examined on sixteen trial sites located in the EU – in Germany, France (Northern and Southern) and Italy. The characteristic of the trial sites is presented below in the table 2.8.1.-29. The next table – 2.8.1.-30, provides the brief characteristic of the weather conditions recorded at each trial site during the experiment.

Table 2.8.1.-29: The brief characteristic of field trials.

Study	Information on the trial site			Data on application		Data on crop cover		
	Trial number	Name of the trial site	Location - country	Application rate [g/ha]	Application date	Crop	Date of sowing	Sowing – days before application
[Sommer; 1995]	30159/0	Breitenfelde	Germany	480	15. 04. 1993	Bare soil	Not applicable	Not applicable
	30162/0	Kirchlauter	Germany	480	13. 04. 1993	Bare soil	Not applicable	Not applicable
	30163/9	Monheim	Germany	480	30. 04. 1993	Bare soil	Not applicable	Not applicable
	30164/7	Burscheid	Germany	480	22. 04. 1993	Bare soil	Not applicable	Not applicable
	30248/1	Fresne-L'Archeveque	France (North)	600	11. 05. 1993	Maize	04. 05. 1993	7
	30250/3	Fresne-L'Archeveque (I)	France (North)	600	27. 05. 1993	Maize	24. 05. 1993	3
	30251/1	Laudun	France (South)	600	18. 05. 1993	Sunflower	22. 04. 1993	26
	30253/8	St. Etienne du Gres	France (South)	600	17. 05. 1993	Sunflower	16. 05. 1993	1
[Sommer; 1995b]	30254/6	Saussay-la-Campagne	France (South)	240	11. 03. 1994	Winter wheat	14. 10. 1993	158
	30455/7	Fresne-L'Archeveque	France (North)	240	28. 04. 1994	Winter wheat	22. 10. 1993	169
[Sommer; 1995a]	30499/9	Burscheid	Germany	240	26. 10. 1993	Bare soil	Not applicable	Not applicable
	30500/6	Monheim	Germany	240	26. 10. 1993	Bare soil	Not applicable	Not applicable
[Sommer; 1995c]	40163/3	Laudun	France (South)	600	17. 05. 1994	Sunflower	04. 05. 1994	13
	40164/1	St. Etienne du Gres	France (South)	600	22. 04. 1994	Sunflower	16. 04. 1994	6
	40494/2	Ravenna	Italy	600	27. 04. 1994	Soybean	25. 04. 1994	2
	40495/0	S. Romualdo	Italy	600	27. 04. 1994	Soybean	26. 04. 1994	1

Table 2.8.1.-30: The climatic conditions and weather data recorded at on each trial site.

Information on the trial:			Duration of the trial after application of the test compound [days]	Weather data			
Trial number	Trial site - name	Location - country		Source of the weather data	Mars grid cell	Experimental weather data collected at trial site	
						Cumulative rainfall [mm]	Mean temperature T [°C]
30159/0	Breitenfelde	Germany	240	German Weather Service, Lübeck	64060	592	11.0
30162/0	Kirchlauter	Germany	237	Weather station in 4 km from the trial site	56060	319	11.1
30163/9	Monheim	Germany	231	Trial Station Laacherhof	58055	653	12.1
30164/7	Burscheid	Germany	239	Trial Station Höfchen	58055	839	10.6
30248/1	Fresne-L'Archeveque	France (North)	303	Meteo France Station de Boos	55047	870	9.6
30250/3	Fresne-L'Archeveque	France (North)	297	Meteo France Station de Boos	55047	778	9.4
30251/1	Laudun	France (South)	255	Meteo France Station Chusclan	43051	683	15.2
30253/8	St. Etienne du Gres	France (South)	260	Meteo France Station Chateuarenard	42051	670	14.8
30254/6	Saussay-la-Campagne	France (South)	242	Meteo France Station de Boos (76)	55047	598	12.7
30455/7	Fresne-L'Archeveque	France (North)	240	Meteo France Station de Boos (76)	55047	661	13.0
30499/9	Burscheid	Germany	234	Versuchsgut Höfchen, 41399 Burscheid	58055	695	6.3
30500/6	Monheim	Germany	240	Versuchsgut Laacherhof, 40789 Monheim	58055	815	6.3
40163/3	Laudun	France (South)	240	Meteo France	43051	658	16.8
40164/1	St. Etienne du Gres	France (South)	236	Meteo France	42051	640	18.7
40494/2	Ravenna	Italy	236	Ar. Sperim. M. Marani/Ravenna	44063	407	17.0
40495/0	S. Romualdo	Italy	236	Ar. Sperim. M. Marani/Ravenna	44063	407	17.0

The residues of Flufenacet on the trial sites were determined by sampling, at pre-determined intervals, soil cores down to 30-cm or 50-cm depth. The number of sampling points was, depending on the trial site, eight or nine. The soil samples were dissected into 10-cm layers and analysed for the content of Flufenacet and its three major soil degradates – FOE Alcohol, FOE Oxalate and FOE Sulfonic acid.

The performed analysis showed that FOE Alcohol was not formed on any trial site in detectable amounts - $>3 \mu\text{g/kg}$ soil (LOD). Other two degradation products were detectable and, on some trial sites even quantifiable (recorded in amounts $> \text{LOQ} = 10 \mu\text{g/kg}$ soil), but in none of the trials were observed in amounts higher than $30 \mu\text{g/kg}$ soil. Neither Flufenacet nor any of its degradation products were detected in deeper soil layers – below 20 cm.

The obtained results were kinetically examined in line with the recommendations of the FOCUS Work Group on the Degradation Kinetics. The results of the determination of the persistence of Flufenacet and its two quantifiable degradation products – FOE Oxalate and FOE Sulfonic acid, are presented below in three separate tables – 2.8.1.-31 (Flufenacet), 2.8.1.-32 (FOE Oxalate) and 2.8.1.-33 (FOE Sulfonic acid).

Table 2.8.1.-31: The persistence kinetic endpoints determined for Flufenacet in field dissipation trials.

Data on the trial		Soil properties (0-30 cm layer)			Identified best-fit model	Kinetic parameter		Evaluation of the fit		Kinetic endpoints	
Trial code	Location; type of trial	Soil type (USDA classif.)	pH ¹⁾	OC [%]		par.	value	Visual fit ^{2)/r³⁾}	χ^2 % error	DT ₅₀ [days]	DT ₉₀ [days]
30159/0	Breitenfelde, Germany; bare soil	Sandy loam	6.2	1.69	SFO	<i>k</i>	0.02092	A./0.9648	13.3	33.1	110.0
30162/0	Kirchlauter, Germany; bare soil	Heavy sandy loam ⁴⁾	7.1	0.61	SFO	<i>k</i>	0.0131	G./0.988	6.43	52.9	176.0
30163/9	Monheim, Germany; bare soil	Sandy loam	6.7	1.45	SFO	<i>k</i>	0.0144	A./0.9275	16.1	48.2	160.0
30164/7	Burscheid, Germany; bare soil	Silt loam	6.5	0.97	SFO	<i>k</i>	0.04309	G./0.9915	6.83	16.1	53.4
30248/1	Fresne-L'Archeveque, North France; cropped soil	Silt loam	6.0	1.11	SFO	<i>k</i>	0.01827	A./0.9536	15.8	38.0	126.0
30250/3	Fresne-L'Archeveque1, North France; cropped soil	Silt loam	5.2	1.86	SFO	<i>k</i>	0.01352	A./0.9672	11.0	51.3	170.0
30251/1	Laudun, South France; cropped soil	Loam	7.6	0.62	SFO	<i>k</i>	0.02278	A./0.9804	10.2	30.4	101.0
30253/8	St. Etienne du Gres, South France; cropped soil	Loam	7.7	0.80	SFO	<i>k</i>	0.01687	G./0.9902	6.68	41.1	137.0
30499/9	Burscheid, Germany; bare soil	Silt loam	6.5	0.97	DFOP	<i>k</i> ₁	1.501	A./0.9674	7.11	31.5	140.0
						<i>k</i> ₂	0.01481				
						<i>g</i>	0.2025				
30500/6	Monheim, Germany; bare soil	Sandy loam	6.7	1.45	SFO	<i>k</i>	0.01017	G./0.991	5.1	68.1	226.0
30254/6	Sausay-la-Campagne, South France; cropped soil	Silt loam	7.4	0.92	FOMC	α	4.673	G./0.9993	2.79	14.2	56.7
						β	88.960				
30455/7	Fresne-L'Archeveque, North France; cropped soil	Silt loam	6.6	1.00	SFO	<i>k</i>	0.04024	G./0.9989	3.32	17.2	57.2
40163/3	Laudun, South France; cropped soil	Clay loam	7.7	1.28	SFO	<i>k</i>	0.01451	A./0.9774	9.86	49.0	163.0
40164/1	St. Etienne du Gres, South France; cropped soil	Silt loam	7.7	0.96	SFO	<i>k</i>	0.01442	A./0.9892	7.08	48.1	160.0
40494/2	Ravenna, Italy; cropped soil	Silt loam	7.8	0.98	SFO	<i>k</i>	0.02016	G./0.991	7.23	34.4	114.0
40495/0	S. Romualdo, Italy; cropped soil	Silty loam	7.8	1.11	SFO	<i>k</i>	0.01368	G./0.9884	6.58	50.7	168.0

Footnotes to the table:

- 1) Determined in 0.01M CaCl₂;
- 2) Following abbreviations were used: P – Poor; A – Acceptable; G – Good;
- 3) *r* = correlation coefficient;
- 4) The DIN 19682 classification presented because the USDA classification not provided; in another report it was stated to be Sandy loam (USDA) containing 58.5% sand, 22.7% silt and 18.8% clay.

Table 2.8.1.-32: The reliable persistence kinetic endpoints determined for FOE Oxalate in field dissipation trials.

Data on the trial		Soil properties (0-30 cm layer)			Identified best-fit model	Kinetic parameter		Evaluation of the fit		Kinetic endpoints	
Trial code	Location; type of trial	Soil type (USDA classif.)	pH ¹⁾	OC [%]		par.	value	Visual fit ^{2)/r³⁾}	χ^2 % error	DT ₅₀ [days]	DT ₉₀ [days]
30250/3	Fresne-L'Archeveque1, North France; cropped soil	Silt loam	5.2	1.86	SFO	<i>k</i>	0.01091	G./0.9895	4.53	68.0	226.0

Footnotes to the table:

- 1) Determined in 0.01M CaCl₂;
- 2) Following abbreviations were used: P – Poor; A – Acceptable; G – Good;
- 3) *r* = correlation coefficient;

Table 2.8.1.-33: The reliable persistence kinetic endpoints determined for FOE Sulfonic acid in field dissipation trials.

Data on the trial		Soil properties (0-30 cm layer)			Identified best-fit model	Kinetic parameter		Evaluation of the fit		Kinetic endpoints	
Trial code	Location; type of trial	Soil type (USDA classif.)	pH ¹⁾	OC [%]		par.	value	Visual fit ^{2)/ r³⁾}	χ^2 % error	DT ₅₀ [days]	DT ₉₀ [days]
30248/1	Fresne-L'Archeveque; North France; cropped soil	Silt loam	6.0	1.11	SFO	<i>k</i>	0.01144	A./0.7441	23.3	60.6	201.0
30250/3	Fresne-L'Archeveque1, North France; cropped soil	Silt loam	5.2	1.86	SFO	<i>k</i>	0.00921	G./0.9477	9.83	75.3	250.0
30253/8	St. Etienne du Gres, South France; cropped soil	Loam	7.7	0.80	SFO	<i>k</i>	0.02249	G./0.9379	12.1	30.8	102.0
40164/1	St. Etienne du Gres, South France; cropped soil	Silt loam	7.7	0.96	SFO	<i>k</i>	0.007303	A./0.9319	20.5	94.9	315.0

Footnotes to the table:

- 1) Determined in 0.01M CaCl₂;
- 2) Following abbreviations were used: P – Poor; A – Acceptable; G – Good;
- 3) *r* = correlation coefficient;

The results obtained for Flufenacet and FOE Sulfonic acid were also kinetically examined with aim to derive the kinetic endpoints suitable for modelling. The kinetic analysis was performed using the inverse modelling approach. The assessment was conditionally accepted by the RMS. However, RMS decided, because of the stated deficiencies, not to use its results in the model exposure assessment, nor to report them in the List of End Points. They may however be used, at zonal or MS level, as refined input parameters in Tier 2a GW exposure assessment. The results are presented below in the table 2.8.1.-34.

Table 2.8.1.-34: The proposed modelling kinetic endpoints for Flufenacet and FOE Sulfonic acid determined from the data obtained in field dissipation trials using the inverse modelling approach.

Data on the trial		Soil properties (0-30 cm layer)			Results obtained for:					
Trial code	Location; type of trial	Soil type (USDA classif.)	pH ¹⁾	OC [%]	Flufenacet			FOE Sulfonic acid		
					Kinetic model	χ^2 % error	DT ₅₀ [days] (20°C/pF2)	Kinetic model	χ^2 % error	DT ₅₀ [days] (20°C/pF2)
30159/0	Breitenfelde, Germany; bare soil	Sandy loam	6.2	1.69	SFO	10.2	17.1	SFO	24.8	17.7
30162/0	Kirchlauter, Germany; bare soil	Heavy sandy loam ⁴⁾	7.1	0.61	SFO	19.5	33.3	----	----	----
30163/9	Monheim, Germany; bare soil	Sandy loam	6.7	1.45	SFO	15.4	31.8	----	----	----
30164/7	Burscheid, Germany; bare soil	Silt loam	6.5	0.97	SFO	7.4	11.4	----	----	----
30248/1	Fresne-L'Archeveque, North France; cropped soil	Silt loam	6.0	1.11	SFO	14.4	31.4	SFO	40.4	18.1
30250/3	Fresne-L'Archeveque, North France; cropped soil	Silt loam	5.2	1.86	SFO	8.8	32.9	SFO	42.0	20.8
30251/1	Laudun, South France; cropped soil	Loam	7.6	0.62	SFO	10.6	24.7	----	----	----
30253/8	St. Etienne du Gres, South France; cropped soil	Loam	7.7	0.80	SFO	8.9	37.6	SFO	32.0	19.6
30499/9	Burscheid, Germany; bare soil	Silt loam	6.5	0.97	SFO	9.3	8.5	----	----	----
30500/6	Monheim, Germany; bare soil	Sandy loam	6.7	1.45	SFO	13.5	14.7	----	----	----
30254/6	Sausay-la-Campagne, South France; cropped soil	Silt loam	7.4	0.92	SFO	11.5	6.0	----	----	----
30455/7	Fresne-L'Archeveque, North France; cropped soil	Silt loam	6.6	1.00	SFO	10.8	7.1	----	----	----
40163/3	Laudun, South France; cropped soil	Clay loam	7.7	1.28	SFO	16.5	45.3	SFO	35.1	21.8
40164/1	St. Etienne du Gres, South France; cropped soil	Silt loam	7.7	0.96	SFO	16.2	41.0	SFO	25.8	25.0
40494/2	Ravenna, Italy; cropped soil	Silt loam	7.8	0.98	SFO	14.5	36.2	----	----	----
40495/0	S. Romualdo, Italy; cropped soil	Silty loam	7.8	1.11	SFO	10.3	51.1	----	----	----
Geomean							22.3 (n = 16)	----	----	20.5 (n = 6)
Median							31.6 (n = 16)	----	----	20.2 (n = 6)

Footnotes to the table:1) Determined in 0.01M CaCl₂;

2) The DIN 19682 classification presented because the USDA classification not provided; in another report it was stated to be Sandy loam (USDA) containing 58.5% sand, 22.7% silt and 18.8% clay.

The soil residues studies and soil accumulation studies were not performed as the results of the field dissipation studies demonstrated that they were not required – the results of those studies clearly indicated that neither Flufenacet nor its degradation products would accumulate in soil.

Finally three relevant open-literature studies examining the dissipation of Flufenacet in soil under realistic – field conditions were identified. Their key results are presented below in the table 2.8.1.-35.

Table 2.8.1.-35: The key results obtained in the literature studies examining the field dissipation of Flufenacet.

Data on the trial			Soil characterisation			Data on application		Soil persistence of the test compound - Flufenacet		Mobility of the test compound – Flufenacet in soil profile
<i>Trial site</i>	<i>Duration of the study – Days After application</i>	<i>Crop cover</i>	<i>Soil textural type</i>	<i>Soil pH</i>	<i>OM content</i>	<i>Application date</i>	<i>Application rate [g/ ha]</i>	<i>DisT₅₀ [days]</i>	<i>Kinetic model</i>	
Melle/ Belgium	266	Bare soil	Sandy loam	6.2	2.2	21/11/1997	240	98	1 st order, linear regression	No residues below 15 cm
Melle/ Belgium	182	Spring corn	Sandy loam	6.2	2.2	24/03/1998	600	74	1 st order, linear regression	No residues below 15 cm
Melle/ Belgium	168	Summer corn	Sandy loam	6.2	2.2	28/05/1998	600	56	1 st order, linear regression	No residues below 15 cm
Melle/ Belgium	241	Winter wheat	Sandy loam	7.0	1.5	25/11/1999	240	66	1 st order, linear regression	Residues detected down to 20 cm, but mainly confined to top 10 cm
Zingem/ Belgium	241	Winter wheat	Loamy sand	6.4	1.6	25/11/1999	240	97	1 st order, linear regression	Residues detected down to 20 cm, but mainly confined to top 10 cm
Zevekote/ Belgium	241	Winter wheat	Clay loam	6.6	2.1	26/11/1999	240	64	1 st order, linear regression	Residues detected down to 20 cm, but mainly confined to top 10 cm
Crotil-Noirmont/ Belgium	241	Winter wheat	Silt loam	6.7	1.2	01/12/2000	240	54	1 st order, linear regression	Residues detected down to 20 cm, but mainly confined to top 10 cm
Melle/ Belgium	~150	Winter wheat	Sandy loam	7.0	1.5	17/03/2000	240	44	1 st order, linear regression	No information provided
Zingem/ Belgium	~150	Winter wheat	Loamy sand	6.4	1.6	04/04/2000	240	66	1 st order, linear regression	No information provided

II) Mobility in soil::

The sorption of Flufenacet onto soil at equilibrium was extensively examined in four studies using fourteen test soils. The results of that examination were used to obtain Freundlich sorption isotherms for adsorption and desorption processes and derive Freundlich sorption isotherm parameters. In case of adsorption reliable parameters of Freundlich isotherm were obtained for ten test soils, while for desorption the reliable Freundlich parameters were derived using nine test soils. They are presented below in two tables: 2.8.1.-36 for adsorption and 2.8.1.-37 for desorption. The results obtained for adsorption indicate that Flufenacet is moderately to strongly sorbed onto soil and that the process is not preferential. It was also determined that it was not pH-dependent. The results obtained for desorption indicate that Flufenacet shows a time dependent sorption effect resulting in an increased sorption over time.

Table 2.8.1.-36: The results of the determination of the adsorption of Flufenacet onto soil at equilibrium – the reliable parameters of the Freundlich adsorption isotherm.

Soil name	Soil properties			Adsorption distribution coefficients		Freundlich adsorption isotherm parameters			
	Soil type (USDA)	pH	OC [%]	K_d [mL/g]	$K_{d oc}$ [mL/g]	K_f [mL/g]	$K_{f oc}$ [mL/g]	1/n	R^2
<i>Stanley (307)</i>	Silt loam	5.9	1.68	----	----	3.18	189.28	0.848	0.9971
<i>Hagerstown (318)</i>	Clay loam	6.4	1.28	----	----	2.81	219.53	0.878	0.9986
<i>Howe (395)</i>	Loamy sand	6.4	0.23	----	----	1.48	643.48	0.894	0.9932
<i>Monheim (3253)</i>	Sandy loam	6.4	1.4	----	----	4.55	325.00	0.920	0.9991
<i>Laacher Hof AXXa (AA)</i>	Loamy sand	5.8	2.2	----	----	3.55	161.6	0.928	0.9991
<i>Hoefchen am Hohenseh (HH)</i>	Silt loam	6.5	1.6	----	----	3.28	205.0	0.926	0.9965
<i>Hanscheider Hof (HN)</i>	Silt loam	5.3	2.7	----	----	5.10	188.9	0.926	0.9992
<i>Dollendorf II (DD)</i>	Loam	7.3	4.4	----	----	7.49	178.5	0.903	0.9994
<i>Wurmwiese (WW)</i>	Sandy loam	5.1	1.7	----	----	3.39	195.2	0.980	0.9966
<i>Kamikawa</i>	Loam	4.9	2.1	----	----	8.96	426.5	0.958	0.9984
Geomean (n = 10)						3.89	245.9	----	----
Arithmetic mean (n = 10)						----	----	0.916	----
pH dependence						No			----

Table 2.8.1.-37: The results of the determination of the desorption of Flufenacet onto soil at equilibrium – the reliable parameters of the Freundlich desorption isotherm.

Soil name	Soil properties			Desorption distribution coefficients		Freundlich desorption isotherm parameters			
	Soil type (USDA)	pH	OC [%]	K_d [mL/g]	$K_{d oc}$ [mL/g]	K_f [mL/g]	$K_{f oc}$ [mL/g]	1/n	R^2
<i>Stanley (307)</i>	Silt loam	5.9	1.68	----	----	3.81	226.79	0.864	0.9998
<i>Hagerstown (318)</i>	Clay loam	6.4	1.28	----	----	2.75	214.84	0.893	0.9996
<i>Howe (395)</i>	Loamy sand	6.4	0.23	----	----	2.10	913.04	0.911	0.9992
<i>Monheim (3253)</i>	Sandy loam	6.4	1.4	----	----	5.25	375.00	0.928	0.9993
<i>Laacher Hof AXXa (AA)</i>	Loamy sand	5.8	2.2	----	----	5.58	253.6	0.944	0.9988
<i>Hoefchen am Hohenseh (HH)</i>	Silt loam	6.5	1.6	----	----	5.64	352.3	0.943	0.9980
<i>Hanscheider Hof (HN)</i>	Silt loam	5.3	2.7	----	----	8.49	314.4	0.937	0.9996
<i>Dollendorf II (DD)</i>	Loam	7.3	4.4	----	----	11.71	278.7	0.908	0.9996
<i>Wurmwiese (WW)</i>	Sandy loam	5.1	1.7	----	----	5.49	349.4	0.989	0.9967
Geomean (n = 9)						5.01	329.38	----	----
Arithmetic mean (n = 9)						----	----	0.924	----
pH dependence						No			----

The additional information on the soil sorption of Flufenacet at equilibrium were provided by three open-literature scientific papers. The key results obtained in them are presented below in the table 2.8.1.-38. The values reported below may be considered as indicative and should not be used to derive the regulatory endpoints characterising soil sorption of Flufenacet.

Table 2.8.1.-38: The results of the determination of the adsorption of Flufenacet onto soil at equilibrium obtained in the open-source literature scientific papers.

Study	Soil name	Soil properties			Freundlich adsorption isotherm parameters			
		Soil type	pH	OC [%]	K_f [mL/g]	$K_{f oc}$ [mL/g]	1/n	r
<i>Gupta, Gajbhiye & Agnihotri; 2001</i>	<i>Inceptisol</i>	Sandy loam	7.1	0.34	2.26	664.71	0.988	0.99
<i>Gajbhiye & Gupta; 2001</i>	<i>Delhi</i>	Loamy sand	7.69	0.501	2.10	419.16	0.996	0.99
	<i>Ranchi</i>	Sandy clay loam	5.54	0.042	3.62	8619.05	0.981	0.98
	<i>Nagpur</i>	Clay	8.35	0.399	3.20	802.00	1.221	0.99
	<i>Kerala</i>	Sandy clay loam	4.45	0.456	4.39	962.72	1.015	0.99
<i>Rouchaud, Neus, Eelen, Bulcke; 2001</i>	<i>Melle</i>	Sandy loam	7.0	1.51 ¹⁾	16	1802	0.89	----
	<i>Zingem</i>	Loamy sand	6.4	1.60 ¹⁾	43	4602	0.91	----
	<i>Zevekote</i>	Clay loam	6.6	2.1 ¹⁾	15	1231	0.93	----
	<i>Cortil-Noirmont</i>	Silt loam	6.7	1.2 ¹⁾	9	1257	0.94	----

Footnotes to the table:

1) OM content reported, no values for OC content

In the studies by [Gupta, Gajbhiye and Agnihotri; 2001] and [Gajbhiye and Gupta; 2001] for adsorption of Flufenacet onto test soil the value of the free Gibbs energy of adsorption – ΔG , was determined. It was in range $\Delta G = (-3.27) - (-5.08)$ [Kcal/mol], indicating that adsorption of Flufenacet onto soil was a spontaneous process and mechanistically it was predominantly physisorption. It was also demonstrated, in the study by [Gupta, Gajbhiye and Agnihotri; 2001] that the soil sorption of Flufenacet was strongly positively correlated with soil OC/OM content. As the results obtained in these two studies are in line with those from reliable regulatory studies, that conclusion may be considered to be a general conclusion with regard to the adsorption of Flufenacet onto soil.

Also examined was sorption onto soil at equilibrium of major soil degradation products of Flufenacet: FOE Oxalate, FOE Sulfonic acid, FOE Methylsulfone, FOE Thiadone, FOE 5043-Trifluoroethanesulfonic acid (FOE TFESA) and Trifluoroacetic acid (TFA). The key results – Freundlich sorption parameters, are presented below, individually for each test compound.

For FOE Oxalate the reliable Freundlich isotherm parameters for adsorption were determined in three test soils. The desorption was not examined because of the low level of adsorption onto soil. The results are presented below in the table 2.8.1.-39.

Table 2.8.1.-39: The Freundlich adsorption and desorption parameters determined for FOE Oxalate.

Test soil – USDA type (name)	Key soil properties		Freundlich adsorption isotherm parameters			Freundlich desorption isotherm parameters		
	pH ¹⁾	OC [%]	K _F [mL/g]	K _{F OC} [mL/g]	1/n	K _F [mL/g]	K _{F OC} [mL/g]	1/n
<i>Sandy loam (Shipshe)</i>	6.3	0.75	0.096	12.80	0.933	Not determined		
<i>Silty clay loam (Drummer)</i>	6.6	2.13	0.153	7.18	0.824	Not determined		
<i>Silty clay (Oska-Martin)</i>	6.0	1.21	0.157	12.97	0.978	Not determined		
Geomean (n = 3)			0.132	10.60	----			
Arithmetic mean (n = 3)			----	----	0.912			
pH dependence			No					

Footnotes to the table:

1) Measured in water;

For FOE Sulfonic acid the reliable Freundlich isotherm parameters for adsorption were determined in four test soils. The desorption was not examined because of the low level of adsorption onto soil. The results are presented below in the table 2.8.1.-40.

Table 2.8.1.-40: The Freundlich adsorption and desorption parameters determined for FOE Sulfonic acid.

Test soil – USDA type (name)	Key soil properties		Freundlich adsorption isotherm parameters			Freundlich desorption isotherm parameters		
	pH ¹⁾	OC [%]	K _F [mL/g]	K _{F OC} [mL/g]	1/n	K _F [mL/g]	K _{F OC} [mL/g]	1/n
<i>Sand (Winder)</i>	5.8	0.27	0.051	18.88	0.865	Not determined		
<i>Sandy loam (Shipshe)</i>	6.3	0.75	0.106	14.13	1.002	Not determined		
<i>Silty clay loam (Drummer)</i>	6.6	2.13	0.204	9.58	0.931	Not determined		
<i>Silty clay (Oska-Martin)</i>	6.0	1.21	0.072	5.95	1.183	Not determined		
Geomean (n = 4)			0.094	11.10	----			
Arithmetic mean (n = 4)			----	----	0.995			
pH dependence			No					

Footnotes to the table:

1) Measured in water;

For FOE Methylsulfone reliable Freundlich isotherm parameters for adsorption and desorption were determined in five test soils. The results are presented below in the table 2.8.1.-41.

Table 2.8.1.-41: The Freundlich adsorption and desorption parameters determined for FOE Methylsulfone.

Test soil – USDA type (name)	Key soil properties		Freundlich adsorption isotherm parameters			Freundlich desorption isotherm parameters		
	pH ¹⁾	OC [%]	K _F [mL/g]	K _{F OC} [mL/g]	1/n	K _F [mL/g]	K _{F OC} [mL/g]	1/n
<i>Loam (Wurmwiese)</i>	5.5	1.8	0.658	37.4	0.892	0.769	43.7	0.898
<i>Silt loam (Hoefchen am Hohenseh)</i>	6.8	2.4	1.280	52.9	0.888	1.467	60.6	0.893
<i>Clay loam (Dollendorf II)</i>	7.4	4.6	1.569	33.2	0.900	1.820	38.6	0.912
<i>Sandy loam (Guadalupe)</i>	6.8	0.7	0.525	75.0	0.910	0.567	81.0	0.905
<i>Silt loam (Springfield)</i>	7.2	1.7	2.920	171.8	0.860	3.594	211.4	0.883
Geomean (n = 5)			1.152	61.03	----	1.332	70.57	----
Arithmetic mean (n = 5)			----	----	0.860	----	----	0.898
pH dependence			No			No		

Footnotes to the table:

1) Measured in water;

For FOE Thiadone the reliable Freundlich isotherm parameters for adsorption and desorption were determined in four test soils. The results are presented below in the table 2.8.1.-42.

Table 2.8.1.-42: The Freundlich adsorption and desorption parameters determined for FOE Thiadone.

Test soil – USDA type (name)	Key soil properties		Freundlich adsorption isotherm parameters			Freundlich desorption isotherm parameters		
	pH ¹⁾	OC [%]	K _F [mL/g]	K _{F OC} [mL/g]	1/n	K _F [mL/g]	K _{F OC} [mL/g]	1/n
<i>Sand (Winder)</i>	5.8	0.27	0.115	42.59	0.781	0.467	172.96	0.909
<i>Sandy loam (Shipshe)</i>	6.3	0.75	0.332	44.27	0.806	1.368	182.40	0.867
<i>Silty clay loam (Drummer)</i>	6.6	2.13	0.611	28.68	0.672	1.559	73.91	0.654
<i>Silty clay (Oska-Martin)</i>	6.0	1.21	0.703	58.10	0.796	2.104	173.88	0.887
Geomean (n = 4)			0.358	42.10	----	1.203	141.90	----
Arithmetic mean (n = 4)			----	----	0.764	----	----	0.829
pH dependence			No			No		

Footnotes to the table:

1) Measured in water;

For Trifluoroacetic acid Freundlich isotherm parameters for adsorption were determined in five test soils. The desorption was not examined because of the very low level of adsorption onto soil. The results are presented below in the table 2.8.1.-43.

Table 2.8.1.-43: The Freundlich adsorption and desorption parameters determined for Trifluoroacetic acid.

Test soil – USDA type (name)	Key soil properties		Freundlich adsorption isotherm parameters			Freundlich desorption isotherm parameters		
	pH ¹⁾	OC [%]	K _F [mL/g]	K _{F OC} [mL/g]	1/n	K _F [mL/g]	K _{F OC} [mL/g]	1/n
<i>Loam (Wurmwiese)</i>	5.5	1.76	0.0	0.0001	1.00	Not determined		
<i>Silt loam (Hoefchen am Hohenseh)</i>	6.8	2.42	0.0	0.0001	1.00	Not determined		
<i>Clay loam (Dollendorf II)</i>	7.4	4.72	0.0	0.0001	1.00	Not determined		
<i>Sandy loam (Guadalupe)</i>	6.8	0.7	0.0	0.0001	1.00	Not determined		
<i>Silt loam (Springfield)</i>	7.2	1.7	0.0	0.0001	1.00	Not determined		
Geomean (n = 5)			0.0	0.0001	----			
Arithmetic mean (n = 5)			----	----	1.00			
pH dependence			No					

Footnotes to the table:

1) Measured in water;

For FOE 5043-Trifluoroethanesulfonic acid reliable Freundlich isotherm parameters for adsorption were determined in five test soils. The desorption was not examined because of the very low level of adsorption onto soil. The results are presented below in the table 2.8.1.-44.

Table 2.8.1.-44: The of Freundlich adsorption and desorption parameters determined for FOE 5043-Trifluoroethanesulfonic acid.

Test soil – USDA type (name)	Key soil properties		Freundlich adsorption isotherm parameters			Freundlich desorption isotherm parameters		
	pH ¹⁾	OC [%]	K _F [mL/g]	K _{F OC} [mL/g]	1/n	K _F [mL/g]	K _{F OC} [mL/g]	1/n
<i>Loamy sand (Laacher Hof AXXa)</i>	6.6	1.8	0.0	0.0001	1.00	Not determined		
<i>Silt loam (Hoefchen am Hohenseh)</i>	6.7	1.7	0.0	0.0001	1.00	Not determined		
<i>Slit loam (Hnascheider Hof)</i>	5.3	2.8	0.0	0.0001	1.00	Not determined		
<i>Loam (Dollendorf II)</i>	7.5	5.0	0.0	0.0001	1.00	Not determined		
<i>Sandy loam (Wurmwiese)</i>	5.4	1.9	0.0	0.0001	1.00	Not determined		
Geomean (n = 5)			0.0	0.0001	----			
Arithmetic mean (n = 5)			----	----	1.00			
pH dependence			No					

Footnotes to the table:

1) Measured in water;

The results showed that FOE Methylsulfone and FOE Thiadone were moderately sorbed onto soil. FOE Oxalate and FOE Sulfonic acid were only weakly sorbed onto soil, while FOE 5043-Trifluoroethanesulfonic acid and Trifluoroacetic acid were practically not sorbed onto soil. No pH-dependence of the adsorption was stated for any of the degradation products, but in case of FOE Thiadone, FOE Sulfonic acid and FOE Oxalate that may be due to the limited number of soils used in the experiment as well as their narrow pH range.

Additionally for FOE Methylsulfide – major aquatic degradation product of Flufenacet, the K_{OC} value was estimated using KOCWIN – a part of EPISuite 4.1 modelling tool. The estimated value is K_{OC} = 598 L/kg and is recommended to be used as an input value in SW/SED model exposure assessment.

For FOE Sulfonic acid the additional examination of the soil sorption in function of time – time-dependent sorption, was performed. The key results of that examination – adsorption parameters in function of time, are provided below in the table 2.8.1.-45.

Table 2.8.1.-45: The key results of the examination of the time-dependent sorption of FOE Sulfonic acid onto soil.

Results obtained for <i>Laacherhof AXXa</i> test soil					Results obtained for <i>Laacherhof AIII</i> test soil				
Soil key properties		Results			Soil key properties		Results		
Parameter	Value	Time point [DAT]	K _d [mL/g]	K _{d OC} [mL/g]	Parameter	Value	Time point [DAT]	K _d [mL/g]	K _{d OC} [mL/g]
Soil type (USDA)	Sandy loam	0	0.12	8	Soil type (USDA)	Silt loam	0	0.12	13
		3	0.16	11			3	0.14	16
		7	0.16	11			7	0.14	16
OC [%]	1.47	14	0.17	11	OC [%]	0.88	14	0.15	17
		28	0.20	13			28	0.15	17
Soil pH (in H ₂ O)	6.9	56	0.18	12	Soil pH (in H ₂ O)	7.6	56	0.15	18
DT ₅₀ [days]	49.8	100	0.23	16	DT ₅₀ [days]	40.4	100	0.18	20

The calculated adsorption coefficient increase factor was 2 for Laacherhof AXXa test soil and 1.5 for Laacherhof AIII test soil, indicating that the compound became more strongly sorbed onto soil with elapsing time. However that increase did not strongly influenced the mobility of FOE Sulfonic acid in soil, which remained very mobile, as indicated K_d and K_{d OC} values.

The examination of the mobility of Flufenacet and its major transformation products in soil covered following issues:

- column leaching,
- aged residue column leaching,
- lysimeter studies,
- determination of the Plant Uptake Factor – PUF, as “Other studies”

The Applicant did not submit any studies covering the issue of the column leaching of Flufenacet. Instead, in the provided justification for the non-submission, stated that it was covered by the results of the examination of sorption in soil at equilibrium (batch sorption studies) and those aimed on the examination of leaching of the aged residues. That justification was found acceptable by the RMS. It shall be indicated however, that the evaluation of the study examining the leaching behaviour of the aged residues of Flufenacet demonstrated that the study was not acceptable.

Two additional open-literature studies found by the RMS, considered supplementary, indicated that under typical EU conditions Flufenacet should not move in the soil profile below the depth of 25 cm. Such statement seem to be confirmed by the results of the field dissipation studies performed for Flufenacet.

Additionally, a study was submitted examining the column leaching of one of the major soil degradation products of Flufenacet – TFA. That study, performed using four European soils, showed that TFA was very mobile in soil. The key results of that study are presented below.

The leaching behaviour of TFA was examined using soil columns filled with one of the following test soils:

- Loamy sand (*Laacherhof AXXa*) test soil, having OC = 1.8% and pH = 6.2;
- Loam (*Dollendorf II*) test soil, having OC = 5.2% and pH = 7.4;
- Silt loam (*Höfchen am Hohenseh*) test soil, having OC = 1.6 and pH = 6.5;
- Sandy loam (*Laacherhof Wurmwielse*) test soil, having OC = 1.9 and pH = 5.3.

The experiment was performed in two variants, denominated **Study design A** and **Study design B**, that may be characterised as follows:

- in **Study design A** leaching lasted 48 hours and was performed with 393 mL of artificial rain (0.01M CaCl_2 aq), corresponding to 200 mm of rain;
- in **Study design B** leaching lasted 120 hours and was performed with 984 mL of artificial rain (0.01M CaCl_2 aq), corresponding to 502 mm of rain;

In the variant denominated **Study design A** the following results were obtained for TFA:

- amount of TFA in the eluates (mean values of the two replicates), expressed as % AR, was:
 - 95.5% AR for columns filled with Loamy sand (*Laacherhof AXXa*) test soil;
 - 73.2% AR for columns filled with Loam (*Dollendorf II*) test soil;
 - 92.1% AR for columns filled with Silt loam (*Höfchen am Hohenseh*) test soil;
 - 66.2% AR for columns filled with Sandy loam (*Laacherhof Wurmwielse*) test soil.
- the extractable radioactivity retained within soil columns attributed to TFA was (mean values of the two replicates):
 - 5.0% AR for columns filled with Loamy sand (*Laacherhof AXXa*) test soil;
 - 28.3% AR for columns filled with Loam (*Dollendorf II*) test soil;
 - 6.5% of AR for columns filled with Silt loam (*Höfchen am Hohenseh*) test soil;
 - 35.6% AR for columns filled with Sandy loam (*Laacherhof Wurmwielse*) test soil.
- the NER fraction attributed to TFA, expressed as % AR, in the soil columns (mean values of the two replicates) was:
 - 1.2% AR for columns filled with Loamy sand (*Laacherhof AXXa*) test soil;
 - 1.8% AR for columns filled with Loam (*Dollendorf II*) test soil;
 - 0.8% AR for columns filled with Silt loam (*Höfchen am Hohenseh*) test soil;
 - 1.1% AR for columns filled with Sandy loam (*Laacherhof Wurmwielse*) test soil.
- the distribution of residues of TFA in soil was following:
 - for columns filled with Loamy sand (*Laacherhof AXXa*) test soil they were found predominantly in the lowest segment – S5;
 - for columns filled with Loam (*Dollendorf II*) test soil the highest concentration of TFA residues was determined in the top section of the column (segments S1 and S2) with the peak amount in segment S2, and it gradually decreased towards the bottom of the soil column;
 - for columns filled with Silt loam (*Höfchen am Hohenseh*) test soil they were found predominantly in the lowest segment – S5;
 - for columns filled with Sandy loam (*Laacherhof Wurmwielse*) test soil the residues of TFA were generally found in the lower part of the column, with the peak amount in the middle section S3.
- The K_d and K_{dOC} values determined for TFA in this experiment were following:
 - for the test soil Loamy sand (*Laacherhof AXXa*) $K_d = 0.0$ mL/g and $K_{dOC} = 0.0$ mL/g;
 - for the test soil Loam (*Dollendorf II*) $K_d = 0.0$ mL/g and $K_{dOC} = 0.0$ mL/g;
 - for the test soil Silt loam (*Höfchen am Hohenseh*) $K_d = 0.0$ mL/g and $K_{dOC} = 0.0$ mL/g;
 - for the test soil Sandy loam (*Laacherhof Wurmwielse*) $K_d = 0.0$ mL/g and $K_{dOC} = 0.0$ mL/g;
 - mean $K_d = 0.0$ mL/g and $K_{dOC} = 0.0$ mL/g.

In the variant denominated **Study design B** the following results were obtained for TFA:

- amount of TFA in the eluates (mean values of the two replicates), expressed as % AR, was:
 - 101.1% AR for columns filled with Loamy sand (*Laacherhof AXXa*) test soil;

-
- 96.3% AR for columns filled with Loam (*Dollendorf II*) test soil;
 - 98.6% AR for columns filled with Silt loam (*Höfchen am Hohenseh*) test soil;
 - 100.9% AR for columns filled with Sandy loam (*Laacherhof Wurmwielse*) test soil.
 - the amount of radioactivity retained within soil columns attributed to TFA was not analysed because it was wholly recovered in leachates.
 - The K_d and K_{dOC} values determined for TFA in this experiment were following:
 - for the test soil with Loamy sand (*Laacherhof AXXa*) $K_d = 0.1$ mL/g and $K_{dOC} = 4.5$ mL/g;
 - for the test soil Loam (*Dollendorf II*) $K_d = 0.0$ mL/g and $K_{dOC} = 0.0$ mL/g;
 - for the test soil Silt loam (*Höfchen am Hohenseh*) $K_d = 0.2$ mL/g and $K_{dOC} = 11.3$ mL/g;
 - for the test soil Sandy loam (*Laacherhof Wurmwielse*) $K_d = 0.2$ mL/g and $K_{dOC} = 7.1$ mL/g;
 - mean $K_d = 0.2$ mL/g and $K_{dOC} = 9.1$ mL/g.

The aged residues leaching was examined in one study, submitted also for the previous authorisation of Flufenacet in the EU. RMS evaluated that study for its compliance with the current guidelines, in particular the OECD Guideline for testing chemicals No. 312. Several minor deficiencies were stated that had no impact on the validity of the study. However, the thorough examination of the study report showed that there was a significant discrepancy between the application rate declared to be used to treat soil subjected to the ageing procedure and that used in the leaching experiment with aged soil.

Second problem identified in the study report was the fact that the analytical procedure used to characterise quantitatively and qualitatively the residues in soil after ageing was not presented.

As a result, mainly due to the discrepancies in the amount of the radioactivity introduced into soil at the beginning of the ageing period and that used in leaching experiment, introduced with aged soils, RMS decided to consider the study not acceptable because of the significant uncertainty related to the reliability of the obtained results.

The leaching behaviour of Flufenacet and its degradation products through the undisturbed soil profiles under the agronomic and climatic conditions relevant for Germany was examined on four outdoor lysimeters. The results of that examination were presented in two study reports submitted by the Applicant for the purpose of the current evaluation. Additionally the Applicant submitted the interim reports of the same experiments, not summarised in the Renewal Assessment Report for Flufenacet, but analysed for their compliance with the adequate final reports. The third study submitted for evaluation was aimed on the validation of the lysimeter studies by comparing their results with those of the modelling exposure assessment carried out for the GW compartment. RMS however decided not to use it, as the modelling tools and scenarios were not those recommended by FOCUS. The key data and results obtained in these two studies are summarily presented below in tables 2.8.1-46 – 2.8.1.-46c.

Table 2.8.1.-46: The key data and results obtained in the outdoor lysimeter studies.

Parameter				Data for Lysimeter			
				#15	#16	#17	#18
General information	Trial site	Test facility		Lysimeter station of Bayer AG	Lysimeter station of Bayer AG	Lysimeter station of Bayer AG	Lysimeter station of Bayer AG
		Location (town, region, country)		Monheim, NRW, Germany	Monheim, NRW, Germany	Monheim, NRW, Germany	Monheim, NRW, Germany
		Geographic coordinates	Longitude	6° 55' E	6° 55' E	6° 55' E	6° 55' E
			Latitude	51° 4' N	51° 4' N	51° 4' N	51° 4' N
	Long-term weather conditions at trial site (1996 – 1995)	Average rainfall [mm]	Annual	745	745	745	745
			Monthly min. (month)	42.7 (February)	42.7 (February)	42.7 (February)	42.7 (February)
			Monthly max. (month)	78.1 (June)	78.1 (June)	78.1 (June)	78.1 (June)
		Average annual relative air humidity [%]		73	73	73	73
		Average temperature at 2 metres above the ground [°C]	Annual	10.0	10.0	10.0	10.0
			Monthly min. (month)	2.6 (January)	2.6 (January)	2.6 (January)	2.6 (January)
			Monthly max. (month)	18.4 (June)	18.4 (June)	18.4 (June)	18.4 (June)
		Average annual wind velocity [m/s.]		2.5	2.5	2.5	2.5
		Average radiant heat [kJ/cm ²]	Annual	29.1	29.1	29.1	29.1
			Monthly min. (month)	5.8 (December)	5.8 (December)	5.8 (December)	5.8 (December)
			Monthly max. (month)	53.1 (July)	53.1 (July)	53.1 (July)	53.1 (July)
	Duration of the study	Preliminary period	Duration [years]	1	1	1	1
			Beginning	March 1992	March 1992	March 1992	March 1992
			End	May 1993	May 1993	May 1993	May 1993
		Experimental period	Duration [years]	3	3	2.5	2.5
			Beginning	May 1993	May 1993	May 1993	May 1993
			End	April 1996	April 1996	November 1995	November 1995
Characterisation of lysimeter	Lysimeter depth	Total [cm]		135	135	120	120
		Soil monolith [cm]		130	130	115	115
		Gravel layer [cm]		5	5	5	5
		Soil type (FAO)		Eutric Cambisol	Eutric Cambisol	Eutric Cambisol	Eutric Cambisol
	Characteristic of soil monolith	Soil properties, depth 0 – 30 cm	Soil texture (USDA)	Sandy loam	Sandy loam	Sandy loam	Sandy loam
			pH (CaCl ₂)	7.04	7.04	7.04	7.04
			OC%	1.41	1.41	1.41	1.41
			CEC [meq/100g]	9.61	9.61	9.61	9.61
			Microbial biomass [mg/kg]	235	235	235	235
		Soil properties, depth 30 – 60 cm	Soil texture (USDA)	Sandy loam	Sandy loam	Sandy loam	Sandy loam
			pH (CaCl ₂)	7.24	7.24	7.24	7.24
			OC%	0.34	0.34	0.34	0.34
			CEC [meq/100g]	7.43	7.43	7.43	7.43
			Microbial biomass [mg/kg]	34	34	34	34
		Soil properties, depth 60 – 100 cm	Soil texture (USDA)	Loamy sand	Loamy sand	Loamy sand	Loamy sand
			pH (CaCl ₂)	7.18	7.18	7.18	7.18
			OC%	0.19	0.19	0.19	0.19
			CEC [meq/100g]	7.57	7.57	7.57	7.57
			Microbial biomass [mg/kg]	11	11	11	11
		Soil properties, depth 100 – 115 cm	Soil texture (USDA)	Loamy sand	Loamy sand	Loamy sand	Loamy sand
			pH (CaCl ₂)	7.46	7.46	7.46	7.46
			OC%	0.17	0.17	0.17	0.17
			CEC [meq/100g]	8.52	8.52	8.52	8.52
			Microbial biomass [mg/kg]	13	13	13	13
Maintenance data	Application of the test compound	Test compound		¹⁴ C-Flufenacet	¹⁴ C-Flufenacet	¹⁴ C-Flufenacet	¹⁴ C-Flufenacet
		Number of applications/ experiment		2	2	2	2
		1 st application	Year of experiment	1	1	1	1
			Application date	12/05/1993	12/05/1993	13/05/1993	13/05/1993
			Application rate	48.14 mg/m ² (480 g/ha)	48.14 mg/m ² (480 g/ha)	48.14 mg/m ² (480 g/ha)	48.14 mg/m ² (480 g/ha)
		2 nd application	Year of experiment	2	2	1	1
			Application date	05/05/1994	05/05/1994	03/11/1993	03/11/1993
			Application rate	48.04 mg/m ² (480 g/ha)	48.04 mg/m ² (480 g/ha)	18.02 mg/m ² (180 g/ha)	18.02 mg/m ² (180 g/ha)

Table 2.8.1.-46a: The key data and results obtained in the outdoor lysimeter studies (continued).

Parameter				Data for Lysimeter			
				#15	#16	#17	#18
Maintenance data, continued	Crop data	1 st crop, target	Crop	Maize, grain	Maize, grain	Maize, fodder	Maize, fodder
			Year of experiment	1	1	1	1
			Date of sowing	10/05/1993	10/05/1993	10/05/1993	10/05/1993
			Date of harvest	12/11/1993	12/11/1993	28/09/1993	28/09/1993
			Harvested parts	Corncoobs	Corncoobs	Silage material	Silage material
		2 nd crop, target	Crop	Maize, grain	Maize, grain	Winter wheat	Winter wheat
			Year of experiment	2	2	1 – 2	1 – 2
			Date of sowing	05/05/1994	05/05/1994	02/11/1993	02/11/1993
			Date of harvest	10/05/1994	10/05/1994	03/08/1994	03/08/1994
			Harvested parts	Corncoobs	Corncoobs	Grain and straw	Grain and straw
		3 rd crop, succeeding	Crop	Sugar beet	Sugar beet	Sugar beet	Sugar beet
			Year of experiment	3	3	3	3
			Date of sowing	13/04/1995	13/04/1995	13/04/1995	13/04/1995
			Date of harvest	07/11/1995	07/11/1995	07/11/1995	07/11/1995
			Harvested parts	Leaves and tubers	Leaves and tubers	Leaves and tubers	Leaves and tubers
	Irrigation and precipitation during experiment	1 st year	Precipitation [mm]	897.1	897.1	897.1	897.1
			Irrigation [mm]	46.0	46.0	51.0	51.0
			Sum [mm]	943.1	943.1	948.1	948.1
		2 nd year	Precipitation [mm]	814.2	814.2	813.9	813.9
			Irrigation [mm]	100.0	100.0	75.0	75.0
			Sum [mm]	914.2	914.2	888.9	888.9
		3 rd year	Precipitation [mm]	496.1	496.1	338.0	338.0
			Irrigation [mm]	104.0	104.0	104.0	104.0
			Sum [mm]	600.1	600.1	442.0	442.0
		Total	Precipitation [mm]	2207.5	2207.5	2049.0	2049.0
			Irrigation [mm]	250	250	250	250
			Sum [mm]	2457	2457	2279.0	2279.0
Radioactivity - recovery	Radioactivity recovered [% AR]	in soil monolith	0- 30 cm	40.289	41.414	37.80	~48.2
			30 – 60 cm	2.095	3.128	2.46	~3.1
			below 60 cm	0.777	0.485	~2.00	~1.7
			total	43.16	45.03	42.33	52.96
		in leachates	1 st year	0.772	0.815	1.436	1.563
			2 nd year	0.250	0.161	0.122	0.150
			3 rd year	0.006	0.006	0.006	0.007
			total	0.64	0.58	~1.56	~1.72
		in crops	1 st crop	0.014	0.015	0.38	0.39
			2 nd crop	0.016	0.014	0.04	0.05
			3 rd crop	0.059	0.061	0.07	0.07
			total	0.08	0.08	0.48	0.50
		Total recovered		43.89	45.68	44.38	55.18
		Lost (eg as ¹⁴ CO ₂) [% AR]		56.11	54.32	55.62	44.82
		Total [% AR]		40.29	41.41	37.80	48.2
Radioactivity in soil monoliths	in 0 – 30 cm layer	identified as Flufenacet	[µg/layer]	1860.96	1839.68	450.75	528.48
			[µg/kg soil FW]	3.91	3.91	1.07	1.06
		identified as FOE Alcohol	[µg/layer]	143.49	159.02	60.09	87.67
			[µg/kg soil FW]	0.30	0.34	0.14	0.18
		identified as FOE Oxalate	[µg/layer]	212.84	167.72	28.23	63.74
			[µg/kg soil FW]	0.45	0.36	0.07	0.13
		Identified as FOE Sulfonic acid	[µg/layer]	71.44	138.39	45.74	43.42
			[µg/kg soil FW]	0.15	0.29	0.11	0.09
		Total [% AR]		2.095	3.128	2.46	3.1
		Total [% AR]		0.777	0.485	2.00	1.7
Detailed characterisation of leachates	1 st year early leachate	Collection time	Week of experiment	24	24	24	24
			Collection date	29/10/1993	29/10/1993	29/10/1993	29/10/1993
		Volume of leachate [L]		3.7	4.7	8.2	8.2
		Characterisation of TRR – Total Radioactivity Recovered	Total TRR [µg a. i. equivalent/L]	0.256	0.221	0.588	0.505
			acidic TRR [µg a. i. equivalent/L]	0.218	0.183	0.539	0.477
			¹⁴ CO ₂ -associated radioactivity [% total TRR]	14.87	17.23	8.34	5.64
		Characterisation of acidic TRR ¹⁾	Flufenacet [µg /L]	<0.011	<0.014	0.006	<0.005
			FOE ALC [µg /L]	<0.001	0.006	0.002	0.095
			FOE OXA [µg /L]	0.002	0.007	<0.001	0.005
			FOE SA [µg /L]	0.065	0.025	0.225	0.182
			FOE TGS [µg /L]	0.017	0.009	0.015	0.027

Footnotes to the table:

1) Abbreviations used: FOE ALC – FOE Alcohol, FOE OXA – FOE Oxalate, FOE SA – FOE Sulfonic acid, FOE TGS – FOE Thioglycolate sulfoxide.

Table 2.8.1._CP-46b: The key data and results obtained in the outdoor lysimeter studies (continued).

Parameter				Data for Lysimeter			
				#15	#16	#17	#18
Detailed characterisation of leachates - continued	<i>1st year leachate with max. TRR</i>	Collection time	Week of experiment	37	35	38	38
			Collection date	28/01/1994	12/01/1994	04/02/1994	04/02/1994
		Volume of leachate [L]		17.2	21.5	21.3	21.3
		Characterisation of TRR – Total Radioactivity Recovered	Total TRR [µg a. i. equiv./L]	2.350	1.989	5.106	5.455
			acidic TRR [µg a. i. equiv./L]	2.228	1.915	4.940	5.255
			¹⁴ CO ₂ -associated radioactivity [% total TRR]	5.19	3.72	4.26	3.58
		Characterisation of acidic TRR ¹⁾	Flufenacet [µg /L]	≤0.007	<0.017	<0.011	<0.001
			FOE ALC [µg /L]	0.001	0.004	0.006	0.044
			FOE OXA [µg /L]	0.007	0.041	0.005	0.036
			FOE SA [µg /L]	1.293	1.090	3.375	3.682
			FOE TGS [µg /L]	0.079	0.036	0.017	0.028
	<i>1st year late leachate</i>	Collection time	Week of experiment	47	47	47	47
			Collection date	11/04/1994	11/04/1994	11/04/1994	11/04/1994
		Volume of leachate [L]		11.5	15.5	19.4	15.0
		Characterisation of TRR – Total Radioactivity Recovered	Total TRR [µg a. i. equiv./L]	0.850	0.798	2.545	3.102
			acidic TRR [µg a. i. equiv./L]	0.767	0.732	1.389	2.916
			¹⁴ CO ₂ -associated radioactivity [% total TRR]	9.82	8.27	6.13	6.00
		Characterisation of acidic TRR ¹⁾	Flufenacet [µg /L]	<0.035	0.005	0.002	0.002
			FOE ALC [µg /L]	0.001	<0.001	0.008	0.041
			FOE OXA [µg /L]	0.012	0.031	0.026	0.017
			FOE SA [µg /L]	0.332	0.301	1.302	1.920
			FOE TGS [µg /L]	0.014	0.010	0.005	0.012
	<i>1st year annual leachate (pooled)</i>	Collection time	Week of experiment	50	50	50	50
			Collection date	29/04/1994	29/04/1994	29/04/1994	29/04/1994
		Volume of leachate [L]		349.8	402.4	399.1	383.1
		Characterisation of TRR – Total Radioactivity Recovered	Total TRR [µg a. i. equiv./L]	1.062	0.931	2.380	2.699
			acidic TRR [µg a. i. equiv./L]	0.99	0.87	2.26	2.56
			¹⁴ CO ₂ -associated radioactivity [% total TRR]	6.47	6.82	5.31	5.35
		Characterisation of acidic TRR ¹⁾	Flufenacet [µg /L]	0.020	0.033	0.004	0.005
			FOE ALC [µg /L]	<0.002	0.000	0.034	0.016
			FOE OXA [µg /L]	0.015	0.004	0.017	0.006
			FOE SA [µg /L]	0.589	0.489	1.355	1.616
			FOE TGS [µg /L]	0.016	0.014	0.030	0.027
	<i>2nd year annual leachate (pooled)</i>	Collection time	Week of experiment	103	103	103	103
			Collection date	05/05/1995	05/05/1995	05/05/1995	05/05/1995
		Volume of leachate [L]		317.6	299.9	365.4	368.9
		Characterisation of TRR – Total Radioactivity Recovered	Total TRR [µg a. i. equiv./L]	0.758	0.516	0.221	0.269
			acidic TRR [µg a. i. equiv./L]	0.670	0.46	0.19	0.22
			¹⁴ CO ₂ -associated radioactivity [% total TRR]	11.10	11.19	17.06	23.02
		Characterisation of acidic TRR ¹⁾	Flufenacet [µg /L]	0.003	0.003	0.002	0.005
			FOE ALC [µg /L]	0.003	0.005	0.001	0.004
			FOE OXA [µg /L]	<0.018	<0.014	0.009	0.006
			FOE SA [µg /L]	0.235	0.149	0.013	0.016
			FOE TGS [µg /L]	0.020	0.015	0.022	0.019

Footnotes to the table:

1) Abbreviations used: FOE ALC – FOE Alcohol, FOE OXA – FOE Oxalate, FOE SA – FOE Sulfonic acid, FOE TGS – FOE Thioglycolate sulfoxide.

Table 2.8.1._CP-46c: The key data and results obtained in the outdoor lysimeter studies (continued).

Parameter				Data for Lysimeter			
				#15	#16	#17	#18
Detailed characterisation of leachates - continued	3 rd year annual leachate (pooled)	Collection time	Week of experiment	115	115	115	115
			Collection date	26/07/1995	26/07/1995	26/07/1995	26/07/1995
		Volume of leachate [L]		13.0	17.0	17.5	19.1
		Characterisation of TRR – Total Radioactivity Recovered	Total TRR [µg a. i. equival./L]	0.432	0.353	0.239	0.238
			acidic TRR [µg a. i. equival./L]	0.334	0.23	0.15	0.14
			¹⁴ CO ₂ -associated radioactivity [% total TRR]	22.80	34.56	35.22	40.88
			Characterisation of acidic TRR: compound/concentration [µg /L]	FOE SA ¹⁾ ≤ 0.25	FOE SA ¹⁾ ≤ 0.17	not performed	not performed
	Total leachate	Collection time	Weeks of experiment	115	115	115	115
			Collection dates: beginning/end	12/05/1993 26/07/1995	12/05/1993 26/07/1995	12/05/1993 26/07/1995	12/05/1993 26/07/1995
		Volume of leachate [L] (total)		680.4	719.3	782.0	771.1
		Characterisation of TRR – Total Radioactivity Recovered; average values	Total TRR [µg a. i. equival./L]	0.906	0.742	1.310	1.492
			acidic TRR [µg a. i. equival./L]	0.83	0.68	1.25	1.38
			¹⁴ CO ₂ -associated radioactivity [% total TRR]	8.42	8.39	6.28	6.85

Footnotes to the table:

1) Abbreviations used: FOE SA – FOE Sulfonic acid.

It may be stated that of all the compounds possible to be identified as originating from Flufenacet radiolabelled in fluorophenyl ring (including Flufenacet itself) only FOE Sulfonic acid was demonstrated to be found in leachates in amounts > 0.1 µg/L, what confirmed the risk to GW associated to that degradation product demonstrated in GW model exposure assessment (for details please refer to the results of calculations presented under the point B.8.5 of this document).

Neither Flufenacet nor the second major soil degradation product characteristic for that radiolabelling position – FOE Oxalate, were detected in leachates in amounts >0.1 µg/L, what may indicate that they would not pose a threat to the GW compartment.

In soil and leachates FOE Alcohol was detected – the compound determined in the studies examining the route of degradation of Flufenacet in aerobic soil to be minor/transient and therefore not taken into account in the GW model exposure assessment. It shall be indicated however that the would-be risk it may pose to the GW compartment was covered by the calculations carried out for FOE Oxalate – its immediate degradate.

Also detected in leachates was FOE Thioglycolate sulfoxide (FOE TGS), the compound not taken in the model GW exposure assessment into consideration, being identified as minor soil degradation product. It shall be indicated however, that in the study it was determined in leachates in amounts <0.1 µg/L, what may indicate that it would not pose a serious threat to the GW compartment.

Finally, it shall be indicated that, due to the fact that in the experiments was used Flufenacet radiolabelled only in the fluorophenyl ring, they gave no information of the laching potential of the degradation products formed from the second moiety present within the molecule of Flufenacet – thiadiazole.

The comparative analysis of the application pattern (crops, application timing and application rates) used in the experiments and the EU-representative application pattern proposed for the current authorisation of Flufenacet in the EU showed that they may be considered as providing supplementary information with regard to the risk posed by Flufenacet and its soil degradation products to the GW compartment, but for the purpose of the decision making should be considered with care.

The PUF – plant uptake factor was determined in three separate experiments for the following major soil degradation products of Flufenacet: FOE Sulfonic acid, FOE Methylsulfone, FOE 5043-Trifluoroethanesulfonic acid – FOE TFESA (for all three in one experiment), and Trifluoroacetic acid – TFA (in two separate experiments). The PUF values for FOE Sulfonic acid, FOE Methylsulfone and FOE TFESA were determined for Wheat as the experimental crop, while for TFA the test crops for which the PUF values were determined were Wheat, Corn (Maize) and Tomato.

Additionally was submitted a study, being in fact a position paper, supporting the value of PUF proposed for TFA.

For all four test compounds the experimental PUF values were determined for Wheat, the crop that may be considered representative for all cereals.

The determined values are:

- for FOE Sulfonic acid the PUF in cereals is **0.46**;
- for FOE Methylsulfone the PUF in cereals is **1.31**;
- for FOE 5043-Trifluoroethanesulfonic acid the PUF in cereals is **1.36**;
- for TFA (Trifluoroacetic acid) the PUF in cereals is **0.59**.

The Applicant proposed to use two of these experimentally derived values – PUF for FOE Sulfonic acid and PUF for TFA, as input values for GW model exposure assessment (please also refer to the point B.8.3. in the document Vol. 3_CP – B.8. of this Renewal Assessment Report).

RMS decided to verify the correctness of that selection in light of the recommendations of the current Guidelines. That was done using the *Generic Guidance for Tier 1 FOCUS Ground Water Assessments, Version 2.2, May 2014*, document, which in paragraph 2.4.4 – *Crop related substance parameters* provides the recommendations with regard to the appropriate selection of the Plant Uptake Factor value. It is stated that the recommended default value for all compounds is 0. However, when a reliable measured K_{OW} value, determined for neutral pH, is available, the Briggs equation proposed for calculation of TSCF (Transpiration Stream Concentration Factor) may be used and so determined TSCF value used as input parameter for PUF in GW model exposure assessment. The Briggs equation for calculating TSCF presented in the cited above Guidance document looks as follows:

$$TSCF = 0.784 \exp \{(-[\text{Log}(K_{OW}) - 1.78]^2 / 2.44)\}$$

RMS decided to use it in order to calculate the TSCF values for Flufenacet and all its major soil degradation products, for which the GW model exposure assessment shall be performed and for which were available the reliable $\text{Log } P_{OW}$ (= $\text{Log } K_{OW}$) presented in section B.2 (Physicochemical properties) of this Renewal Assessment Report. The results of the calculations, together with the input parameters used in them, are presented below in the table 2.8.1.-47. As a next step the calculated values were compared with the proposed in the same Guideline maximum recommended TSCF value – 0.8, and, where available, with the experimental value. That was done in order to determine the suitable value representing TSCF/PUF to be used as input parameter in GW model exposure assessment. These value are also presented in the table B.8.1.2._CP-12. The TSCF/PUF values recommended as input for GW/SW modelling are given in **bold**.

Table 2.8.1.-47: The results of the determination of TSCF/PUF value suitable for GW/SW model exposure assessment

Compound	Ionisable substance	Experimental values		TSCF		Measured PUF	TSCF/PUF value selected for modelling
		$\text{Log } P_{OW}$	measured at pH	calculated	Regulatory upper limit		
Flufenacet	No	3.5	7.0	0.744	0.8	n. a. ³⁾	0.744
FOE Oxalate	No	2.2	7.0	0.983	0.8	n. a. ³⁾	0.8
FOE Sulfonic acid	Yes	-2.72	7.0	0.133	0.8	0.46	0.46
FOE Methylsulfone	No	1.7	7.0	0.999	0.8	1.31	0.8
FOE Thiadone	No	0.62	7.0	0.874	0.8	n. a. ³⁾	0.8
FOE TFESA ¹⁾	Yes	-2.95	7.0	0.107	0.8	1.36	0.8
TFA ²⁾	Yes	-2.6	7.0	0.148	0.8	0.59	0.59

Footnotes to the table:

- 1) FOE TFESA = FOE 5043-Trifluoroethanesulfonic acid;
- 2) TFA = Trifluoroacetic acid;
- 3) n. a. = value not available (not determined experimentally).

2.8.2. Summary of fate and behaviour in water and sediment

The determination of transformation pathways and persistence of Flufenacet in the aquatic environment was performed by examining potentially relevant abiotic and biologically-mediated processes.

The examination of abiotic degradation of Flufenacet in the aquatic environment comprised the following processes:

- abiotic aqueous hydrolysis;
- direct aqueous photolysis;
- indirect aqueous photolysis.

The **abiotic hydrolysis of Flufenacet** was examined at three different pH – pH = 5, pH = 7 and pH = 9 (environmentally relevant pH range), and T = 25°C. The results of that examination, presented in one study report,

demonstrated that Flufenacet was hydrolytically stable within the whole examined pH range. The determined in that experiment half-lives at $T = 25^{\circ}\text{C}$ were: $\text{DT}_{50} > 1000$ days for pH 5-7 and $\text{DT}_{50} = 655$ days for pH = 9.

Additionally the results presented in the open source paper identified as a relevant for the evaluation of Flufenacet showed that the pH of the aqueous solution, and hence the hydrolysis, had only minimal influence on the rate of dissipation/degradation of Flufenacet from water (biologically viable). The results of that study were considered however only as indicative and were not used to derive the regulatory endpoints.

Also stable to abiotic hydrolysis in the aquatic environment, for the same environmentally relevant conditions, was demonstrated to be the major soil and aquatic major degradation product of Flufenacet – FOE Thiadone. The determined half-lives were $\text{DT}_{50} > 1000$ days for the whole tested range pH = 5-9 and $T = 25^{\circ}\text{C}$.

The **direct aqueous photolysis of Flufenacet** was examined in a sterile buffer solution having pH = 5 and $T = 21^{\circ}\text{C}$. The samples were exposed to UV-Vis radiation generated by the artificial light source. The irradiation conditions were similar to those recorded during 30-days exposure to natural summer sunlight in Phoenix, Arizona, USA. The results demonstrated that Flufenacet was not prone to the direct aqueous photolysis – practically no photodegradation of Flufenacet, in comparison to what was observed in the dark control samples, was stated. The determined half-lives were: for irradiated sample $\text{DT}_{50} = 7430$ days when expressed in Natural Sunlight days, and for the dark control samples $\text{DT}_{50} = 4160$ days.

In a separate experiment the quantum yield of the process of direct photodegradation of Flufenacet in water was determined. The quantum yield value determined in that experiment was $\phi = 0.00096$ [mol/Einstein]. The calculated using that value environmental photolytical half-lives for Flufenacet, calculated using GC-Solar method, in water were:

- for the latitude 30°N in range $\text{DT}_{50} = 126 - 308$ days;
- for the latitude 40°N in range $\text{DT}_{50} = 131 - >365$ days;
- for the latitude 50°N in range $\text{DT}_{50} = 142 - >365$ days;
- for the latitude 60°N in range $\text{DT}_{50} = 160 - >365$ days;

Additionally, in a separate study, was examined the direct aquatic photolysis of the major soil and aquatic degradation product of Flufenacet – FOE Thiadone. The experiment was performed in a sterile buffer solution having pH = 7 and $T = 25^{\circ}\text{C}$. The samples were exposed to UV-Vis radiation generated by the artificial light source. The irradiation conditions were similar to those recorded during 30-days exposure to natural summer sunlight in Phoenix, Arizona, USA. The results demonstrated that FOE Thiadone was not prone to the direct aqueous photolysis – practically no photodegradation of that compound was observed in either irradiated samples or in dark control and it was not possible to determine the reliable DT_{50} values.

The **indirect aqueous photolysis of Flufenacet** was examined in four types of aqueous solutions:

- natural pond water having pH = 6.5, TOC = 20.7 mg/L and containing 160 mg/L of suspended solids (total), subsequently named Howe pond water;
- natural pond water having pH = 7.8, TOC = 1.55 mg/L and containing 9 mg/L of suspended solids, subsequently named Stilwell pond water;
- ultrapure water containing 15 ppm of humic material;
- ultrapure water containing 50 ppm KNO_3 .

The samples were exposed to UV-Vis radiation generated by artificial light source, but bearing the characteristic of the natural sunlight. The irradiation conditions were similar to those recorded during the 30-days exposure to natural summer light in Phoenix, Arizona, USA. The experiment showed that Flufenacet was prone to indirect photolysis in water, although that process should not be regarded as one of the driving mechanisms in disappearance of Flufenacet from natural waters. The experiments were aimed on the determination of the kinetic parameters of the process – the rates of the indirect photodegradation of Flufenacet in water, therefore no attempt was made to identify and quantify the formed degradation products.

The calculated, net, half-lives for the indirect photodegradation of Flufenacet in water were following:

- for Howe pond water the experimentally derived (continuous irradiation) $\text{DT}_{50} = 160.08$ days, what corresponded to $\text{DT}_{50} = 468.53$ days for exposure to natural summer sunlight at $33^{\circ} 26' \text{ N}$ (in June at Phoenix, Arizona, USA);
- for Stilwell pond water the experimentally derived (continuous irradiation) $\text{DT}_{50} = 281$ days, what corresponded to $\text{DT}_{50} = 822$ days for exposure to natural summer sunlight at $33^{\circ} 26' \text{ N}$ (in June at Phoenix, Arizona, USA);
- for ultrapure water containing 15 ppm of Humic material the experimentally derived (continuous irradiation) $\text{DT}_{50} = 114$ days, what corresponded to $\text{DT}_{50} = 332$ days for exposure to natural summer sunlight at $33^{\circ} 26' \text{ N}$ (in June at Phoenix, Arizona, USA);
- for ultrapure water containing 50 ppm of KNO_3 the experimentally derived (continuous irradiation) $\text{DT}_{50} = 27.5$ days, what corresponded to $\text{DT}_{50} = 158$ days for exposure to natural summer sunlight at $33^{\circ} 26' \text{ N}$ (in June at Phoenix, Arizona, USA).

It shall be however indicated that these values were determined using the results obtained in non-GLP experiments (being an additional part of a GLP study aimed on the examination of the direct aqueous photolysis of Flufenacet). For that reason RMS decided to consider them as only indicative and not to include them into the EU List of Endpoints.

Additionally, in a separate experiment, was examined the indirect aqueous photolysis of FOE Thiadone – the major soil and aquatic degradation product of Flufenacet. The test medium was sterilised natural (riverine) water. The samples were exposed to UV-Vis radiation generated by artificial light source, but bearing the characteristic of the natural sunlight. The irradiation conditions were similar to those recorded during the 30-days exposure to natural summer light in Phoenix, Arizona, USA. The experiment showed that FOE Thiadone was prone to indirect photolysis in water, although that process should not be regarded as one of the driving mechanisms in disappearance of Flufenacet from natural waters. The experiment was performed with the test compound radiolabelled at C2 position in thiadiazole ring, what resulted in identification only CO and CO₂ as degradation products. Therefore it remains unknown what are the degradation products associated with the second carbon atom within the thiadiazole ring – C5. However, it may be assumed that one of such products could be TFA. The calculated, net, rate of indirect photodegradation of FOE Thiadone in water was $k = 0.1194 \text{ [days}^{-1}\text{]}$, corresponding to $DT_{50} = 5.8 \text{ days}$ in samples continuously irradiated with artificial sunlight. When recalculated to the natural conditions that value corresponded to:

- $DT_{50} = 15.8 \text{ days}$ determined for summer sunlight conditions (June) in Phoenix, Arizona, USA (33° 26' N);
- $DT_{50} = 24.4 \text{ days}$ determined for summer sunlight conditions (June) in Athens, Greece, EU (38° 03' N);
- $DT_{50} = 30.5 \text{ days}$ determined for summer sunlight conditions (July) in London, UK, EU (51° 30' N).

These results were reported in the EU List of EndPoints for Flufenacet.

The assessment of biologically-mediated transformation of Flufenacet in the aquatic environment covered the following issues:

- examination of the ready biodegradability;
- examination of the aerobic mineralisation in surface water;
- examination of the fate and behaviour of Flufenacet in aerobic water/sediment systems;
- examination of the fate and behaviour of Flufenacet in irradiated aerobic water/sediment systems;
- examination of the degradation of Flufenacet in saturated zone (anaerobic water/sediment system).

The Applicant has not submitted any study report presenting the results of the examination of **ready biodegradability of Flufenacet**. Instead the following justification for non-submission was provided:

“Flufenacet was stated to be not ready biodegradable. This was accepted by the European Commission (7469/VI/98-Final -3rd July 2003). Therefore no additional study was performed for the flufenacet renewal of approval.” The justification for non-provision of the adequate study may be considered acceptable. RMS examining the submitted documentation stated that the Applicant submitted a study examining the degradation of Flufenacet in natural water. Also are available two studies examining the fate and behaviour of Flufenacet in aerobic water/sediment systems. These studies provided information on the mineralisation of Flufenacet in aquatic environment. Their results confirm that Flufenacet shall be classified as not ready biodegradable, hence the conclusion drawn during the previous evaluation of Flufenacet for its authorisation in the EU remains valid.

The **aerobic mineralisation of Flufenacet in surface water** was examined in pelagic (pond) freshwater collected from the pond representative for the agricultural area of the use of Flufenacet. The test water had the following characteristic:

- type of water sample: pelagic water (no associated sediment);
- pH: 7.5;
- total alkalinity: 230 mg CaCO₃/L;
- total hardness: 329 mg CaCO₃/L;
- specific conductivity: 500 µmhos/cm;
- [O₂]: 9.6 mg/L;
- Suspended solids: 8.5 mg/L;
- Microbial activity, expressed in number of the colony forming units (CFU): 5.9 E3 CFU/mL.

The examination of the degradation of Flufenacet in water was performed in irradiated test systems, under light regime similar to natural sunlight conditions. The mean temperature of incubation was in range 23.1 – 24.4°C (mean estimated by the RMS is 23.75°C), therefore slightly deviating from the assumed $T = 25 \pm 1^\circ\text{C}$.

The experiment was performed with Flufenacet radiolabelled in only one position – in fluorophenyl ring, therefore the proposed transformation scheme cannot be considered complete. In case of the biologically viable samples three degradation products were identified and quantified:

- FOE Alcohol, recorded for the first time on DAT 60, peaking at 4.4% of the applied amount of the parent compound on DAT 368 (end of the study) and that amount was still seemingly increasing;
- FOE Oxalate, recorded for the first time on DAT 60, peaking at 24.0% of the applied amount of the parent compound on DAT 368 (end of the study) and that amount was still increasing;
- FOE Sulfonic acid, recorded for the first time on DAT 278, peaking at 8.6% of the applied amount of the parent compound on DAT 368 (end of the study) and that amount was still increasing;

In sterilised samples only one degradation product was identified – FOE Alcohol, observed for the first time on DAT 278 and formed in amount up to 6.8% of the applied amount of the parent compound (value recorded at the end of the study – on DAT 368).

The proposed, partial, transformation scheme for Flufenacet in natural, microbiologically viable water, resulting from that examination, is presented below on figure 2.8.2.-1.

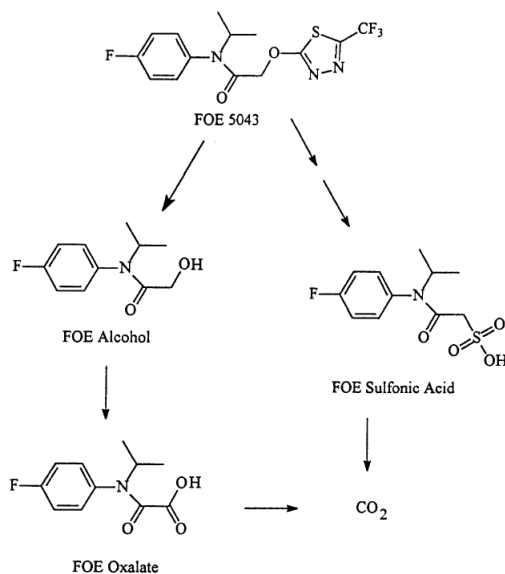


Figure 2.8.2.-1: The proposed, partial transformation pathway of Flufenacet in natural, microbiologically viable water (copied from the study report).

During that experiment, lasting for 368 days, it was stated that Flufenacet radiolabelled in fluorophenyl moiety underwent very limited mineralisation – up to 3.0% of the applied dose was fully mineralised in the biologically viable samples. That indicates that Flufenacet cannot be considered ready biodegradable. In sterilised samples the level of mineralisation was up to 0.8% at the end of incubation period – DAT 368.

It shall be pointed out that the so determined transformation pathway of Flufenacet was only partial, as it fully covered only one moiety within the molecule – that comprising fluorophenyl ring and attached to it n-alkyl chain. At the same time however it shall be indicated that the main functional group within that moiety – fluorophenyl ring, displayed high persistence, what enabled to estimate with quite good accuracy not only persistence of Flufenacet in natural, microbiologically viable water, but also overall level of mineralisation of the molecule.

The process of degradation of Flufenacet in pelagic water was slow, with $DT_{50} = 473$ days and $DT_{90} = 1570$ days in non sterilised water, and it followed the SFO kinetic model. When recalculated to the standard temperature – $T = 20^{\circ}\text{C}$ (using Arrhenius activation energy $E_a = 65.4$ kJ/mol) these values were: $DT_{50} = 664$ days and $DT_{90} = 2204.1$ days.

In sterilised water the rate of degradation, also following the SFO kinetics, was much slower, with $DT_{50} = 2230$ days and $DT_{90} = 7410$ days. When recalculated to the standard temperature – $T = 20^{\circ}\text{C}$ (using Arrhenius activation energy $E_a = 65.4$ kJ/mol) these values were: $DT_{50} = 3130.7$ days and $DT_{90} = 10402.9$ days.

The kinetic examination of the results for any of the identified and quantified degradation products was not possible due to the fact that all they were still forming at the study end.

These results demonstrated that the process of the degradation of Flufenacet in natural pelagic water was predominantly biologically mediated and that the abiotic degradation processes – hydrolysis and aqueous photolysis (direct and indirect) played only minor role, if any.

The transformation pattern of Flufenacet in aerobic water/sediment systems was examined in two separate studies, using Flufenacet radiolabelled at two different positions – uniformly in fluorophenyl ring as [Phenyl- $U-^{14}\text{C}$]Flufenacet – one of the studies ([Kelley et al.; 1995]), and in C2 position of Thiadiazole moiety as [Thiadiazole $-2-^{14}\text{C}$]Flufenacet – second study ([Halarankar and Irwin; 1997]). In each study two water/sediment

systems were used, bearing codenames (common for both studies) NESA and BRP. It shall be indicated however that although sampled on the same locations the test systems did not bear the same characteristics, therefore shall be considered as individual test systems and not the replicates. RMS examining the data set noticed that the examination of the transformation of the thiadiazole moiety of Flufenacet was performed for only C2 radiolabelling position, while C5 radiolabelling position was not covered. That resulted in the lack of data concerning the potential formation of TFA and, possibly (if the degradation pattern was similar to that observed in aerobic soil) FOE TFESA. RMS considers this to be a potential data gap with regard to the full examination of the transformation of Flufenacet in the water/sediment systems.

In the study with [Phenyl-U-¹⁴C]Flufenacet two water/sediment systems were used:

- NESA test system (NESA), containing silty clay loam sediment, having pH = 7.9, OC content of 0.7% and CEC of 33.5 meq/100 g, and associated water, having pH = 7.5, dissolved O₂ content of 9.2 ppm and the content of total dissolved solids of 82 ppm;
- BRP test system (BRP), containing silty clay loam sediment, having pH = 7.8, OC content of 1.4% and CEC of 25.6 meq/100 g, and associated water, having pH = 7.3, dissolved O₂ content of 8.5 ppm and the content of total dissolved solids of 120 ppm.

The experiment lasted for 156 days and the samples were incubated in the darkness at constant temperature T = 20°C.

In the study with [Thiadiazole-2-¹⁴C]Flufenacet two water/sediment systems were used:

- NESA test system (NESA 1), containing silty clay sediment, having pH = 7.8, OC content of 0.38% and CEC of 22.0 meq/100 g, and associated water, having pH = 7.2, dissolved O₂ content of 9.2 ppm and the OC content of 331 ppm;
- BRP test system (BRP 1), containing silty clay loam sediment, having pH = 7.8, OC content of 1.54% and CEC of 13.02 meq/100 g, and associated water, having pH = 6.9, dissolved O₂ content of 10.0 ppm and the OC content of 415 ppm.

The experiment lasted for 156 days and the samples were incubated in the darkness at constant temperature T = 20°C.

The key results of both studies with regard to the distribution of radioactivity in the test systems are presented below in the table 2.8.2.-1. The detailed results of the profiling of radioactivity in the test water/sediment systems are presented in the table 2.8.2.-2.

Table 2.8.2.-1: Distribution of the Applied Radioactivity (AR) in the test water/sediment systems.

Water/ Sediment system and test compound	Characteristic of the system:			AR distribution in the system [%]:				Identified metabolites ¹⁾
				In water phase max/min	Max. in sediment - extractable	NER	Minerali- sation level (¹⁴ CO ₂)	
NESA; [Phenyl-U- ¹⁴ C] Flufenacet	Sediment's texture class - USDA		Slity clay loam	total: max. 97.1%, DAT 0; min. 38.1%, DAT 157 Flufenacet: max. 94.9%, DAT 0; Min. 15.8% DAT 157	total: max. 23.5%, DAT 120; min. 3.5%, DAT 0 Flufenacet: max. 22.9%, DAT 30; min. 3.5% DAT 0	28.5%; DAT 157	3.4%; DAT 157	FOE Oxalate – max. 4.6%; FOE Alcohol – max. 0.7%; FOE Sulfonic acid – max. 1.7%; FOE Methyl- sulfide – max. 11.4%; FOE Methyl- sulfone – max. 6.4%; FOE Methyl- sulfoxide – max. 3.2%; FOE TGS – max. 2.0%
	pH	Water phase	7.5					
		Sediment	7.9					
	OC content	Sediment [%]	0.7					
	Incubation temperature [°C]		20					
BRP; [Phenyl-U- ¹⁴ C] Flufenacet	Sediment's texture class - USDA		Slity clay loam	total: max. 95.5%, DAT 0; min. 21.9%, DAT 157 Flufenacet: max. 95.0%, DAT 0; min. 7.53% DAT 157	total: max. 35.0%, DAT 30; min. 0.5%, DAT 0 Flufenacet: max. 34.2%, DAT 30; min. 0.5% DAT 0	46.4%; DAT 157	1.5%; DAT 157	FOE Oxalate – max. 5.4%; FOE Alcohol – max. 1.3%; FOE Sulfonic acid – max. 3.2%; FOE Methyl- sulfide – max. 4.5%; FOE Methyl- sulfone – max. 7.2%; FOE Methyl- sulfoxide – max. 2.2%; FOE TGS – max. 1.9%
	pH	Water phase	7.3					
		Sediment	7.8					
	OC content	Sediment [%]	1.4					
	Incubation temperature [°C]		20					
NESA 1; [Thiadiazole-2- ¹⁴ C]Flufenacet	Sediment's texture class - USDA		Slity clay	total: max. 88.0%, DAT 28; min. 68.0%, DAT 156 Flufenacet: max. 83.99%, DAT 0; min. 3.1% DAT 55	total: max. 12.8%, DAT 7; min. 2.7%, DAT 100 Flufenacet: max. 12.4%, DAT 7; min. 0.6% DAT 100	3.3%; DAT 55	15.3%; DAT 156	FOE Thiadone – max. 84.3%
	pH	Water phase	7.2					
		Sediment	7.8					
	OC content	Sediment [%]	0.38					
	Incubation temperature [°C]		20					
BRP 1; [Thiadiazole-2- ¹⁴ C]Flufenacet	Sediment's texture class - USDA		Slity clay loam	total: max. 84.5%, DAT 0; min. 0.9%, DAT 156 Flufenacet: max. 83.2%, DAT 0; min. 0.9% DAT 156	total: max. 29.9%, DAT 14; min. 4.4%, DAT 156 Flufenacet: max. 26.1%, DAT 14; min. 2.3% DAT 156	9.6%; DAT 100	15.0%; DAT 156	FOE Thiadone – max 63.8%.
	pH	Water phase	6.9					
		Sediment	7.8					
	OC content	Sediment [%]	1.54					
	Incubation temperature [°C]		20					

Footnotes to the table:

1) FOE TGS = FOE Thioglycolate sulfoxide;

Table 2.8.2.-2: The results of the profiling of radioactivity in the test water/sediment systems.

Water/ Sediment system and test compound	Compound	Concentration [% AR] in:								
		Whole system			Water phase			Sediment phase:		
		Begin- ning of the study ¹⁾	End of the study ²⁾	Max. amount (DAT)	Begin- ning of the study ¹⁾	End of the study ²⁾	Max. amount (DAT)	Begin- ning of the study ¹⁾	End of the study ²⁾	Max. amount (DAT)
NESA; [Phenyl- U- ¹⁴ C] Flufenacet	Flufenacet	98.4	27.7	98.4; (0)	94.9	15.8	94.9; (0)	3.5	11.9	22.9; (30)
	FOE Oxalate	0.0	4.6	4.6; (157)	0.0	4.6	4.6; (157)	0.0	0.0	0.2; (100)
	FOE Alcohol	0.0	0.6	0.7; (120)	0.0	0.2	0.2; (157)	0.0	0.4	0.6; (120)
	FOE Sulfonic acid	0.0	1.7	1.7; (157)	0.0	1.7	1.7; (157)	0.0	0.0	0.0
	FOE Methylsulfide	0.0	11.4	11.4; (157)	0.0	8.0	8.0; (157)	0.0	3.5	3.5; (157)
	FOE Methylsulfone	0.0	5.3	6.4; (100)	0.0	4.4	5.0; (100)	0.0	0.9	1.4; (100)
	FOE Methylsulfoxide	0.4	3.2	3.2; (157)	0.4	0.0	0.4; (0)	0.0	3.2	3.2; (157)
	FOE TGS ³⁾	0.0	2.0	2.0; (157)	0.0	2.0	2.0; (157)	0.0	0.0	0.0
BRP; [Phenyl- U- ¹⁴ C] Flufenacet	Flufenacet	95.5	22.3	100.2; (1)	95.0	7.5	95.0; (0)	0.5	14.8	34.2; (30)
	FOE Oxalate	0.0	5.4	5.4; (157)	0.0	4.8	4.8; (157)	0.0	0.6	0.6; (157)
	FOE Alcohol	0.0	1.3	1.3; (157)	0.0	0.0	0.0;	0.0	1.3	1.3; (157)
	FOE Sulfonic acid	0.0	3.2	3.2; (157)	0.5	3.0	3.0; (157)	0.0	0.3	0.3; (156)
	FOE Methylsulfide	0.0	4.5	4.5; (157)	0.0	1.9	2.7; (120)	0.0	2.7	2.7; (157)
	FOE Methylsulfone	0.0	3.8	7.2; (120)	0.0	2.9	6.5; (120)	0.0	0.9	1.0; (100)
	FOE Methylsulfoxide	0.0	1.7	2.2; (120)	0.0	0.5	1.0; (60)	0.0	1.2	2.2; (120)
	FOE TGS ³⁾	0.0	1.4	1.9; (60)	0.0	1.4	2.0; (60)	0.0	0.0	0.0
NESA 1; [Thia- diazole-2- ¹⁴ C] Flu- fenacet	Flufenacet	94.2	0.9	94.2; (0)	83.9	0.0	83.9; (0)	10.4	1.0	12.4; (7)
	FOE Thiadone	0.0	68.7	84.3; (55)	0.0	65.5	81.8; (55)	0.0	3.0	3.0; (156)
BRP 1; [Thia- diazole-2- ¹⁴ C] Flu- fenacet	Flufenacet	96.3	3.3	96.3; (0)	83.2	0.9	83.2; (0)	12.2	2.39	26.1; (14)
	FOE Thiadone	0.2	54.2	63.8; (100)	0.0	52.2	60.0; (100)	0.1	1.9	3.8; (100)

Footnotes to the table:

1) DAT 0 for all experiments;

2) DAT 157 for experiments with [Phenyl-U-¹⁴C] Flufenacet and DAT 156 for experiments with [Thiadiazole-2-¹⁴C] Flufenacet;

3) FOE TGS = FOE Thioglycolate sulfoxide.

The results obtained in the water/sediment systems confirm that Flufenacet cannot be considered readily biodegradable. It was also stated that the transformation pathway of Flufenacet in aerobic water/sediment systems was very similar to that determined in aerobic soil. It is presented below on figure 2.8.2.-2. As already stated that transformation scheme cannot be considered complete due to the fact that the transformation of the thiadiazole moiety was not fully examined. In particular not examined was the formation of TFA from FOE Thiadone, the mechanism indicated in some literature studies (please refer to the point **B.8.2.6. – Impact on water treatment procedures** in the document Vol. 3 B.8.-CA). That would result in the underestimation of the exposure in SW compartment based on the model calculations.

RMS was able to identify one open literature study examining the fate of several halogenoacetic acids, including TFA, in the test systems similar to the design used in water/sediment studies. On that basis it may be concluded that TFA, when formed from FOE Thiadone, will not undergo any substantial transformation in natural SW bodies and it will occur predominantly in water column.

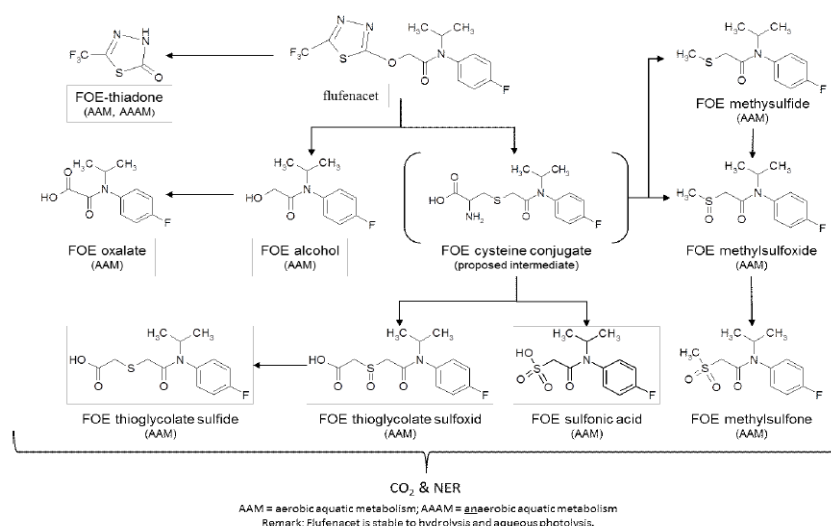


Figure 2.8.2.-2: The transformation pathway of Flufenacet determined in aerobic water/sediment system (copied from the Applicant's report).

The results of the regulatory water/sediment studies were subjected to the kinetic examination in a separate study.

The kinetic analysis was performed for the data obtained for Flufenacet in the whole test systems as well as in water and sediment phases of each test system and was carried out on the Level P-I. Its aim was, in case of the whole-system data to determine the persistence endpoints for Flufenacet and the modelling endpoints. In case of water and sediment phases the kinetic analysis was aimed on the determination of the persistence endpoints. The analysis was performed in line with the recommendations given by FOCUS Kineitics Guidance document [FOCUS; 2006]. The key results of that examination are presented below in the table 2.8.2.-3.

Table 2.8.2.-3: The key results of the kinetic examination at the Level P-I of the data obtained for Flufenacet in water/sediment studies.

Study	Test system	Compartment	Kinetic model	Evaluation of fit		Kinetic parameter(s)		Kinetic endpoints	
				Visual	χ^2 % error	Parameter	Value	DT ₅₀ [days]	DT ₉₀ [days]
[Kelley <i>et al.</i> ; 1995]	NESA	Whole system	SFO	Good	2.185	<i>k</i>	0.00767	90.34	300.10
		Water	SFO	Good	4.936	<i>k</i>	0.0118	58.72	195.10
		Sediment	SFO – top down	Good	2.079	<i>k</i>	0.00493	140.50	466.80
	BRP	Whole system	SFO	Good	3.804	<i>k</i>	0.00779	89.00	295.70
		Water	FOMC	Good	4.041	α	1.339	31.23	211.00
		Sediment	SFO – top down	not reported	7.534	<i>k</i>	0.005754		
[Halarankar and Irwing; 1997]	NESA	Whole system	SFO	Good	9.836	<i>k</i>	0.03525	19.67	65.33
		Water	SFO	Good	6.823	<i>k</i>	0.04083	16.98	56.40
		Sediment	SFO – top down	Good	7.312	<i>k</i>	0.03929	17.64	58.61
	BRP	Whole system	SFO	Good	4.933	<i>k</i>	0.01819	38.11	126.60
		Water	SFO	Good	12.50	<i>k</i>	0.02908	23.84	79.20
		Sediment	SFO – top down	Good	7.738	<i>k</i>	0.01447	47.91	159.10

The calculated geomean values for the kinetic endpoints – DT₅₀ and DT₉₀, determined in the whole system are following **DT₅₀ = 49.54 days, DT₉₀ = 164.59 days**. These values are determined by the RMS. The geomean whole-system DT₅₀ value given in the study report is following: **DT₅₀ = 49.6 days**. The difference between the two values is minimal and can be attributed to the rounding procedure used by the Applicant. Therefore the value proposed by the Applicant may be considered a reliable kinetic endpoint to be used as input parameter in SW model exposure assessment.

For water and sediment phases at the Level P-I the Applicant derived two sets of the kinetic endpoints – those representing persistence and those suitable for modelling. RMS however noticed that Flufenacet displayed quite

high adsorption potential onto soil, with the geometric mean $K_{\text{foc}} = 245.9 \text{ mL/g}$ (range 161.6 – 643.48 mL/g) and rather low solubility in water – 56 mg/L. That may indicate that the compound would display substantial affinity to the sediment phase. The examination of degradation of Flufenacet in natural water, not containing suspended sediment, showed that that process takes long – more than 600 days. Additionally, studies on abiotic degradation of Flufenacet in water showed that only indirect photolysis may substantially contribute to the dissipation of Flufenacet from water, while abiotic hydrolysis is not a relevant degradation mechanism for Flufenacet. All that taken into account, also bearing in mind that the water/sediment studies were performed in absence of light, it may be assumed that the process of dissipation of Flufenacet from water column is, at least, of mixed nature, partly being degradation and to some extent, if not predominantly, migration to the sediment where the proper degradation occurs.

In order to verify that RMS decided to perform additional kinetic examination of the data for Flufenacet using the procedure corresponding to the Level P-II assessment. In that fitting the data for Flufenacet in water phase were treated as those for the parent compound, while the sediment phase was defined as the metabolite A1 compartment.

Unlike at the Level P-I for the sediment phase whole data set was fitted together with that for water phase.

The results obtained for water phase were comparable to those obtained for that compartment by the Applicant at the Level P-I. The kinetic endpoints obtained for the sediment phase were usually shorter than those obtained by the Applicant at the Level P-I, what also reflected differences in the kinetic approach. It shall be indicated that the fits obtained for Flufenacet in the sediment phase were also not always fully reliable, but of sufficient quality to draw the conclusions.

Finally, it was noticed that the values of the kinetic formation fraction – ff , characterising the flux from water to sediment phase were in all cases very close or equal to 1. That may indicate that the dominant mechanism of dissipation from water column is migration to the sediment.

On that basis the RMS stated that the geometric whole-system DT_{50} value when used in the modelling should be considered as representing the degradation of Flufenacet in sediment, not in the water column.

The Applicant also made an attempt to derive the kinetic endpoints for the two identified major degradation products – FOE Methylsulfide and FOE Thiadone. The kinetic analysis aimed on that was performed at the Level M-I using the whole-system data for Flufenacet and related degradation products kinetically fitted together. The results obtained for Flufenacet were very similar to those obtained for the same compound fitted alone at the Level P-I. However, it was not possible to obtain the reliable kinetic endpoints for the degradation products, due to the fact that the concentrations still increased at the end of the experiment – which was the case for FOE Methylsulfide, or the number of data point after maximum was reached was too low to obtain the reliable decline curve, what was observed in case of FOE Thiadone. Additionally, it shall be indicated that due to the poor fitting results the kinetic formation fractions determined for both degradation products shall be considered with care.

Also was submitted the study examining the **fate and behaviour of Flufenacet in anaerobic water/sediment system**. The study was evaluated for its compliance with OECD Guideline 308 – Aerobic and Anaerobic Transformation in Aquatic Sediment Systems. RMS stated that the study deviated from the reference Guideline in the following areas:

- **selection of sediment:** in the study soil was used instead of anaerobic sediment; the water overlying “sediment layer” was not that associated with it, but taken from pond located at the test facility, in the vicinity of the soil sampling area;
- **number of water/sediment systems:** the Guideline recommends at least two types of water/sediment systems to be used in experiment; in this case only one type was used;
- **duration of the experiment:** Guideline recommends that the study should usually not be longer than 100 days; in this case the study lasted for 388 days;
- the anaerobic conditions were not maintained throughout the incubation period and there is no indication in the study report when the change occurred; although in the study report it is declared that anaerobic conditions lasted for ~99 days of incubation there is no experimental evidence confirming that statement;
- although the study lasted for 388 days and the test soil, used as a surrogate for sediment, was known, from other studies, to have problems with maintaining biological viability, in the study report the biological viability of the test system was not reported.

As a result, RMS stated that the study could not be considered as complying with the provisions of the reference Guideline, hence it was found not acceptable for the present assessment. Therefore RMS decided not to summarise it and use its results in the evaluation.

The issue of the determination of **fate and behaviour of Flufenacet in irradiated water/sediment system** was covered by the Applicant by submitting a study report presenting the kinetic evaluation of the results obtained in the indoor mesocosm study. The indoor mesocosm study ([Foekema and Jak.; 1999]) was indicated by the Applicant as the study covering the problem of transformation in irradiated water/sediment systems. RMS evaluated the study and stated that it displayed several deficiencies not enabling to consider it a reliable regulatory study addressing the problem of fate and behaviour in irradiated water/sediment systems. As a result also the study presenting the kinetic analysis of its results cannot be considered valid for regulatory purposes. At the same time it shall be indicated that the kinetic analysis it presents was performed in line with the recommendations of the FOCUS Work Group on the Degradation Kinetics ([FOCUS; 2006]), therefore formally met the acceptability criteria.

It shall be however indicated that the lack of the proper regulatory study examining the problem of the transformation of Flufenacet in the irradiated water/sediment systems does not result in the data gap, as the issue is satisfactorily covered by the other studies submitted for this assessment.

The problem of the **degradation of Flufenacet in the saturated zone** was not examined for the purpose of the present evaluation. Instead the Applicant in the document MCA for the Section 7: Environmental Fate and Behaviour, in order to address the problem, made the following statement: *“The degradation of flufenacet in the saturated zone was not studied since flufenacet is not expected to reach the saturated zone after its use according to good agricultural practices.”*. That statement may be considered justified as long as it concerns GW recharge, however it cannot be excluded that the problem of the degradation of Flufenacet in the saturated zone may be relevant with regard to other issues, in particular bank filtration as a first stage of drinking water abstraction from the surface water (riverine). The problem is discussed in a more detailed way under the point B.8.2.6 of this document, therefore RMS is of the opinion that it does not require more extensive consideration under this point.

It shall be indicated that for the purpose of the former evaluation of Flufenacet for its authorisation in the EU the then-RMS – France, made the following statement in this area (please also refer to the point B.7.4.4 of the Annex B.7 of the Assessment Report): *“No special studies were performed on the degradation of FOE 5043 and its metabolites in the saturated zone. However, this requirement is considered to be covered by the lysimeter studies under the point 7.2.4. Additional information can be derived from the studies on the metabolism in soil (section 7.1.1.) and on hydrolytic degradation (section 7.4.1.).”*.

RMS – Poland, is of the opinion that for the purpose of the current assessment this statement may be considered valid.

Finally, it shall be indicated that the results of the examination of the transformation pathways of Flufenacet in the aquatic systems, in particular water/sediment studies, showed that it should be very similar, if not identical, to that determined in soil. Therefore RMS is of the opinion that there is no need for more extensive examination of that problem and that it may be covered by the data obtained in the other areas of the assessment.

Summarising the data presented above it may be stated that in the aquatic compartment of the environment Flufenacet is expected to be moderately persistent, with half life in water $DT_{50} = 29.4$ days (geomean; range 16.9 – 58.8 days) and that in sediment $DT_{50} = 61.5$ days (geomean; range 17.6 – 140.5 days). The half life in the whole compartment (water and sediment together) is estimated to be $DT_{50} = 49.6$ days (geomean; range 19.6 – 90.3 days). The dissipation from water column was demonstrated to occur mainly by migration to sediment, where the compound will be degraded to several degradation products, identical to those identified in soil.

The degradation of Flufenacet in the aquatic environment was demonstrated to be biologically-mediated process, while the abiotic processes – abiotic hydrolysis and direct photolysis were shown to be not relevant degradation mechanism for Flufenacet in that component of the environment. Of the abiotic degradation processes only indirect aqueous photolysis may be considered relevant, contributing to degradation of Flufenacet in water column (understood as the decomposition of the molecule) to similar extent as the microbial transformation.

Flufenacet was demonstrated to be not readily biodegradable.

The thorough examination of the impact of Flufenacet on water treatment procedures, presented in the document Vol. 3 B.8-CA under the point B.8.2.6, demonstrated that neither Flufenacet nor any of its identified major degradation products are expected to pose any serious threat or have any significant impact on the water treatment processes aimed on the abstraction of drinking water or purification of wastewater.

2.8.3. Summary of fate and behaviour in air

As the first step in the assessment of the fate and behaviour of Flufenacet in the air compartment RMS analysed the basic data on the volatility potential of that active compound and its major degradation products in order to identify the substances of concern for the atmosphere. The basic data on the volatility potential of Flufenacet and its major degradation products are presented below in the table 2.8.3.CA-1. The data were taken from the section B.2 (AS) for Flufenacet, unless it was clearly stated that they were derived from other sources.

Table 2.8.3.-1: The key physico-chemical properties of Flufenacet and its major degradation products relevant for the determination of the fate and behaviour in the atmosphere.

Parameter	Compound ¹⁾							
	FOE 5043	FOE Oxalate	FOE S. A.	FOE Methylsulfone	FOE Methylsulfide	FOE Thiadone	FOE TFESA	TFA ²⁾
Molecular weight [g/mol]	363.4	225.2	275.3	257.3	241.0	170.1	164.1	114.02
Vapour pressure V_p [Pa] at $T = 20^\circ\text{C}$	9 E-5 ³⁾	4.5 E-7	1.35 E-7 ⁶⁾	8.6 E-4	8.06 E-3 ¹⁰⁾	2.05	<1.0 E-8	<1.0 E-6
Solubility in water, S_{aq} [mg/L] at $T = 20^\circ\text{C}$	pH 5	56 ⁴⁾	> 1.2 E5	5.5 E4 ⁷⁾	4.1 E3 ⁹⁾	2.0 E3 ¹¹⁾	95.5 E3 ¹³⁾	>1.6 E5
	pH 7	56	> 1.2 E5	5.5 E4 ⁷⁾	4.1 E3 ⁹⁾	2.0 E3 ¹¹⁾	> 1.0 E5	>1.6 E5
	pH 9	53	>1.2 E5	5.5 E4 ⁷⁾	4.1 E3 ⁹⁾	2.0 E3 ¹¹⁾	> 1.0 E5	>1.6 E5
Henry's law constant, H , [Pa·m ³ /mol] at $T = 20^\circ\text{C}$	pH 5	1.2 E-3 ⁵⁾	<8.4 E-10	n. a. ⁸⁾	n. a. ⁸⁾	1.72 E-2 ¹²⁾	0.012 ¹⁴⁾	<1.2 E-11
	pH 7	1.3 E-3 ⁵⁾	<6.8 E-10	n. a. ⁸⁾	5.7 E-5	1.72 E-2 ¹²⁾	n. a. ⁸⁾	<1.2 E-11
	pH 9	1.1 E-3 ⁵⁾	<6.8 E-10	n. a. ⁸⁾	n. a. ⁸⁾	1.72 E-2 ¹²⁾	n. a. ⁸⁾	<1.2 E-11

Footnotes to the table:

- The following code-names were used to denominate the substances: FOE 5043 for Flufenacet, FOE S. A. for FOE Sulfonic acid, FOE TFESA for FOE Trifluoroethanesulfonic acid and TFA for Trifluoroacetic acid;
- In aqueous solution TFA, being a very strong acid with $pK_a = 1.6$, is fully dissociated, therefore the values are provided for trifluoroacetate and the test substance used to determine them was TFA-Na salt;**
- In section B.2 it was stated that Flufenacet isomerised by evaporation forming a mixture containing 10% of Flufenacet and 90% of its *N*-isomer; as a result, the value is that characteristic for *N*-isomer of Flufenacet;
- The value determined at pH = 4;
- The values determined for *N*-isomer of Flufenacet, using the solubility values determined for that compound;
- The measured value not provided; instead the Applicant presented the value determined theoretically, using QSAR method, and for $T = 25^\circ\text{C}$; RMS subsequently converted that value to presented here value for $T = 20^\circ\text{C}$ using appropriate Van't Hoff equation (presented in the "Manual for FOCUS TOXSWA version 2.2.1", Alterra Report No. 586, Wageningen, 2006);
- The value determined in unbuffered solution and representative for the whole environmentally relevant pH range, since it was experimentally demonstrated that water solubility of FOE S. A. is not pH-dependent;
- Value not available;
- The value determined in pH = 7 buffer solution, but considered representative for the whole environmentally relevant pH range, since it was experimentally demonstrated that water solubility of FOE Methylsulfone is not pH-dependent;
- The theoretical value determined by the RMS using QSAR methods – it was calculated using Modified Grain method for $T = 25^\circ\text{C}$; for more details please refer to the data presented in the table B.8.8-a.3_CA-4 under the point B.8.8.-A.3 – Appendix 3, of this Renewal Assessment Report;
- The value determined in pH = 6.1 buffer solution, but considered representative for the whole environmentally relevant pH range, since it was experimentally demonstrated that water solubility of FOE Methylsulfide is not pH-dependent;
- The theoretical value determined by the RMS using QSAR methods – it was calculated using Modified Grain method for $T = 25^\circ\text{C}$; for more details please refer to the data presented in the table B.8.8-a.3_CA-4 under the point B.8.8.-A.3 – Appendix 3, of this Renewal Assessment Report;
- The value determined at pH = 5.77;
- The e value determined at pH < 5.

The further analysis was carried out using the vapour pressure classification presented in the Guidance document "Pesticides in Air: Considerations for Exposure Assessment" – Report of the FOCUS Working Group on Pesticides in Air (FOCUS; 2008).

According to that Guidance document the trigger values indicating the need to establish whether the substance has the potential to reach the air are:

- $V_p \geq 10^{-4}$ Pa at $T = 20^\circ\text{C}$ for volatilisation from soil, and
- $V_p \geq 10^{-5}$ Pa at $T = 20^\circ\text{C}$ for volatilisation from plants.

Using these criteria RMS identified the following compounds as those of potential concern:

- Flufenacet, being medium volatile according to the classification presented above and having a potential to reach air via volatilisation from plants;
- FOE Methylsulfone, being medium volatile according to the classification presented above and having a potential to reach air via volatilisation from soil and plants;
- FOE Methylsulfide, being medium volatile according to the classification presented above and having a potential to reach air via volatilisation from soil and plants; it shall be indicated however that for that compound the assessment is based on theoretically determined values;
- FOE Thiadone, being volatile according to the classification presented above and having a potential to reach air via volatilisation from soil and plants.

RMS also decided to take into consideration TFA. Although the experimental values presented in the table 2.8.3.-1 do not indicate that it is a compound of concern, they were derived for trifluoroacetate. The examination of the available open-sources data showed that the non-dissociated acid displayed high volatility potential resulting from its high vapour pressure – 11 kPa at $T = 20^\circ\text{C}$ (source: Pubchem – open chemistry database, url: <https://pubchem.ncbi.nlm.nih.gov>). For that reason RMS decided to evaluate its fate and behaviour in the atmosphere as well. **At the same time it shall be indicated that the $pK_a = 1.6$ value determined for TFA in**

aqueous solutions clearly indicate that when formed from Flufenacet either in soil or surface water compartments the compound, being entirely dissociated would display very limited volatility and hence risk to atmosphere, unless the environment becomes very acidic.

The examination of the fate and behaviour of Flufenacet in air showed that that compound displayed some tendency for migration to the atmosphere, with the determined average level of volatilisation from soil surface equal to 16.5% of the applied dose (with range of 7.9 – 29.2%), but was not expected to be persistent in that compartment – the determined for the process of the photooxidative degradation initiated by the •OH radicals **DT₅₀ = 6.8 hours**. That value, being significantly shorter than the DT₅₀ = 2 days, indicates that Flufenacet, even in case of reaching the atmosphere in significant amounts, would not pose a serious threat to that compartment. It would also not be prone to medium- or long-range transport in that compartment and therefore it would not pose a threat of secondary pollution resulting from the wet and dry deposition from the atmosphere.

That statement may be confirmed by the results of the monitoring study carried out in the USA by the employees of USGS and aimed on the examination of the content of Flufenacet in the rainfall. The monitoring was performed in years 2003 – 2004 on four representative locations, in the areas of intensive agricultural activity, in California, Indiana, Nebraska and Maryland. Flufenacet was found only in two of 52 samples examined, and only at one location – in Nebraska, where the main crops were maize and soybean, on which Flufenacet was routinely used. The maximum concentration detected in rain samples was 0.05 µg/L and it occurred on the 4th May 2004, presumably shortly after Flufenacet was applied. The median concentration reported in the study was <0.02 µg/L and the wet deposition, estimated on the basis of the obtained results, was 3.09 µg/m² with maximum occurring on the 4th May 2004.

In none of the other examined locations Flufenacet was reported to be found in rainwater samples. It has to be indicated, that other herbicides being the target compounds in that study were detected more frequently and in much higher amounts, although their estimated use pattern was comparable to that of Flufenacet.

These results may indicate that Flufenacet, even in case of reaching the air compartment will not be subjected to the medium- and long distance transport, but rather deposited locally, at the site of use. The aeric mean deposition determined in that study (for not precisely defined application rates) was not significant, by comparison to e. g. that determined in the SW modelling exposure assessment at Step 3 for the use of that compound in Autumn on Winter cereals at application rate 240 g/ha: 0.05 – 0.46 mg/m².

Of seven major soil, aquatic or soil and aquatic degradation products of Flufenacet, four were identified as posing potential threat to the atmosphere, being volatile or semivolatile – FOE Methylsulfone, FOE Methylsulfide, FOE Thiadone and Trifluoroacetic acid – TFA. For them was performed the additional estimation of their persistence in air, by determining the DT₅₀ values for the process of the photooxidative degradation initiated by the •OH radicals. The calculated for FOE Methylsulfide and FOE Methylsulfone DT₅₀ values for that process were **0.517 days** and **0.563 days** respectively, what clearly indicates that even in case of reaching the atmosphere in significant amounts, these compounds would not pose a serious threat to that compartment. They would also not be prone to medium- or long-range transport in that compartment and therefore it would not pose a threat of secondary pollution resulting from the wet and dry deposition from the atmosphere.

The model assessment of the persistence of FOE Thiadone in air showed that the compound would be very persistent in air. For the structural formula exactly matching that of FOE Thiadone the results indicated that no reaction with •OH radicals occurred. For the structure that was slightly altered by comparison to that of FOE Thiadone – the double bond was repositioned from C=N to N=N, that reaction was demonstrated to be very slow with the half-life, calculated assuming 12-hours lasting day and the concentration of the •OH radicals of 1.5 E6 [radicals/cm³], **DT₅₀ = 29.594 days**. That value is significantly longer than the DT₅₀ = 2 days. The results therefore indicate that FOE Thiadone in case of reaching the atmosphere in significant amounts, would pose a serious threat to that compartment. It would be prone to medium- or long-range transport in that compartment and therefore it may pose a threat of secondary pollution resulting from the wet and dry deposition from the atmosphere.

For that compound RMS was not able to identify any literature data dealing with the fate and behaviour of that compound in air. It shall however be indicated that FOE Thiadone was observed in soil in amounts not surpassing 10%. It was also demonstrated to be quickly degraded in that compartment. Additionally the results of the studies aimed on the examination of soil photolysis of FOE Thiadone showed that the compound would be mineralised to much greater extent that it would evaporate from soil surface (in irradiated samples within 14 days of the experiment only ~5% of the radioactivity applied was recovered as VOC fraction, in the dark control samples that amount was only ~2.5%). Also in the experiments with radiolabelled FOE Thiadone aimed on the determination of its persistence in aerobic soil under laboratory conditions the levels of radioactivity recovered as VOC fraction was low: 2 – 4%AR at the study's end (10 – 14 days after the experiment was initiated) with no more than 5% of the initial amount of FOE Thiadone remaining in soil. **That may indicate, assuming that the VOC fraction is entirely FOE Thiadone, that despite its high vapour pressure the compound would not migrate to atmosphere from soil in amounts that may pose any threat to that compartment. Also not relevant may be considered the**

volatilisation from plants as the route of exposure, because that compound would probably not be formed as a transformation product of Flufenacet on plant surfaces.

The only potential route of exposure of air is volatilisation from SW bodies, where FOE Thiadone was demonstrated to be formed as a major degradation product, but at present there is no clear methodology to assess that issue.

The model assessment of the persistence of TFA in air showed that the compound would be persistent in air, with the half-life, calculated assuming 12-hours lasting day and the concentration of the $\bullet\text{OH}$ radicals of $1.5 \text{ E6} [\text{radicals/cm}^3]$, $\text{DT}_{50} = 20.569 \text{ days}$. That value is significantly longer than the $\text{DT}_{50} = 2 \text{ days}$, what indicates that TFA in case of reaching the atmosphere in significant amounts, would pose a serious threat to that compartment. It may also be prone to medium- or long-range transport in that compartment and therefore it may pose a threat of secondary pollution resulting from the wet and dry deposition from the atmosphere.

The Applicant did not submit any relevant data enabling the elucidation of the fate and behaviour of TFA in air compartment. However in the documentation submitted for the evaluation it was stated several times that the TFA formed as a degradation product of Flufenacet will be present as Trifluoroacetate – the dissociated form displaying very low volatility potential and as such not posing any substantial risk to the atmosphere.

The literature search performed by the RMS resulted in identification of several scientific papers addressing the issue of behaviour of TFA in the atmosphere, four of which specifically with persistence, transformation mechanisms and mechanisms of elimination of TFA from air. On their basis it was possible to state that TFA clearly demonstrated high persistence in the atmosphere with the DT_{50} values for the process of photooxidative degradation initiated by the $\bullet\text{OH}$ radicals as high as 230 days. The only relevant mechanism of elimination of TFA from that compartment would therefore be, predominantly, wet deposition – with rain or fog with estimated $\text{DT}_{50} = \sim 9 \text{ days}$, and, to some extent also by dry deposition, with estimated $\text{DT}_{50} = 10\text{-}30 \text{ days}$. The identified products of photooxidative degradation of TFA in air initiated by the $\bullet\text{OH}$ radicals are COF_2 and FNO. It was also indicated that the dimerisation of TFA may be the factor limiting the rate of degradation of that compound in air in the process of photooxidative degradation initiated by the $\bullet\text{OH}$ radicals.

The determination of the Henry's law constant for TFA demonstrated that the compound displayed high affinity towards water, therefore atmospheric water, either in form of clouds or as fog, may be an effective sink for that compound. At the same time however it was postulated that the evaporation of TFA from water phase to air cannot be totally excluded.

The examination of the available literature data showed that the presence of the TFA in the atmosphere was not expected to be related to the degradation in that environmental compartment of the active substances of the plant protection products containing in their molecules the CF_3 - functional groups, nor to the possible volatilisation from soil of TFA formed there as a result of degradation of such agrochemicals.

On the basis of the results obtained in the area of the examination of the fate and behaviour of Flufenacet and its major degradation products in air, as well as their transport via air it was stated that the further examination of the local and global effects related to their would be presence in air was not necessary.

2.8.4. Summary of monitoring data concerning fate and behaviour of the active substance, metabolites, degradation and reaction products

The Applicant addressing the problem of the monitoring of Flufenacet in the environment stated that there were numerous monitoring programmes carried out by the competent authorities, into which that compound and its transformation products were included. These data however were not available, so the Applicant was not able to identify and present them. For that reason the presentation of the monitoring data was limited to the available literature data. The Applicant was able to identify three papers presenting the results of the monitoring studies for Flufenacet and its degradation products. One of them was aimed on the determination of the several active substances of the plant protection products in the watercourse of the small agricultural catchment located in Germany, other two presented the results of the determination of TFA (Trifluoroacetic acid) – the most persistent degradate of Flufenacet, in Oceans which are considered to be the terminal environmental sink of TFA.

RMS performing the repeated literature search was able to identify several publications presenting the results of the monitoring studies in which Flufenacet and two its major degradates – FOE Oxalate and FOE Sulfonic acid were the target compounds.

The results may be divided into two groups, according to the geographical location of the monitoring studies. To one of them belong the results obtained in the monitoring studies carried out from 1999 until 2004 in USA, and more specifically in Mid-Western States, the so-called corn-belt states, by USGS (US Geological Service) employees.

The extensive monitoring of groundwater sampled from 55 wells in Indiana in 2000 showed that neither Flufenacet, nor its degradates FOE Oxalate and FOE Sulfonic acid were detected in analysed samples. The limit of detection in that study was set to $0.05 \mu\text{g/L}$. Also neither Flufenacet nor its degradates – FOE Oxalate and FOE

Sulfonic acid were found in groundwater analysed in a similar monitoring project carried out in Iowa in 2001, in which samples from 86 municipal wells were analysed for the content of several active substances of the plant protection products and their degradates.

The analysis of the concentrations of Flufenacet and its degradation products – FOE Oxalate and FOE Sulfonic acid in the Mississippi River basin showed that these compounds, if detected, were present sporadically and in low concentrations. In the study carried out in the year 2000 and aimed on the determination of the levels of selected chloroacetanilide plant protection products and their degradates in surface water bodies of the Mississippi River catchment, Flufenacet was detected in 3% of 39 analysed samples in maximum amount of 0.12 µg/L, while FOE Oxalate and FOE Sulfonic acid were not detected at all in 38 samples analysed for their presence. Samples were taken at key junctures of the Mississippi River Basin. In another monitoring study on Mississippi River catchment with one sampling point set at Baton Rouge, LA, and carried out at the same period (1999 – 2000), neither Flufenacet nor FOE Oxalate were detected in any analysed samples, while FOE Sulfonic acid was detected in amounts > 0.05 µg/L in two of them (6% of analysed samples).

Finally, in 2002 within the big monitoring programme, the concentrations of Flufenacet, FOE Oxalate and FOE Sulfonic acid were monitored, alongside other herbicides, their degradates and pharmaceuticals, in 51 streams selected as representative for nine Mid-Western states of the USA. Samples were collected at spring during pre-emergence period (May – June), in summer during post-emergence period (June – July) and during the harvest period in autumn (September – November). Flufenacet was detected in 11 of 51 pre-emergence samples with the max. amount 0.93 µg/L, 9 of 52 post-emergence samples with max. amount 1.6 µg/L and only one of 51 harvest-period samples. It was found more frequently in samples taken from Nebraskan streams, while not detected at all during the whole experimental period in those from Indiana, Minnesota and Wisconsin.

The frequency of detection of FOE Oxalate and FOE Sulfonic acid was much lower – the compounds were found during each sampling period in max. 4 samples of analysed 51/52. Their maximum concentrations were up to 0.09 µg/L in pre-emergence samples, up to 0.18 µg/L in post-emergence samples and up to 0.13 µg/L in harvest samples.

Finally in the study in which the concentrations of Flufenacet were monitored in precipitation water in four agricultural catchments across the USA that compound was detected only in two samples taken in Nebraska in May.

For all those monitoring studies the method detection limit MDL, corresponding to LOQ, was 0.05 µg/L.

In case of Europe the quantitative results of the monitoring of the residues of Flufenacet in water samples were available for two countries – Germany and Switzerland. Additionally the qualitative results were available for the Netherlands.

The results of the monitoring study performed for the small rural catchment of Lamspringe in Lower Saxony, Germany, in years 1998 – 2000 showed that Flufenacet, applied to the fields in the research area in 1999 and 2000 was detected in stream water samples collected only in the year 2000. It was detected in three samples, in maximum amount 0.07 µg/L, slightly above the LOQ = 0.05 µg/L set for the analytical method used in the study.

In another study, in order to validate the developed novel analytical method for determination of polar degradates of organic micropollutants in water samples, including FOE Oxalate and FOE Sulfonic acid, 200 samples of natural water were analysed, of which six of waste water, fourteen of surface water, another fourteen of deep well water, 156 of groundwater and seventeen of drinking water. All samples were collected in Rhine-and Rhur region of the North Rhine-Westphalia, Germany. In case of all analysed samples of waste water, surface water, deep well water, and groundwater the concentrations of both FOE Oxalate and FOE Sulfonic acid were well below 0.05 µg/L, usually in range of 0.00 – 0.25 µg/L. Only in case of drinking water samples the concentrations of FOE Sulfonic acid were above the level of 0.05 µg/L, but still below the threshold value of 0.1 µg/L.

In case of Switzerland the results of monitoring were available for the catchment of the river La Petite Glâne, located in western Switzerland in the canton Vaud, for the Lake Constance – the example of the interboundary landlocked catchment collecting surface water from three countries, and five small- to medium in size river catchments located across Switzerland, displaying at least partly agricultural character. All results are quite recent, being collected in the first and second decades of the 21st century, between the years 2008 and 2012.

The monitoring of the surface water samples collected in the catchment of the river La Petite Glâne, carried out from May to October of the 2008 with aim of determination of selected active substances of the plant protection products and their degradates in the water collected after rainfall events from the stream passing through the catchment, showed that the highest concentrations of Flufenacet in analysed water were recorded at spring, during application period of that compound. The median concentration was 0.071 µg/L with range 0.026 – 350 µg/L. Much lower were concentrations recorded after the rainfall events in summer and at autumn – the median values were 0.008 µg/L and 0.004 µg/L respectively. In case of the two monitored degradation products – FOE Oxalate and FOE Sulfonic acid, their levels in stream water samples collected after the rainfall events were generally much lower, in case of FOE Oxalate not surpassing 0.003 µg/L and for FOE Sulfonic acid 0.008 µg/L. It was noticed that while in case of FOE Oxalate the highest concentrations were recorded for the application period of Flufenacet – at spring, in case of FOE Sulfonic acid the highest levels were recorded in autumn, what may reflect the temporal formation patterns and persistence of these compounds in soil..

The levels of those three compounds in the base-flow samples – collected in periods between the occurrence of the rainfall events, were very low, not surpassing 0.01 µg/L. Additionally the samples of groundwater collected in and around the catchment were analysed for the content of the compounds of concern. It was stated that in none of the analysed samples Flufenacet, FOE Oxalate or FOE Sulfonic acid were detected. The detection (LOD) and quantification (LOQ) limits for those compounds were set, for the purpose of that study, as follows:

- for Flufenacet LOD = 0.3 ng/L and LOQ = 1.0 ng/L;
- for FOE Oxalate LOD = 0.3 ng/L and LOQ = 1.0 ng/L;
- for FOE Sulfonic acid LOD = 0.3 ng/L and LOQ = 1.0 ng/L.

In another study, aimed on the determination of the levels of several organic micropollutants in the surface water collected from five river catchments located across Switzerland – Fürtbach river, Limpach river, Mentue river, Salmsacher river and Surb river, the results obtained for Flufenacet, FOE Sulfonic acid and FOE Oxalate were following:

Flufenacet was detected in samples from all five rivers, with average detection frequency of 53% and the maximum concentration of 290 ng/L. In individual rivers those parameters looked as follows:

- in Fürtbach river it was detected in 56% of the analysed samples with maximum concentration of 80 ng/L;
- in Limpach river it was detected in 78% of the analysed samples with maximum concentration of 160 ng/L;
- in Mentue river it was detected in 67% of the analysed samples with maximum concentration of 35 ng/L;
- in Salmsacher Aach river it was detected in 11% of the analysed samples with maximum concentration of 31 ng/L;
- in Surb river it was detected in 56% of the analysed samples with maximum concentration of 290 ng/L.

FOE Sulfonic acid was detected in samples from all five rivers, with average detection frequency of 62% and the maximum concentration of 38 ng/L. In individual rivers those parameters looked as follows:

- in Fürtbach river it was detected in 44% of the analysed samples with maximum concentration of 14 ng/L;
- in Limpach river it was detected in 100% of the analysed samples with maximum concentration of 30 ng/L;
- in Mentue river it was detected in 89% of the analysed samples with maximum concentration of 38 ng/L;
- in Salmsacher Aach river it was detected in 44% of the analysed samples with maximum concentration of 7.9 ng/L;
- in Surb river it was detected in 33% of the analysed samples with maximum concentration of 17 ng/L.

FOE Oxalate was not detected in any of the analysed water samples.

The quantitation limits for these compounds were following: for Flufenacet LOQ = 3 ng/L, for FOE Oxalate LOQ = 7 ng/L and for FOE Sulfonic acid LOQ = 3 ng/L.

The analysis of the concentrations of Flufenacet, FOE Oxalate and FOE Sulfonic acid in water samples from lake Constance was carried out as a preliminary part of the study aimed on the determination of the concentrations of selected micropollutants in that water body and in its tributaries. In none of the analysed samples, collected from four locations on the lake Constance the compounds of concern were detected.

In another study reporting results of the monitoring of Flufenacet in the borderline surface water bodies in the Netherlands it was stated that Flufenacet was detected in the borderland zones, but not hinterland. On that basis, as Flufenacet was not a compound authorised to be used in the Netherlands, but having such authorisation in the neighbouring countries – Belgium and Germany, it was stated that it may be prone to transboundary transport in surface water. However, the estimations provided in that study were rather qualitative than quantitative.

On the basis of the obtained monitoring results derived from the open-source literature data it may be stated that neither Flufenacet nor its two degradates – FOE Oxalate and FOE Sulfonic acid are expected to be present in natural water samples in amounts significantly surpassing the level of 0.1 µg/L – the drinking water limit.

Of the other degradation products of Flufenacet identified as major the monitoring data are available only for Trifluoroacetic acid – TFA, the compound considered to be common organic pollutant of the environment, originating from various sources.

As TFA is considered to be the organic pollutant found primarily in atmosphere as a result of the photooxidative transformation of several halogenated compounds, such as HCFs and HFCFs and is removed from there by means of wet and dry deposition, several studies were carried out with aim of the determination of the concentrations of trifluoroacetate in the atmospheric water – rain- and fog water. The concentrations of TFA determined in rain water are in general lower than those measured in fog water, usually not surpassing 500 ng/L on average. They strongly depend on the character of region, where the samples were collected, being higher in urbanised and industrial

regions. The levels of TFA in fog samples were sometimes of the order of magnitude higher than those in rainwater samples collected at the same sampling sites.

In the open-source literature oceans are indicated as the terminal environmental sink of the TFA with the surface water bodies, such as rivers, being the intermediate collectors. Also landlocked lakes were indicated as a possible sink for TFA.

In the global ocean the level of TFA was estimated to be, on the basis of the available results of the monitoring studies, ~200 ng/L and quite stable. The levels of TFA determined in fresh surface water bodies were similar, but it was indicated that in some landlocked lakes they may be higher. For example the results of the determination of the concentrations of TFA in Canadian lakes carried out in the year 1997 showed that the concentrations of TFA in those SW bodies were in range of <0.5 ng/L – 360 ng/L, being highest in lakes located in the highly urbanised and industrialised areas with high level of antropression.

It shall be indicated that in all available publication presenting the results of the monitoring studies for TFA the man-made sources were indicated as a primary sources of that compound in inland environment. However, it was also indicated that in case of the oceans, and possibly also some inland ecosystems there may be some, still not identified natural sources contributing to the overall concentrations of TFA in the geosphere.

2.8.5. Definition of the residues in the environment requiring further assessment

The Applicant presented the proposal for the residue definition in the document MCA-Section 7 for Flufenacet under the points 7.4.1. – definition of the residue for the risk assessment, and 7.4.2 – definition of the residue for monitoring. RMS, having verified that proposal, proposes the following residue definition, with its justification:

- **Definition of residue for the risk assessment:**

Soil:

Flufenacet, FOE Oxalate, FOE Sulfonic acid, FOE Methylsulfone, FOE Thiadone, FOE 5043-Trifluoroethanesulfonic acid, Trifluoroacetic acid;

Justification: RMS with this confirms the Applicant's proposal. All listed degradation products are major soil degradation products.

Groundwater:

Flufenacet, FOE Oxalate, FOE Sulfonic acid, FOE Methylsulfone, FOE Thiadone, FOE 5043-Trifluoroethanesulfonic acid, Trifluoroacetic acid (same as for soil compartment); additional compounds that may require assessment (on the basis of the results of lysimeter studies) are FOE Alcohol and FOE TGS;

Justification: The proposed residue definition is the same as proposed by the Applicant and contains the degradation products classified as major soil metabolites and displaying high leaching potential (excluding FOE Thiadone). The reason for inclusion of FOE Alcohol and FOE TGS is that in the lysimeter studies despite being minor soil degradates they were detected in leachates in quantifiable amounts. Therefore it cannot be excluded that under unfavourable conditions they would pose a risk to GW compartment.

Surface water:

Flufenacet, FOE Oxalate, FOE Sulfonic acid, FOE Methylsulfide, FOE Methylsulfone, FOE Thiadone, FOE 5043-Trifluoroethanesulfonic acid, Trifluoroacetic acid;

Justification: The proposed residue definition is the same as proposed by the Applicant and contains the degradation products classified as major soil, aquatic or soil and aquatic metabolites. At the same time it shall be indicated that in case of FOE Trifluoroethanesulfonic acid and TFA the assessment in the aquatic environment could not be finalised due to the fact that there was no water/sediment study with Flufenacet radiolabelled in position enabling adequately address the problem.

Sediment:

Flufenacet;

Justification: only Flufenacet was included into that residue definition because of the degradation products listed above in the definition for SW compartment none displayed any significant affinity to the sediment compartment – if detected there they were found in low amounts, not surpassing 5%.

Air:

Flufenacet, FOE Thiadone and Trifluoroacetic acid;

Justification: Flufenacet was included by default, although it shall be indicated that it does not pose a serious threat to the atmosphere; the reason for including FOE Thiadone and TFA is that they are volatile (although in case of TFA it was demonstrated that, being dissociated, that compound when formed from Flufenacet is not expected to migrate to air in any significant amounts) and persistent in air, so they may pose a serious threat to the atmosphere.

- **Definition of the residue for monitoring:**

Soil:

Flufenacet, FOE Sulfonic acid, FOE Methylsulfone, Trifluoroacetic acid;

Justification: all listed compounds, including Flufenacet, displayed some potential (in case of TFA significant) for accumulation in soil (conclusion based on the results of the calculations of PEC_{SOIL} values);

Groundwater:

Flufenacet, FOE Oxalate, FOE Sulfonic acid, FOE Methylsulfone, FOE 5043-Trifluorethanesulfonic acid and Trifluoroacetic acid;

Justification: the parent compound was included by default. In case of the degradation products listed above the reason for their inclusion was that for the proposed EU-representative application pattern in the GW model exposure assessment they were demonstrated to leach to the groundwater recharge in amounts $> 0.1 \mu\text{g/L}$. In many cases the calculated $PEC_{GW} > 0.75 \mu\text{g/L}$ and in case of TFA the calculated $PEC_{GW} > 10 \mu\text{g/L}$. The high leaching potential of FOE Sulfonic acid was confirmed in regulatory lysimeter studies. Finally, it shall be indicated that FOE Oxalate and FOE Sulfonic acid were detected in Groundwater in some monitoring studies, the results of which were presented in the publications summarised under the point B.8.5.

Surface water:

Flufenacet, FOE Oxalate, FOE Sulfonic acid, FOE Methylsulfide, FOE Thiadone and Trifluoroacetic acid

Justification: the parent compound was included by default. In case two degradation products – FOE Methylsulfide and FOE Thiadone, they were included into the definition due the fact that they are major aquatic degradation products (additionally FOE Thiadone was identified as major soil degradation product) with not defined persistence in natural water. The reason for including FOE Oxalate and FOE Sulfonic acid was that they are major soil degradation products and potentially major aquatic degradation products (in the water/sediment studies their formation potential was not fully assessed) with unknown persistence in water and highly mobile. Additionally in some monitoring studies they were detected in SW bodies in quite significant amounts, as was Flufenacet. The reason for including TFA is that it is a very persistent and common pollutant. Additionally the problem of its formation from Flufenacet in SW compartment was not satisfactorily addressed.

Sediment:

Flufenacet;

Justification: the definition comprises the parent compound only, which was included by default, but also because the degradation in the SW bodies will comprise the migration from water phase to sediment (main dissipation process for Flufenacet in water), where it will undergo degradation. None of the degradation products listed for SW compartment were included due to the fact that they were either not detected in sediment or found in that compartment in very low amounts ($< 5\%$ of the initial amount of Flufenacet).

Air:

Flufenacet, FOE Thiadone and Trifluoroacetic acid;

Justification: the parent compound was included by default. In case two degradation products – FOE Thiadone and TFA they were included because of their high volatility and persistence in air, what results in a high level of risk they pose to the atmosphere – the monitoring should exclude Flufenacet as a potential source of FOE Thiadone and, in particular TFA, in the air compartment.

2.8.6. Summary of exposure calculations and product assessment

Below are presented the key results of the exposure assessment for soil, groundwater (GW) surface water (SW) – water and sediment, and air compartments, performed using the methodology and modelling tools recommended by FOCUS.

1) Calculations of PEC_{SOIL} :

The model exposure assessment for the soil compartment, by calculating the PEC_{SOIL} values, was carried out by the RMS. The Applicant submitted the calculations, but they were not accepted, because the input parameters had to be updated. The calculations performed by the RMS are summarized below.

The calculations were carried out in line with the recommendations given in the Guidance document:

- FOCUS (2006): “Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration.” Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference SANCO/10058/2005 version 2.0, 434 pp.;

Also consulted, for the appropriate crop-related parameters – CI factor, was the following Guidance Document:

- FOCUS (2014): “Generic guidance for Tier 1 FOCUS Ground Water Assessments”, version 2.2, May 2014.

The calculations were performed for Flufenacet and its six major soil degradation products – FOE Oxalate, FOE Sulfonic Acid, FOE Methylsulfone, FOE Thiadone, FOE 5043-Trifluoroethanesulfonic acid and Trifluoroacetic acid (TFA), using ESCAPE 1 modelling tool (version updated online). The calculations were performed for the parent compound and the degradation products formed in sequence and/or in parallel. However, due to the limitations of the modelling tool – the calculations can be carried out at once for maximum two degradation products, the four cycles of calculations had to be performed. Additionally, also due to the model limitations, it was not possible to carry out the calculations for the degradation product TFA fully in line with the transformation pattern determined during examination of the route of degradation of Flufenacet in soil. Therefore for that compound the transformation scheme had to be modified. As a separate step, verifying the results of other calculations, were performed calculations for parent alone. The transformation pathways assumed in calculations are presented below on figure 2.8.6.-1. In case of FOE 5043-Trifluoroethanesulfonic acid the abbreviation FOE TFESA was used in the block scheme. In case of Trifluoroacetic acid the abbreviation TFA was used in the block scheme.

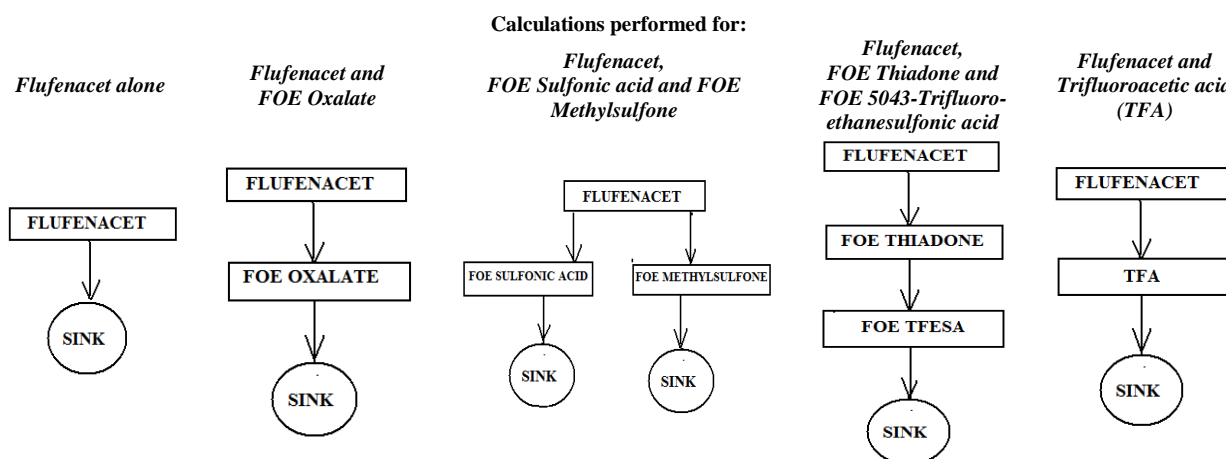


Figure 2.8.6.-1: The block schemes representing the transformation patterns assumed in calculations.

The assumed programme settings and scenario settings used in calculations were following:

- Calculation mode: Residues from different applications are considered separately;
- Application mode: Single annual application pattern (calculation period 1 year);
- soil density: 1.5 g/cm³;
- soil depth for calculation of 1-year PEC_{SOIL} and accumulation PEC_{SOIL} values: 5 cm;
- soil depth for calculation of background concentrations (tillage depth): 20 cm.

The application pattern assumed in calculations is presented below in the table 2.8.6.-1.

Table 2.8.6.-1: The application pattern assumed in calculations of PEC_{SOIL}.

Crop	BBCH growth phase	Number of Applications	Crop interception factor – CI [%] ²	Application rate [g Flufenacet/ha]
Winter cereals	11 – 13	1	0	240
Winter cereals	10 – 13	1	0	160
Winter cereals	0 – 22	1	0	120

The substance-specific input parameters used in calculations are presented below in the table 2.8.6.-2. Due to the fact that the calculations were performed for the parent compound and degradation products forming from it RMS decided to use the highest values of the kinetic formation fractions – *ff*, instead of the observed soil maximum values to avoid the underestimation of the obtained results. That approach is in line with the recommendations of the manual for the modelling tool Escape. In case of TFA, due to the complex transformation scheme resulting in two values of *ff* – from Flufenacet and from FOE Thiadone, RMS decided to use the average values instead of the highest one and calculate one summary value.

Table 2.8.6.-2: The substance-specific input parameters used in calculations.

Parameter	Compound						
	<i>Flufenacet</i>	<i>FOE Oxalate</i>	<i>FOE Sulfonic acid</i>	<i>FOE Methylsulfone</i>	<i>FOE Thiadone</i>	<i>FOE TFESA</i>	<i>TFA</i>
<i>Molecular weight – M [g/mol]</i>	363.3	225.2	275.3	273.3	170.1	164.1	114.0
<i>Kinetic formation fraction – ff [%]</i>	Not applicable – parent compound	48.4	27.2	9.6	91.3	65.5	91.1
<i>Degradation parameters</i>	DT ₅₀	57.6	18.9	318.0	174.0	15.9	20.9
	Kinetic model	SFO	SFO	SFO	SFO	SFO	SFO
	Type of data	Longest not normalised lab value	Longest not normalised lab value	Longest not normalised lab value	Longest not normalised lab value	Longest not normalised lab value	Longest not normalised lab value

The key results of the calculations are presented below, individually for each application pattern, in tables 2.8.6.-3 – 2.8.6.-5.

Table 2.8.6.-3: The key results of the calculations – maximum PEC values for Flufenacet and its major soil degradation products, performed for a single use in Winter cereals at 240 g a. s./ha.

Crop scenario	Type of the value	Results obtained for the compound:						
		<i>Flufenacet</i>	<i>FOE Oxalate</i>	<i>FOE Sulfonic acid</i>	<i>FOE Methyl-sulfone</i>	<i>FOE Thiadone</i>	<i>FOE TFESA</i>	<i>TFA</i>
<i>Cereals, BBCH 10-13 240 g/ha; CI = 0%</i>	1-year max. actual PEC _{SOIL} [mg/kg]	0.3200	0.0186	0.0452	0.0134	0.0236	0.0160	0.0888
	Occurring on day after application of parent	0	45	173	137	41	77	431
	Background concentration [mg/kg]	0.0010	0.0001	0.0122	0.0016	0.0001	0.0001	0.5296
	Obtained after [years]	10	10	10	10	10	10	49
	Accumulation max. actual PEC _{SOIL} [mg/kg]	0.3210	0.0187	0.0574	0.0150	0.0237	0.0161	0.6184

Table 2.8.6.-4: The key results of the calculations – maximum PEC values for Flufenacet and its major soil degradation products, performed for a single use in Winter cereals at 160 g a. s./ha.

Crop scenario	Type of the value	Results obtained for the compound:						
		<i>Flufenacet</i>	<i>FOE Oxalate</i>	<i>FOE Sulfonic acid</i>	<i>FOE Methyl-sulfone</i>	<i>FOE Thiadone</i>	<i>FOE TFESA</i>	<i>TFA</i>
<i>Cereals, BBCH 11-13 160 g/ha; CI = 0%</i>	1-year max. actual PEC _{SOIL} [mg/kg]	0.2133	0.0124	0.0302	0.0089	0.0157	0.0107	0.0592
	Occurring on day after application of parent	0	45	173	137	41	77	431
	Background concentration [mg/kg]	0.0007	0.0001	0.0081	0.0011	0.0001	0.0001	0.3530
	Obtained after [years]	10	10	10	10	10	10	49
	Accumulation max. actual PEC _{SOIL} [mg/kg]	0.2140	0.0125	0.0383	0.0100	0.0158	0.0107	0.4122

Table 2.8.6.-5: The key results of the calculations – maximum PEC values for Flufenacet and its major soil degradation products, performed for a single use in Winter cereals at 120 g a. s./ha.

Crop scenario	Type of the value	Results obtained for the compound:						
		<i>Flufenacet</i>	<i>FOE Oxalate</i>	<i>FOE Sulfonic acid</i>	<i>FOE Methyl-sulfone</i>	<i>FOE Thiadone</i>	<i>FOE TFESA</i>	<i>TFA</i>
<i>Cereals, BBCH 00-22 120 g/ha; CI = 0%</i>	1-year max. actual PEC _{SOIL} [mg/kg]	0.1600	0.0093	0.0226	0.0067	0.0118	0.0080	0.0444
	Occurring on day after application of parent	0	45	173	137	41	77	431
	Background concentration [mg/kg]	0.0005	<0.0001	0.0061	0.0008	0.0001	<0.0001	0.2648
	Obtained after [years]	10	10	10	10	10	10	49
	Accumulation max. actual PEC _{SOIL} [mg/kg]	0.1605	0.0094	0.0287	0.0075	0.0119	0.0080	0.3092

On the basis of the obtained results it was stated that neither Flufenacet nor its following major soil degradation products: FOE Oxalate, FOE Methylsulfone, FOE Thiadone and FOE 5043-Trifluoroethanesulfonic acid displayed any accumulation potential in soil. In case of FOE Sulfonic acid such potential was demonstrated by the results of the calculations, although it was not considerable.

The considerable accumulation potential was demonstrated for another major soil transformation product of Flufenacet – Trifluoroacetic acid (TFA). It shall be indicated however that that compound occurs in the environment as a common pollutant coming from other sources. Therefore, in order to assess the risk related to TFA generated as a metabolite of Flufenacet, the calculated here max. accumulation PEC_{SOIL} values should be compared to the background values for that compound recorded in soil and reported in various monitoring studies.

Calculations of the PEC_{SOIL} values for representative formulation:

Additionally the RMS carried out the calculations of the PEC values for the representative formulation. The calculations were performed using the same tool as used to calculate the PEC values for the active substance and its major soil degradation products – ESCAPE ver. 1.1. In the assessment the standard FOCUS assumptions were used:

- thickness of the soil layer: 5 cm;
- soil density: 1.5 g/cm³.

The results of the calculations, together with some specific assumptions concerning the entity for which the calculations were performed, are presented below in the table 2.8.6.-6. Only the ini. PEC_{SOIL} values are presented, as only they are relevant for the formulation. At the same time it shall be indicated that due to the nature of the representative formulation – it contains two active substances, the values are of rather informative value and limited usefulness in the current assessment and they were provided for completeness.

Table 2.8.6.-6: The results of the calculation of PEC_{SOIL} values for the representative formulation

Crop scenario ¹⁾	Type of formulation ²⁾	Density of formulation	Application rate of formulation		Calculated on the basis of:	Crop interception factor CI [%]	max. PEC_{SOIL} of formulation [mg/kg]
			[L/ha]	[g/ha]			
<i>Cereals, BBCH 10 – 13; 240 g/ha; CI = 0%</i>	400 g/L FFA + 200 g/L DFF SC	1.251 g/cm ³ (T = 20°C)	0.6	750.6	formulation's density	0	1.0008
<i>Cereals, BBCH 11 – 13; 160 g/ha; CI = 0%</i>	400 g/L FFA + 200 g/L DFF SC	1.251 g/cm ³ (T = 20°C)	0.4	500.4	formulation's density	0	0.6672
<i>Cereals, BBCH 00 – 22; 120 g/ha; CI = 0%</i>	400 g/L FFA + 200 g/L DFF SC	1.251 g/cm ³ (T = 20°C)	0.3	375.3	formulation's density	0	0.5004

Footnotes to the table:

- 2) The given application rate is for Flufenacet;
 3) FFA stands for Flufenacet and DFF for Diflufenican.

2) Calculations of PEC_{GW} :

The model exposure assessment for the groundwater compartment, by calculating the PEC_{GW} values, was carried out by the RMS. The Applicant submitted the calculations, but they were not accepted, because the input parameters had to be updated. The calculations performed by the RMS are summarized below.

The aim of the GW model exposure assessment was to determine the leaching potential and risk posed by Flufenacet and its major soil degradation products – FOE Oxalate, FOE Sulfonic acid, FOE Methylsulfone, FOE Thiadone, FOE 5043-Trifluoroethanesulfonic acid and Trifluoroacetic acid, to the Groundwater compartment.

The calculations were carried out using two modelling tools recommended by FOCUS: FOCUS PELMO 4.4.3. (compatible with FOCUS PELMO 5.5.3 used by the Applicant) and FOCUS PEARL 4.4.4. The calculations using FOCUS MACRO model were not performed due to the fact that for all compounds of concern the K_{fOC} values were well below 1000 mL/g, so the estimation of the risk to GW compartment resulting from the macropore flow was considered not necessary, being covered by the results of the calculations performed using two models listed above.

The calculations were performed for the following general transformation pattern of Flufenacet in aerobic soil (presented below on figure 2.8.6.-2):

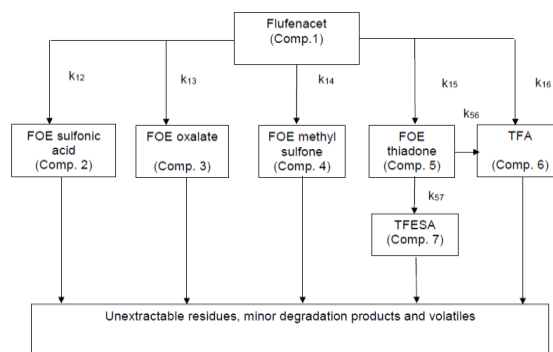


Figure 2.8.6.-2: The general transformation pattern of Flufenacet in aerobic soil used in the assessment (as proposed by the Applicant).

The examination of the transformation of Flufenacet in soil demonstrated that its initial step consisted on the cleavage of the molecule on the bridging oxygen attached to the thiadiazole ring. The resulting moieties entered two separate transformation pathways. Therefore RMS, in order to simplify the calculations and not to introduce the “ghost” compartment for the moiety containing phenyl ring, decided to perform the calculations separately for the part of the Flufenacet containing phenyl ring and that containing thiadiazole moiety. Additionally, in order to verify the calculations for the parent compound – Flufenacet, third batch of calculations was performed assuming the simplified transformation pattern of the parent compound – to the sink compartment. It was assumed that the total formation fractions for the initial cleavage of the O-C bond within the aliphatic chain were:

- for the moiety containing phenyl ring $ff = 1$;
- for the moiety containing thiadiazole group $ff = 1$.

The schematic transformation pathways assumed in calculations are presented below on figure 2.8.6-3. It shall be indicated that although on that figure are presented the transformation patterns assumed in FOCUS PELMO modelling tool, the second modelling tool – FOCUS PEARL, was parameterised in exactly the same way with regard to the transformation pathway.

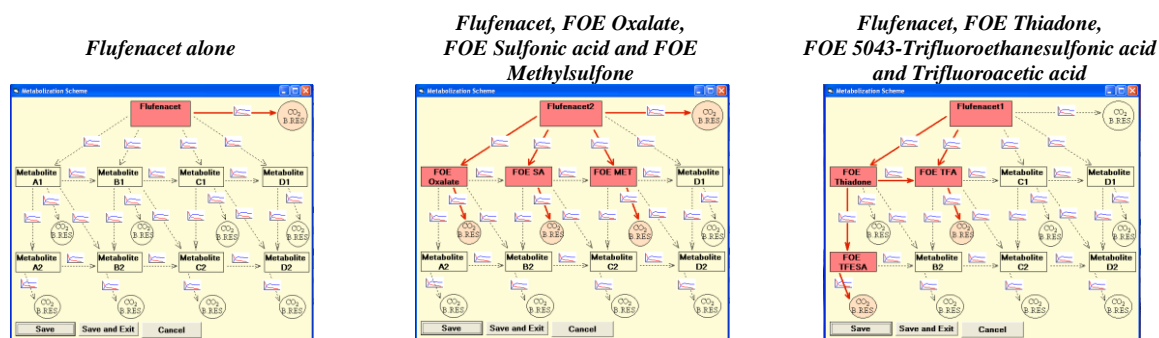


Figure 2.8.6.-3: The transformation schemes assumed in modelling, as provided by FOCUS PELMO (identical in FOCUS PEARL).

The substance-specific input parameters used in calculations are presented below in tables 2.8.6.-7 for the parent compound (Flufenacet) and 2.8.6.-8 for all degradation products. Only the key parameters introduced by the RMS are listed. All remaining parameters not listed in the tables were left as they were pre-defined (FOCUS defaults). The following abbreviations were used to denominate the degradation products, for which assessment was performed: FOE OXA for FOE Oxalate, FOE SA for FOE Sulfonic acid, FOE MET for FOE Methylsulfone, FOE THIA for FOE Thiadone, FOE TFESA for FOE 5043-Trifluoroethanesulfonic acid and TFA for Trifluoroacetic acid. The application patterns assumed for each GAP-defined use are presented in the table 2.8.6.-9.

Table 2.8.6.-7: The substance-specific input parameters for Flufenacet.

Parameter		Value	Remarks
<i>Physico-chemical properties</i>	Molar weight [g/mol]	363.3	as defined by the Applicant
	Vapour pressure at T = 20°C [Pa]	0.00009	as defined by the Applicant a
	Water solubility at T = 20°C [mg/L]	56	as defined by the Applicant
	pKa	20	FOCUS default
<i>Soil degradation-related parameters</i>	DT ₅₀ [days]	17.87	normalised lab geomean value, determined by RMS
	rate constant <i>k</i> [days ⁻¹]	0.0387	normalised lab geomean value, determined by RMS
	Values determined at (temperature, soil moisture)	T = 20°C, pF2	FOCUS defaults
	Q ₁₀ (FOCUS PELMO)	2.58	FOCUS default
	E _a [kJ/mol] (FOCUS PEARL)	65.4	FOCUS default
	Walker's exponent β	0.7	FOCUS default
<i>Soil sorption-related parameters</i>	K _{ROC} [mL/g] (FOCUS PELMO)	245.9	geomean value determined by RMS
	K _{ROM} [mL/g] (FOCUS PEARL)	142.63	value recalculated from K _{ROC} using the equation: K _{ROC} = 1.724 K _{ROM}
	1/n	0.916	arithmetic mean value determined by RMS
<i>Plant uptake-related parameters</i>	PUF	0.744	TSCF value calculated using recommendations given by FOCUS and log P _{OW} = 3.5

Table 2.8.6-8: The substance-specific input parameters for degradation products assumed in calculations.

Parameter		Input for the compound:					
		FOE OXA	FOE SA	FOE MET	FOE THIA	FOE TFESA	TFA
<i>Physico-chemical properties</i>	Molar weight [g/mol]	225.2	275.3	273.3	170.1	164.1	114.0
	Vapour pressure at T = 20°C [Pa]	4.5 E-7	1.35 E-7	0.00086	2.05	1 E-8	1.0 E-6
	Water solubility at T = 20°C [mg/L]	120000		4100	100000	160000	500000
	pKa	1.6	1.0	1.0	5.73	1	1.3
<i>Soil degradation-related parameters</i>	DT ₅₀ [days]	11.08	45.11	81.70	1.95	6.41	1000
	rate constant <i>k</i> [days ⁻¹]	0.0639	0.0154	0.00848	0.3557	0.1082	not calculated
	Values determined at (temperature, soil moisture)	T = 20°C, pF2	T = 20°C, pF2	T = 20°C, pF2	T = 20°C, pF2	T = 20°C, pF2	T = 20°C, pF2
	Q ₁₀ (FOCUS PELMO)	2.58	2.58	2.58	2.58	2.58	2.58
	E _a [kJ/mol] (FOCUS PEARL)	65.4	65.4	65.4	65.4	65.4	65.4
	Walker's exponent β	0.7	0.7	0.7	0.7	0.7	0.7
	Precursor	Flufenacet	Flufenacet	Flufenacet	Flufenacet	FOE thiadone	1) Flufenacet 2) Thiadone
	Kinetic formation fraction <i>ff</i>	0.426	0.195	0.070	0.570	0.469	1) 0.43 2) 0.581
	Precursor's rate constant <i>k_a</i> (FOCUS PELMO)	0.0164862	0.0075465	0.002709	0.022059	0.1668233	1) 0.0166414 2) 0.1888767
<i>Soil sorption-related parameters</i>	K _{ROC} [mL/g] (FOCUS PELMO)	10.60	11.10	61.03	42.10	0.0001	0.0001
	K _{ROM} [mL/g] (FOCUS PEARL)	6.15	6.44	35.40	24.42	0.0001	0.0001
	1/n	0.912	0.995	0.860	0.764	1.0	1.0
<i>Plant uptake-related parameters</i>	PUF	0.8	0.46	0.8	0.8	0.8	0.59

Table 2.8.6.-9: The Application pattern assumed in calculations.

Application pattern defined in the GAP	Application pattern defined in model calculations:					
	FOCUS Crop	Number of applications and Application time	Type of Application	Crop interception factor CI [%]	Application rate [g/ha]	
					GAP-defined	Corrected for CI (model input)
<i>Winter Cereals, Autumn, early post-emergence, BBCH 10-13), 240 g a. s./ha</i>	Winter cereals	Single application, 1 day after emergence	To the soil surface	0	240	240
<i>Winter Cereals, post-emergence, BBCH 11-13, 160 g a. s./ha</i>	Winter cereals	Single application, 2 days after emergence (Autumn uses)	To the soil surface	0	160	160
	Winter cereals	Spring uses: single application on: 15/03 – Chat., Pia., Por., Sev., Thi.; 01/04: Ham., Krem., Oke.; 15/04: Jok.	To the soil surface	0	160	160
<i>Winter Cereals, pre- and post-emergence, BBCH 00-22, 120 g a. s./ha</i>	Winter cereals	10 days before emergence (Autumn uses)	To the soil surface	0	120	120
	Winter cereals	Spring uses: single application on: 15/03 – Chat., Pia., Por., Sev., Thi.; 01/04: Ham., Krem., Oke.; 15/04: Jok.	To the soil surface	0	120	120

The results of the calculations are presented in the tables below, individually for each use. The following abbreviations were used to denominate the degradation products, for which assessment was performed:

- FOE OXA: FOE Oxalate;
- FOE SA: FOE Sulfonic acid;
- FOE MET: FOE Methylsulfone;
- FOE THIA: FOE Thiadone;
- FOE TFESA: FOE 5043-Trifluoroethanesulfonic acid;
- TFA: Trifluoroacetic acid.

Table 2.8.6.-10: The results of calculations obtained for the use in Winter Cereals in autumn and at application rate 240g Flufenacet/ha.

Modelling tool	FOCUS Scenario	Results – 80 th percentile PEC _{GW} [µg/L] for the compound:						
		Flufenacet	FOE OXA	FOE SA	FOE MET	FOE THIA	FOE TFESA	TFA
FOCUS PEARL 4.4.4.	<i>Châteaudun</i>	<0.0001	0.0680	2.0485	0.0395	<0.0001	0.0788	22.4267
	<i>Hamburg</i>	<0.0001	0.5403	3.6530	0.1590	<0.0001	0.5185	14.2007
	<i>Jokioinen</i>	<0.0001	0.5581	4.9120	0.0644	<0.0001	1.3008	20.9169
	<i>Kremsmünster</i>	<0.0001	0.1713	2.2715	0.1066	<0.0001	0.0843	11.1477
	<i>Okehampton</i>	<0.0001	0.7009	2.8135	0.1637	<0.0001	0.4407	9.7383
	<i>Piacenza</i>	<0.0001	0.1010	1.3799	0.0811	<0.0001	0.0663	13.8053
	<i>Porto</i>	<0.0001	0.4724	1.7835	0.0843	<0.0001	0.3424	7.5005
	<i>Sevilla</i>	<0.0001	0.0005	0.2023	<0.0001	<0.0001	0.0007	9.0195
FOCUS PELMO 4.4.3.	<i>Thiva</i>	<0.0001	0.0084	0.8712	0.0147	<0.0001	0.0096	19.8584
	<i>Châteaudun</i>	<0.001	0.056	1.713	0.025	<0.001	0.086	16.810
	<i>Hamburg</i>	<0.001	0.733	3.550	0.156	<0.001	0.840	10.902
	<i>Jokioinen</i>	<0.001	0.787	4.396	0.075	<0.001	1.574	14.859
	<i>Kremsmünster</i>	<0.001	0.177	2.216	0.100	<0.001	0.144	9.988
	<i>Okehampton</i>	<0.001	0.848	2.945	0.159	<0.001	0.582	9.198
	<i>Piacenza</i>	<0.001	0.262	1.724	0.088	<0.001	0.267	10.928
	<i>Porto</i>	<0.001	0.989	2.201	0.123	<0.001	0.756	6.564
FOCUS PELMO 4.4.3.	<i>Sevilla</i>	<0.001	0.017	0.296	<0.001	<0.001	0.040	10.733
	<i>Thiva</i>	<0.001	0.024	0.764	0.007	<0.001	0.039	14.622

Table 2.8.6.-11: The results of calculations obtained for the use in Winter Cereals in autumn and at application rate 160 g Flufenacet/ha.

Modelling tool	FOCUS Scenario	Results – 80 th percentile PEC _{GW} [µg/L] for the compound:						
		Flufenacet	FOE OXA	FOE SA	FOE MET	FOE THIA	FOE TFESA	TFA
FOCUS PEARL 4.4.4.	<i>Châteaudun</i>	<0.0001	0.0319	1.3486	0.0204	<0.0001	0.0512	14.9187
	<i>Hamburg</i>	<0.0001	0.3314	2.4278	0.0908	<0.0001	0.3406	9.4560
	<i>Jokioinen</i>	<0.0001	0.3419	3.2612	0.0339	<0.0001	0.8550	13.8753
	<i>Kremsmünster</i>	<0.0001	0.1063	1.5073	0.0611	<0.0001	0.0550	7.4321
	<i>Okehampton</i>	<0.0001	0.4388	1.8649	0.0944	<0.0001	0.2918	6.4439
	<i>Piacenza</i>	<0.0001	0.0641	0.9147	0.0462	<0.0001	0.0429	9.1896
	<i>Porto</i>	<0.0001	0.2889	1.1708	0.0475	<0.0001	0.2225	5.0259
	<i>Sevilla</i>	<0.0001	0.0003	0.1355	<0.0001	<0.0001	0.0005	6.0499
FOCUS PELMO 4.4.3.	<i>Thiva</i>	<0.0001	0.0050	0.5788	0.0071	<0.0001	0.0062	13.2606
	<i>Châteaudun</i>	<0.001	0.030	1.139	0.013	<0.001	0.054	11.156
	<i>Hamburg</i>	<0.001	0.452	2.337	0.089	<0.001	0.555	7.226
	<i>Jokioinen</i>	<0.001	0.487	2.921	0.040	<0.001	1.028	9.933
	<i>Kremsmünster</i>	<0.001	0.110	1.471	0.058	<0.001	0.092	6.654
	<i>Okehampton</i>	<0.001	0.527	1.951	0.094	<0.001	0.384	6.105
	<i>Piacenza</i>	<0.001	0.163	1.135	0.051	<0.001	0.177	7.267
	<i>Porto</i>	<0.001	0.615	1.495	0.070	<0.001	0.496	4.349
FOCUS PELMO 4.4.3.	<i>Sevilla</i>	<0.001	0.010	0.202	<0.001	<0.001	0.026	7.141
	<i>Thiva</i>	<0.001	0.014	0.497	0.003	<0.001	0.025	9.677

Table 2.8.6.-12: The results of calculations obtained for the use in Winter Cereals in autumn and at application rate 120 g Flufenacet/ha.

Modelling tool	FOCUS Scenario	Results – 80 th percentile PEC _{GW} [µg/L] for the compound:						
		Flufenacet	FOE OXA	FOE SA	FOE MET	FOE THIA	FOE TFESA	TFA
FOCUS PEARL 4.4.4.	<i>Châteaudun</i>	<0.0001	0.0413	1.0941	0.0134	<0.0001	0.0482	11.4205
	<i>Hamburg</i>	<0.0001	0.2892	1.8507	0.0627	<0.0001	0.3108	7.2430
	<i>Jokioinen</i>	<0.0001	0.2622	2.5267	0.0215	<0.0001	0.7172	11.0793
	<i>Kremsmünster</i>	<0.0001	0.0866	1.1617	0.0410	<0.0001	0.0558	5.5921
	<i>Okehampton</i>	<0.0001	0.3628	1.4783	0.0657	<0.0001	0.2290	5.3218
	<i>Piacenza</i>	<0.0001	0.0511	0.7227	0.0316	<0.0001	0.0500	6.9839
	<i>Porto</i>	<0.0001	0.2826	0.9804	0.0340	<0.0001	0.2021	3.9382
	<i>Sevilla</i>	<0.0001	0.0001	0.0902	<0.0001	<0.0001	0.0006	4.8563
FOCUS PELMO 4.4.3.	<i>Thiva</i>	<0.0001	0.0053	0.5133	0.0049	<0.0001	0.0085	10.3094
	<i>Châteaudun</i>	<0.001	0.035	0.880	0.009	<0.001	0.048	8.645
	<i>Hamburg</i>	<0.001	0.454	1.897	0.062	<0.001	0.498	6.033
	<i>Jokioinen</i>	<0.001	0.370	2.235	0.026	<0.001	0.811	7.568
	<i>Kremsmünster</i>	<0.001	0.090	1.163	0.039	<0.001	0.082	5.102
	<i>Okehampton</i>	<0.001	0.428	1.526	0.064	<0.001	0.312	4.752
	<i>Piacenza</i>	<0.001	0.145	0.966	0.036	<0.001	0.163	5.545
	<i>Porto</i>	<0.001	0.589	1.204	0.050	<0.001	0.409	3.626
FOCUS PELMO 4.4.3.	<i>Sevilla</i>	<0.001	0.062	0.416	<0.001	<0.001	0.051	5.507
	<i>Thiva</i>	<0.001	0.021	0.517	0.003	<0.001	0.032	7.962

Table 2.8.6._CP-13: The results of calculations obtained for the use in Winter Cereals at spring and at application rate 160 g Flufenacet/ha.

Modelling tool	FOCUS Scenario	Results – 80 th percentile PEC _{GW} [µg/L] for the compound:						
		Flufenacet	FOE OXA	FOE SA	FOE MET	FOE THIA	FOE TFESA	TFA
FOCUS PEARL 4.4.4.	<i>Châteaudun</i>	<0.0001	0.0121	0.9863	0.0147	<0.0001	0.0036	15.3016
	<i>Hamburg</i>	<0.0001	0.1436	2.3552	0.0794	<0.0001	0.1016	10.8856
	<i>Jokioinen</i>	<0.0001	0.1290	2.7188	0.0285	<0.0001	0.1862	13.9942
	<i>Kremsmünster</i>	<0.0001	0.0829	1.4960	0.0546	<0.0001	0.0326	7.6491
	<i>Okehampton</i>	<0.0001	0.0986	1.4263	0.0737	<0.0001	0.0317	6.4081
	<i>Piacenza</i>	<0.0001	0.0264	0.7279	0.0370	<0.0001	0.0079	9.6696
	<i>Porto</i>	<0.0001	0.0184	0.7583	0.0288	<0.0001	0.0070	7.1608
	<i>Sevilla</i>	<0.0001	0.0005	0.2407	<0.0001	<0.0001	0.0009	11.5395
FOCUS PELMO 4.4.3.	<i>Thiva</i>	<0.0001	0.0016	0.4601	0.0046	<0.0001	0.0014	17.6164
	<i>Châteaudun</i>	<0.001	0.006	0.672	0.007	<0.001	0.002	9.638
	<i>Hamburg</i>	<0.001	0.076	1.548	0.070	<0.001	0.036	5.829
	<i>Jokioinen</i>	<0.001	0.141	2.210	0.031	<0.001	0.151	7.271
	<i>Kremsmünster</i>	<0.001	0.080	1.450	0.050	<0.001	0.032	6.061
	<i>Okehampton</i>	<0.001	0.094	1.251	0.067	<0.001	0.035	4.053
	<i>Piacenza</i>	<0.001	0.021	0.837	0.037	<0.001	0.014	6.882
	<i>Porto</i>	<0.001	0.031	0.609	0.040	<0.001	0.015	3.749
	<i>Sevilla</i>	<0.001	0.001	0.156	<0.001	<0.001	0.001	5.365
	<i>Thiva</i>	<0.001	<0.001	0.175	0.001	<0.001	<0.001	5.964

Table 2.8.6._CP-14: The results of calculations obtained for the use in Winter Cereals at spring and at application rate 120 g Flufenacet/ha.

Modelling tool	FOCUS Scenario	Results – 80 th percentile PEC _{GW} [µg/L] for the compound:						
		Flufenacet	FOE OXA	FOE SA	FOE MET	FOE THIA	FOE TFESA	TFA
FOCUS PEARL 4.4.4.	<i>Châteaudun</i>	<0.0001	0.0085	0.7389	0.0092	<0.0001	0.0027	11.4799
	<i>Hamburg</i>	<0.0001	0.1028	1.7648	0.0537	<0.0001	0.0760	8.1665
	<i>Jokioinen</i>	<0.0001	0.0919	2.0373	0.0176	<0.0001	0.1396	10.4972
	<i>Kremsmünster</i>	<0.0001	0.0597	1.1211	0.0363	<0.0001	0.0244	5.7373
	<i>Okehampton</i>	<0.0001	0.0718	1.0690	0.0503	<0.0001	0.0237	4.8073
	<i>Piacenza</i>	<0.0001	0.0190	0.5452	0.0250	<0.0001	0.0059	7.2530
	<i>Porto</i>	<0.0001	0.0131	0.5682	0.0189	<0.0001	0.0053	5.3731
	<i>Sevilla</i>	<0.0001	0.0003	0.1806	<0.0001	<0.0001	0.0007	8.6689
FOCUS PELMO 4.4.3.	<i>Thiva</i>	<0.0001	0.0011	0.3450	0.0027	<0.0001	0.010	13.2204
	<i>Châteaudun</i>	<0.001	0.004	0.503	0.005	<0.001	0.002	7.226
	<i>Hamburg</i>	<0.001	0.055	1.160	0.047	<0.001	0.027	4.374
	<i>Jokioinen</i>	<0.001	0.102	1.656	0.019	<0.001	0.113	5.456
	<i>Kremsmünster</i>	<0.001	0.058	1.087	0.033	<0.001	0.024	4.546
	<i>Okehampton</i>	<0.001	0.068	0.938	0.046	<0.001	0.026	3.039
	<i>Piacenza</i>	<0.001	0.015	0.626	0.025	<0.001	0.010	5.155
	<i>Porto</i>	<0.001	0.023	0.456	0.026	<0.001	0.011	2.808
	<i>Sevilla</i>	<0.001	0.001	0.117	<0.001	<0.001	0.001	4.026
	<i>Thiva</i>	<0.001	<0.001	0.131	0.001	<0.001	<0.001	4.471

Conclusions:

The presented above results of the calculations of PEC_{GW} values for Flufenacet and its major soil degradation products demonstrated that for all uses covered by the EU-representative GAP neither **Flufenacet** nor **FOE Thiadone** – one of its major degradation products, should pose any risk for the Groundwater compartment – the calculated PEC_{GW} values for these two compounds were well below the regulatory threshold value of 0.1 µg/L. For the remaining degradation products leaching above the trigger value of 0.1 µg/L was observed at least in some scenarios and one of the evaluated uses. As a result it can be stated that:

- **FOE Oxalate** will require an assessment of its toxicological and ecotoxicological relevance;
- **FOE Sulfonic acid** will require an assessment of its toxicological and ecotoxicological relevance;
- **FOE Methylsulfone** may require an assessment of its toxicological and ecotoxicological relevance;
- **FOE 5043-Trifluoroethanesulfonic acid** will require an assessment of its toxicological and ecotoxicological relevance;
- **Trifluoroacetic acid (TFA)** will require an assessment of its toxicological and ecotoxicological relevance; additionally, as TFA in the environment comes from other sources, the comparison of the obtained values with the background concentrations may be necessary to appropriately evaluate the risk.

3) Calculations of PEC_{SW} and PEC_{SED} :

The model exposure assessment for the surface water compartment, by calculating the PEC_{SW} and PEC_{SED} values, was carried out by the RMS. The Applicant submitted the calculations, but they were not accepted, because the input parameters had to be updated. The calculations performed by the RMS are summarized below.

The aim of the SW model exposure assessment was to calculate the PEC_{SW} and PEC_{SED} values for Flufenacet and its major degradation products – FOE Oxalate, FOE Sulfonic acid, FOE Methylsulfone, FOE Methylsulfide, FOE Thiadone, FOE 5043-Trifluoroethanesulfonic acid and Trifluoroacetic acid, to be subsequently used in the risk assessment for the aquatic organisms. The calculations were performed in line with the tiered approach recommended by FOCUS.

Following modelling tools were used:

- “FOCUS STEPS 1-2” ver. 2.1 calculator for the assessment at STEP 1 and STEP 2;
- FOCUS SWASH ver 3.1 modelling tool for the assessment at STEP 3;
- SWAN 3.0.0 and TOXSWA 3.3.1 for the assessment at STEP 4.

Calculations at STEPS 1-4 were performed for Flufenacet, while for all degradation products the assessment was limited to the lower tiers – STEP 1 and STEP 2.

The substance-specific input parameters used in calculations are presented below in tables 2.8.6.-15 – 2.8.6.-19.

Table 2.8.6.-15: The substance-specific input parameters for Flufenacet.

Parameter	Value	Remarks
<i>Physico-chemical properties</i>	Molar weight [g/mol]	363.3
	Vapour pressure at T = 20°C [Pa]	0.00009
	Water solubility at T = 20°C [mg/L]	56
	pKa	20
<i>Degradation parameters</i>	Soil DT ₅₀ [days]	17.87
	Water/sediment (whole system) DT ₅₀ [days]	
	Water DT ₅₀ [days]	1000
	Sediment DT ₅₀ [days]	
	Plant DT ₅₀ [days]	10
	Values determined at: temperature, soil moisture	T = 20°C, pF2
	Q ₁₀ (PRZM)	2.58
	Exponent [1/K] (MACRO)	0.095
	E _a [J/mol] (TOXSWA)	65.4
	Walker's exponent β	0.7
<i>Adsorption-related parameters</i>	K _{foc} [mL/g] (FOCUS PELMO)	245.9
	1/n	0.916
<i>Plant uptake-related parameters</i>	PUF	0.744
<i>Wash-off factor from crop</i>	for MACRO [mm ⁻¹]	0.5
	for PRZM [cm ⁻¹]	0.05

Table 2.8.6.-16: The substance-specific input parameters for FOE Oxalate and FOE Sulfonic acid.

Parameter		Input for the compound:			
		FOE Oxalate		FOE Sulfonic acid	
		Value	Remarks	Value	Remarks
Physico-chemical properties	Molar weight [g/mol]	225.2	as defined by the Applicant	275.3	as defined by the Applicant
	Water solubility at T = 20°C [mg/L]	120000	as defined by the Applicant		as defined by the Applicant
Degradation parameters	Soil DT ₅₀ [days]	11.08	normalised lab geomean value, determined by RMS	45.11	normalised lab geomean value, determined by RMS
	Water/Sediment (whole system) DT ₅₀ [days]	1000	FOCUS default, as defined by the Applicant	1000	FOCUS default, as defined by the Applicant
	Water DT ₅₀ [days]	1000	FOCUS default	1000	FOCUS default
	Sediment DT ₅₀ [days]	1000	FOCUS default	1000	FOCUS default
	Maximum occurrence in soil [%]	26.3	as defined by the Applicant	26.5	as defined by the Applicant
	Maximum occurrence in Water/Sediment system [%]	5.4	Experimental value from water/sediment studies; RMS's proposal	3.2	Experimental value from water/sediment studies; RMS's proposal
Adsorption parameters	K _{roc} [mL/g]	10.60	geomean value	11.10	geomean value

Table 2.8.6.-17: The substance-specific input parameters for FOE Methylsulfone and FOE Methylsulfide.

Parameter		Input for the compound:			
		FOE Methylsulfone		FOE Methylsulfide	
		Value	Remarks	Value	Remarks
Physico-chemical properties	Molar weight [g/mol]	273.3	as defined by the Applicant	241.33	as defined by the Applicant
	Water solubility at T = 20°C [mg/L]	4100	as defined by the Applicant	113.1	as defined by the Applicant
Degradation parameters	Soil DT ₅₀ [days]	81.70	normalised lab geomean value, determined by RMS	1000	as defined by the Applicant
	Water/Sediment (whole system) DT ₅₀ [days]	1000	FOCUS default, as defined by the Applicant	1000	FOCUS default, as defined by the Applicant
	Water DT ₅₀ [days]	1000	FOCUS default	1000	FOCUS default
	Sediment DT ₅₀ [days]	1000	FOCUS default	1000	FOCUS default
	Maximum occurrence in soil [%]	6.6	as defined by the Applicant	0.0001	RMS's proposal
	Maximum occurrence in Water/Sediment system [%]	7.2	Experimental value from water/sediment studies; RMS's proposal	11.4	Experimental value from water/sediment studies; Applicant's proposal
Adsorption parameters	K _{roc} [mL/g]	61.03	geomean value	598.0	KOCWIN value; RMS's proposal

Table 2.8.6.-18: The substance-specific input parameters for FOE Thiadone and FOE TFESA.

Parameter		Input for the compound:			
		FOE Thiadone		FOE 5043-Trifluoroethanesulfonic acid	
		Value	Remarks	Value	Remarks
Physico-chemical properties	Molar weight [g/mol]	170.1	as defined by the Applicant	164.1	as defined by the Applicant
	Water solubility at T = 20°C [mg/L]	100000	as defined by the Applicant	160000	as defined by the Applicant
Degradation parameters	Soil DT ₅₀ [days]	1.95	normalised lab geomean value, determined by RMS	6.41	normalised lab geomean value, determined by RMS
	Water/Sediment (whole system) DT ₅₀ [days]	1000	FOCUS default, as defined by the Applicant	1000	FOCUS default, as defined by the Applicant
	Water DT ₅₀ [days]	1000	FOCUS default	1000	FOCUS default
	Sediment DT ₅₀ [days]	1000	FOCUS default	1000	FOCUS default
	Maximum occurrence in soil [%]	5.9	as defined by the Applicant	6.0	as defined by the Applicant
	Maximum occurrence in Water/Sediment system [%]	84.3	as defined by the Applicant	0.0001	RMS's proposal
Adsorption parameters	K _{roc} [mL/g]	42.10	geomean value	0.0001	RMS's proposal

Table 2.8.6.-19: The substance-specific input parameters for Trifluoroacetic acid (TFA).

	Parameter	Value	Remarks
<i>Physico-chemical properties</i>	Molar weight [g/mol]	114.0	as defined by the Applicant
	Water solubility at T = 20°C [mg/L]	500000	as defined by the Applicant
<i>Degradation parameters</i>	Soil DT ₅₀ [days]	1000	normalised lab value, determined by RMS
	Water/sediment (whole system) DT ₅₀ [days]	1000	FOCUS default
	Water DT ₅₀ [days]	1000	FOCUS default
	Sediment DT ₅₀ [days]	1000	FOCUS default
	Maximum occurrence in soil [%]	81.5	as defined by the Applicant
	Maximum occurrence in Water/Sediment system [%]	0.0001	RMS's proposal
<i>Adsorption-related parameters</i>	K _{OC} [mL/g]	0.0001	RMS's proposal

The application patterns assumed for each GAP-defined use are presented below in two tables: table 2.8.6.-20 for calculations at STEP 1 and STEP 2 and table 2.8.6.-21 for calculations at STEP 3 (and STEP 4).

Table 2.8.6.-20: The application patterns used in PEC_{SW}/PEC_{SED} calculations at STEPS 1 and 2.

Application parameter	Data on application for the GAP-defined use:				
	Single, post-emergence use in Winter cereals (BBCH 10-13) at 240 g Flufenacet/ha	Single, post-emergence use in Winter cereals (BBCH 11-13) at 160 g Flufenacet/ha		Single, pre-emergence use in Winter cereals (BBCH 00-22) at 120 g Flufenacet/ha	
		Autumn use	Spring use	Autumn use	Spring use
<i>FOCUS Crop</i>	Winter cereals	Winter cereals	Winter cereals	Winter cereals	Winter cereals
<i>Number of applications</i>	1	1	1	1	1
<i>Application timing</i>	October – February	October – February	March – May	October – February	March – May
<i>Crop cover and corresponding crop interception factor CI [%]</i>	No interception; 0%	No interception; 0%	No interception; 0%	No interception; 0%	No interception; 0%
<i>Application rate [g a. s./ha]</i>	240	160	160	120	120

Table 2.8.6.-21: The application patterns used in PEC_{SW}/PEC_{SED} calculations at STEPS 3 and 4.

Application parameter	Data on application for the GAP-defined use:				
	Single, post-emergence use in Winter cereals (BBCH 10-13) at 240 g Flufenacet/ha	Single, post-emergence use in Winter cereals (BBCH 11-13) at 160 g Flufenacet/ha		Single, pre-emergence use in Winter cereals (BBCH 00-22) at 120 g Flufenacet/ha	
		Autumn use	Spring use	Autumn use	Spring use
<i>FOCUS Crop</i>	Winter cereals	Winter cereals	Winter cereals	Winter cereals	Winter cereals
<i>Number of applications</i>	1	1	1	1	1
<i>Application method</i>	Ground spray	Ground spray	Ground spray	Ground spray	Ground spray
<i>Application type (R scenarios)</i>	CAM 1	CAM 1	CAM 1	CAM 1	CAM 1
<i>Application rate [g a. s./ha]</i>	240	160	160	120	120
<i>Date of application in relation to crop event (beginning of application window)</i>	1 day after emergence	2 days after emergence	Estimated beginning of growth period	10 days before emergence	Estimated beginning of growth period
<i>Range of application (PAT) window</i>	30 days	30 days	30 days	30 days	30 days
<i>Date of application – first day of application expressed as day/month and Julian Day (JD)</i>	D1	26/09 (269)	27/09 (270)	25/03 (84)	15/09 (258)
	D2	26/10 (299)	27/10 (300)	04/04 (94)	15/10 (288)
	D3	22/11 (326)	23/11 (327)	16/04 (106)	11/11 (315)
	D4	23/09 (266)	24/09 (267)	18/03 (77)	12/09 (255)
	D5	11/11 (315)	12/11 (316)	15/03 (74)	31/10 (304)
	D6	01/12 (335)	02/12 (336)	16/02 (47)	20/11 (324)
	R1	13/11 (317)	14/11 (318)	01/04 (91)	02/11 (306)
	R3	02/12 (336)	03/12 (337)	15/03 (74)	21/11 (325)
	R4	11/11 (315)	12/11 (316)	15/03 (74)	31/10 (304)

The calculations for Flufenacet at STEP 4 were carried out using the safe PEC_{SW} = 0.3 µg/L, initially identified in the ecotox section. It shall be indicated that that value was not a definitive value at the time it was determined and

underwent modification as a result of the finalised assessment. The mitigation measures used in these calculations are presented below in the table 2.8.6.-22.

Table 2.8.6.-22: The mitigation measures used in STEP-4 calculations for Flufenacet.

Mitigation measures			Assumed buffer zone		
			10-metres wide buffer zone (FOCUS) for SD and RO	20-metres wide buffer zone (FOCUS) for SD and RO	10-metres wide buffer zone in VFS-mod
Spray drift reduction	non-spray zone		10-metres wide	20-metres wide	10-metres wide
	drift-reducing nozzles		not applied	not applied	not applied
Runoff reduction – FOCUS L&M factors	for run-off	volume	0.6	0.8	not applied
		flux	0.6	0.8	not applied
	for erosion	mass	0.85	0.95	not applied
		flux	0.85	0.95	not applied
Runoff reduction – VFS-mod			not applied	not applied	10-metres wide VFS

The key results of the calculations – maximum PEC_{SW} and PEC_{SED} for each compound at each assessment level are presented below, individually for each use listed in the GAP table, in tables 2.8.6.-23 – 2.8.6.-38.

a) Results obtained for the use in autumn at 240 g Flufenacet/ha:

Table 2.8.6.-23: The maximum PEC_{SW} and PEC_{SED} values obtained for Flufenacet.

Results obtained at Step 1 and Step2					
STEP 1		STEP 2			
		North Europe		South Europe	
PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]
62.454	150.122	27.593	66.541	22.433	54.030
Results obtained at Step 3					
FOCUS Scenario	PEC _{SW} [µg/L]		PEC _{SED} [µg/kg]	Dominant migration route	Date of maximum
	total	dissolved			
<i>D1 ditch</i>	6.543	6.541	17.365	Drainage	16. 03.1982/9:59
<i>D1 stream</i>	4.082	4.080	10.378	Drainage	16. 03. 1982/6:59
<i>D2 ditch</i>	6.199	6.197	7.619	Drainage	15. 12. 1986/6:00
<i>D2 stream</i>	3.882	3.881	4.466	Drainage	15. 12. 1986/6:00
<i>D3 ditch</i>	1.514	1.513	0.401	Spray drift	22. 11. 1992/9:00
<i>D4 pond</i>	1.168	1.168	3.689	Drainage	24. 12. 1985/9:59
<i>D4 stream</i>	1.647	1.647	1.648	Drainage	07. 12. 1985/9:00
<i>D5 pond</i>	1.170	1.170	3.505	Drainage	15. 02. 1979/17:00
<i>D5 stream</i>	1.420	1.419	1.074	Spray drift	27. 11. 1978/9:00
<i>D6 ditch</i>	5.693	5.692	4.168	Drainage	25. 12. 1986/12:00
<i>R1 pond</i>	0.116	0.116	0.408	Run-off	31. 12. 1978/15:00
<i>R1 stream</i>	5.811	5.810	1.280	Run-off	25. 11. 1978/7:59
<i>R3 stream</i>	7.641	7.639	1.891	Run-off	16. 12. 1980/9:00
<i>R4 stream</i>	5.980	5.979	1.550	Run-off	21. 12. 1979/2:00
Results obtained at Step 4, 10-metres buffer zone, FOCUS					
FOCUS Scenario	PEC _{SW} [µg/L]		PEC _{SED} [µg/kg]	Dominant migration route	Date of maximum
	total	dissolved			
<i>D1 ditch</i>	6.543	6.541	17.365	Drainage	16. 03.1982/9:59
<i>D1 stream</i>	4.082	4.080	10.378	Drainage	16. 03. 1982/6:59
<i>D2 ditch</i>	6.199	6.197	7.554	Drainage	15. 12. 1986/6:00
<i>D2 stream</i>	3.882	3.881	4.455	Drainage	15. 12. 1986/6:00
<i>D3 ditch</i>	0.218	0.217	0.0611	Spray drift	22. 11. 1992/9:00
<i>D4 pond</i>	1.159	1.159	3.560	Drainage	24. 12. 1985/9:59
<i>D4 stream</i>	1.674	1.674	1.641	Drainage	07. 12. 1985/9:00
<i>D5 pond</i>	1.163	1.162	3.468	Drainage	15. 02. 1979/17:00
<i>D5 stream</i>	1.249	1.248	1.064	Drainage	04. 02. 1979/11:00
<i>D6 ditch</i>	5.693	5.692	3.818	Drainage	25. 12. 1986/12:00
<i>R1 pond</i>	0.0543	0.0543	0.201	Run-off	31. 12. 1978/15:00
<i>R1 stream</i>	2.602	2.601	0.572	Run-off	25. 11. 1978/7:59
<i>R3 stream</i>	3.446	3.445	0.853	Run-off	16. 12. 1980/9:00
<i>R4 stream</i>	2.699	2.698	0.707	Run-off	21. 12. 1979/2:00
Results obtained at Step 4, 20-metres buffer zone, FOCUS					
FOCUS Scenario	PEC _{SW} [µg/L]		PEC _{SED} [µg/kg]	Dominant migration route	Date of maximum
	total	dissolved			
<i>D1 ditch</i>	6.543	6.541	7.549	Drainage	16. 03.1982/9:59
<i>D1 stream</i>	4.082	4.080	10.378	Drainage	16. 03. 1982/6:59
<i>D2 ditch</i>	6.199	6.197	7.549	Drainage	15. 12. 1986/6:00
<i>D2 stream</i>	3.882	3.881	4.454	Drainage	15. 12. 1986/6:00
<i>D3 ditch</i>	0.113	0.113	0.0324	Spray drift	22. 11. 1992/9:00
<i>D4 pond</i>	1.154	1.154	3.629	Drainage	24. 12. 1985/11:00
<i>D4 stream</i>	1.674	1.674	1.640	Drainage	07. 12. 1985/9:00
<i>D5 pond</i>	1.159	1.158	3.449	Drainage	15. 02. 1979/18:00
<i>D5 stream</i>	1.249	1.248	1.063	Drainage	04. 02. 1979/11:00
<i>D6 ditch</i>	5.693	5.692	3.789	Drainage	25. 12. 1986/12:00
<i>R1 pond</i>	0.0310	0.0310	0.117	Run-off	25. 11. 1978/7:59
<i>R1 stream</i>	1.354	1.354	0.301	Run-off	25. 11. 1978/7:59
<i>R3 stream</i>	1.799	1.799	0.452	Run-off	16. 12. 1980/9:00
<i>R4 stream</i>	1.410	1.410	0.375	Run-off	21. 12. 1979/2:00

Table 2.8.6.-24: The maximum PEC_{SW} and PEC_{SED} values obtained for Flufenacet - continued.

Results obtained at Step 4, 10-metres buffer zone, VFS-mod					
FOCUS Scenario	PEC _{SW} [µg/L]		PEC _{SED} [µg/kg]	Dominant migration route	Date of maximum
	total	dissolved			
<i>D1 ditch</i>	6.543	6.541	17.365	Drainage	16. 03.1982/9:59
<i>D1 stream</i>	4.082	4.080	10.378	Drainage	16. 03. 1982/6:59
<i>D2 ditch</i>	6.199	6.197	7.554	Drainage	15. 12. 1986/6:00
<i>D2 stream</i>	3.882	3.881	4.455	Drainage	15. 12. 1986/6:00
<i>D3 ditch</i>	0.218	0.217	0.0611	Spray drift	22. 11. 1992/9:00
<i>D4 pond</i>	1.159	1.159	3.560	Drainage	24. 12. 1985/9:59
<i>D4 stream</i>	1.674	1.674	1.641	Drainage	07. 12. 1985/9:00
<i>D5 pond</i>	1.163	1.162	3.468	Drainage	15. 02. 1979/17:00
<i>D5 stream</i>	1.249	1.248	1.064	Drainage	04. 02. 1979/11:00
<i>D6 ditch</i>	5.693	5.692	3.818	Drainage	25. 12. 1986/12:00
<i>R1 pond</i>	0.0326	0.0326	0.989	Spray drift	14. 11. 1978/9:00
<i>R1 stream</i>	0.194	0.194	0.0214	Spray drift	14. 11. 1978/9:00
<i>R3 stream</i>	0.272	0.272	0.0391	Spray drift	05. 12. 1980/9:00
<i>R4 stream</i>	0.192	0.192	0.0179	Spray drift	10. 12. 1979/9:00

Table 2.8.6.-25: The maximum PEC_{SW} and PEC_{SED} values obtained for the degradation products of Flufenacet.

Compound	Obtained results:					
	STEP 1		STEP 2			
			North Europe		South Europe	
	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]
<i>FOE Oxalate</i>	12.933	1.370	5.079	0.538	4.078	0.432
<i>FOE Sulfonic acid</i>	15.882	1.762	7.500	0.831	6.007	0.666
<i>FOE Methylsulfone</i>	3.792	2.307	1.888	1.150	1.533	0.933
<i>FOE Methylsulfide</i>	0.167	0.556	0.167	0.554	0.167	0.554
<i>FOE Thiadone</i>	2.928	1.212	1.086	0.450	1.036	0.430
<i>FOE 5043-Trifluoroethanesulfonic acid</i>	2.168	0.000	0.703	0.000	0.563	0.000
<i>Trifluoroacetic acid (TFA)</i>	20.457	0.000	10.200	0.000	8.160	0.000

b) Results obtained for the use in autumn at 160 g Flufenacet/ha:

Table 2.8.6.-26: The maximum PEC_{SW} and PEC_{SED} values obtained for Flufenacet.

Results obtained at Step 1 and Step2					
STEP 1		STEP 2			
		North Europe		South Europe	
PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]
41.636	100.081	18.395	44.361	14.956	36.020
Results obtained at Step 3					
FOCUS Scenario	PEC _{SW} [□g/L]		PEC _{SED} [□g/kg]	Dominant migration route	Date of maximum
	total	dissolved			
<i>D1 ditch</i>	4.328	4.327	11.617	Drainage	16. 03.1982/9:59
<i>D1 stream</i>	2.699	2.699	6.958	Drainage	16. 03. 1982/8:00
<i>D2 ditch</i>	3.957	3.955	4.987	Drainage	15. 12. 1986/6:00
<i>D2 stream</i>	2.480	2.479	2.919	Drainage	15. 12. 1986/6:00
<i>D3 ditch</i>	1.010	1.010	0.272	Spray drift	22. 11. 1992/9:00
<i>D4 pond</i>	0.756	0.755	2.430	Drainage	24. 12. 1985/14:00
<i>D4 stream</i>	1.081	1.080	1.081	Drainage	07. 12. 1985/9:00
<i>D5 pond</i>	0.766	0.765	2.315	Drainage	15. 02. 1979/18:00
<i>D5 stream</i>	0.946	0.946	0.714	Spray drift	27. 11. 1978/9:00
<i>D6 ditch</i>	3.732	3.731	2.722	Drainage	25. 12. 1986/12:00
<i>R1 pond</i>	0.0797	0.0796	0.281	Run-off	31. 12. 1978/15:00
<i>R1 stream</i>	3.790	3.789	0.845	Run-off	25. 11. 1978/7:59
<i>R3 stream</i>	4.980	4.979	1.248	Run-off	16. 12. 1980/9:00
<i>R4 stream</i>	3.957	3.955	1.037	Run-off	21. 12. 1979/2:00

Table 2.8.6.-27: The maximum PEC_{SW} and PEC_{SED} values obtained for Flufenacet - continued.

Results obtained at Step 4, 10-metres buffer zone, FOCUS					
FOCUS Scenario	PEC _{SW} [µg/L]		PEC _{SED} [µg/kg]	Dominant migration route	Date of maximum
	total	dissolved			
D1 ditch	4.328	4.327	11.671	Drainage	16. 03.1982/15:59
D1 stream	2.699	2.699	6.958	Drainage	16. 03. 1982/6:59
D2 ditch	3.957	3.955	4.943	Drainage	15. 12. 1986/6:00
D2 stream	2.480	2.479	2.912	Drainage	15. 12. 1986/6:00
D3 ditch	0.145	0.145	0.0413	ray drift	22. 11. 1992/9:00
D4 pond	0.750	0.750	2.403	Drainage	24. 12. 1985/15:00
D4 stream	1.081	1.080	1.076	Drainage	07. 12. 1985/9:00
D5 pond	0.761	0.760	2.291	Drainage	15. 02. 1979/18:59
D5 stream	0.812	0.812	0.707	Drainage	04. 02. 1979/11:00
D6 ditch	3.732	3.731	2.485	Drainage	25. 12. 1986/12:00
R1 pond	0.0370	0.0370	0.138	Run-off	31. 12. 1978/15:00
R1 stream	1.697	1.696	0.377	Run-off	25. 11. 1978/7:59
R3 stream	2.246	2.246	0.562	Run-off	16. 12. 1980/9:00
R4 stream	1.786	1.785	0.473	Run-off	21. 12. 1979/2:00
Results obtained at Step 4, 20-metres buffer zone, FOCUS					
FOCUS Scenario	PEC _{SW} [µg/L]		PEC _{SED} [µg/kg]	Dominant migration route	Date of maximum
	total	dissolved			
D1 ditch	4.328	4.327	11.617	Drainage	16. 03.1982/15:59
D1 stream	2.699	2.699	6.958	Drainage	16. 03. 1982/8:00
D2 ditch	3.957	3.955	4.939	Drainage	15. 12. 1986/6:00
D2 stream	2.480	2.479	2.911	Drainage	15. 12. 1986/6:00
D3 ditch	0.0754	0.0753	0.0291	Spray drift	22. 11. 1992/9:00
D4 pond	0.747	0.746	2.389	Drainage	24. 12. 1985/15:00
D4 stream	1.081	1.080	1.076	Drainage	07. 12. 1985/9:00
D5 pond	0.758	0.758	2.278	Drainage	15. 02. 1979/18:59
D5 stream	0.812	0.812	0.706	Drainage	04. 02. 1979/11:00
D6 ditch	3.732	3.731	2.466	Drainage	25. 12. 1986/12:00
R1 pond	0.0208	0.0208	0.0806	Run-off	31. 12. 1978/15:00
R1 stream	0.883	0.883	0.199	Run-off	25. 11. 1978/7:59
R3 stream	1.173	1.172	0.298	Run-off	16. 12. 1980/9:00
R4 stream	0.933	0.933	0.251	Run-off	21. 12. 1979/2:00
Results obtained at Step 4, 10-metres buffer zone, VFS-mod					
FOCUS Scenario	PEC _{SW} [µg/L]		PEC _{SED} [µg/kg]	Dominant migration route	Date of maximum
	total	dissolved			
D1 ditch	4.328	4.327	11.671	Drainage	16. 03.1982/15:59
D1 stream	2.699	2.699	6.958	Drainage	16. 03. 1982/6:59
D2 ditch	3.957	3.955	4.943	Drainage	15. 12. 1986/6:00
D2 stream	2.480	2.479	2.912	Drainage	15. 12. 1986/6:00
D3 ditch	0.145	0.145	0.0413	Spray drift	22. 11. 1992/9:00
D4 pond	0.750	0.750	2.403	Drainage	24. 12. 1985/15:00
D4 stream	1.081	1.080	1.076	Drainage	07. 12. 1985/9:00
D5 pond	0.761	0.760	2.291	Drainage	15. 02. 1979/18:59
D5 stream	0.812	0.812	0.707	Drainage	04. 02. 1979/11:00
D6 ditch	3.732	3.731	2.485	Drainage	25. 12. 1986/12:00
R1 pond	0.0218	0.0217	0.0675	Spray drift	14. 11. 1978/9:00
R1 stream	0.129	0.129	0.0143	Spray drift	14. 11. 1978/9:00
R3 stream	0.181	0.181	0.0262	Spray drift	05. 12. 1980/9:00
R4 stream	0.128	0.128	0.0120	Spray drift	10. 12. 1979/9:00

Table 2.8.6.-28: The maximum PEC_{SW} and PEC_{SED} values obtained for the degradation products of Flufenacet.

Compound	Obtained results:					
	STEP 1		STEP 2			
			North Europe		South Europe	
	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]
<i>FOE Oxalate</i>	8.622	0.913	3.386	0.359	2.719	0.288
<i>FOE Sulfonic acid</i>	10.588	1.174	4.997	0.554	4.005	0.444
<i>FOE Methylsulfone</i>	2.528	1.538	1.259	0.767	1.022	0.622
<i>FOE Methylsulfide</i>	0.111	0.371	0.111	0.370	0.111	0.370
<i>FOE Thiadone</i>	1.952	0.808	0.724	0.300	0.691	0.286
<i>FOE 5043-Trifluoroethanesulfonic acid</i>	1.445	0.000	0.469	0.000	0.375	0.000
<i>Trifluoroacetic acid (TFA)</i>	13.638	0.000	6.800	0.000	5.444	0.000

c) Results obtained for the use in autumn at 120 g Flufenacet/ha:

Table 2.8.6.-29: The maximum PEC_{SW} and PEC_{SED} values obtained for Flufenacet.

Results obtained at Step 1 and Step2					
STEP 1		STEP 2			
		North Europe		South Europe	
PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]
31.227	75.061	13.797	33.271	11.217	27.015
Results obtained at Step 3					
FOCUS Scenario	PEC _{SW} [µg/L]		PEC _{SED} [µg/kg]	Dominant migration route	Date of maximum
	total	dissolved			
<i>D1 ditch</i>	2.680	2.679	7.476	Drainage	16. 03.1982/15:59
<i>D1 stream</i>	1.672	1.671	4.470	Drainage	16. 03. 1982/8:00
<i>D2 ditch</i>	3.227	3.226	4.085	Drainage	20. 11. 1986/6:59
<i>D2 stream</i>	2.021	2.020	2.424	Drainage	20. 11. 1986/6:59
<i>D3 ditch</i>	0.758	0.757	0.207	Spray drift	14. 11. 1992/9:00
<i>D4 pond</i>	0.398	0.397	1.324	Drainage	24. 12. 1985/15:00
<i>D4 stream</i>	0.658	0.658	0.580	Spray drift	12. 09. 1985/9:00
<i>D5 pond</i>	0.560	0.559	1.672	Drainage	15. 02. 1979/18:59
<i>D5 stream</i>	0.710	0.710	0.532	Spray drift	27. 11. 1978/9:00
<i>D6 ditch</i>	2.764	2.763	2.013	Drainage	25. 12. 1986/12:00
<i>R1 pond</i>	0.0609	0.0609	0.216	Run-off	31. 12. 1978/15:00
<i>R1 stream</i>	2.800	2.800	0.629	Run-off	25. 11. 1978/7:59
<i>R3 stream</i>	3.783	3.782	5.248	Run-off	26. 11. 1980/1:59
<i>R4 stream</i>	1.167	1.166	0.315	Run-off	21. 12. 1979/2:00
Results obtained at Step 4, 10-metres buffer zone, FOCUS					
FOCUS Scenario	PEC _{SW} [µg/L]		PEC _{SED} [µg/kg]	Dominant migration route	Date of maximum
	total	dissolved			
<i>D1 ditch</i>	2.680	2.679	7.476	Drainage	16. 03.1982/15:59
<i>D1 stream</i>	1.672	1.671	4.470	Drainage	16. 03. 1982/8:00
<i>D2 ditch</i>	3.227	3.226	4.036	Drainage	20. 11. 1986/6:59
<i>D2 stream</i>	2.021	2.020	2.385	Drainage	20. 11. 1986/6:59
<i>D3 ditch</i>	0.109	0.109	0.0315	Spray drift	14. 11. 1992/9:00
<i>D4 pond</i>	0.394	0.393	1.304	Drainage	24. 12. 1985/17:00
<i>D4 stream</i>	0.550	0.549	0.577	Drainage	07. 12. 1985/9:00
<i>D5 pond</i>	0.556	0.556	1.654	Drainage	15. 02. 1979/18:59
<i>D5 stream</i>	0.579	0.579	0.526	Spray drift	04. 02. 1979/11:00
<i>D6 ditch</i>	2.764	2.763	1.834	Drainage	25. 12. 1986/12:00
<i>R1 pond</i>	0.0283	0.0282	0.106	Run-off	31. 12. 1978/15:00
<i>R1 stream</i>	1.354	1.253	0.281	Run-off	25. 11. 1978/7:59
<i>R3 stream</i>	1.728	1.727	1.213	Run-off	26. 11. 1980/1:59
<i>R4 stream</i>	0.527	0.526	0.144	Run-off	21. 12. 1979/2:00

Table 2.8.6.-30: The maximum PEC_{SW} and PEC_{SED} values obtained for Flufenacet - continued.

Results obtained at Step 4, 20-metres buffer zone, FOCUS					
FOCUS Scenario	PEC _{SW} [µg/L]		PEC _{SED} [µg/kg]	Dominant migration route	Date of maximum
	total	dissolved			
<i>D1 ditch</i>	2.680	2.679	7.476	Drainage	16. 03.1982/15:59
<i>D1 stream</i>	1.672	1.671	4.470	Drainage	16. 03. 1982/8:00
<i>D2 ditch</i>	3.227	3.226	4.032	Drainage	20. 11. 1986/6:59
<i>D2 stream</i>	2.021	2.020	2.380	Drainage	20. 11. 1986/6:59
<i>D3 ditch</i>	0.0567	0.0567	0.0167	Spray drift	14. 11. 1992/9:00
<i>D4 pond</i>	0.391	0.391	1.293	Drainage	24. 12. 1985/17:00
<i>D4 stream</i>	0.550	0.549	0.576	Drainage	07. 12. 1985/9:00
<i>D5 pond</i>	0.554	0.554	1.644	Drainage	15. 02. 1979/18:59
<i>D5 stream</i>	0.579	0.579	0.526	Spray drift	04. 02. 1979/11:00
<i>D6 ditch</i>	2.764	2.763	1.819	Drainage	25. 12. 1986/12:00
<i>R1 pond</i>	0.0158	0.0158	0.0615	Run-off	31. 12. 1978/15:00
<i>R1 stream</i>	0.652	0.652	0.148	Run-off	25. 11. 1978/7:59
<i>R3 stream</i>	0.907	0.906	0.532	Run-off	26. 11. 1980/1:59
<i>R4 stream</i>	0.275	0.275	0.0761	Run-off	21. 12. 1979/2:00
Results obtained at Step 4, 10-metres buffer zone, VFS-modFOCUS					
FOCUS Scenario	PEC _{SW} [µg/L]		PEC _{SED} [µg/kg]	Dominant migration route	Date of maximum
	total	dissolved			
<i>D1 ditch</i>	2.680	2.679	7.476	Drainage	16. 03.1982/15:59
<i>D1 stream</i>	1.672	1.671	4.470	Drainage	16. 03. 1982/8:009
<i>D2 ditch</i>	3.227	3.226	4.036	Drainage	20. 11. 1986/6:59
<i>D2 stream</i>	2.021	2.020	2.385	Drainage	20. 11. 1986/6:59
<i>D3 ditch</i>	0.109	0.109	0.0315	Spray drift	14. 11. 1992/9:00
<i>D4 pond</i>	0.394	0.393	1.304	Drainage	24. 12. 1985/15:00
<i>D4 stream</i>	0.550	0.549	0.577	Spray drift	12. 09. 1985/9:00
<i>D5 pond</i>	0.556	0.556	1.654	Drainage	15. 02. 1979/18:59
<i>D5 stream</i>	0.579	0.579	0.526	Spray drift	27. 11. 1978/9:00
<i>D6 ditch</i>	2.764	2.763	1.834	Drainage	25. 12. 1986/12:00
<i>R1 pond</i>	0.0164	0.0164	0.0517	Spray drift	14. 11. 1978/9:00
<i>R1 stream</i>	0.0969	0.0969	0.0108	Spray drift	14. 11. 1978/9:00
<i>R3 stream</i>	1.275	1.274	2.078	Run-off	26. 12. 1980/1:59
<i>R4 stream</i>	0.0975	0.0975	0.0125	Spray drift	03. 11. 1979/9:00

Table 2.8.6.-31: The maximum PEC_{SW} and PEC_{SED} values obtained for the degradation products of Flufenacet.

Compound	Obtained results:					
	STEP 1		STEP 2			
	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]	North Europe		South Europe	
			PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]
<i>FOE Oxalate</i>	6.466	0.685	2,540	0.269	2.039	0.216
<i>FOE Sulfonic acid</i>	7.941	0.881	3.748	0.416	3.004	0.333
<i>FOE Methylsulfone</i>	1.896	1.154	0.944	0.575	0.767	0.467
<i>FOE Methylsulfide</i>	0.084	0.278	0.084	0.277	0.084	0.277
<i>FOE Thiadone</i>	1.464	0.606	0.543	0.225	0.518	0.215
<i>FOE 5043-Trifluoroethanesulfonic acid</i>	1.084	0.000	0.352	0.000	0.281	0.000
<i>Trifluoroacetic acid (TFA)</i>	10.228	0.000	5.100	0.000	4.080	0.000

d) Results obtained for the use at spring at 160 g Flufenacet/ha:

Table 2.8.6.-32: The maximum PEC_{SW} and PEC_{SED} values obtained for Flufenacet.

Results obtained at Step 1 and Step2					
STEP 1		STEP 2			
		North Europe		South Europe	
PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]
41.636	100.081	8.076	19.337	14.956	36.020
Results obtained at Step 3					
FOCUS Scenario	PEC _{SW} [□ g/L]		PEC _{SED} [□ g/kg]	Dominant migration route	Date of maximum
	total	dissolved			
<i>D1 ditch</i>	1.129	1.128	0.884	Spray drift	29. 03.1982/9:00
<i>D1 stream</i>	0.838	0.838	0.322	Spray drift	29. 03. 1982/9:00
<i>D2 ditch</i>	2.412	2.412	1.088	Drainage	19. 05. 1986/7:00
<i>D2 stream</i>	1.574	1.573	0.530	Drainage	19. 05. 1986/6:00
<i>D3 ditch</i>	1.014	1.013	0.336	Spray drift	20. 04. 1992/9:00
<i>D4 pond</i>	0.0357	0.0356	0.0968	Spray drift	19. 03. 1985/9:00
<i>D4 stream</i>	0.763	0.763	0.0252	Spray drift	19. 03. 1985/9:00
<i>D5 pond</i>	0.0387	0.0387	0.114	Spray drift	08. 04. 1978/9:00
<i>D5 stream</i>	0.818	0.818	0.0322	Spray drift	08. 04. 1978/9:00
<i>D6 ditch</i>	1.009	1.009	0.215	Spray drift	27. 02. 1986/9:00
<i>R1 pond</i>	0.0913	0.0912	0.254	Run-off	30. 05. 1984/12:00
<i>R1 stream</i>	1.021	1.020	0.333	Run-off	20. 05. 1984/2:00
<i>R3 stream</i>	1.450	1.449	0.606	Run-off	20. 04. 1980/1:59
<i>R4 stream</i>	0.668	0.668	0.203	Spray drift	21. 03. 1984/9:00
Results obtained at Step 4, 10-metres buffer zone, FOCUS					
FOCUS Scenario	PEC _{SW} [µg/L]		PEC _{SED} [µg/kg]	Dominant migration route	Date of maximum
	total	dissolved			
<i>D1 ditch</i>	0.259	0.259	0.561	Spray drift	29. 03.1982/9:00
<i>D1 stream</i>	0.218	0.218	0.308	Spray drift	29. 03. 1982/9:00
<i>D2 ditch</i>	2.412	2.412	1.076	Drainage	19. 05. 1986/7:00
<i>D2 stream</i>	1.574	1.573	0.530	Drainage	19. 05. 1986/6:00
<i>D3 ditch</i>	0.146	0.146	0.0514	Spray drift	20. 04. 1992/9:00
<i>D4 pond</i>	0.0224	0.0224	0.0690	Spray drift	19. 03. 1985/9:00
<i>D4 stream</i>	0.148	0.148	0.0189	Spray drift	19. 03. 1985/9:00
<i>D5 pond</i>	0.0255	0.0255	0.0778	Spray drift	08. 04. 1978/9:00
<i>D5 stream</i>	0.160	0.160	0.0134	Spray drift	08. 04. 1978/9:00
<i>D6 ditch</i>	0.153	0.152	0.0565	Spray drift	27. 02. 1986/9:00
<i>R1 pond</i>	0.0422	0.0422	0.124	Run-off	30. 05. 1984/12:00
<i>R1 stream</i>	0.464	0.464	0.148	Run-off	20. 05. 1984/2:00
<i>R3 stream</i>	0.662	0.662	0.262	Run-off	20. 04. 1980/1:59
<i>R4 stream</i>	0.287	0.286	0.0927	Run-off	15. 05. 1984/12:59
Results obtained at Step 4, 20-metres buffer zone, FOCUS					
FOCUS Scenario	PEC _{SW} [µg/L]		PEC _{SED} [µg/kg]	Dominant migration route	Date of maximum
	total	dissolved			
<i>D1 ditch</i>	0.232	0.232	0.534	Drainage	20. 11.1982/2:00
<i>D1 stream</i>	0.168	0.168	0.308	Drainage	26. 10. 1982/15:59
<i>D2 ditch</i>	2.412	2.412	1.075	Drainage	19. 05. 1986/7:00
<i>D2 stream</i>	1.574	1.574	0.530	Drainage	19. 05. 1986/6:00
<i>D3 ditch</i>	0.0756	0.0756	0.0273	Spray drift	20. 04. 1992/9:00
<i>D4 pond</i>	0.0153	0.0152	0.0599	Spray drift	19. 03. 1985/9:00
<i>D4 stream</i>	0.0769	0.0769	0.0189	Spray drift	19. 03. 1985/9:00
<i>D5 pond</i>	0.0183	0.0183	0.0582	Spray drift	08. 04. 1978/9:00
<i>D5 stream</i>	0.0836	0.0835	0.0113	Spray drift	08. 04. 1978/9:00
<i>D6 ditch</i>	0.0834	0.0834	0.0448	Spray drift	27. 02. 1986/9:00
<i>R1 pond</i>	0.0237	0.0237	0.0725	Run-off	30. 05. 1984/12:00
<i>R1 stream</i>	0.0243	0.0243	0.0780	Run-off	20. 05. 1984/2:00
<i>R3 stream</i>	0.348	0.348	0.138	Run-off	20. 04. 1980/1:59
<i>R4 stream</i>	0.150	0.150	0.0492	Run-off	15. 05. 1984/12:59

Table 2.8.6.-33: The maximum PEC_{SW} and PEC_{SED} values obtained for Flufenacet - continued.

Results obtained at Step 4, 10-metres buffer zone, VFS-mod					
FOCUS Scenario	PEC _{SW} [µg/L]		PEC _{SED} [µg/kg]	Dominant migration route	Date of maximum
	total	dissolved			
<i>D1 ditch</i>	0.259	0.259	0.561	Spray drift	29. 03.1982/9:00
<i>D1 stream</i>	0.218	0.218	0.308	Spray drift	29. 03. 1982/9:00
<i>D2 ditch</i>	2.412	2.412	1.076	Drainage	19. 05. 1986/7:00
<i>D2 stream</i>	1.574	1.574	0.530	Drainage	19. 05. 1986/6:00
<i>D3 ditch</i>	0.146	0.146	0.0514	Spray drift	20. 04. 1992/9:00
<i>D4 pond</i>	0.0224	0.0224	0.0690	Spray drift	19. 03. 1985/9:00
<i>D4 stream</i>	0.148	0.148	0.0189	Spray drift	19. 03. 1985/9:00
<i>D5 pond</i>	0.0255	0.0255	0.0778	Spray drift	08. 04. 1978/9:00
<i>D5 stream</i>	0.160	0.160	0.0134	Spray drift	08. 04. 1978/9:00
<i>D6 ditch</i>	0.153	0.152	0.0565	Spray drift	27. 02. 1986/9:00
<i>R1 pond</i>	0.0218	0.0217	0.0541	Spray drift	26. 04. 1984/9:00
<i>R1 stream</i>	0.129	0.129	0.0149	Spray drift	26. 04. 1984/9:00
<i>R3 stream</i>	0.452	0.452	0.190	Run-off	20. 04. 1980/1:59
<i>R4 stream</i>	0.129	0.129	0.0150	Spray drift	21. 03. 1984/9:00

Table 2.8.6.-34: The maximum PEC_{SW} and PEC_{SED} values obtained for the degradation products of Flufenacet.

Compound	Obtained results:					
	STEP 1		STEP 2			
			North Europe		South Europe	
	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]
<i>FOE Oxalate</i>	8.622	0.913	1.384	0.147	2.719	0.288
<i>FOE Sulfonic acid</i>	10.588	1.174	2.020	0.224	4.005	0.444
<i>FOE Methylsulfone</i>	2.528	1.538	0.549	0.334	1.022	0.622
<i>FOE Methylsulfide</i>	0.111	0.371	0.111	0.369	0.111	0.369
<i>FOE Thiadone</i>	1.952	0.808	0.624	0.259	0.691	0.286
<i>FOE 5043-Trifluoroethanesulfonic acid</i>	1.445	0.000	0.188	0.000	0.375	0.000
<i>Trifluoroacetic acid (TFA)</i>	13.638	0.000	2.720	0.000	5.438	0.000

e) Results obtained for the use at spring at 120 g Flufenacet/ha:

Table 2.8.6.-35: The maximum PEC_{SW} and PEC_{SED} values obtained for Flufenacet.

Results obtained at Step 1 and Step2					
STEP 1		STEP 2			
		North Europe		South Europe	
PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]
31.227	75.061	6.057	14.503	11.217	27.015
Results obtained at Step 3					
FOCUS Scenario	PEC _{SW} [µg/L]		PEC _{SED} [µg/kg]	Dominant migration route	Date of maximum
	total	dissolved			
<i>D1 ditch</i>	0.846	0.846	0.665	Spray drift	29. 03.1982/9:00
<i>D1 stream</i>	0.629	0.628	0.421	Spray drift	29. 03. 1982/9:00
<i>D2 ditch</i>	1.702	1.701	0.786	Drainage	19. 05. 1986/7:00
<i>D2 stream</i>	1.111	1.010	0.379	Drainage	19. 05. 1986/6:00
<i>D3 ditch</i>	0.760	0.760	0.254	Spray drift	20. 04. 1992/9:00
<i>D4 pond</i>	0.0267	0.0267	0.0733	Spray drift	19. 03. 1985/9:00
<i>D4 stream</i>	0.572	0.572	0.0189	Spray drift	19. 03. 1985/9:00
<i>D5 pond</i>	0.0289	0.0288	0.0852	Spray drift	08. 04. 1978/9:00
<i>D5 stream</i>	0.614	0.613	0.0238	Spray drift	08. 04. 1978/9:00
<i>D6 ditch</i>	0.756	0.756	0.161	Spray drift	27. 02. 1986/9:00
<i>R1 pond</i>	0.0687	0.0687	0.193	Run-off	30. 05. 1984/12:00
<i>R1 stream</i>	0.764	0.764	0.251	Run-off	20. 05. 1984/2:00
<i>R3 stream</i>	1.080	1.080	0.457	Run-off	20. 04. 1980/1:59
<i>R4 stream</i>	0.501	0.501	0.155	Spray drift	21. 03. 1984/9:00

Table 2.8.6.-37: The maximum PEC_{SW} and PEC_{SED} values obtained for Flufenacet - continued.

Results obtained at Step 4, 10-metres buffer zone, FOCUS					
FOCUS Scenario	PEC _{SW} [µg/L]		PEC _{SED} [µg/kg]	Dominant migration route	Date of maximum
	total	dissolved			
D1 ditch	0.194	0.194	0.420	Spray drift	29. 03.1982/9:00
D1 stream	0.163	0.163	0.231	Spray drift	29. 03. 1982/9:00
D2 ditch	1.702	1.701	0.777	Drainage	19. 05. 1986/7:00
D2 stream	1.111	1.110	0.379	Drainage	19. 05. 1986/6:00
D3 ditch	0.109	0.109	0.0389	Spray drift	20. 04. 1992/9:00
D4 pond	0.0169	0.0169	0.0520	Spray drift	19. 03. 1985/9:00
D4 stream	0.111	0.111	0.0142	Spray drift	19. 03. 1985/9:00
D5 pond	0.0190	0.0190	0.0583	Spray drift	08. 04. 1978/9:00
D5 stream	0.120	0.120	0.00969	Spray drift	08. 04. 1978/9:00
D6 ditch	0.114	0.114	0.0410	Spray drift	27. 02. 1986/9:00
R1 pond	0.0318	0.0318	0.0945	Run-off	30. 05. 1984/12:00
R1 stream	0.347	0.347	0.111	Run-off	20. 05. 1984/2:00
R3 stream	0.493	0.493	0.197	Run-off	20. 04. 1980/1:59
R4 stream	0.217	0.217	0.0707	Run-off	15. 05. 1984/12:59
Results obtained at Step 4, 20-metres buffer zone, FOCUS					
FOCUS Scenario	PEC _{SW} [µg/L]		PEC _{SED} [µg/kg]	Dominant migration route	Date of maximum
	total	dissolved			
D1 ditch	0.169	0.169	0.400	Drainage	20. 11.1982/2:00
D1 stream	0.121	0.121	0.231	Drainage	26. 10. 1982/15:15
D2 ditch	1.702	1.701	0.776	Drainage	19. 05. 1986/7:00
D2 stream	1.111	1.110	0.379	Drainage	19. 05. 1986/6:00
D3 ditch	0.0569	0.0568	0.0207	Spray drift	20. 04. 1992/9:00
D4 pond	0.0114	0.0114	0.0450	Spray drift	19. 03. 1985/9:00
D4 stream	0.0577	0.0577	0.0142	Spray drift	19. 03. 1985/9:00
D5 pond	0.0135	0.0135	0.0431	Spray drift	08. 04. 1978/9:00
D5 stream	0.0626	0.0626	0.00804	Spray drift	08. 04. 1978/9:00
D6 ditch	0.0622	0.0622	0.0314	Spray drift	27. 02. 1986/9:00
R1 pond	0.0178	0.0178	0.0550	Run-off	30. 05. 1984/12:00
R1 stream	0.182	0.182	0.0588	Run-off	20. 05. 1984/2:00
R3 stream	0.259	0.259	0.104	Run-off	20. 04. 1980/1:59
R4 stream	0.114	0.113	0.0375	Run-off	15. 05. 1984/12:59
Results obtained at Step 4, 10-metres buffer zone, VFS-mod					
FOCUS Scenario	PEC _{SW} [µg/L]		PEC _{SED} [µg/kg]	Dominant migration route	Date of maximum
	total	dissolved			
D1 ditch	0.194	0.194	0.420	Spray drift	29. 03.1982/9:00
D1 stream	0.163	0.163	0.231	Spray drift	29. 03. 1982/9:00
D2 ditch	1.702	1.701	0.777	Drainage	19. 05. 1986/7:00
D2 stream	1.111	1.110	0.379	Drainage	19. 05. 1986/6:00
D3 ditch	0.109	0.109	0.0389	Spray drift	20. 04. 1992/9:00
D4 pond	0.0169	0.0169	0.0520	Spray drift	19. 03. 1985/9:00
D4 stream	0.111	0.111	0.0142	Spray drift	19. 03. 1985/9:00
D5 pond	0.0190	0.0190	0.0583	Spray drift	08. 04. 1978/9:00
D5 stream	0.120	0.120	0.00969	Spray drift	08. 04. 1978/9:00
D6 ditch	0.114	0.114	0.0410	Spray drift	27. 02. 1986/9:00
R1 pond	0.0164	0.0164	0.0411	Spray drift	26. 04. 1984/9:00
R1 stream	0.0971	0.0971	0.0112	Spray drift	26. 04. 1984/9:00
R3 stream	0.337	0.337	0.143	Run-off	20. 04. 1980/1:59
R4 stream	0.0971	0.0970	0.0113	Spray drift	21. 03. 1984/9:00

Table 2.8.6.-38: The maximum PEC_{SW} and PEC_{SED} values obtained for the degradation products of Flufenacet.

Compound	Obtained results:					
	STEP 1		STEP 2			
	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]	North Europe		South Europe	
	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]
FOE Oxalate	6.466	0.685	1.038	0.110	2.039	0.216
FOE Sulfonic acid	7.941	0.881	1.515	0.168	3.004	0.333
FOE Methylsulfone	1.896	1.154	0.412	0.250	0.767	0.467
FOE Methylsulfide	0.084	0.278	0.084	0.277	0.084	0.277
FOE Thiadone	1.464	0.606	0.468	0.194	0.518	0.215
FOE 5043-Trifluoroethanesulfonic acid	1.084	0.000	0.141	0.000	0.281	0.000
Trifluoroacetic acid (TFA)	10.228	0.000	2.040	0.000	4.080	0.000

Calculations of the PEC_{SW} values for representative formulation:

Additionally the RMS carried out the calculations of the PEC values for the representative formulation. The calculations were performed using the drift calculator – tool inbuilt into the FOCUS SWASH modelling tool. They were performed for the SW water bodies and adequate FOCUS distances defined at Step 3.

The assumptions used in calculations are presented below in the table 2.8.6.-39 and the obtained results in the next table – 2.8.6.-40. Only the ini. PEC_{SWL} values are presented, as only they are relevant for the formulation. At the same time it shall be indicated that due to the nature of the representative formulation – it contains two active substances, the values are of rather informative value and limited usefulness in the current assessment, and they were provided for completeness.

Table 2.8.6.-39: The assumptions used in calculations of PEC_{SW} for the formulation.

Crop scenario ¹⁾	Type of formulation ²⁾	Density of formulation	Application rate of formulation		Calculated on the basis of:
			[L/ha]	[g/ha]	
<i>Cereals, BBCH 10 – 13; 240 g/ha; CI = 0%</i>	400 g/L FFA + 200 g/L DFF SC	1.251 g/cm ³ (T = 20°C)	0.6	750.6	formulation's density
<i>Cereals, BBCH 11 – 13; 160 g/ha; CI = 0%</i>	400 g/L FFA + 200 g/L DFF SC	1.251 g/cm ³ (T = 20°C)	0.4	500.4	formulation's density
<i>Cereals, BBCH 00 – 22; 120 g/ha; CI = 0%</i>	400 g/L FFA + 200 g/L DFF SC	1.251 g/cm ³ (T = 20°C)	0.3	375.3	formulation's density

Footnotes to the table:

- 1) The given application rate is for Flufenacet;
 2) FFA stands for Flufenacet and DFF for Diflufenican.

Table 2.8.6.-40: The results of the calculations of PEC_{SW} for the formulation.

Crop	Formulation	Application rate of the formulation [g/ha]	Results		
			Type of water body	Distance from the water body to the edge of the field [metres]	PEC _{SW} [µg/L]
<i>Cereals, BBCH 10 – 13; 240 g/ha; CI = 0%</i>	400 g/L FFA + 200 g/L DFF SC	750.6	<i>FOCUS ditch</i>	1.00	4.8223
			<i>FOCUS pond</i>	3.50	0.1644
			<i>FOCUS stream</i>	1.50	3.5788
<i>Cereals, BBCH 11 – 13; 160 g/ha; CI = 0%</i>	400 g/L FFA + 200 g/L DFF SC	500.4	<i>FOCUS ditch</i>	1.00	3.2149
			<i>FOCUS pond</i>	3.50	0.1096
			<i>FOCUS stream</i>	1.50	2.3858
<i>Cereals, BBCH 00 – 22; 120 g/ha; CI = 0%</i>	400 g/L FFA + 200 g/L DFF SC	375.3	<i>FOCUS ditch</i>	1.00	2.4112
			<i>FOCUS pond</i>	3.50	0.0822
			<i>FOCUS stream</i>	1.50	1.7894

The detailed numerical results of the calculations can be found in the document Vol. 3 B.8_CP, under the data point B.8.5., on pages 90 – 184. The graphical results of the assessment are presented in the same document, in the Appendix A4 for STEP-3 calculations and the Appendix A5 for the STEP-4 calculations.

4) Calculations of PEC_{AIR}:

The results of the assessment of fate and behaviour of Flufenacet and its degradation products in air showed that none of these compound posed any significant threat to the atmosphere. For that reason it was not necessary to calculate PEC_{AIR} values.

2.9. EFFECTS ON NON-TARGET SPECIES

2.9.1. Summary of effects on birds and other terrestrial vertebrates

The acute, dietary and reproductive toxicity studies with flufenacet have been performed with bobwhite quail and dietary and reproduction studies were performed on mallard duck. Studies were already submitted for the first EU peer-review of the active substance flufenacet. Two new acute toxicity studies, one for Canary (*Serinus canaria*) and another one for Mallard duck (*Anas platyrhynchos*), with the active substance-flufenacet, were submitted for the renewal of the authorization of the compound in the EU. All studies were performed in line with recommendations of the current guidelines and were considered acceptable by the RMS.

Two metabolites –TFA and FOE oxalate, were identified in cereals above 10% of TRR. For them no experiments aimed on the determination of their toxicity were performed and hence no toxicity endpoints were reported. However, in case of TFA the results of the toxicity of that compound to mammals showed that the compound was much less toxic than the active substance – Flufenacet.

Additionally, it was demonstrated, in a separate dietary study for hens, that the TFA administered in the food of the plant origin in amount up 78 mg TFA/kg food, equivalent to 0.5 mg/kg b.w, had no toxic effect on the test animals.

The calculations of intake by skylark of the residues found in grain and straw material after application of 270 g a.s./ha, resulted in uptake of 0.34 mg TFA /kg bw for herbal food with intake factor of 2.26, and 0.05 TFA/kg b.w./d. for grain food with intake of factor of 0.23. In practice the uptake of that compound with food was estimated to be lower than 0.5 mg TFA/kg/ b.w., the estimate provided in the hen dietary study. Therefore, the risk of dietary poisoning with TFA originating from flufenacet may be considered in case of wild avifauna, to be low.

As a result, it can be stated that the risk assessment for birds performed for Flufenacet will also cover that for TFA for the same group of organisms.

FOE oxalate (M1) was demonstrated to be a major metabolite in wheat forage, straw, hay and grain components.

It was shown to be found predominantly in grain. That metabolite, containing alkylo-fluorophenyl moiety, was included in the plant residue definition. The studies examining the toxicity of this metabolite to the livestock (lying hen, lactating goats, rats) and its residues in these organism showed that FOE Oxalate was not a product of metabolism of Flufenacet. Therefore, the sole route of exposure to it is with diet.

Dietary studies performed for lying hens, showed that FOE Oxalate when administered to the test animals with food was minimally absorbed. The absorbed FOE Oxalate was not metabolized and the tissue analysis showed that it was retained predominantly in liver. It may be assumed that from there it would be depurated with urine. Low levels of that compound in muscles and fat indicate that FOE Oxalate uptaken with food will not be cumulated in the organism. At the same time it shall be indicated that these results were obtained for FOE Oxalate administered at the level 5 mg/kg body weight, corresponding to approximately 350 times of exposure of poultry.

That indicates that the risk to wild bird resulting from the consumption of food containing that compound is expected to be minimal, if not negligible.

That indicates that the risk to wild bird resulting from the consumption of food containing that compound is expected to be minimal, if not negligible. From the available data it was not possible to derive the toxicity endpoint, but RMS is of the opinion that, on the basis of the evaluation presented above there is no need for doing that.

All derived endpoints are presented below in the Table 2.9.1-1, together with the listed source studies.

Table 2.9.1-1: Summary of toxicity flufenacet to birds.

Test species	Test design	Toxicity endpoints			Reference
Flufenacet					
Bobwhite quail (Colinus virginianus)	acute, oral	LD ₅₀	1608	mg a.s./kg bw	██████████ (1992) M-003866-01-1
Mallard duck (Anas platyrhynchos)		LD ₅₀	> 2000	mg a.s./kg bw	██████████ (1997) M-003851-01-1
Canary (Serinus canaria)		LD ₅₀	434	mg a.s./kg bw	██████████ 2013 M-468210-01-1
Bobwhite quail (Colinus virginianus)	5-day dietary	LC ₅₀ LDD ₅₀	> 5317 > 755	ppm mg a.s./kg bw/d	██████████ (1994) M-003859-0 -1
Mallard duck Anas platyrhynchos		LC ₅₀ LDD ₅₀	> 4970 > 949	ppm mg a.s./kg bw/d	██████████ (1993) M-003864-01-1
Bobwhite quail Colinus virginianus)	22-weeks feeding, reproduction	NOEC NOEL	441 34	ppm mg a.s./kg bw/d	██████████ (1994) M-003861-01-1

Test species	Test design	Toxicity endpoints			Reference
Mallard duck (Anas platyrhynchos)	21-weeks feeding, reproduction	NOEC NOEL	88 9.4	ppm mg a.s./kg bw/d	██████████ (1994) M-003858-01-1

Endpoints used in the regulatory risk included in the bold

Effects of flufenacet on mammals were investigated in numerous studies and were evaluated in Toxicology Section. For purposes of evaluation of the risk to wild mammals species, results of the studies on the acute, subchronic, dietary and developmental toxicity, as well as those of two-generation studies were considered.

All derived endpoints are presented in the table 2.9.2-1, together with the listed source studies.

Additionally for TFA metabolite, the results of the acute, subchronic dietary and developmental studies were taken into account. No toxicity endpoints are available for FOE oxalate.

In the studies performed on mammals – rats and lactating goats (representing livestock) it was demonstrated that that FOE Oxalate was not a product of metabolism of Flufenacet. It shall be therefore stated that, as it was in case of birds, the sole route of exposure to it was via food.

FOE Oxalate was demonstrated not to be metabolized within the body once absorbed from the digestive track. At the same time it shall be indicated that the level of absorption was low 70% was removed with faeces and 28% of the administered dose with urine. The depuration was fast – it occurred within 24 hours after uptake of the contaminated food. The accumulation of FOE Oxalate within the tissues was not observed. These results were obtained for the dose level of 1 mg/kg body weight (in studies with rats).

That indicates that the risk to wild mammals resulting from the consumption of food containing that compound is expected to be minimal, if not negligible.

All derived endpoints are presented in the Table 2.9.1-2 and Table 2.9.1-3 together with the listed source studies.

Table 2.9.1-2: Toxicity of flufenacet to mammals.

Test species	Study	Toxicity endpoints		Reference
Flufencet				
Rat	acute oral	LD ₅₀	♂ 1617 ♀ 589* mg a.s./kg bw	██████████ (1993) M-004865-02-1 and M-004865-02-1
Rat	two-generation reproduction	NOAEL	500 ppm (37.4 (F) and 41.4 (M)/ mg a.s./kg bw/d) ¹	██████████ (1995) M-004984-03-1

Bold values: Endpoints used for TER calculation for screening and/or Tier 1 Step.

* The value was included in the the LoEPs (2017), Section Toxicology.

¹ The ecotoxicological relevant NOAEL was discussed in the Vol.3 (CA), B9, under Point B.9.1.2.2.

Table 2.9.1-3: Toxicity of metabolite TFA to mammals.

Test species	Study	Toxicity endpoints		Reference
TFA				
Rat	acute oral	LD ₅₀	> 2000 mg met /kg bw	██████████ (2013) M-444479-01-1
Rat	90 days dietary	NOAEL _{ecotox}	1600 ppm (♂ 98, ♀ 123 mg met/kg bw/d)	██████████ (2007) M-283994-01-1 Evaluated by Diesing (2014)

Bold values: Endpoints used for TER calculation for screening and Tier 1 TER calculation.

NOAEL_{ecotox}=98 mg met/kg bw derived from administered dose of 1600 ppm (evaluated by Diesing (2014), M-477154-01-1, see Vol. 3, B.9, CA).

2.9.2. Summary of effects on aquatic organisms

Effects of flufenacet to aquatic organisms were investigated in acute and long-term toxicity studies performed with numerous species representative for each test group, including saltwater organism.

Due to the fact that green algae, e. g., *Pseudokirchneriella subcapitata* and aquatic macrophytes, e. g. *Lemna* sp., are the most sensitive groups to parent compound, the risk assessment for metabolites included in residue definition for the aquatic risk assessment, was in principle carried out in general only for these organisms. Only in some specific cases it was extended to other groups of the aquatic organisms.

However, for some aquatic metabolites the acute toxicity to fish or/and to aquatic invertebrates, including saltwater organism (*Americamysis bahia*, *Crassostrea virginica*), was examined. Studies on acute toxicity to *Lemna gibba* and *Pseudokirchneriella subcapitata* were carried out with the formulated product. It shall be indicated that not fully reliable studies for aquatic plants – *Lemna* sp., for the metabolite FOE sulfonic acid and for algae for metabolite Tiadone, were available. However it can be concluded that these studies can be used as supportive information appears that metabolites are clearly less toxic than parent compound.

All derived endpoints are presented in Tables B.2.9.2-1 (active substance), B.2.9.2-2 (metabolites) and B.2.9.2-3 (formulated product).

Table 2.9.2-1: Toxicity of Flufenacet to aquatic organism.

Organism	Test substance	Endpoint (type of the test)	Value (mg a.s./L)	Reference
Fish				
<i>Oncorhynchus mykiss</i> (Rainbow trout)	Flufenacet	96 h LC ₅₀ (static-renewal, Mortality)	5.84 mm	(1995) M-002379-01-1
<i>Lepomis macrochirus</i> (Bluegill sunfish)	Flufenacet	96 h LC ₅₀ (static-renewal, Mortality)	2.13 mm	(1995) M-002378-01-1
<i>Cyprius carpio</i>	Flufenacet	96 h LC ₅₀ (static-renewal, Mortality)	10-12 nom .>sat.con	(2010) M-361666-03-1
<i>Cyprinodon variegatus</i> (Sheepshead Minnow)	Flufenacet	96 h LC ₅₀ (static-renewal, Mortality)	3.31 mm	(1994) M-002422-01-1
<i>Oncorhynchus mykiss</i> (Rainbow trout)	Flufenacet	97-day NOEC (flow-through, ELS study, growth)	0.334 mm	(1995) M-002357-01-1
<i>Cyprinodon variegatus</i> (Sheepshead Minnow)	Flufenacet	35-day NOEC (flow-through, ELS study, growth)	0.049 mm	(2013) M-464909-01-1
<i>Pimephales promelas</i> (Fathead minnow)	Flufenacet	279-day NOEC (flow-through, FFLC study, growth)	0.138 mm	(2002) M-082934-01-1
Aquatic invertebrates				
<i>Daphnia magna</i> (Waterflea)	Flufenacet	48 h EC ₅₀ (static, motility)	30.9 mm	Bowers L.M (1994) M-003805-01-1
<i>Americamysis bahia</i> Mysid shrimp	Flufenacet	96 h LC ₅₀ (flow-through, mortality)	5.6 mm	Claude M.B., et al (2013)
<i>Crassostrea virginica</i> Eastern oyster	Flufenacet	96 h LC ₅₀ (mortality), 96 h EC ₅₀ (shell growth)	>13.9 mm 12.6 mm	Wheat & Evans (1993) M-002427-01-1
<i>Hyalella azteca</i>	Flufenacet	96 h LC ₅₀ (acute, static, mortality)	2.45 mm	Bowers L.M. (1995) M-002374-01-1
<i>Daphnia magna</i> Waterflea	Flufenacet	21-day NOEC (static-renewal, reproduction)	3.26 mm	Gagliano & Bowers (1994)
<i>Americamysis bahia</i> (Mysid shrimp)	Flufenacet	NOEC 28 d (flow-through, mortality,	0.221 mm	Claude, M.B. et al. (2013)

Organism	Test substance	Endpoint (type of the test)	Value (mg a.s./L)	Reference
		reproduction)		M-452207-01-1
Sediment dwelling organism				
Chironomus riparius	Flufenacet	28 d NOEC (static, developmental rate)	5 mg /L	Bruns E. (2010) M-372857-01-1
Algae				
Green algae Pseudokirchneriella subcapitata	Flufenacet	96 h E _r C ₅₀ NOE _r C 72 h E _y C ₅₀ NOE _y C (static)	0.00315 im < 0.00064 im 0.00178 im 0.00064 im	Bowers L.M.(1995) Dorgerloh M (1998) M-086475-01-1
Green algae Pseudokirchneriella subcapitata	Flufenacet	72 h E _r C ₅₀ NOE _r C 72 h E _y C ₅₀ NOE _y C (static test)	0.0212 geom 0.000138 geom 0.00538 geom 0.000138 geom	Bruns E (2010) M-363891-03-1
Pseudokirchneriella subcapitata (Green algae)	Flufenacet	96 h E _r C ₅₀ NOEC Static test	0.00645 nom. 0.00225 nom	Anderson J.P.E. (1997) M-002343-01-1
Green algae Pseudokirchneriella subcapitata	Flufenacet	72/96 h E _r C ₅₀ Geomean*	0.00755	Bruns E (2010) M-363891-03-1 Dorgerloh M M-086475-01-1 Anderson, J. P. E. (1997) M-002343-01-1
Green algae Desmodesmus subspicatus	Flufenacet	72 h E _r C ₅₀ NOE _r C 72 h E _y C ₅₀ NOE _y C (static test)	0.675 geom 0.0084 geom 0.07696 geom 0.0084 geom	Bruns E. (2011) M-415813-01-1
Chlorella vulgaris Green algae	Flufenacet	72 h E _r C ₅₀ NOE _r C 72 h E _y C ₅₀ NOE _y C (static test)	11.1 nom 0.98 nom 3.71 nom 0.98 nom	Bruns E. (2011) M-416169-01-1
Blue algae Synechococcus leopoliensis	Flufenacet	72 h E _r C ₅₀ NOE _r C 72 h E _y C ₅₀ NOE _y C (static test)	>10 nom 0.307 nom >10 nom 0.096 nom	Bruns E. (2011) M-415814-01-1
Blue-green algae Anabaena flos-aquae	Flufenacet	96h E _r C ₅₀ 96h E _y C ₅₀ NOE _r C NOE _y C (statitic test)	>53.2 mm 26.65 mm 3.77 mm <1.930 mm	Hugens&Alexander (1993) M-002423-01-1
Freshwater diatom <i>Navicula pelliculosa</i>	Flufenacet	96h E _r C ₅₀ 96h E _y C ₅₀ NOE _r C NOE _y C (static test)	5.044 mm 2.13 mm 1.120 mm 1.120 mm	Bowers, L. M.; Dobbs, M. G. (1995) M-002355-01-1 ¹
Chlamydomonas terricola	Flufenacet	216 h E _r C ₅₀ NOE _r C 216 E _y C ₅₀ NOE _y C	0.657 nom 0.096 nom 0.332 nom 0.0960 nom	Sobczyk H (2011) M-418627-01-1
Aquatic macrophyte				
Lemna gibba Duckwed	Flufenacet	7-day E _r C ₅₀ (frond no) NOE _r C 7-day E _y C ₅₀ (frond area) NOE _r C 7 -day E _y C ₅₀ (frond no) NOE _y C 7 -day E _y C ₅₀ (frond area) NOEC	0.0161 nom 0.000658 nom 0.0139 nom 0.000658 nom 0.00763 nom 0.00658 nom 0.006824 nom 0.00658 nom	Bruns (2013) M-451198-01-1

Organism	Test substance	Endpoint (type of the test)	Value (mg a.s./L)	Reference
Lemna gibba Duckweed	Flufenacet	Peak exposure: one or two 24-h-peaks; total test duration 14 d	No inhibition >50% up to 0.126 mg a.s./L peak E ₁ C ₅₀ >0.126 mg/L nom	Bruns (2013) ² M-452567-01-1

Values in bold were used in the risk assessment

mm = mean measured concentration, n... nominal, geom..... geometric mean measured concentration, im ...initial measured concentration
¹ The study is not fully reliable but can be used as supportive information.

² The study not used in the risk assessment. The study is valid it may be used in the refined risk assessment for macrophytes only if:

- Further evidence is provided that rooted macrophytes are not more sensitive to flufenacet than Lemna sp.
- The peak exposure design of the study covers the peaks observed in the FOCUS scenarios.

* geometric mean value E₁C₅₀ of there laboratory studies with Pseudokirchneriella subcapitata (Dorgerloch M, 1998: M-086475-01-1, Bruns E., 2010: M-363891-03-1 and and Anderson, J. P. E., 1997: M-002343-01-1)

Table 2.9.2-2: Toxicity of metabolites of flufenacet to aquatic organism.

Organism	Test substance	Endpoint (type of the test)	Value (mg/L)	Reference
Fish				
Oncorhynchus mykiss (Rainbow trout)	FOE sulfonic acid	96 h LC ₅₀ (static-renewal, mortality)	>86.7 nom	██████████ (1995) M-004932-01-1
Oncorhynchus mykiss (Rainbow trout)	FOE-Thiadone	96 h LC ₅₀ (static, mortality)	9.1 mm	██████████ (1998) M-005388-01-1
Lepomis Macrochirus (Bluegill)	FOE-Thiadone	96 h LC ₅₀ (static, mortality)	18.6 mm	██████████ (1999) M-009214-01-1
Sheepshead minnow (Cyprinodon variegatus)	FOE-Thiadone	96 h LC ₅₀ (static, mortality)	15.3 mm	██████████ C.V. (1999) M-005388-01-1
Brachydanio rerio (Zebra fish)	TFA	96 h LC ₅₀ (static, mortality)	>1200 nom	██████████ (1992) M-247889-01-1
Brachydanio rerio (Zebra fish)	TFA	144 h EC ₅₀ (embryo acute, static)	700 nom 3000 nom	██████████ (2013) M-462660-01-1 [*]
Aquatic invertebrates				
Daphnia magna (Waterflea)	FOE sulfonic acid	48 h EC ₅₀ (static, moratlity)	>87.3 nom	Heimbach F., (1995) M-004930-01-1
Daphnia magna (Waterflea)	FOE-Thiadone	48 h EC ₅₀ (static, mortality)	31.7 mm	Bowers L.M. & C.VLam (1998) M-005390-01-1
Mysidopsis bahia	FOE-Thiadone	96 h LC ₅₀ (Flow-through, mortality)	>15.1 mm	Palmer, S. J.; Krueger, H. O. (1998) M-005110-01-1
Crassostrea virginica Eastern oyster	FOE-Thiadone	96 h LC ₅₀ (Flow-through, mortality)	22 mm	Palmer S.J. & Krueger H. (1998) M-005110-01-1
Daphnia magna (Waterflea)	TFA	48 h LC ₅₀ (Static, mortality)	>1200 nom	Groeneveld et al. (1992) M-247890-01-1
Algae				
Green algae Pseudokirchneriella subcapitata	FOE oxalate	72 h E ₁ C ₅₀ NOE ₁ C 72 h E ₆ C ₅₀ NOE ₆ C (static test)	>100 nom >100 nom >100 nom >100 nom	Bruns E. (2009) M-358823-011
Green algae Desmodesmus subspicatus	FOE 5043-sulfonic acid	72 h E ₁ C ₅₀ NOE ₁ C 72 h E ₆ C ₅₀ NOE ₆ C (static test)	>86.7 nom ≥86.7 nom >86.7 nom ≥86.7 nom	Anderson (1995) M-004931-01-1
Green algae Pseudokirchneriella subcapitata	FOE methylsulfide	72 h E ₁ C ₅₀ NOE ₁ C 72 h E ₆ C ₅₀ NOE ₆ C	83.8 nom 10.0 nom 30.5 nom 10 nom	Dorgerlorh (1998) M-002341-01-1

Organism	Test substance	Endpoint (type of the test)	Value (mg/L)	Reference
Green algae <i>Pseudokirchneriella subcapitata</i>	FOE methylsulfone	72 h E_rC_{50} NOE _r C (static test)	> 10 nom >10 nom	Bruns (2010) M-364591-01-1
Green algae <i>Desmodesmus subspicatus</i>	FOE sulfonic acid	72 h E_rC_{50} 72 h E_bC_{50} NOE _b C NOE _r C (static test)	> 86.7 nom >86.7 nom ≥86.7 nom ≥86.7 nom	Anderson (1995) M-004931-01-1
Green algae <i>Pseudokirchneriella subcapitata</i>	TFA	72 h E_rC_{50} 72 h E_yC_{50} NOErC NOE _y C (static test)	192.48 nom 4.19 nom 0.36 <0.36	Groeneveld et al. (1992) M-247820-01-1
Green algae <i>Pseudokirchneriella subcapitata</i>	TFA	72 h E_rC_{50} 72 h E_bC_{50} NOE _{b,r} C	> 1.2 nom >1.2 nom 0.12 nom	Berends & Molenaar (1993) M-247818-02-1
Green algae <i>Scenedesmus supspicatus</i>	TFA	EC ₅₀	>120 nom	Berends, Keetelaar-Jansen, van Dijk (1995) M-247825-01-1 ¹
Green algae (various species)	TFA	E_rC_{50}	>112 to >2400 °	Berends (1996) M-247818-02-1*
Green algae <i>Pseudokirchneriella subcapitata</i>	FOE5043- (Trifluoroethane sulfonic acid)	96h E_rC_{50} 96h E_yC_{50} NOE _r C NOE _y C	> 100 nom >100 nom >100 nom >100 nom	Bruns (2012) M-444217-01-1
Green algae <i>Pseudokirchneriella subcapitata</i>	FOE Thiadone	72 h E_rC_{50} 72 h NOE _r C 72 h E_bC_{50} 72 h NOE _b C	15.0 nom 2.10 nom 4.10 nom 0.66 nom	Hall, A. T.; Lam, C. V., (1999) M-009214-01-1 ¹
Aquatic macrophyte				
Lemna gibba Duckweed	FOE oxalate	7-day E_rC_{50} (frond no) NOE _r C 7-day E_rC_{50} (frond area) NOE _r C	>100 nom 50 nom >100 nom >100 nom	Bruns E. (2009) M-358823-01-1
Lemna gibba Duckweed	FOE methylsulfide	7- day E_rC_{50} (frond no) NOE _r C 7-day E_rC_{50} (frond area) NOE _r C 7-day E_yC_{50} (frond no) NOE _y C 7-day E_yC_{50} (frond area) NOEC	125.30 nom 29.60 nom 106.0 nom 13.2 nom 65.02 nom 13.20 nom 61.97 nom 29.60 nom	Bruns E. (2010) M-393709-01-1
Lemna gibba Duckweed	FOE methylsulfone	7 day E_rC_{50} (frond no) NOE _r C 7-day E_rC_{50} (frond area) NOE _r C	> 100 nom >100 nom >100 nom ≥100 nom	Bruns E. (2010) M-369703-01-1
<i>Lemna gibba</i> Duckweed	FOE sulfonic acid	14 d E_rC_{50} (frond no) 14 d NOE _r C (frond no)	>79.5 mm >79.5 mm	Dorgerloh, M. (1995) M-004929-01-1 ¹
Lemna gibba Duckweed	TFA	7-d E_rC_{50} (frond no) 7-d NOEC 7 d E_yC_{50} (frond no) NOEC	1990 nom 300 nom 768.6 nom 600 nom	Smyth et al. (1993) M-247900-01-1
Lemna gibba <i>Myriophyllum spicatum</i> <i>Myriophyllum sibiricum</i>	TFA	7d EC ₅₀ 14 EC ₅₀ 14 EC ₅₀	618.3 (wet mass) 222.1 (root length) 357.1 (wet mass)	Hanson & Solomon, (2004) M-455787-01-1 *
Lemna gibba Duckweed	FOE-5043- Thiadone	7 d E_rC_{50} (frond no) NOE _r C 7 d E_rC_{50} (frond area) NOE _r C 7-day E_yC_{50} (frond no) NOE _y C 7-day E_yC_{50} (frond area) NOEC	20.80 nom <1.25 nom 18.32 nom 5.0 nom 9.86 nom <1.25 nom 8.68 nom <1.25 nom	Bruns E. (2010) M-393718-01-3
Lemna gibba Duckweed	FOE5043 (Trifluoroethane sulfonic acid)	7 d day E_rC_{50} (frond no) NOE _r C 7-day E_rC_{50} (frond area) NOE _r C	> 10 nom >10 nom >10 nom >10 nom	Weyers (2013) M-445884-01-1

Organism	Test substance	Endpoint (type of the test)	Value (mg/L)	Reference
		7 -day E_rC_{50} (frond no) NOE _{YC}	>10 nom >10 nom	
		7 -day E_rC_{50} (frond area) NOEC	>10 nom >10 nom	

mm = mean measured concentration, ...nominal concentration

values in bold were used in the risk assessment

¹ The study is not fully reliable but can be used as supportive information indicating that metabolite is clearly less toxic than active substance.

*The study is considered as additional information only

Table 2.9.2-3: Toxicity of representative formulaion to aquatic organism.

Organism	Test s ubstance	Endpoint (type of the test)	Value	Reference
<i>Lemna gibba</i> <i>Duckweed</i>	DFF+FFA 600 SC	7 d E_rC_5 (frond no) 7 d NOE _{YC} (frond no) 7 d E_bC_{50} (dry weight) 7 d NOE _{YC} (dry weight)	307 µg product/L nom 20 µg product/L nom 258 µg product/L nom 40 µg product/L nom	Dorgerloh, M., Sommer, H., (2001) M-073160-01-1 *
<i>Pseudokirchneriella</i> <i>subcapitata</i>	DFF+FFA 600 SC	72 h E_rC_{50} 72 h E_bC_{50} 72 h NOE _{YC} 72 h NOE _{YC}	6.63 µg product/L nom 2.42 µg product/L nom <0.938 µg product/Lnom <0.938 µg product/L nom	Dorgerloh, M., Sommer, H., (2001) M-073137-01-1 *

** The endpoints will not be used in the risk assessment until the Applicant reanalyses the results of the study using the measured initial concentrations.

Due to log Pow > 3, the determination of the potential for bioaccumulation in fish was required.

For none of the metabolites of flufenacet the log P_{ow} ≥ 3 (trigger value), therefore it was not necessary to assess the risk related to their bioaccumulation.

Table 2.9.2-4: Log Pow values for flufenacet and its metabolites

Substance	log P _{ow}
Flufenacet	3.5
	0.80
FOE oxalate (M01)	pH-dependent -2.0 (pH 5) -2.2 (pH 7) - 2.4 (pH 9)
FOE sulfonic acid (M02)	Not pH-dependent - 2.72
FOE methylsulfide (M05)	2.6 (pH 5) 2.6 (pH 7) 2.6 (pH 9)
FOE methylsulfone (M07)	1.7 (pH 5) 1.7 (pH 7) 1.7 (pH 9)
FOE-thiadone (M09)	pH-dependent 1.92 (pH 4.3) 0.62 (pH 7) - 0.90 (pH 9.4)
FOE 5043-trifluoroethanesulfonic acid (M44)	pH-dependent -3.0 (pH 5) -2.95 (pH 7) -3.16 (pH 9)
trifluoroacetic acid (TFA) (M45)	pH-dependent -2.5 (pH 5) -2.6 (pH 7) -2.8 (pH 9)

2.9.3. Summary of effects on arthropods

2.9.3.1. Effects on bees

Effects of flufenacet and representative formulation DFF+FFA SC 600 on bees were addressed in acute oral and contact toxicity studies. In addition, results of chronic laboratory test for adult bees were performed for the active substance - flufenacet. Also were presented the results of the examination of the toxicity of technical Flufenacet to bumble bees. The values shown in the table below are only those used in the risk assessment. Other data on the toxicity to pollinators were also made available and these are presented under the relevant data points in the Volume 3, B.9. (CA).

Table 2.9.3-1: Toxicity of flufenacet and formulation DFF+FFA SC 600 to bees.

Organism	Test substance	Time scale	Endpoint	Toxicity value	Reference
Honeybee (<i>Apis mellifera</i>)	Flufenacet tech.	48 h acute oral and contact toxicity test	LD ₅₀ -oral LD ₅₀ -contact	> 109.2 µg a.s./bee ¹ > 100 µg a.s./bee ¹	Schmitzer (2011) M-421687-01-1
Bumble bees	Flufenacet tech.	48 h acute contact	LD ₅₀ -contact	> 100 µg a.s./bee	Vergé (2014) M-356881-01-1
Honeybee (<i>Apis mellifera</i>)	DFF+FFA 600 SC	48 h acute oral and contact toxicity test	LD ₅₀ -oral LD ₅₀ -contact	>217.8 µg product/bee >200 µg product/bee	Schmitzer & Sekine (2009) M-356881-01-1
Chronic toxicity to adult bees (laboratory)					
Honeybee (<i>Apis mellifera</i>)	Flufenacet tech.	10 d chronic adult feeding study	LC ₅₀ NOEC	> 120 mg a.s./kg ≥ 120 mg a.s./kg (=4.42 µg a.s./bee)	Kling (2014) M-477339-01-1

¹ New proposed endpoints for active substance

A bee brood feeding study (Hecht-Rost (2012), M-456504-01-1) according to Oomen *et al.* (1992) was performed to observe the effect of the test substance (Flufenacet 508.8 SC) to immature honey bee life stages.

In course of its evaluation RMS stated that there were discrepancies between the study protocol, numerical results and their graphical presentation. Additionally it was stated that there were no statistically significant differences between response in the negative control and positive control (reference) in case of eggs and young larvae, although that was observed for the old larvae. RMS indicated that problem to the Applicant, receiving the information that the study will be updated and in that form it should be ready for commenting period. At the same time the Applicant informed RMS about the new, ongoing semi-field study performed fully in line with the requirements of the current OECD 75 Guideline, which should also be made available during the commenting period. Therefore, RMS would like to propose to include both studies into the assessment and evaluate them during the peer-review stage of the assessment process.

2.9.3.2. Effect on non-target arthropods other than bees

The toxicity of Flufenacet + Diflufenican SC 600 (DFF + FFA 600 SC) to non-target arthropods has been investigated by carrying out Tier I glass plate tests on the parasitoid wasp *Aphidius rhopalosiphii* and the predatory mite *Typhlodromus pyri*. In accordance with the ESCORT 2 guidance document (Candolfi *et al* 2001), due to their high sensitivity, these indicator species are considered to be representative of non-target arthropods for both in- and off-field environments. Tier 2 studies (extended laboratory studies) were generated for *Typhlodromus pyri*, green lacewing *Chrysoperla carnea* and the rove beetle *Aleochara bilineata*.

An aged residue study (extended laboratory study after ageing under semi-field conditions) has been conducted for DFF+FFA SC 600 with *T. pyri* to demonstrate the potential for recovery of this species.

The results of these studies are summarised in the Table 2.9.3. 2-1 below:

Table 2. 9.3.2- 1: Ecotoxicological endpoints for arthropods other than beefor DFF+FFA SC 600.

Test species, references	Tested Formulation, study type, exposure	% effects		
Typhlodromus pyri M-058604-01-1 Rep.No.: 9352063 Goßmann, A.; 2001	DFF+FFA SC 600 Laboratory, glass plates 22.5 mL prod./ha, 45 mL prod./ha, 90 mL prod./ha, 180 mL prod./ha, 360 mL prod./ha,	LR ₅₀ 81.8 mL prod./ha, Corr. Mortality [%] Effect on Reproduction [%]		
		1.9	1.3	
		9.2	-12.5 ^A	
		61.1	n.a.	
		92.6	n.a.	
		100	n.a.	
Typhlodromus pyri M-034242-01-1 Rep.No.: 01TYBYL12 Chauzat, M.P.; 2002	DFF+FFA SC 600 Extended lab., exposure on detached bean leaves 9.9 mL prod./ha, 28.7 mL prod./ha, 83.2 mL prod./ha, 241.4 mL prod./ha, 700 mL prod./ha,	LR ₅₀ 110.2 mL prod./ha, ER ₅₀ >83.2 mL prod./ha, Corr. Mortality [%] Effect on Reproduction [%]		
		0	4.4	
		0	13.3	
		17.1	-17.8 ^A	
		94.3	n.a.	
		100	n.a.	
Typhlodromus pyri M-355238-01-1 Rep.Nr.: CW09/026 Jans, D.; 2009	DFF+FFA SC 600 Aged residues, spray deposits on maize plants, 1 appl. of 0.7 L/ha, Residues aged for 0 days: Residues aged for 14 days: Residues aged for 28 days:	Corr. Mortality [%] Effect on Reproduction [%]		
		98.9	n.a.	
		87.1	n.a.	
		9.5	8.4	
Aphidius rhopalosiphi M-058618-01-1 Rep.No.: 9351001 Moll, M.; Buetzler, R.; 2001	DFF+FFA SC 600 Laboratory, glass plates 500 mL prod./ha, 600 mL prod./ha, 700 mL prod./ha,	LR ₅₀ > 700 mL prod./ha, ER ₅₀ > 700 mL prod./ha, Corr. Mortality [%] Effect on Reproduction [%]		
		0	9.0	
		2.0	14.0	
		2.0	3.5	
Chrysoperla carnea M-352372-01-1 Rep.No.: CW09/010 Waibel, J.; 2009	DFF+FFA SC 600 Extended lab., exposure on detached maize leaves Control 30 mL prod./ha, 63 mL prod./ha, 134 mL prod./ha, 284 mL prod./ha, 600 mL prod./ha,	LR ₅₀ > 600 mL prod./ha, No effect on reproduction Corr. Mortality Eggs/Female/Day Hatching [%]		
		-	26.4	79.9
		0.0	24.1	81.4
		7.7	23.9	80.7
		2.6	27.5	83.4
		7.7	28.4	82.5
		20.5	27.6	82.7
Aleochara bilineata M-353760-01-1 Rep.No.: 09 10 48 027 A Roehlig, U.; 2009	DFF+FFA SC 600 Extended lab., spray deposits on soil (LUFA 2.1) 60 mL prod./ha, 107 mL prod./ha, 190 mL prod./ha, 337 mL prod./ha, 600 mL prod./ha,	ER ₅₀ > 600 mL prod./ha, Effect on Reproduction [%]		
		4.3		
		-2.3 ^A		
		1.7		
		5.8		
		7.9		

^A: A negative value indicates a higher reproduction rate in the treatment than in the control.

n.a.: not assessed

2.9.4. Summary of effects on non-target soil meso- and macrofauna

2.9.4.1 Effects on earthworm

Effects of flufenacet, its metabolites and representative formulation DFF+FFA SC 600 on earthworms were investigated in long-term toxicity studies.

All studies were performed in line with recommendation of validated and agreed guidelines and were considered acceptable by the RMS. Summary of the deviated endpoints is presented in the Table 2.9.4.1-1 below:

Table 2.9.4.1-1: Toxicity of flufenacet, relevant soil metabolites and formulation DFF+FFA SC 600 to earthworms.

Test Substance	Test species	Toxicity endpoints		Reference
FOE oxalate	Earthworm, reproduction (10% peat in test soil)	NOEC	>100 mg p.m./kg dws	Leicher (2010) M-398163-01-1
FOE sulfonic acid-Na-salt	Earthworm, reproduction (5% peat in test soil)	NOEC	500 mg p.m./kg dws dws	Leicher (2009) M-358264-01-1
FOE methylsulfone	Earthworm, reproduction (5% peat in test soil)	NOEC	125 mg p.m./kg dws	Leicher (2010) M-362081-01-1
TFA	Earthworm, reproduction (10% peat in test soil)	NOEC	320 mg p. m./kg dws	Luehrs (2005) M-251328-01-1
FOE5043 -trifluoroethane sulfonic acid	Earthworm, reproduction (5% peat in test soil)	NOEC	100 mg p.m./kg dws	Kratz (2012) M-436340-01-1
FOE-Thiadone	Earthworm, reproduction (5% peat in test soil).	NOEC	3.2 mg p.m.kg dws	Kratz (2012) M-442579-01-1
DFF + FFA SC 600	Earthworm, reproduction (5% peat in test soil)	NOEC	2.6 mg product/kg sdw 1.3 mg product/kg sdw*	Leicher (2010) M-362809-01-1

* Endpoints corrected to allow for log $P_{ow} > 2$
pm pure metabolite

Two field studies were examined the influence on the population of earthworms.

One of them was the one-year earthworm field study with Flufenacet SC 500 (Leicher, 2008) applied on an arable field up to an application rate of 1.2 L/ha (600 g flufenacet/ha).

It was performed to examine the effect of the increasing application rate on the toxicity of flufenacet to natural earthworm population. Based on the results of that study it can be concluded that there was no long-term adverse effects, determined 5 and 11 months after application, in population of juvenile and adult earthworms resulting from application of 1.2 L Flufenacet 500 SC/ha.

Therefore, the determined NOAER = 1.2 L Flufenacet 500 SC/ha, corresponding to NOAER = 0.438 mg flufenacet/kg soil dw (measured value). However it should be indicated that the study was not used because the most sensitive species to flufenacet - *Octolasion lacteum*, identified as such in another field study, was not tested. Therefore, the NOAER value of 0.438 mg flufenacet/kg dws) was considered not appropriate to use in the risk assessment.

A one-year earthworm field study with the representative formulation DFF+ FFA SC 200+400 G was conducted in Southern Germany under field conditions, after one autumn application of Diflufenican SC 500A on bare soil, at a rate of 243.75 g diflufenican/ha (application 1), followed by once application of DFF+ FFA SC 200+400 G (diflufenican+flufenacet, application 2-DDA2): at different rates (0.6 L product/ha, 1.2 L product/ha and 1.8 L product/ha. Not statistically significant reduction in numbers and in biomass of total earthworms, total juveniles, total adults and single species occurred at any post treatment sampling (35, 183, 364 days) after application of the test item at rates of 0.6, 1.2 and 1.8 L/ha, following the plateau application of diflufenican at a rate of 243.77 g a.s/ha. However, it should be noted that biological significant effects (19-33%) could still be observed on the population *Octolasion lacteum* after 364 d at rates of 1.2. and 1.8 L/ha.

At rate of 0.6 L DFF+ FFA SC 200+400 G /ha biological significant but transient effects for this species were observed.

Therefore, **NOAER of 0.6 L DFF+ FFA SC 200+400 G /ha (leading to 0.203 mg flufenacet/kg soil dw, measured value)** was estimated from the study and this value was used in the risk assessment.

Table 2.9.4.1-2: Field studies to earthworms.

Test substance	Test species	Endpoint		Reference
FFA SC 500	Earthworm field study	NOAER	1.2 L prod./ha (correspond to 0.438 mg flufenacet/kg soil ws, measured value)*	Leicher (2008) M-307211-01-1
DFF + FFA SC 600	Earthworm field study	NOEAER	0.6 L product /ha (correspond to 0.203 mg flufenacet/kg soil dw, measured value)	Hamberger (2014) M-478092-01-1

* The study not included because the most sensitive species to flufenacet - *Octolasion lacteum*, identified as such in another field study, was not tested. Therefore, the NOAER value of 0.438 mg flufenacet/kg dws was not used in the risk assesment. (see C.A. Vol.3. B9 and CP. Vol.3 B9).

2.9.4.2. Other soil non target-macro-organism

Effects of flufenacet its metabolites and formulation DFF+ FFA SC 600 on soil non-target meso- and macrofauna were investigated in long-term toxicity studies performed with Collembolans and soil mite.

All studies were performed in line with recommendations of validated and agreed guidelines and were considered acceptable by the RMS. Summary of all derived endpoints is presented in the Table 2.9.4-3 below.

Table 2.9.4-3: Toxicity of flufenacet, relevant soil metabolites and formulation DFF+FFA 600 SC to other soil meso-and macrofauna.

Test substance	Test species	Toxicity endpoints	Reference
Flufenacet	<i>Folsomia candida</i>	NOEC=31.5* mg a.s./kg dws	Frommholz (2010) M-394712-01-1
	<i>Hypoaspis aculeifer</i>	NOEC=281* mg a.s./kg dws	Kratz (2013) M-455214-01-1
FOE oxalae	<i>Folsomia candida</i>	NOEC ≥100 mg p.m./kg dws	Frommholz (2010) M-394712-01-1
	<i>Hypoaspis aculeifer</i>	NOEC ≥100 mg p.m./kg dws	Kratz (2010) M-393634-01-1
FOE sulfonic acid-Na-salt	<i>Folsomia candida</i>	NOEC ≥100 mg p.m./kg dws	Frommholz (2010) M-396039-01-1
	<i>Hypoaspis aculeifer</i>	NOEC ≥100 mg p.m./kg dws	Kratz (2013) M-455654-01-1
FOE methylsulfone	<i>Folsomia candida</i>	NOEC≥100 mg p.m./kg dws	Frommholz (2010) M-392345-01-1
	<i>Hypoaspis aculeifer</i>	NOEC= 500 mg p.m./kg dws	Kratz (2009) M-357707-01-1
TFA	<i>Folsomia candida</i>	NOEC≥100 mg p.m./kg dws	Frommholz (2012) M-436127-01-1
	<i>Hypoaspis aculeifer</i>	NOEC≥100 mg p.m./kg dws	Kratz (2012) M-436326-01-1
FOE 5043-trifluoroethane sulfonic acid	<i>Folsomia candida</i>	NOEC≥100 mg p.m./kg dws	Frommholz (2012) M-436128-01-1
	<i>Hypoaspis aculeifer</i>	NOEC ≥100 mg p.m./kg dws	Kratz (2012) M-436315-01-1
FOE-Thiadone	<i>Folsomia candida</i>	NOEC=1.8 mg p.m./kg dws	Frommholz (2012) M-440372-01-1
	<i>Hypoaspis aculeifer</i>	NOEC=32 mg p.m./kg dws EC ₁₀ =28 mg p.m./kg dws	Kratz (2012) M-442897-01-1
DFF + FFA SC 600	<i>Folsomia candida</i>	NOEC _{corr} =89 mg product/kg* dws	Frommholz (2011) M-415903-01-1
	<i>Hypoaspis aculeifer</i>	NOEC ≥65.3 mg prod/kg dws	Feije (2002) M-061660-04-1

* Endpoints corrected to allow for log P_{ow} > 2
pm pure metabolite

2.9.5. Summary of effects on soil nitrogen transformation

Effects on soil nitrogen turnover were investigated in studies performed with flufenacet its soil metabolites and formulation DDF+FFA SC 600. Summary of all derived endpoints is presented in Table 2.9.5-1 below.

Table B. 2.9.5-1: Effects of flufenacet and its soil metabolites on soil nitrogen transformation.

Test item	Test design	Max tested concentration	% effect on soil nitrogen transformation rate at 28 days after treatment compared to control	Reference
Flufenacet	silty sand soils, 28 d	0.83 mg s.a./kg dws	+3.20	Anderson J.P.E (1994) M-003871-01-2
		4.13 mg s.a./kg dws	-0.60	
FOE oxalate	1 soil, 28 d	2.48 mg p.m./kg dws	+8	Lechelt-Kunze, 2005 M-250511-01-1
FOE sulfonic acid-Na-salt	1 soil, 28 d	3.27 mg p.m./kg dws	-8	Lechelt-Kunze, 2005 M-250265-01-1
FOE methylsulfone	1 soil, 28 d	0.60 mg p.m./kg dws	+4	Lechelt-Kunze, 2005 M-398568-01-1
		6.01 mg p.m./kg dws	-5	
TFA	1 soil, 28 d	0.32 mg p m /kg dws	+3.1	Frommholz, 2010 M-444423-01-1
		1.60 mg p.m./kg dws	+24.4	
FOE trifluoroethane sulfonic acid	1 soil, 28 d	0.164 mg p.m./kg dws	-2.3	Schulz, 2013 M-457331-01-1
		0.820 mg p.m./kg dws	+15.4	
FOE-Thiadone	1 soil, 28 d	0.149 mg p.m./kg dws	+19.3	Schulz, 2013 M-457326-01-1
		0.749 mg p.m./kg dws	-3.2	

2.9.6. Summary of effects on terrestrial non-target higher plants

Effects of representative formulation DFF+FFA SC 600 on seedling emergence and vegetative vigour of non-target terrestrial plants were investigated in a Tier 2 studies. Both studies were performed in line with recommendations of validated and agreed guidelines and were considered acceptable by the RMS.

In addition, the study for formulation Flufenacet SC 500 was evaluated by RMS to show the effects for flufenacet singularly. Summary of obtained results is presented in table 2.9 6-1 and Table 2.9.6-2 below.

Table 2.9.6-1: Tier 2 tests: Effects on seedling emergence and vegetative vigour of representative formulation DFF+FFA SC 600.

Species	Family	Shoot fresh weight ER ₅₀ (g of sum a.s./ha)		Reference
		Vegetative vigour study	Seedling emergence study	
MONOCOTYLEDONS				
Allium cepa (onion)	Liliaceae	> 332.3	100	Kalsch. W. 2002 M-071692-01-1 (Vegetative vigour test)
Avena sativa (oat)	Poaceae	227.54	207.88	
DICOTYLEDONS				
Brassica napus (oilseed rape)	Brassicaceae	92.07	214.22	Kalsch. W. 2002 (Seedling emergence test) M-072308-01-1
Cucumis sativa (cucumber)	Cucurbitaceae	27.75	218.41	
Glycine max (soybean)	Fabaceae	55.14	>332.3	
Lycopersicon esculentum (tomato)	Solanaceae	n.d.	>332.3	

Note: The single lowest endpoint for seedling emergence and vegetative vigour is indicated in bold. This endpoints were used in the risk assessment.

Note The endpoints are expressed in terms of sum of active substances (Flufenacet +Diflufenican).

Table 2.9.6-2: Tier 2 tests: Effects on seedling emergence and vegetative vigour of Flufenacet SC 500 formulation.

Table 2.10-2. Tier 2 tests: Effects on seedling emergence and vegetative vigour of Fenchone EC 50% formulation.				
Species	Family	Shoot fresh weight EC ₅₀ (g a.s./ha)*		Reference
		Vegetative vigour study	Seedling emergence study	
MONOCOTYLEDONS				
Zea mays (Corn)	Gramineae	>600	477.9	Friedrich S., (2005) M-248250-01-1 (Vegetative vigor test)
Avena sativa (Oats)	Gramineae	196	80.9	
Sorghum bicolor (Sweet sorghum)	Gramineae	43	10.5	
Lolium perenne (Perennial ryegrass)	Gramineae	17	11.5	
Allium cepa (Onion)	Liliaceae	132	53.3	Friedrich S., (2005) M-248250-01-1 (Seedlings emergence test)
DICOTYLEDONS				
Brassica rapa (Turnip)	Brassicaceae	167	282.7	
Beta vulgaris (Sugar beet)	Chenopodiaceae	525	275.4	
Cucumis sativa (Cucumber)	Cucurbitaceae	102	101.1	
Lycopersion esculentum (Tomato)	SolanaceaeFabacea	>600	93.6	
Soybean (Glycine max)	Fabaceae	168	>600	
		HC ₅ : 19.1 g a.s./ha Lolium perenne (Rye grass)	HC ₅ : 8.34 g a.s./ha Sorghu bicolor (Sorghum)	

Note: The single lowest endpoint for seedling emergence and vegetative vigour is indicated in bold.

*a.s.-flufenacet only

2.9.7. Summary of effects on other terrestrial organisms (flora and fauna)

Studies on effects on other terrestrial organisms are neither available nor required.

2.9.8. Summary of effects on biological methods for sewage treatment

Effects of flufenacet on biological methods for sewage treatment were addressed in study on toxicity to the activated sludge. The study was performed in line with recommendations of validated and agreed guideline and was considered acceptable by the RMS. Summary of results is presented in table 2.9.8-1 below together with the reference to documents where the study summary may be found.

Table B 2.9.8-1: Effects data of flufenacet to activated sludge.

Organism	Test design	Test substance	Endpoint	Reference
Activated sludge	Respiration inhibition, 3 h, static	Flufenacet	Activated sludge, inhibition of respiratory activity EC ₅₀ > 10000 mg a.s./L	Weyers A (2007) M-283846-01-1

2.9.9. Summary of product exposure and risk assessment

Exposure:

Aquatic organism

Exposure of birds and mammals was calculated with consideration of indicator species relevant for each crop and attributed SV values. Results of calculations are presented below in subchapter “Terrestrial vertebrates”. Exposure of aquatic organisms was calculated according to recommendations of the FOCUS group in a stepwise approach. Relevant modelling programs were used for determination of predicted environmental concentrations of fufenacet and its metabolites in surface water (PEC_{sw}) and sediment (PEC_{sed}) with consideration of intended use pattern as well as relevant degradation data and properties of particular compounds. With regard to metabolites, predicted concentrations were calculated for major aquatic metabolites as well as for soil metabolites, which may migrate to surface water as a result of run-off or drainage events. PEC_{sw} and PEC_{sed} values were calculated in a stepwise approach from Step 1 (worst case) to Step 4.

Details of performed simulations are presented under the point 2.8.6 of this document.

Maximum exposure of aquatic organisms was calculated for applications to cereals for the following scenarios:

- autumn use in winter cereals at rate 120 g a.s./ha, pre-emergence
- spring use in winter cereals at rate 120 g a.s./ha, post emergence
- autumn use in winter cereals at rate 160 g a.s./ha, post emergence
- spring use in winter cereals at rate 160 g a.s./ha, post emergence
- autumn use in winter cereals at rate 240 g a.s./ha, post emergence

Summary of worst case PEC_{sw} values for the active substance and metabolites taken into account in aquatic risk assessment is presented in Tables 2.9.9-1 to 2.9.9-6 below.

Table 2.9.9-1: Summary of maximum FOCUS Step 1 and Step 2 values for flufenacet.

Compound	FOCUS Step	Scenario	Winter cereals 120 g s.a./ha	Winter cereals 160 g s.a./ha	Winter cereals 240 g s.a./ha
			max PEC _{sw} (µg/L)	max PEC _{sw} (µg/L)	max PEC _{sw} (µg/L)
Flufenacet	STEP 1	Not relevant	31.227	41.636	62.454
	STEP 2	Northern Europe	13.797 ^a	18.395 ^a	27.593
			6.057 ^s	8.076 ^s	
		Southern Europe	11.217 ^a	14.956 ^a	22.433
			11.217 ^s	14.956 ^s	

a autumn application

s spring application

Table 2.9.9-2: Summary of maximum FOCUS Step 1 and Step 2 values for metabolites of flufenacet.

Compound	FOCUS Step	Scenario	Winter cereals 120 g s.a./ha	Winter cereals 160 g s.a./ha	Winter cereals 240 g s.a./ha
			max PEC _{sw} (µg/L)	max PEC _{sw} (µg/L)	max PEC _{sw} ^a (µg/L)
FOE Oxalate	STEP 1	Not relevant	6.466 ^a	8.622 ^a	12.933
	STEP 2		6.466 ^s	8.622 ^s	
		Northern Europe	2.540 ^a	3.386 ^a	5.079
			1.038 ^s	1.384 ^s	
FOE Sulfonic acid	STEP 1	Not relevant	2.039 ^a	2.719 ^a	4.078
	STEP 2		2.039 ^s	2.719 ^s	
		Northern Europe	7.941 ^a	10.588 ^a	15.882
			7.941 ^s	10.588 ^s	
FOE Methylsulfone	STEP 1	Not relevant	3.748 ^a	4.997 ^a	7.500
	STEP 2		1.515 ^s	2.020 ^s	
		Northern Europe	3.004 ^a	4.005 ^a	6.007
			3.004 ^s	4.005 ^s	
FOE Methylsulfide	STEP 1	Not relevant	1.896 ^a	2.528 ^a	3.792
	STEP 2		1.896 ^s	2.528 ^s	
		Northern Europe	0.944 ^a	1.259 ^a	1.888
			0.412 ^s	0.549 ^s	
FOE Thiadone	STEP 1	Not relevant	0.767 ^a	1.022 ^a	1.533
	STEP 2		0.756 ^s	1.022 ^s	
		Northern Europe	0.084 ^a	0.111 ^a	0.167
			0.084 ^s	0.111 ^s	
FOE- Trifluoroethanesulfo nic acid	STEP 1	Not relevant	0.084 ^a	0.111 ^a	0.167
	STEP 2		0.084 ^s	0.111 ^s	
		Northern Europe	0.084 ^a	0.111 ^a	0.167
			0.084 ^s	0.111 ^s	
TFA Trifluoroacetic acid	STEP 1	Not relevant	1.464 ^a	1.952 ^a	2.928
	STEP 2		1.464 ^s	1.952 ^s	
		Northern Europe	0.543 ^a	0.724 ^a	1.086
			0.468 ^s	0.624 ^s	
TFA Trifluoroacetic acid	STEP 1	Not relevant	0.518 ^a	0.691 ^a	1.036
	STEP 2		0.518 ^s	0.691 ^s	
		Northern Europe	1.084 ^a	1.445 ^a	2.168
			1.084 ^s	1.445 ^s	
TFA Trifluoroacetic acid	STEP 1	Not relevant	0.352 ^a	0.469 ^a	0.703
	STEP 2		0.141 ^s	0.188 ^s	
		Northern Europe	0.281 ^a	0.375 ^a	0.563
			0.281 ^s	0.375 ^s	
TFA Trifluoroacetic acid	STEP 1	Not relevant	10.228 ^a	13.638 ^a	20.457
	STEP 2	Northern Europe	10.228 ^s	13.638 ^s	
			5.100 ^a	6.800 ^a	10.200

Compound	FOCUS Step	Scenario	Winter cereals 120 g s.a./ha	Winter cereals 160 g s.a./ha	Winter cereals 240 g s.a./ha
			max PEC _{sw} (µg/L)	max PEC _{sw} (µg/L)	max PEC _{sw} ^a (µg/L)
			2.040 ^s	2.720 ^s	
		Southern Europe	4.080 ^a 4.080 ^s	5.444 ^a 5.438 ^s	8.160

^a autumn application^s spring application**Table 2.9.9-3: Summary of maximum FOCUS Step 3 values for flufenacet.**

Compound	FOCUS Step	Winter cereals 120 g s.a./ha		Winter cereals 160 g s.a./ha		Winter cereals 240 g s.a./ha
		Spring application max PEC _{sw} (µg/L)	Autumn application max PEC _{sw} (µg/L)	Spring application max PEC _{sw} (µg/L)	Autumn application max PEC _{sw} (µg/L)	Autumn application max PEC _{sw} (µg/L)
Flufenacet	D1 ditch	0.846	2.680	1.129	4.328	6.543
	D1 stream	0.629	1.672	0.838	2.699	4.082
	D2 ditch	1.702	3.227	2.412	3.957	6.199
	D2 stream	1.111	2.021	1.574	2.480	3.882
	D3 ditch	0.760	0.758	1.014	1.010	1.514
	D4 pond	0.0267	0.398	0.0357	0.756	1.168
	D4 stream	0.572	0.658	0.763	1.081	1.647
	D5 pond	0.0289	0.560	0.0387	0.766	1.170
	D5 stream	0.614	0.710	0.818	0.946	1.420
	D6 ditch	0.756	2.764	1.009	3.732	5.693
	R1 pond	0.0687	0.0609	0.0913	0.0797	0.116
	R1 stream	0.764	2.800	1.021	3.790	5.811
	R3 stream	1.080	3.783	1.450	4.980	7.641
	R4 stream	0.501	1.167	0.668	3.957	5.980

Table 2.9.9-4: Summary of maximum FOCUS Step 4, 10 m-meter buffer zone for flufenacet.

Compound	FOCUS Step	Buffer zone for [10 m]	Winter cereals 120 g s.a./ha		Winter cereals 160 g s.a./ha		Winter cereals 240 g s.a./ha
			Spring application max PEC _{sw} (µg/L)	Autumn application max PEC _{sw} (µg/L)	Spring application max PEC _{sw} (µg/L)	Autumn application max PEC _{sw} (µg/L)	Autumn application max PEC _{sw} (µg/L)
Flufenacet	D1 ditch	SD	0.194	2.680	0.259	4.328	6.543
	D1 stream	SD	0.163	1.672	0.218	2.699	4.082
	D2 ditch	SD	1.702	3.227	2.412	3.957	6.199
	D2 stream	SD	1.111	2.021	1.574	2.480	3.882
	D3 ditch	SD	0.109	0.109	0.146	0.145	0.218
	D4 pond	SD	0.0169	0.394	0.0224	0.750	1.159
	D4 stream	SD	0.111	0.550	0.148	1.081	1.674
	D5 pond	SD	0.0190	0.556	0.0255	0.761	1.163
	D5 stream	SD	0.120	0.579	0.160	0.812	1.249
	D6 ditch	SD	0.114	2.764	0.153	3.732	5.693
	R1 pond	SD	0.0318	0.0283	0.0422	0.0370	0.0543
	R1 stream	SD+RO	0.347	1.354	0.464	1.697	2.602
	R3 stream	SD+RO	0.493	1.728	0.662	2.246	3.446
	R4 stream	SD+RO	0.217	0.527	0.287	1.786	2.699

Table 2.9.9-5: Summary of maximum FOCUS Step 4, 20 m-meter buffer zone for flufenacet.

Compound	FOCUS Step	Buffer zone [20 m]	Winter cereals 120 g s.a./ha		Winter cereals 160 g s.a./ha		Winter cereals 240 g s.a./ha
			Spring application max PEC _{sw} (µg/L)	Autumn application max PEC _{sw} (µg/L)	Spring application max PEC _{sw} (µg/L)	Autumn application max PEC _{sw} (µg/L)	Autumn application max PEC _{sw} (µg/L)
Flufenacet	D1 ditch	SD	0.169	2.680	0.232	4.328	6.543
	D1 stream	SD	0.121	1.672	0.168	2.699	4.082
	D2 ditch	SD	1.702	3.227	2.412	3.957	6.199
	D2 stream	SD	1.111	2.021	1.574	2.480	3.882
	D3 ditch	SD	0.0569	0.0567	0.0756	0.0754	0.113
	D4 pond	SD	0.0114	0.391	0.0153	0.747	1.154
	D4 stream	SD	0.0577	0.550	0.0769	1.081	1.674
	D5 pond	SD	0.0135	0.554	0.0183	0.758	1.159
	D5 stream	SD	0.0626	0.579	0.0836	0.812	1.249
	D6 ditch	SD	0.0622	2.764	0.0834	3.732	5.693

Compound	FOCUS Step	Buffer zone [20 m]	Winter cereals 120 g s.a./ha		Winter cereals 160 g s.a./ha		Winter cereals 240 g s.a./ha
			Spring application max PEC _{sw} (µg/L)	Autumn application max PEC _{sw} (µg/L)	Spring application max PEC _{sw} (µg/L)	Autumn application max PEC _{sw} (µg/L)	Autumn application max PEC _{sw} (µg/L)
	R1 pond	SD	0.0178	0.0158	0.0237	0.0208	0.0310
	R1 stream	SD+RO	0.182	0.652	0.0243	0.883	1.354
	R3 stream	SD+RO	0.259	0.907	0.348	1.173	1.799
	R4 stream	SD+RO	0.114	0.275	0.150	0.933	1.410

Table 2.9.9-6: Summary of maximum FOCUS Step 4, 10 m-meter buffer zone, VFS-mod. for flufenacet.

Compound	FOCUS Step	Buffer zone for	Winter cereals 120 g s.a./ha		Winter cereals 160 g s.a./ha		Winter cereals 240 g s.a./ha
			Spring application max PEC _{sw} (µg/L)	Autumn application max PEC _{sw} (µg/L)	Spring application max PEC _{sw} (µg/L)	Autumn application max PEC _{sw} (µg/L)	Autumn application max PEC _{sw} (µg/L)
Flufenacet	D1 ditch	SD	0.194	2.680	0.259	4.328	6.543
	D1 stream	SD	0.163	1.672	0.218	2.699	4.082
	D2 ditch	SD	1.702	3.227	2.412	3.957	6.199
	D2 stream	SD	1.111	2.021	1.574	2.480	3.882
	D3 ditch	SD	0.109	0.109	0.146	0.145	0.218
	D4 pond	SD	0.0169	0.394	0.0224	0.750	1.159
	D4 stream	SD	0.111	0.550	0.148	1.081	1.674
	D5 pond	SD	0.0190	0.556	0.0255	0.761	1.163
	D5 stream	SD	0.120	0.579	0.160	0.812	1.249
	D6 ditch	SD	0.114	2.764	0.153	3.732	5.693
	R1 pond	SD	0.0164	0.0164	0.0218	0.0218	0.0326
	R1 stream	SD+RO	0.0971	0.0969	0.129	0.129	0.194
	R3 stream	SD+RO	0.337	1.275	0.452	0.181	0.272
	R4 stream	SD+RO	0.0971	0.0975	0.129	0.128	0.192

Bees and other non-target arthropods species

Calculations of exposure of bees and other non-target arthropod species are presented below in subchapters “Bees” and “Non-target arthropods other than bees”.

Soil organism

The exposure of soil organisms to flufenacet and its metabolites was estimated by calculating the maximum Predicted Environmental Concentrations in soil (PEC_{SOIL}).

The maximum PEC_{SOIL} of the formulation DFF+FFA SC 600, flufenacet and its metabolites in soil have been assessed using the FOCUS groundwater crop interception values (FOCUS 2011) and the maximum DT₅₀ values.

Since DT₅₀ values metabolites - FOE sulfonic acid-Na-salt, FOE-methylsulfone and TFA, are >100 days, potential for accumulation in soil was also taken into account by calculation of plateau concentrations.

Plateau PEC_{soil} values were summed up with maximum initial PEC_{soil} values in order to obtain PEC_{soil,accu}, recommended for long-term risk assessment.

Based on the recommended uses rate of 240 g flufenacet/ha, 160 g a.s./ha and 120 g a.s./ha, an as spray application in winter cereals, the max PEC_{SOIL} values are presented in Table 2.9.9-7 below:

Table 2.9.9-7: Maximum Predicted Environmental Concentration of the compounds in soil after application of the DFF + FFA SC 600 formulation to cereals.

Compound	Winter cereals 240 g a.s./ha BBCH 10-13, CI= 0%		Winter cereals 160 g a.s./ha BBCH 11-13, 0% CI=0%		Winter cereals 120 g a.s./ha BBCH 00-22, 0% CI=0%	
	PECs ¹ (mg/kg)	PEC _{acc} ² (mg/kg)	PECs ¹ (mg/kg)	PEC _{acc} ² (mg/kg)	PECs ¹ (mg/kg)	PEC _{acc} ² (mg/kg)
Flufenacet	0.3200	0.3210	0.2133	0.2140	0.1600	0.1605
FOE oxalate	0.0186	0.0187	0.0124	0.0125	0.0093	0.0094
FOE sulfonic acid-Na-salt	0.0452	0.0574	0.0302	0.0383	0.0226	0.0287
FOE methylsulfone	0.0134	0.0150	0.0089	0.010	0.0067	0.0075
TFA	0.0888	0.6184	0.0592	0.4122	0.0444	0.3092
FOE 5043-trifluoroethane sulfonic	0.0160	0.0160	0.0107	0.0107	0.0080	0.0080

Compound	Winter cereals 240 g a.s./ha BBCH 10-13, CI= 0%		Winter cereals 160 g a.s./ha BBCH 11-13, 0% CI=0%		Winter cereals 120 g a.s./ha BBCH 00-22, 0% CI=0%	
	PECs ¹ (mg/kg)	PEC _{acc} ² (mg/kg)	PECs ¹ (mg/kg)	PEC _{acc} ² (mg/kg)	PECs ¹ (mg/kg)	PEC _{acc} ² (mg/kg)
acid						
FOE-Thiadone	0.0236	0.0237	0.0157	0.0157	0.0118	0.0119
DFF + FFA SC 600*	1.0		0.667		0.500	

¹ PECs

PECsoil actual

² PEC_{acc}

PECsoil accumulated

In bold

PECs used in the risk assessment

*PEC

formulation, mg product/kg soil, density=1.251 g/mL

Non target terrestrial plants

Exposure of non-target terrestrial plants was calculated with consideration of drift rates relevant for given number of applications, as presented in Appendix 6 of the ESCORT 2 Guidance Document (Candolfi, M.P. et al., 2000). Results are presented below in subchapter “Non-target terrestrial plants”.

Risk assessment

Terrestrial vertebrates

The risk assessment for birds and mammals was performed according to recommendations of the EFSA Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009;7(12):1438).

The risk assessment is performed in stepwise approach, starting from screening step which considers worst case exposure assumptions and enables identification of substances that do not require further consideration.

For the screening step of the assessment, it was assumed that birds and mammals feed exclusively on the contaminated food which is not avoided and obtained only from the area where the formulation was applied.

In case, when the TER values at the screening step were less than the relevant trigger values, the Tier 1 assessment was performed. The generic focal species identified in EFSA (2009) together with respective SV values for the proposed uses in cereals were considered in the Tier 1 risk assessment.

The risk assessment was performed by calculation of TER values derived by comparison of relevant toxicity data and exposure estimates. The risk for TFA metabolite is covered by risk assessment of active substance.

Summary of toxicity endpoints is presented in point 2.9.1 of this document.

The acute and long-term risk assessment for birds and mammals was presented in the Tables 2.9.9-8 below:

Screening step – Birds

Table.2.9.9-8: Screening step – estimates of acute exposure and risk to flufenacet following application of DFF+FFA 600 SC in cereals.

Crop group	Indicator species	SVs	App. rate (kg a.s./ha)	MAF	DDD	LD ₅₀ (mg a.s./kg bw)	TER _A	Trigger value
Flufenacet								
Bare soil	small granivorous	24.7	0.120	1	2.96	434	146.62	≥10
Cereals	small omnivorous bird	158.8			19.05		22.78	
Cereals	small omnivorous bird	158.8	0.160	1 ¹	25.40		17.08	
Cereals	small omnivorous bird	158.8	0.240	1	38.1		11.39	

Table 2.9.9-9: Screening step – estimates of long-term exposure and risk to flufenacet following application of DFF+FFA SC 600 in cereals.

Crop group	Indicator species	SV _m	App. rate (kg a.s./ha)	MAF	f _{twa}	DDD	NOEL (mg a.s./kg bw/day)	TER _{LT}	Trigger value
Flufenacet									
Bare soil	small granivorous bird	11.4	0.120	1	0.53	0.72	9.4	13.05	≥5
Cereals	small omnivorous bird	64.8		1	0.53	4.12		2.28	
Cereals	small omnivorous bird	64.8	0.160	1	0.53	5.49		1.71	
Cereals	small omnivorous bird	64.8	0.240	1	0.53	8.24		1.14	

Note: TER shown in bold falls below the relevant trigger

All TER_{LT} values are above the relevant trigger values, except for long-term TER_{LT} value for flufenacet for omnivorous birds in cereals. Therefore, further consideration was needed.

Tier 1 Risk assessment - Birds

Table 2.9.9-10: Tier 1 – estimates of long-term exposure and risk to flufenacet following application of DFF+ FFA SC 600 in cereals.

Crop grouping/growth stage	Generic focal species	SV _m	App.rate (kg a.s./ha)	MAF	f _{twa}	DDD	NOEL (mg a.s./kg bw/day)	TER _{LT}	Trigger
Flufenacet									
Cereals BBCH 10-29	Small omnivorous birds “lark”	10.9	0.120	1	0.53	0.70	9.4	13.42	≥5
Cereals BBCH 10-29	Large herbivorous bird “goose” Pink-foot goose	16.2				1.03		9.12	
Cereals BBC 10-29	Small omnivorous birds “lark”	10.9	0.160	1	0.53	0.92	9.4	10.21	≥5
Cereal BBCH 10-29	Large herbivorous bird “goose” Pink-foot goose	16.2				1.37		6.86	
Cereals BBCH 10-29	Small omnivorous birds “lark”	10.9	0.240	1	0.53	1.39	9.4	6.76	≥5
Cereals BBCH 10-29	Large herbivorous bird “goose” Pink-foot goose	16.2				2.06		4.56	

Note: TER shown in bold falls below the relevant trigger

All TER_{LT} values are above the relevant trigger of 5, expect the large herbivores birds – Pink-foot goose for use in winter cereals at rate 240 g a.s./ha.

However, taking into account that flufenacet is intended to be used as a early post-emergence herbicide in winter cereals at maximum application rate of 240 g a.s./ha only in autumn, clearly outside the breeding season of birds, the exposure of some individuals which would could occur, is expected to be negligible.

RMS is of the opinion that the value of 4.56 is very close to the threshold value of 5 and for this reason may be considered acceptable. However, the futher refinement should be considered at MSs level.

Therefore, RMS proposes the refinement based on the longest DT₅₀ value, a flufenacet specific time-weighted average factor (f_{TWA}) for cereals calculated using the following formula from Appendix H of the EFSA Guidance Document:

$$f_{TWA} = \frac{1 - e^{-kt}}{kt}$$

Where: $k = \ln(2)/DT_{50}$ (rate constant)
 $t =$ averaging interval.

Using a standard averaging interval of 21 days, a DT_{50} of 5.101 days corresponds to a 21-day time-weighted-average factor (f_{TWA}) of 0.3302. Using the refined f_{TWA} value of 0.3302, the long-term risk assessment for „large herbivorous birds” is presented in Table B.9.9-11 below.

Table B.9.9-11: Refined reproductive risk (TER_{LT}) to large herbivorous birds using DT_{50} data from flufenacet residue trails in cereals.

Crop grouping/ growth stage	Generic focal species	Shortcut value (mg a.s./kg bw/day)	App. rate (kg a.s./ha)	MAF	f_{TWA}	DDD (mg a.s./kg bw/day)	NOEL (mg a.s./kg bw/day)	TER_{LT}	Trigger value
Cereals Early (shoots)	Large herbivorous bird “goose” Pink-foot goose	16.2	0.24	1	0.33	1.28	9.4	7.34	≥ 5

Considering the refined f_{TWA} value of 0.3302, using the longest DT_{50} days value, the TER_{LT} value is above the Annex VI trigger of 5 indicating acceptable long-term risk large herbivorous for birds.

Screening STEP – Mammals

Table 2.9.9-12: Screening step – estimates of acute exposure risk to flufenacet and TFA metabolite following application of DFF+FFA SC 600 in cereals.

of DDT+TFA SC 000 in cereals.								
Crop group	Indicator species	SVs	App. rate (kg a.s./ha)	MAF	DDD (mg a.s./kg bw)	LD ₅₀ (mg a.s./kg bw)	TER _A	Trigger
Flufenacet								
Bare soil	small granivorous mammal	14.4	0.120	1	1.73	589	340.46	≥10
Cereals	small herbivorous mammal	118.4		1	14.20		41.47	
Cereals	small herbivorous mammal	118.4	0.160	1	18.94		31.09	
Cereals	small herbivorous mammal	118.4	0.240	1	28.4		20.73	
TFA								
Bare soil	small granivorous mammal	14.4	0.0377*	1	0.54	>2000	3703.70	≥10
Cereals	small herbivorous mammal	118.4		1	4.46		448.43	
Cereals	small herbivorous mammal	118.4	0.0502*	1	5.94		336.70	
Cereals	small herbivorous mammal	118.4	0.0754*	1	8.93		223.96	

* Corrected for molecular weight of TFA (114.02g/mol, i.e. 31.4% of the parent flufenacet). Additionally, a formation of 100% TFA from flufenacet was assumed.

Table 2.9.9-13: Screening step – estimates of long-term exposure and risk to flufenacet and its metabolite TFA following application of DFF+FFA SC 600 in cereals.

Crop group	Indicator species	SVm	App. rate (kg a.s./ha)	MAF	f_{TWA}	Long-term DDD	NOAEL (mg a.s./kg bw/day)	TER_{LT}	Trigger
Flufenacet									
Bare soil	Small granivorous mammal	6.6	0.120	1	0.53	0.42	37.4	89.04	≥ 5
Cereals	Small herbivorous mammal	48.3				3.07		12.18	
Cereals	Small herbivorous mammal	48.3	0.160	1	0.53	4.09		9.14	

Crop group	Indicator species	SVm	App. rate (kg a.s./ha)	MAF	f _{twa}	Long-term DDD	NOAEL (mg a.s./kg bw/day)	TER _{LT}	Trigger
Cereals	Small herbivorous mammal	48.3	0.240	1	0.53	6.14		6.09	
TFA									
Bare soil	Small granivorous mammal	6.6	0.0377*	1	0.53	0.13	98	753.84	≥5
Cereals	Small herbivorous mammal	48.3				0.96		102.08	
Cereals	Small herbivorous mammal	48.3	0.0502*	1	0.53	1.28		76.56	
Cereals	Small herbivorous mammal	48.3	0.0754*	1	0.53	1.93		50.77	

* Corrected for molecular weight of TFA (114.02g/mol, i.e. 31.4% of the parent flufenacet).

Additionally, a formation of 100% TFA from flufenacet was assumed.

Note: TER shown in bold falls below the relevant trigger

Based on the screening assessment, the long-term TER values of the different exposure scenarios for flufenacet and its metabolite TFA following the proposed use of DFF+FFA SC 600 are above the Annex VI trigger value of 5, indicating an acceptable long-term risk to mammals.

Risk to birds through drinking water

According to the EFSA Guidance Document, two scenarios need to be considered for assessing the risk via the consumption of drinking water.

Taking into account intended use pattern, only puddle scenario was considered relevant. Detailed risk assessment was not required since ratio between effective application rates and endpoints relevant for acute and long-term exposure were all below the trigger of 3000 (trigger of 3000 was used since K_{foc} of flufenacet is >500 mL/g).

Calculated ratio of effective application rate to endpoints for flufenacet following use of DFF+ FFA SC 600 values are presented in Table 2.9.9-14.

Table 2.9.9-14: Ratios of effective application rate to endpoints for flufenacet following the use of DFF+FFA SC 600 in cereals.

Organism	Intended use	App. rate (g a.s./ha)	MAF	AR _{eff} (g a.s./ha)	LD ₅₀ (mg a.s./kg bw)	Ratio of AR _{eff} to LD ₅₀	NOA(E)L (mg a.s./kg bw/day)	Ratio of AR _{eff} to NOEL	Ratio trigger
Birds	Cereals	240	1	240*	434	0.55	9.4	25.53	≤50
Mammals	Cereals	240	1	240*	589	0.40	37.4	6.41	≤50

*The worst case scenario covers all remained uses

The resulting ratio is clearly below the trigger value of 50 indicating that the acute and long-term risk to birds via the consumption of drinking water can be considered acceptable without further calculations.

Effects of secondary poisoning:

According to the **EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009)**, substances with a log P_{OW} greater than 3 have potential for bioaccumulation. Only flufenacet has a log P_{OW} > 3 and therefore, based on the low log P_{OW} value, the risk assessment from bioaccumulation of that substance to fish-eating and worm-eating birds is required. For none of the metabolites of flufenacet the log P_{OW} exceed the trigger value of 3, therefore, the risk from bioaccumulation has not to be assessed for those metabolites.

Risk of secondary poisoning of earthworm-eating birds and mammals**Table 2.9.9.15. Estimates of exposure and risk to flufenacet through bioconcentration in earthworms following the application of DFF+FFA 600 SC in cereals.**

Organism	Log P _{ow}	K _{OC} (mL/g)	BCF _{worm}	PEC _{soil} (mg/kg)*	PEC _{worm}	DDD	NOA(E)L (mg a.s./kg bw/day)	TER	Trigger
Birds	3.5	245.9	7.9	0.320 ¹	2.53	2.65	9.4	3.54	≥5
				0.2133 ²	1.68	1.77		5.31	
				0.160 ³	1.26	1.32		7.12	
Mammals				0.320 ¹	2.53	3.23	37.4	11.57	
				0.2133 ²	1.68	2.15		17.39	
				0.160 ³	1.26	1.61		23.22	

1 Application rate 1 x 0.240 kg a.s./ha, 2 Application rate 1 x 0.160 kg a.s./ha, 3 Application rate 1 x 0.120 kg a.s./ha

*max PEC soil

The TER values for earthworm-eating birds was below the Annex VI trigger of 5 for maximum of application rate - 1 x 240 g a.s./ha, indicating the needs for further refinement.

Thus, the 21 d PEC_{sTWA} was used to refined the exposure through bioconcentration of flufenacet in earthworms following the application of DFF+FFA 600 SC in cereals.

Table 2.9.9.16: Estimates of exposure and risk to flufenacet through bioconcentration in earthworms following the application of DFF+FFA SC 600 at rate 240 g a.s./ha in cereals.

Organism	Log P _{ow}	K _{OC} (mL/g)	BCF _{worm}	21 d twa PEC _{soil} (mg/kg)	PEC _{worm}	DDD	NOEL (mg a.s./kg bw/day)	TER	Trigger
Birds	3.5	245.9	7.9	0.282*	2.23	2.35	9.4	4.0	≥5

*21 d PEC TWA for application rate 1 x 240 g a.s. /ha

The TER values for earthworm-eating birds was still below the Annex VI trigger of 5 for maximum of application rate - 1 x 240 g a.s./ha, indicating the needs for further refinement.

RMS proposes the refinement of DDD based on complete diet of blackbird according to information given in Bird Bible (*Buxton et al. 1998*).

The Bird Bible (*Buxton et al. 1998*) reported for blackbird diets that may be synthesized as:

1. 78% earthworms and 22% other invertebrates (April-May: nestling diet), OR
2. 43% earthworms and 57% other invertebrates (June; nestling diet), OR
3. 2% vegetable materials, 42% earthworms and 56% other invertebrates (no seasonal data; nestling)

The diet of the backbird in the first option of the refinement of the risk consists of 78% earthworms and 22% other invertebrates. It is relevant for nestlings, for the period April-May and Winter Oilseed Rape as a crop. Based on these assumptions calculations of food energy of total mixed diet, of the food intake rate (FIR) and TER values based on the refined, were all carried out in line with thre recoomendations of the relevant EFSA Guidance (EFSA; 2009). They are presented below in two tables – Table B.2.9.9-17 for the food energy of the total mixed diet and FIR, and Table B.2.9.9-18 for TER.

Table B.2.9.9-17: Calculation of food energy of total mixed diet and the food intake rate (FIR) in the first diet composition for blackbird.

Species	Food type	% in diet wet wt	kJ/g wet weight	kJ/g wet weight adjusted AE	Energy share (kJ) per 1 g mixed diet	Wet weight(g) of food types consumed	Wet weight(g) of food types consumed	FIR/bw
Passerines (Turdus merula-Blackbird)	Ground-dwelling invertebrates (w/o interception)	22%	7.082	5.383	1.1842	19.64	19.64	0.17
	Soil invertebrates	78%	2.972	2.259	1.7619	69.62	69.62	0.62
					sum	Wet wt (g) of whole diet to achieve DEE	Wet wt (g) of whole diet to achieve DEE	
					2.9461	89.26	89.26	

Log a=1.032, log b 0.676, DEE(KJ/d)=262.955

Table B.2.9.9-18: TER value based on the refined FIR/bw, RUD (90th) and PEC_{worm} for blackbird.

Species	FIR/bw	Food type	Wet wt (g) of food types consumed	Predefined RUD	User-defined RUD	IF (FOCUS)	MAF	DDD
Passerines (Turdus merula-Blackbird)	0.17	Ground-dwelling invertebrates (w/o interception)	19.64	13.8		-	0.53	0.303
	0.62	Soil invertebrates	69.62		PEC _{worm} x app.rate= 2.22 mg a.s./kg x 0.24 kg a.s./ha =9.3	-	-	1.37
								sum
								1.67
							TER	5.6

Considering other invertebrates as ground dwelling invertebrates without interception' using 90th percentile RUD and PEC_{worm} of 2.22, the first diet gave a worst TER of 5.6.

Therefore, the risk assessment to vermivorous birds following the intended use of the DFF+ FFA SC 600 is considered acceptable.

The second option of the refinement of the risk consists of 43% earthworms and 57% other invertebrates. It is relevant for nestlings, for the period June and Winter Oilseed Rape as a crop. Based on these assumptions calculations of food energy of total mixed diet, of the food intake rate (FIR) and TER values based on the refined, were all carried out in line with the recommendations of the relevant EFSA Guidance (EFSA; 2009). They are presented below in two tables – Table B.2.9.9-19 for the food energy of the total mixed diet and FIR, and Table B.2.9.9-20 for TER.

Table B.2.9.9-19: Calculation of food energy of total mixed diet and the food intake rate (FIR) in the second diet composition for blackbird.

Species	Food type	% in diet wet wt	kJ/g wet weight	kJ/g wet weight adjusted AE	Energy share (kJ) per 1 g mixed diet	Wet weight(g) of food types consumed	Wet weight(g) of food types consumed	FIR/bw
Passerines (Turdus merula-Blackbird)	Ground-dwelling invertebrates (w/o interception)	57%	7.082	5.383	3.0681	37.11	37.11	0.33
	Soil invertebrates	43%	2.972	2.259	0.9713	27.99	27.99	0.25
					Sum	Wet wt (g) of whole diet to achieve DEE	Wet wt (g) of whole diet to achieve DEE	
					4.039	65.10	65.10	

Log a=1.032, log b 0.676, DEE(KJ/d)=262.955

Table B.2.9.9-20: TER value based on the refined FIR/bw, RUD (90th) and PEC_{worm} for blackbird.

Species	FIR/bw	Food type	Wet wt (g) of food types consumed	Predefined RUD	User-defined RUD	IF (FOCUS)	MAF	DDD
Passerines (Turdus merula-Blackbird)	0.33	Ground-dwelling invertebrates (w/o interception)	37.11	13.8		-	0.53	0.573
	0.25	Soil invertebrates	27.99		PEC _{worm} x app.rate= 2.22 mg a.s./kg x 0.24 kg a.s./ha =9.3	-	-	0.551
								sum
							TER	8.4

Considering other invertebrates as ground dwelling invertebrates without interception' using 90th percentile RUD and PEC_{worm} of 2.22, the second diet gave a TER of 8.4.

Therefore, the risk assessment to vermivorous birds following the intended use of DFF+FFA SC 600 is considered acceptable.

The third option of the refinement of the risk consists of 2% vegetables materials, 42% earthworms and 42% other invertebrates. It is relevant for nestlings, no seasonal data. Based on these assumptions calculations of food energy of total mixed diet, of the food intake rate (FIR) and TER values based on the refined, were all carried out in line with three recommendations of the relevant EFSA Guidance (EFSA; 2009). They are presented below in two tables – Table B.9.9-21 for the food energy of the total mixed diet and FIR, and Table B.9.9-22 for TER.

Table B.9.9-21: Calculation of food energy of total mixed diet and the food intake rate (FIR) in the third diet composition for blackbird.

Species	Food type	% in diet wet wt	kJ/g wet weight	kJ/g wet weight adjusted AE	Energy share (kJ) per 1 g mixed diet	Wet weight(g) of food types consumed	Wet weight(g) of food types consumed	FIR/bw
Passerines (Turdus merula-Blackbird)	Grass and cereals	2%	4.154		3.157	1.31	1.31	0.01
	Ground-dwelling invertebrates (w/o interception)	56%	7.082	5.383	3.0143	36.57	36.57	0.32
	Soil invertebrates	42%	2.972	2.259	0.9487	27.43	27.43	0.24
					Sum	Wet wt (g) of whole diet to achieve DEE	Wet wt (g) of whole diet to achieve DEE	
					4.0261	65.31	65.31	

Log a=1.032, log b 0.676, DEE(KJ/d)=262.955

Table B.9.9-22: TER value based on the refined FIR/bw, RUDs and PEC_{worm} for blackbird.

Species	FIR/bw	Food type	Wet wt (g) of food types consumed	Predefined RUD	User-defined RUD	IF (FOCUS)	MAF	DDD
Passerines (Turdus merula-Blackbird)	0.01	Grass and cereals	1.31	102.3	-	-	0.53	0.149
	0.17	Ground-dwelling invertebrates (w/o interception)	36.57	13.8	-	-	0.53	0.565
	0.62	Soil invertebrates	27.43		PEC _{worm} x app.rate= 2.22 mg a.s./kg x 0.24 kg a.s./ha =9.3	-	-	0.540
								sum
							TER	7.5

Considering grass and cereals and other invertebrates as ground dwelling invertebrates without interception' using 90th percentile RUD and PEC_{worm} of 2.22, the third diet gave a TER of 7.5.

Therefore, the risk assessment to vermivorous birds following the intended use of DFF+FFA SC 600 is considered acceptable.

Risk of secondary poisoning of fish eating birds and mammals

Table 2.9.9.23: Estimates of exposure and risk to flufenacet through bioconcentration in fish following the application of DFF+FFA 600 SC in cereals.

Organism	BCF _{fish}	PEC _{water} (mg/L)	PEC _{fish}	DDD	NOEL/NOAEL (mg a.s./kg bw/day)	TER	Trigger
Birds	71.4	0.0624 ¹	4.45	0.71	9.4	13.23	≥5
		0.0416 ²	2.97	0.47		20.0	
		0.0312 ³	2.22	0.35		26.85	
Mammals		0.0624 ¹	4.45	0.63	37.4	59.36	
		0.0416 ²	2.97	0.42		89.04	
		0.0312 ³	2.22	0.32		116.87	

¹ Application rate 1 x 0.240 kg a.s./ha, ² Application rate 1 x 0.160 kg a.s./ha, ³ Application rate 1 x 0.120 kg a.s./ha

*max PEC_{sw} (STEP 1)

All calculated TER values are above the trigger of 5 indicating acceptable risk of secondary poisoning of earthworm- and fish-eating terrestrial vertebrates following application of DFF+FFA SC 600 according to the intended use pattern.

Overall conclusion regarding risk assessment for birds and mammals:

Birds

According to the outcome of the acute and long-term risk assessment it may be concluded that application of formulation DFF+FFA SC 600 to winter cereals at rates of 120 g a.s./ha, 160 g a.s./ha and 240 g a.s./ha pose no unacceptable acute risk for birds. The acceptability of refinement of the long-term risk for birds proposed by RMS for max application rate 240 g a.s./ha should be decided at MS level.

Mammals:

According to the outcome of the risk assessment it may be concluded that application of formulation DFF+FFA SC 600 to winter cereals at rates of 120 g a.s./ha, 160 g a.s./ha and 240 g a.s./ha pose no unacceptable acute risk for mammals.

Secondary poisoning of earthworm-eating birds/mammals

The risk is acceptable.

Secondary poisoning of fish-eating birds/mammals

The risk is acceptable.

Endocrine disruption:

Wild Mammals

Mechanistic studies submitted for evaluation of Flufenacet demonstrated that effects on thyroid hormone levels and minimal changes in thyroid gland histopathology are secondary to increased T4 clearance by the liver.

Flufenacet itself does not possess endocrine disrupting properties.

Therefore, based on a complete toxicological data set (please refer to Volume 3, (CA), B.6. Section Toxicology) there is no evidence of any endocrine disrupting potential of Flufenacet in mammals.

Birds

The population relevant effects of Flufenacet on birds were studied in reproductive toxicity studies on bobwhite quail and mallard ducks. No statistically significant effects on adult birds, offspring or reproductive parameters were found at 88 mg Flufenacet/kg diet in mallard ducks and 441 mg Flufenacet/kg diet in bobwhite quails. However, in the mallard reproduction study at the highest tested dose, half of females experienced regressed ovaries and a very low egg laying rate were observed. This effects may be linked to the observed reduced body weight increase.

Reduced hatching success and delayed body weight development of hatchlings were the most prominent effects observed in both species.

There are currently no defined criteria for identifying endocrine disruptors or interpreting the significance of any effects in ecotoxicology studies under the Commission Regulation (EU) No. 2009/1107.

Therefore, it is difficult to conclude that endocrine disruptive effects are/are not taking place.

Aquatic organism

The risk assessment is based on the Guidance Document „Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters”, EFSA Panel on Plant Protection Products and their Residues (PPR) 23 European Food Safety Authority (EFSA), Parma, Italy”, on the risk assessment for aquatic organisms.

For flufenacet the risk assessment for fish was performed for two species – one freshwater fish species and one saltwater fish species. The freshwater fish species used was the most sensitive one - *Lepomis macrochirus* (Bluegill sunfish), while the representative of saltwater fish was - *Cyprinodon variegatus* (Sheepshead Minnow).

The acute toxicity studies to fish for metabolite FOE sulfofonic acid, FOE-Thiadone and for TFA were evaluated in this RAR and were taken into consideration in the risk assessment.

No studies with metabolites FOE-oxalate, FOE 5043 trifluoroethane sulfonic acid, FOE methylosulfone and FOE methylosulfide were submitted. However, under consideration that the most sensitive groups of aquatic organism were identified algae and macrophytes acute toxicity studies with fish are not considered necessary.

The risk assessment for metabolites was limited to the most sensitive species tested.

Evaluation was performed by calculation of TER values derived by comparison of relevant toxicity data (Tables 2.9.2-1 to 2.9.2-3) and exposure estimates (Table 2.9.9-1).

Summary of performed risk assessment is presented below separately for each group of organisms.

Acute toxicity to fish

Table 2.9.9-19: TER_A values for fish exposed to flufenacet and its metabolites.

Compound	Species	LC ₅₀ (µg/L)	FOCUS STEP	Max PEC _{sw}	TER _A	Trigger
Autumn use in winter cereals at rate 1 x 120 g a.s./ha, pre emergence						
Flufenacet	Lepomis macrochirus (Bluegill sunfish)	2130	Step 1	31.227	68.21	>100
			Step 2 NE	13.797	154.38	
			Step 2 SE	11.217	189.90	
	Cyprinodon variegatus (Sheepshead Minnow)	3310	Step 1	31.227	105.99	
FOE-Sulfonic acid	Oncorhynchus mykiss (Rainbow trout)	>86 700	Step 1	7.941	>10918.02	
FOE-Thiadone	Oncorhynchus mykiss (Rainbow trout)	9100	Step 1	1.464	6215.84	
TFA	Brachydanio rerio (Zebra fish)	>1200000	Step 1	10.228	>117325	
Spring use in winter cereals at rate 1 x 120 g a.s./ha, post emergence						
Flufenacet	Lepomis macrochirus (Bluegill sunfish)	2130	Step 1	31.277	68.21	>100
			Step 2 NE	6.057	351.66	
			Step 2 SE	11.217	189.90	
	Cyprinodon variegatus (Sheepshead Minnow)	3310	Step 1	31.227	105.99	
FOE Sulfonic acid	Oncorhynchus mykiss (Rainbow trout)	>86700	Step 1	7.941	>10918.02	
FOE-Thiadone	Oncorhynchus mykiss (Rainbow trout)	9100	Step 1	1.464	6215.84	
TFA-	Brachydanio rerio (Zebra fish)	>1200 000	Step 1	10.228	>117325	
Autumn use in winter cereals at rate 1 x 160 g a.s./ha, post emergence						
Flufenacet	Lepomis macrochirus (Bluegill sunfish)	2130	Step 1	41.636	51.15	>100
			Step 2NE	18.395	115.79	
			Step 2SE	14.956	142.41	
	Cyprinodon variegatus (Sheepshead Minnow)	3310	Step 1	41.636	79.49	
			Step 2NE	18.395	179.94	

Compound	Species	LC ₅₀ (µg/L)	FOCUS STEP	Max PEC _{sw}	TER _A	Trigger
			Step 2SE	14.956	221.31	
FOE Sulfonic acid	Oncorhynchus mykiss (Rainbow trout)	>86700	Step 1	10.588	>8188.51	
FOE-Thiadone	Oncorhynchus mykiss (Rainbow trout)	9100	Step 1	1.952	4661.88	
TFA	Brachydanio rerio (Zebra fish)	>120 0000	Step 1	13.638	>87989.44	
Spring use in winter cereals at rate 1 x 160 g a.s./ha, post emergence						
Flufenacet	Lepomis macrochirus (Bluegill sunfish)	2130	Step 1	41.636	51.15	100
			Step 2 NE	8.076	263.75	
			Step 2 SE	14.956	142.41	
	Cyprinodon variegatus (Sheepshead Minnow)	3310	Step 1	41.636	79.49	
			Step 2 NE	8.076	409.85	
			Step 2 SE	14.956	221.31	
FOE Sulfonic acid	Oncorhynchus mykiss (Rainbow trout)	>86 700	Step 1	10.588	>8188.51	
FOE-Thiadone	Oncorhynchus mykiss (Rainbow trout)	9100	Step 1	1.952	4661.88	
TFA- Trifluoroacetic acid	Brachydanio rerio (Zebra fish)	>1200 000	Step 1	13.638	>879894.44	
Autumn use in winter cereals at rate 1x 240 g a.s./ha, post emergence						
Flufenacet	Lepomis macrochirus (Bluegill sunfish)	2130	Step 1	62.454	34.10	100
			Step 2 NE	27.593	77.19	
			Step 2 SE	22.433	94.94	
	Cyprinodon variegatus (Sheepshead Minnow)	3310	Step 1	62.454	52.99	
			Step 2 NE	27.593	119.95	
			Step 2 SE	22.433	147.55	
FOE Sulfonic acid	Oncorhynchus mykiss (Rainbow trout)	>86 700	Step 1	15.882	54590.01	
FOE-Thiadone	Oncorhynchus mykiss (Rainbow trout)	9100	Step 1	2.928	3107.92	
TFA	Brachydanio rerio (Zebra fish)	>1200000	Step 1	22.426 ¹	>53509.31	

1) max PEC_{gw}

values in bold indicate unacceptable risk

All TER_A values calculated for metabolites with consideration of worst case exposure assumptions for all proposed uses are far above the trigger of 100 indicating acceptable acute risk to fish.

TER_A value calculated for flufenacet with consideration of Step 1 PEC_{sw} value was below the trigger of 100. Acceptable acute risk to fish could be concluded for Step 2 exposure estimates for all proposed uses in winter cereals except the maximum application rate - 240 g a.s./ha. Therefore, the TER_A calculations based on FOCUS Step 3 were performed and presented in the Table 2.9.9-20.

Table 2.9.9-20: Acute toxicity exposure ratios (TER_A) for fish.

Compound	Species	LC ₅₀ (µg a.s./L)	FOCUS STEP 3	MaxPEC _{sw} (µg a.s./L)	TER _A	Trigger
Autumn use in winter cereals at rate 240 g a.s./ha, post emergence						
Flufenacet	Lepomis macrochirus (Bluegill sunfish)	2130	D1 ditch	6.543	325.53	≥100
			D1 stream	4.082	521.80	
			D2 ditch	6.199	343.60	
			D2 stream	3.882	548.68	
			D3 ditch	1.514	1406.86	
			D4 pond	1.168	1823.63	
			D4 stream	1.647	1293.26	
			D5 pond	1.170	1820.51	
			D5 stream	1.420	1500	
			D6 ditch	5.693	374.19	
			R1 pond	0.116	18 362	
			R1 stream	5.811	366.54	

Compound	Species	LC ₅₀ (µg a.s./L)	FOCUS STEP 3	MaxPEC _{sw} (µg a.s./L)	TER _A	Trigger
			R3 stream	7.641	278.75	
			R4 stream	5.980	356.18	

Acute TER values calculated for fish exposed after application of flufenacet according to recommendations are clearly above the respective triggers demonstrating acceptable acute risk to fish.

In addition, RMS presented the alternative approach to the acute risk assessment, performed according to the recommendations given in AGD, 2013, based on the usage of geometric mean recommended when the results from more than one species are available. The use of geometric mean - LC₅₀ of 4505 µg a.s./L, determined for four fish species (Oncorhynchus mykiss with LC₅₀ of 5840 µg a.s./L, Lepomis macrochirus with LC₅₀ of 2130 µg a.s./L, Cyprinus carpio with 10000 µg a.s./L and Cyprinodon variegatus with LC₅₀ of 3310 µg a.s./L), is considered relevant (endpoints derived using the same criteria and the difference between the lowest endpoint and geometric mean being lower than the factor of 10, in this particular case being 2).

The TER_A calculations based on FOCUS Step 1 are presented in the Table 2.9.9-21

Table 2.9.9-21: TER_A values for fish exposed to flufenacet based on the geometric LC₅₀ value.

Compound	Species	LC ₅₀ geomean (µg a.s./L)	FOCUS STEP	Max PEC _{sw} (µg a.s./L)	TER _A	Trigger
Autumn use in winter cereals at rate 1 x 120 g a.s./ha, pre emergence						
Flufenacet	Fish	4505	Step 1	31.227	144.03	>100
Spring use in winter cereals at rate 1 x 120 g a.s./ha, post emergence						
Flufenacet	Fish	4505	Step 1	31.277	144.03	>100
Autumn use in winter cereals at rate 1 x 160 g a.s./ha, post emergence						
Flufenacet	Fish	4505	Step 1	41.636	108.19	>100
Spring use in winter cereals at rate 1 x 160 g a.s./ha, post emergence						
Flufenacet	Fish	4505	Step 1	41.636	108.19	>100
Autumn use in winter cereals at rate 1x 240 g a.s./ha, post emergence						
Flufenacet	Fish	4505	Step 1	62.454	72.13	>100
			Step 2 NE	27.593	163.26	
			Step 2 SE	22.433	200.82	

* values in bold indicate unacceptable risk

Acute TER_A values calculated for fish based on geometric LC₅₀ value, exposed after application of flufenacet are clearly above the respective triggers demonstrating acceptable acute risk to fish.

Overall conclusion regarding acute toxicity to fish.

According to the outcome of the risk assessment it may be concluded that application of formulation DFF+FFA SC 600 to winter cereals at application rates of 120 g a.s./ha, 160 g a.s./ha and 240 g a.s./ha pose no unacceptable acute risk to aquatic invertebrates.

Acute risk assessment to aquatic invertebrates:

Acute toxicity studies for flufenacet with four aquatic invertebrate species are available.

The most sensitive species were observed to be the species Hyalella azteca LC₅₀ of 2.45 mg a.s./L. Acute toxicity studies for FOE-thiadone with three aquatic invertebrates Mysidopsis bahia, Crassostrea virginica and Daphnia magna were also considered in the acute risk assessment.

Acute risk assessment for aquatic invertebrates is presented in Table 2.9.9-22 below:

Table 2.9.9-22: TER_A values for aquatic invertebrates exposed to flufenacet and its metabolites for autumn and spring application to winter cereals.

Compound	Species	EC ₅₀ /LC ₅₀ (µg/L)	FOCUS STEP	Max PEC _{sw}	TER _A	Trigger
Autumn use in winter cereals at rate 1 x 120 g a.s./ha, pre-emergence						
Flufenacet	Daphnia magna	309000	Step 1	31.227	9895.28	≥100
	Americamysis bahia	5600	Step 1	31.227	179.33	
	Crassostrea virginica	12600	Step 1	31.227	403.49	
	Hyaella azteca	2450	Step 1	31.227	78.45	
			Step 2 NE	13.797	175.57	
			Step 2 SE	11.217	218.41	
FOE sulfonic acid	Daphnia magna	>87 300	Step 1	7.941	>10993.57	≥100
FOE-Thiadone	Daphnia magna	31700	Step 1	1.464	21653.00	
	Mysidiopsis bahia	>15100	Step 1	1.464	>10314.20	
	Crassostrea virginica	22 000	Step 1	1.464	15027.32	
TFA	Daphnia magna	>1200000	Step 1	10.228	>117324.99	
Spring use in winter cereals at rate 1 x 120 g a.s./ha, post emergence						
Flufenacet	Daphnia magna	309000	Step 1	31.277	9879.46	≥100
	Americamysis bahia	5600	Step 1	31.277	179.04	
	Crassostrea virginica	12600	Step 1	31.277	402.85	
	Hyaella azteca	2450	Step 1	31.277	78.33	
			Step 2 NE	6.057	404.49	
			Step 2 SE	11.217	218.41	
FOE sulfonic acid	Daphnia magna	>87 300	Step 1	7.941	>10993.57	≥100
FOE-Thiadone	Daphnia magna	31700	Step 1	1.464	21653.00	
	Mysidiopsis bahia	>15100	Step 1	1.464	>10314.20	
	Crassostrea virginica	22 000	Step 1	1.464	15027.32	
TFA	Daphnia magna	>1200000	Step 1	10.228	>117324.99	
Autumn use in winter cereals at rate 1x 160 g a.s./ha, post emergence						
Flufenacet	Daphnia magna	309000	Step1	41.636	7421.46	≥100
	Americamysis bahia	5600	Step 1	41.636	134.49	
	Crassostrea virginica	12600	Step 1	41.636	302.62	
	Hyaella azteca	2450	Step 1	41.636	58.84	
			Step 2 NE	18.395	133.18	
			Step 2 SE	14.956	163.81	
FOE sulfonic acid	Daphnia magna	>87 300	Step1	10.588	>8245.18	≥100
FOE-Thiadone	Daphnia magna	31700	Step 1	1.952	16239.75	
	Mysidiopsis bahia	>15100	Step 1	1.952	>7735.65	
	Crassostrea virginica	22 000	Step 1	1.952	11270.49	
TFA	Daphnia magna	>1200000	Step 1	13.638	>87989.44	
Spring use in winter cereals at rate 1x 160 g a.s./ha, post emergence						
Flufenacet	Daphnia magna	309000	Step1	41.636	7421.46	≥100
	Americamysis bahia	5600	Step 1	41.636	134.49	
	Crassostrea virginica	12600	Step 1	41.636	302.62	
	Hyaella azteca	2450	Step 1	41.636	58.84	
			Step 2 NE	8.076	303.36	
			Step 2 SE	14.956	163.81	
FOE sulfonic acid	Daphnia magna	>87 300	Step1	10.588	>8245.18	≥100
FOE-Thiadone	Daphnia magna	31700	Step 1	1.952	16239.75	
	Mysidiopsis bahia	>15100	Step 1	1.952	>7735.65	
	Crassostrea virginica	22 000	Step 1	1.952	11270.49	
TFA	Daphnia magna	>1200000	Step 1	13.638	>87989.44	
Autumn use in winter cereals at rate 1x 240 g a.s./ha, post emergence						
Flufenacet	Daphnia magna	309000	Step 1	62.454	4947.64	≥100
	Americamysis bahia	5600	Step 1	62.454	89.66	
			Step 2 NE	27.593	202.95	
			Step 2 SE	22.433	249.63	
	Crassostrea virginica	12600	Step 1	62.454	201.74	
	Hyaella azteca	2450	Step 1	62.454	39.22	

Flufenacet
Volume 1 – Level 3

Compound	Species	EC ₅₀ /LC ₅₀ (µg/L)	FOCUS STEP	Max PEC _{sw}	TER _A	Trigger
			Step 2 NE	27.593	88.79	
			Step 2 SE	22.433	109.21	
FOE Sulfonic acid	Daphnia magna	>87 300	Step 1	15.882	>5496.78	
FOE-Thiadone	Daphnia magna	31700	Step 1	2.928	10826.50	
	Mysidiopsis bahia	>15100			>5157.10	
	Crassostrea virginica	22 000			7513.66	
TFA	Daphnia magna	>1200 000	Step 1	22.426 ¹	>53509.31	

1) max PEC_{gw}

values in bold indicate unacceptable risk

All TER_A values calculated for metabolites with consideration of worst case exposure assumptions are far above the trigger of 100 indicating acceptable acute risk to aquatic invertebrates.

TER_A value calculated for flufenacet with consideration of Step 2 PEC_{sw} value at rate 240 g a.s./ha for autumn use to winter cereals and the lowest toxicity endpoint for *Hyalella azteca* was below the trigger of 100. Acceptable acute risk to this species could be, however concluded for Step 3 exposure estimates.

The TER_A calculations based on FOCUS Step 3 were performed and presented in the Table 2.9.9-23.

Table 2.9.9-23: Acute toxicity exposure ratios (TER_A) for *Hyalella azteca* based on worst case scenario PEC_{sw} from STEP 3.

Compound	Species	LC ₅₀ (µg a.s./L)	FOCUS STEP 3	Max PEC _{sw} (µg a.s./L)	TER _A	Trigger
Autumn use in winter cereals at rate 1x 240 g a.s./ha, post emergence						
Flufenacet	<i>Hyalella azteca</i>	2450	D1 ditch	6.543	374.44	≥100
			D1stream	4.082	600.19	
			D2 ditch	6.199	395.22	
			D2stream	3.882	631.11	
			D3 ditch	1.514	1618.22	
			D4 pond	1.168	2097.60	
			D4stream	1.647	1487.55	
			D5 pond	1.170	2094.01	
			D5stream	1.420	1725.35	
			D6 ditch	5.693	430.35	
			R1 pond	0.116	21120.68	
			R1stream	5.811	421.61	
			R3stream	7.641	320.63	
			R4stream	5.980	409.69	

All TER_A values calculated for flufenacet with consideration of calculation STEP 3 PEC_{sw} are far above the trigger of 100 indicating acceptable acute risk to aquatic invertebrates.

In addition, RMS presented the alternative approach to the acute risk assessment, performed according to the recommendations given in AGD, 2013, based on the usage of geometric mean recommended when results from more than one species are available. The use of geometric mean - EC₅₀ of 7512 µg a.s./L, determined for three aquatic invertebrates species (*Daphnia magna* with EC₅₀ of 30900 µg a.s./L, *Americanysis bahia* with LC₅₀ of 5600 µg a.s./L and *Hyalella azteca* with LC₅₀=2450 µg a.s./L, is considered relevant (endpoints derived from the same criteria and the difference between the lowest endpoint and geomean being lower than factor of 10, in this particular case being 3).

The TER_A calculations based on FOCUS Step 1 are presented in the Table 2.9.9-24.

Table 2.9.9-24: TER_A values for aquatic invertebrates exposed to flufenacet based on the geomean EC₅₀ value.

Compound	Species	EC ₅₀ /LC ₅₀ geomean (µg a.s./L)	FOCUS STEP	Max PEC _{sw} (µg a.s./L)	TER _A	Trigger
Autumn use in winter cereals at rate 1 x 120 g a.s./ha, pre emergence						
Flufenacet	Aquatic invertebrates	7512	Step 1	31.227	240.17	>100
Spring use in winter cereals at rate 1 x 120 g a.s./ha, post emergence						
Flufenacet	Aquatic invertebrates	7512	Step 1	31.277	240.17	>100
Autumn use in winter cereals at rate 1 x 160 g a.s./ha, post emergence						
Flufenacet	Aquatic invertebrates	7512	Step 1	41.636	180.63	>100
Spring use in winter cereals at rate 1 x 160 g a.s./ha, post emergence						
Flufenacet	Aquatic invertebrates	7521	Step 1	41.636	180.63	>100
Autumn use in winter cereals at rate 1 x 240 g a.s./ha, post emergence						
Flufenacet	Aquatic invertebrates	7512	Step 1	62.454	120.28	>100

All TER_A values calculated for flufenacet with consideration of calculation STEP 1 PEC_{sw} and geomean EC₅₀ value are far above the trigger of 100 indicating acceptable acute risk to aquatic invertebrates.

Overall conclusion regarding acute toxicity to aquatic invertebrates

According to the outcome of the risk assessment it may be concluded that application of formulation DFF+FFA SC 600 to winter cereals at rates of 120 g a.s./ha, 160 g a.s./ha and 240 g a.s./ha pose no unacceptable acute risk aquatic invertebrates.

Long- term risk for fish

For flufenacet the lowest chronic fish NOEC= 49 µg a.s./L for the saltwater fish species Cyprinodon variegatus was used in the risk assessment.

Long-term risk assessment for fish is presented in the Table 2.9.9-25 below:

Table 2.9.9-25: TER_{LT} values for fish exposed to flufenacet for spring and autumn application in winter cereals.

Compound	Species	NOEC (µg a.s./L)	FOCUS Step	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
Autumn use in winter cereals at rate 120 g a.s./ha, pre emergence						
Flufenacet	Cyprinodon variegatus	49	Step 1	31.227	1.56	≥10
			Step 2 NE	13.797	3.55	
			Step 2 SE	11.217	4.36	
Spring use in winter cereals at rate 120 g a.s./ha, post emergence						
Flufenacet	Cyprinodon variegatus	49	Step 1	31.277	1.56	≥10
			Step 2NE	6.057	8.08	
			Step 2SE	11.217	4.36	
Autumn use in winter cereals at rate 160 g a.s./ha, post emergence						
Flufenacet	Cyprinodon variegatus	49	Step 1	41.636	1.17	≥10
			Step 2NE	18.395	2.66	
			Step 2SE	14.956	3.27	
Spring use in winter cereals at rate 160 g a.s./ha, post emergence						
Flufenacet	Cyprinodon variegatus	49	Step 1	41.636	1.17	≥10
			Step 2NE	8.076	6.06	
			Step 2SE	14.956	3.27	

Flufenacet
Volume 1 – Level 3

Compound	Species	NOEC (µg a.s./L)	FOCUS Step	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
Autumn use in winter cereals at rate 240 g a.s./ha, post emergence						
Flufenacet	Cyprinodon variegatus	49	Step 1	62.454	0.78	≥10
			Step 2NE	27.593	1.77	
			Step 2SE	22.433	2.18	

*values in bold indicate unacceptable risk

All TER_{LT} values calculated for flufenacet with consideration of Step 1 and Step 2 PEC_{sw} values for all proposed uses in winter cereals were below the trigger of 10. Therefore, a refined risk assessment based on FOCUS Step 3 were performed and presented in the Table 2.9.9-26 below:

Table 2.9.9-26: TER_{LT} values for fish exposed to flufenacet for autumn and spring application to winter cereals.

Compound	Species	NOEC (µg a.s./L)	FOCUS Step 3	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
Autumn use in winter cereals at rate 120 g a.s./ha, pre-emergence						
Flufenacet	Cyprinodon variegatus	49	D1 ditch	2.68	18.28	≥10
			D1 stream	1.672	29.30	
			D2 ditch	3.227	15.20	
			D2 stream	2.021	24.25	
			D3 ditch	0.758	64.65	
			D4 pond	0.398	123.11	
			D4 stream	0.658	74.50	
			D5 pond	0.56	87.50	
			D5 stream	0.71	69.01	
			D6 ditch	2.764	17.72	
			R1 pond	0.0609	804.6	
			R1 stream	2.8	17.5	
			R3 stream	3.783	12.95	
			R4 stream	1.167	42.00	
Spring use in winter cereals at rate 120 g a.s./ha, post emergence						
Flufenacet	Cyprinodon variegatus	49	D1 ditch	0.846	58.00	≥10
			D1 stream	0.629	77.90	
			D2 ditch	1.702	28.80	
			D2 stream	1.111	44.10	
			D3 ditch	0.760	64.50	
			D4 pond	0.0267	1835.20	
			D4 stream	0.572	85.70	
			D5 pond	0.0289	1695.50	
			D5 stream	0.614	79.80	
			D6 ditch	0.756	64.81	
			R1 pond	0.0687	713.30	
			R1 stream	0.764	64.40	
			R3 stream	1.080	45.40	
			R4 stream	0.501	97.80	
Autumn use to winter cereals at rate 160 g a.s./ha, post emergence						

Flufenacet
Volume 1 – Level 3

Compound	Species	NOEC (µg a.s./L)	FOCUS Step 3	Max PECsw (µg a.s./L)	TER _{LT}	Trigger
Flufenacet	Cyprinodon variegatus	49	D1 ditch	4.328	11.32	≥10
			D1 stream	2.699	18.15	
			D2 ditch	3.957	12.38	
			D2 stream	2.480	19.75	
			D3 ditch	1.010	48.51	
			D4 pond	0.756	64.81	
			D4 stream	1.081	45.32	
			D5 pond	0.766	63.96	
			D5 stream	0.946	51.79	
			D6 ditch	3.732	13.13	
			R1 pond	0.0797	614.80	
			R1 stream	3.790	12.92	
			R3 stream	4.980	9.83	
			R4 stream	3.957	12.38	
Spring use to winter cereals at rate 160 g a.s./ha, post emergence						
Flufenacet	Cyprinodon variegatus	49	D1 ditch	1.129	43.40	≥10
			D1 stream	0.838	58.50	
			D2 ditch	2.412	20.31	
			D2 stream	1.574	31.13	
			D3 ditch	1.014	48.32	
			D4 pond	0.0357	1372.55	
			D4 stream	0.763	64.22	
			D5 pond	0.0387	1266.15	
			D5 stream	0.818	59.90	
			D6 ditch	1.009	48.60	
			R1 pond	0.0913	536.70	
			R1 stream	1.021	48.0	
			R3 stream	1.450	33.80	
			R4 stream	0.668	73.40	
Autumn use in winter cereals at rate 240 g a.s./ha, post emergence						
Flufenacet	Cyprinodon variegatus	49	D1 ditch	6.543	7.48	≥10
			D1 stream	4.082	12.00	
			D2 ditch	6.199	7.90	
			D2 stream	3.882	12.62	
			D3 ditch	1.514	32.36	
			D4 pond	1.168	41.95	
			D4 stream	1.647	29.75	
			D5 pond	1.170	41.88	
			D5 stream	1.420	34.50	
			D6 ditch	5.693	8.60	
			R1 pond	0.116	422.41	

Compound	Species	NOEC (µg a.s./L)	FOCUS Step 3	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
			R1 stream	5.811	8.43	
			R3 stream	7.641	6.41	
			R4 stream	5.980	8.19	

*values in bold indicate unacceptable risk

All TER_{LT} values calculated for flufenacet with consideration of STEP 3 PEC_{sw} values for spring application in winter cereals for all proposed rates were above of the trigger of 10, indicated acceptable long-term risk to fish. TER_{LT} values calculated for flufenacet with consideration of STEP 3 PEC_{sw} values for autumn application to winter cereals were below the trigger of 10 for the following scenarios:

- **R3 (stream) for application rate 160 g a.s./ha**
- **D1 (ditch), D2 (ditch), D6 (ditch) R1 (stream), R3 (stream) and R4 (stream) for application rate 240 g a.s./ha.**

Therefore, a refined risk assessment based on FOCUS Step 4 PEC_{sw} needs refinements for these scenarios. The refined risk assessment based on FOCUS Step 4 PEC_{sw} with 10 m buffer zone was necessary and is presented in the Table 2.9.9-27 below:

Table 2.9.9-27: TER_{LT} values for fish exposed to flufenacet with 10 m FOCUS buffer zone for autumn application to winter cereals.

Compound	Species	NOEC (µg a.s./L)	FOCUS Step 4 (10 m buffer zone)	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
Autumn use in winter cereals at rate 160 g a.s./ha, post emergence						
Flufenacet	Cyprinodon variegatus	49	R3 stream	2.246	21.81	≥10
Autumn use in winter cereals at rate 240 g a.s./ha, post emergence						
Flufenacet	Cyprinodon variegatus	49	D 1 ditch	6.543	7.48	≥10
			D 2 ditch	6.199	7.90	
			D6 ditch	5.693	8.60	
			R1 stream	2.602	18.83	
			R3 stream	3.446	14.21	
			R4 stream	2.699	18.15	

TER_{LT} values calculated for flufenacet with consideration of STEP 4 PEC_{sw} values with 10 m FOCUS buffer zone for R3 scenario at rate 160 g a.s./ha and for R1, R3 and R4 scenarios at rate 240 g a.s./ha for autumn use in winter cereals were above the trigger of 10, indicated acceptable long-term risk to fish.

For D1 (ditch), D2, (ditch) and D6 (ditch) scenarios further refinement was provided using FOCUS STEP 4 PEC_{sw} with 20 m buffer zone.

Table 2.9.9-28: TER_{LT} values for fish exposed to flufenacet with 20 m FOCUS buffer zone for autumn application to winter cereals.

Compound	Species	NOEC (µg a.s./L)	FOCUS Step 4 (20 m buffer zone)	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
Autumn use in winter cereals at rate 240 g a.s./ha, post emergence						
Flufenacet	Cyprinodon variegatus	49	D1 (ditch)	6.543	7.48	≥10
			D2 (ditch)	6.199	7.90	
			D6 ditch)	5.693	8.60	

TER_{LT} values calculated for flufenacet with consideration of STEP 4 PEC_{sw} values with 20 m FOCUS buffer zone for autumn use in winter cereals were still below the trigger of 10, indicated an unacceptable long-term risk to

fish.

Overall conclusion regarding long-term risk to fish

According to the outcome of the risk assessment it may be concluded that application of formulation DFF+FFA SC 600 to winter cereals at rates of 120 g a.s./ha, 160 g a.s./ha and 240 g a.s./ha pose no unacceptable long term risk to fish if the following mitigation options are used:

- 10 m buffer zone SD&RO for scenarios R3 stream for autumn application in winter cereals at rate 160 g a.s./ha.
- 10 m buffer zone SD&RO for scenarios R1, R3 and R4 for autumn application in winter cereals at rate 240 g a.s./ha.

Therefore, the refinement of long-term risk assessment for fish was based on the geomean NOEC- 131 µg a.s./L value. The use of geometric mean determined for three fish species (*Oncorhynchus mykiss* with NOEC of 334 µg a.s./L, *Pimephales promelas* with NOEC of 138 µg a.s./L and *Cyprinodon variegatus* with NOEC of 49 µg a.s./L, is considered relevant (endpoints derived using the criteria and the difference between the lowest endpoint and geomean being lower than the factor of 10, in this particular case being 3).

The TER_{LT} calculations based on FOCUS Step 1-3 are presented in the Table 2.9.9-29 and the Table 2.9.9-30.

Table 2.9.9-29: TER_{LT} values for fish exposed to flufenacet based on the geomean NOEC and PEC_{sw} calculation in FOCUS Step 1-2 for spring and autumn application in winter cereals.

Compound	Species	NOEC geomean (µg a.s./L)	FOCUS Step	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
Autumn use in winter cereals at rate 1 x 120 g a.s./ha, pre emergence						
Flufenacet	Fish	131	Step 1	31.227	4.18	≥10
			Step 2 NE	13.797	9.49	
			Step 2 SE	11.217	11.67	
Spring use in winter cereals at rate 1 x 120 g a.s./ha, post emergence						
Flufenacet	Fish	131	Step 1	31.277	4.18	≥10
			Step 2NE	6.057	21.62	
			Step 2SE	11.217	11.67	
Autumn use in winter cereals at rate 1 x 160 g a.s./ha, post emergence						
Flufenacet	Fish	131	Step 1	41.636	3.14	≥10
			Step 2NE	18.395	7.12	
			Step 2SE	14.956	8.75	
Spring use in winter cereals at rate 1 x 160 g a.s./ha, post emergence						
Flufenacet	Fish	131	Step 1	41.636	3.14	≥10
			Step 2NE	8.076	16.22	
			Step 2SE	14.956	8.75	
Autumn use in winter cereals at rate 1x 240 g a.s./ha, post emergence						
Flufenacet	Fish	131	Step 1	62.454	2.09	≥10
			Step 2NE	27.593	4.74	
			Step 2SE	22.433	5.83	

Table 2.9.9-30: TER_{LT} values for fish exposed to flufenacet for autumn and spring application to winter cereals.

Compound	Species	NOEC geomean (µg a.s./L)	FOCUS Step 3	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
Autumn use in winter cereals at rate 1 x 120 g a.s./ha, pre-emergence						
Flufenacet	Fish	131	D1 ditch	2.68	48.88	≥10
			D1 stream	1.672	78.34	
			D2 ditch	3.227	40.59	
			D2 stream	2.021	64.81	
			D3 ditch	0.758	172.821	
			D4 pond	0.398	329.14	
			D4 stream	0.658	199.08	
			D5 pond	0.56	233.92	
			D5 stream	0.71	184.50	
			D6 ditch	2.764	47.39	
			R1 pond	0.0609	2151.06	
			R1 stream	2.8	46.78	
			R3 stream	3.783	34.62	
			R4 stream	1.167	112.25	
Spring use in winter cereals at rate 1 x 120 g a.s./ha, post emergence						
Flufenacet	Fish	131	D1 ditch	0.846	154.84	≥10
			D1 stream	0.629	208.26	
			D2 ditch	1.702	76.96	
			D2 stream	1.111	117.91	
			D3 ditch	0.760	172.36	
			D4 pond	0.0267	4906.36	
			D4 stream	0.572	229.02	
			D5 pond	0.0289	4532.87	
			D5 stream	0.614	213.35	
			D6 ditch	0.756	173.28	
			R1 pond	0.0687	1906.84	
			R1 stream	0.764	171.46	
			R3 stream	1.080	121.29	
			R4 stream	0.501	261.47	
Autumn use to winter cereals at rate 1 x 160 g a.s./ha, post emergence						
Flufenacet	variegatus Fish	131	D1 ditch	4.328	30.26	≥10
			D1 stream	2.699	48.53	
			D2 ditch	3.957	33.10	
			D2 stream	2.480	52.82	
			D3 ditch	1.010	129.70	
			D4 pond	0.756	173.28	
			D4 stream	1.081	121.18	

Flufenacet
Volume 1 – Level 3

Compound	Species	NOEC geomean (µg a.s./L)	FOCUS Step 3	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
			D5 pond	0.766	171.01	
			D5 stream	0.946	138.47	
			D6 ditch	3.732	35.10	
			R1 pond	0.0797	1643.66	
			R1 stream	3.790	34.56	
			R3 stream	4.980	26.30	
			R4 stream	3.957	33.10	
Spring use to winter cereals at rate 1 x 160 g a.s./ha, post emergence						
Flufenacet	Fish	131	D1 ditch	1.129	116.03	≥10
			D1 stream	0.838	156.32	
			D2 ditch	2.412	54.31	
			D2 stream	1.574	83.22	
			D3 ditch	1.014	129.19	
			D4 pond	0.0357	3669.46	
			D4 stream	0.763	171.69	
			D5 pond	0.0387	3385.01	
			D5 stream	0.818	160.14	
			D6 ditch	1.009	129.83	
			R1 pond	0.0913	1434.83	
			R1 stream	1.021	128.30	
			R3 stream	1.450	90.34	
			R4 stream	0.668	196.10	
Autumn use in winter cereals at rate 1x 240 g a.s./ha, post emergence						
Flufenacet	Fish	131	D1 ditch	6.543	20.02	≥10
			D1 stream	4.082	32.09	
			D2 ditch	6.199	21.13	
			D2 stream	3.882	33.74	
			D3 ditch	1.514	86.52	
			D4 pond	1.168	112.15	
			D4 stream	1.647	79.53	
			D5 pond	1.170	111.96	
			D5 stream	1.420	92.25	
			D6 ditch	5.693	23.01	
			R1 pond	0.116	29.31	
			R1 stream	5.811	22.54	
			R3 stream	7.641	17.14	
			R4 stream	5.980	21.90	

*values in bold indicate unacceptable risk

All TER_{LT} values calculated for flufenacet with consideration of calculation STEP 3 PEC_{sw} and geomean NOEC value are above the trigger of 10 indicating acceptable long-term risk to fish.

Long-term for risk aquatic invertebrates

Chronic toxicity studies with the most sensitive species *Mysidopsis bahia* were submitted addressing the long-term risk to aquatic invertebrates. The lowest endpoint was determined to be NOEC=221 µg a.s./L based on effects on reproduction. Long-term risk assessment for aquatic invertebrates is presented in Table 2.9.9-31 below:

Table 2.9.9-31: TER_{LT} values for aquatic invertebrates exposed to flufenacet.

Compound	Species	NOEC (µg a.s./L)	FOCUS Step	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
Autumn use in winter cereals at rate 120 g a.s./ha, pre emergence						
Flufenacet	Mysidopsis bahia	221	Step 1	31.227	7.06	≥10
			Step 2NE	13.797	16.01	
			Step 2SE	11.217	19.70	
Spring use in winter cereals at rate 120 g a.s./ha, post emergence						
Flufenacet	Mysidopsis bahia	221	Step 1	31.277	7.06	≥10
			Step 2NE	6.057	36.48	
			Step 2SE	11.217	19.70	
Autumn use in winter cereals at rate 160 g a.s./ha, post emergence						
Flufenacet	Mysidopsis bahia	221	Step1	41.636	5.30	≥10
			Step 2NE	18.395	12.01	
			Step 2SE	14.956	14.77	
Spring use in winter cereals at rate 160 g a.s./ha, post emergence						
Flufenacet	Mysidopsis bahia	221	Step 1	41.636	5.30	≥10
			Step 2NE	8.076	27.36	
			Step 2SE	14.956	14.77	
Autumn use in winter cereals at rate 240 g a.s./ha, post emergence						
Flufenacet	Mysidopsis bahia	221	Step 1	62.454	3.53	≥10
			Step 2NE	27.593	8.00	
			Step 2SE	22.433	9.85	

*values in bold indicate unacceptable risk

TER_{LT} values calculated for flufenacet with consideration of Step 2 PEC_{sw} values and the lowest toxicity endpoint were above the trigger of 10 except the maximum application rate of 240 g a.s./ha. Therefore, the TER calculations based on FOCUS Step 3 were conducted.

Table 2.9.9-32: Chronic toxicity exposure ratios (TER_{LT}) for aquatic invertebrates based on worst case scenario PEC_{sw} from STEP 3.

Compound	Species	NOEC (µg a.s./L)	FOCUS STEP 3	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
Autumn use in winter cereals at rate 1 x 240 g a.s./ha, post emergence						
Flufenacet	<i>Mysidopsis bahia</i>	221	D1 ditch	6.543	33.77	≥10
			D1 stream	4.082	54.14	
			D2 ditch	6.199	35.65	
			D2 stream	3.882	56.92	
			D3 ditch	1.514	145.97	
			D4 pond	1.168	189.21	
			D4 stream	1.647	134.18	
			D5 pond	1.170	188.88	

Compound	Species	NOEC ($\mu\text{g a.s./L}$)	FOCUS STEP 3	Max PEC _{sw} ($\mu\text{g a.s./L}$)	TER _{LT}	Trigger
			D5stream	1.420	155.63	
			D6 ditch	5.693	38.81	
			R1 pond	0.116	1905.17	
			R1stream	5.811	38.03	
			R3stream	7.641	28.92	
			R4stream	5.980	36.95	

TER_{LT} value calculated for flufenacet with consideration of Step 3 PEC_{sw} value for maximum application rate 240 g a.s./ha was above the trigger of 10 which indicated acceptable long-term risk to aquatic invertebrates.

In addition, RMS presented the long-term risk assessment for aquatic invertebrates based on the geomean NOEC of 847 $\mu\text{g a.s./L}$. The use of geometric mean of two species (*Daphnia magna* with NOEC of 3260 $\mu\text{g a.s./L}$ and *Americamysis bahia* with NOEC₅₀ of 221 $\mu\text{g a.s./L}$) is considered relevant (endpoints derived from the same criteria and the difference between the lowest endpoint and geomean being lower than factor of 10, in this particular case being 4).

The TER_{LT} calculations based on FOCUS Step 1 are presented in the Table 2.9.9-33.

Table 2.9.9-33: TER_{LT} values for aquatic invertebrates exposed to flufenacet based on the geomean NOEC and PEC_{sw} calculation in FOCUS Step 1 for spring and autumn application in winter cereals.

Compound	Species	NOEC geomean ($\mu\text{g a.s./L}$)	FOCUS Step	Max PEC _{sw} ($\mu\text{g a.s./L}$)	TER _{LT}	Trigger
Autumn use in winter cereals at rate 1 x 120 g a.s./ha, pre emergence						
Flufenacet	Aquatic invertebrates	849	Step 1	31.227	27.18	≥ 10
Spring use in winter cereals at rate 1 x 120 g a.s./ha, post emergence						
Flufenacet	Aquatic invertebrates	849	Step 1	31.277	27.14	≥ 10
Autumn use in winter cereals at rate 1 x 160 g a.s./ha, post emergence						
Flufenacet	Aquatic invertebrates	849	Step 1	41.636	20.39	≥ 10
Spring use in winter cereals at rate 1 x 160 g a.s./ha, post emergence						
Flufenacet	Aquatic invertebrates	849	Step 1	41.636	20.39	≥ 10
Autumn use in winter cereals at rate 1x 240 g a.s./ha, post emergence						
Flufenacet	Aquatic invertebrates	849	Step 1	62.454	13.59	≥ 10

All TER_{LT} values calculated for flufenacet with consideration of calculation STEP 1 PEC_{sw} and geomean NOEC value are below the trigger of 10 indicating needs to further refinement.

Overall conclusion regarding long-term risk to aquatic invertebrates

According to the outcome of the risk assessment it may be concluded that application of formulation DFF+FFA SC 600 to winter cereals at rates of 120 g a.s./ha, 160 g a.s./ha and 240 g a.s./ha pose no unacceptable long-term risk to aquatic invertebrates.

Risk assessment for sediment dwelling organisms

One toxicity study for *Chironomus riparius* was performed (in water-spiked) with NOEC=5 mg a.s./L, based on emergence.

Acute risk assessment for sediment dwellers is presented in the Table 2.9.9-34 below:

Table 2.9.9-34: TER_{LT} values for sediment dwelling organism exposed to flufenacet.

Compound	Species	NOEC (µg a.s./L)	FOCUS Step	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
Autumn use in winter cereals at rate 120 g a.s./ha, pre-emergence						
Flufenacet	Chironomus riparius	5000	Step 1	31.227	160.11	≥10
Spring use in winter cereals at rate 120 g a.s./ha, post emergence						
Flufenacet	Chironomus riparius	5000	Step 1	31.227	160.11	≥10
Autumn use in winter cereals at rate 160 g a.s./ha, post emergence						
Flufenacet	Chironomus riparius	5000	Step 1	41.636	120.08	≥10
Spring use in winter cereals at rate 160 g a.s./ha, post emergence						
Flufenacet	Chironomus riparius	5000	Step 1	41.636	120.08	≥10
Autumn use in winter cereals at rate 240 g a.s./ha, post emergence						
Flufenacet	Chironomus riparius	5000	Step 1	62.454	80.05	≥10

TER values for long-term toxicity of flufenacet to sediment dwelling organisms are above a TER value of 10 indicating low long-term risk following applications of DFF+ FFA SC 600 to winter cereals at proposed use rates.

Risk assessment for algae

The geometric mean value E_rC₅₀ of 7.55 µg s.a./L obtained from three laboratory studies for Pseudokirchneriella subcapitata with 96 h E_rC₅₀ = 3.15 µg s.a./L, 72 h E_rC₅₀ = 21.20 µg s.a./L and 96 h = 6.45 µg s.a./L was used in the risk assessment.

Chronic risk assessment for algae is presented in the Tables 2.9.9-35 below:

Table 2.9.9-35: TER_{LT} values for P.subcapitata exposed to flufenacet and its metabolites.

Compound	Species	E _r C ₅₀ (µg /L)	FOCUS STEP	Max PEC _{sw} (µg /L)	TER _A	Trigger
Autumn use in winter cereals at rate 120 g a.s./ha, pre-emergence						
Flufenacet	P.subcapitata	7.55	Step 1	31.227	0.24	≥10
			Step 2 NE	13.797	0.54	
			Step 2 SE	11.217	0.67	
FOE oxalate	P.subcapitata	>100 000	Step 1	6.466	>15465.51	
FOE methylsulfide	P.subcapitata	83 800	Step 1	0.084	997619.04	
FOE methylsulfone	P.subcapitata	>10 000	Step 1	1.896	>5274.26	
FOE-Sulfonic acid	P.subcapitata	>86700	Step 1	7.941	>10918.02	
TFA	P.subcapitata	>1200	Step 1	10.228	>117.32	
FOE-Trifluoroethane sulfonic acid	P.subcapitata	>100 000	Step 1	1.084	>92250.92	
Spring use in winter cereals at rate 120 g a.s./ha, post-emergence						
Flufenacet	P.subcapitata	7.55	Step 1	31.277	0.24	≥10
			Step 2 NE	6.057	1.24	
			Step 2 SE	11.217	0.67	
FOE oxalate	P.subcapitata	>100 000	Step 1	6.466	>15465.51	
FOE methylsulfide	P.subcapitata	83 800	Step 1	0.084	997619.04	
FOE methylsulfone	P.subcapitata	>10 000	Step 1	1.896	>5274.26	

Flufenacet
Volume 1 – Level 3

Compound	Species	E _r C ₅₀ (µg /L)	FOCUS STEP	Max PEC _{sw} (µg /L)	TER _A	Trigger
FOE-Sulfonic acid	P.subcapitata	>86700	Step 1	7.941	>10918.02	
TFA	P.subcapitata	>1200	Step 1	10.228	>117.32	
FOE Trifluoroethane sulfonic acid	P.subcapitata	>100 000	Step 1	1.084	>92250.92	
Autumn use in winter cereals at rate 160 g a.s./ha, post-emergence						
Flufenacet	P.subcapitata	7.55	Step 1	41.636	0.18	1≥0
			Step 2	18.395	0.41	
			Step 2	14.956	0.50	
FOE oxalate	P.subcapitata	>100 000	Step 1	8.622	>1159.82	
FOE methylsulfide	P.subcapitata	83 800	Step 1	0.111	754954.95	
FOE methylsulfone	P.subcapitata	>10 000	Step1	2.528	3955.69	
FOE-Sulfonic acid	P.subcapitata	>86700	Step1	10.588	8188.51	
TFA	P.subcapitata	>1200	Step 1	13.638	87.98	
FOE-Trifluoroethane sulfonic acid	P.subcapitata	>100 000	Step 1	1.445	69204.15	
Spring use in winter cereals at rate 160 g a.s./ha, post -emergence						
Flufenacet	P.subcapitata	7.55	Step 1	41.636	0.18	≥10
			Step 2NE	8.076	0.93	
			Step 2 SE	14.956	0.50	
FOE oxalate	P.subcapitata	>100 000	Step 1	8.622	>1159.82	
FOE methylsulfide	P.subcapitata	83 800	Step 1	0.111	754954.95	
FOE methylsulfone	P.subcapitata	>10 000	Step 1	2.528	>3955.69	
FOE-Sulfonic acid	P.subcapitata	>86700	Step1	10.588	8188.51	
TFA	P.subcapitata	1200	Step 1	13.638	>87.98	
FOE-Trifluoroethane sulfonic acid	P.subcapitata	>100 000	Step 1	1.445	>69204.15	
Autumn use in winter cereals at rate 240 g a.s./ha, post emergence						
Flufenacet	P.subcapitata	7.55	Step 1	62.454	0.12	≥10
				27.593	0.27	
				22.433	0.33	
FOE oxalate	P.subcapitata	>100 000	Step 1	12.933	>7732.15	
FOE methylsulfide	P.subcapitata	83 800	Step 1	0.167	501796.40	
FOE methylsulfone	P.subcapitata	>10 000	Step 1	3.792	>2637.13	
FOE-Sulfonic acid	P.subcapitata	>86700	Step 1	15.882	5459.01	
TFA	P.subcapitata	>1200	Step 1	22.426 ¹	>53.50	
FOE-Trifluoroethane sulfonic acid	P.subcapitata	>100 000	Step 1	2.168	>46125.46	

1) max PEC_{gw}

Values in bold indicate unacceptable risk

All TER_{LT} values calculated for metabolites of flufenacet with consideration of worst case exposure assumptions are far above the trigger of 10 indicating acceptable chronic risk to algae.

However, the TER_{LT} values for flufenacet obtained by FOCUS Step 2 calculations for spring and autumn

applications to winter cereals are lower than the Annex VI trigger value of 10 and needs further refinement. Therefore, the TER calculations based on FOCUS Step 3 were conducted for all proposed uses of flufenacet. STEP 3.

Table 2.9.9-36: Chronic toxicity exposure ratios (TER_{LT}) for *P.subcapitata* based on worst case scenario PEC_{sw} from STEP 3.

STEP 3:

Compound	Species	E _r C ₅₀ (µg a.s. /L)	FOCUS Step 3	Max PEC _{sw} (µg a.s. /L)	TER _{LT}	Trigger
Autumn use in winter cereals at rate 120 g a.s./ha, pre emergence						
Flufenacet	P.subcapitata	7.55	D1 ditch	2.680	2.81	≥10
			D1 stream	1.672	4.51	
			D2 ditch	3.227	2.33	
			D2 stream	2.021	3.73	
			D3 ditch	0.758	9.96	
			D4 pond	0.398	18.96	
			D4 stream	0.658	11.47	
			D5 pond	0.560	13.48	
			D5 stream	0.710	10.63	
			D6 ditch	2.764	2.73	
			R1 pond	0.0609	123.97	
			R1 stream	2.800	2.69	
			R3 stream	3.783	1.99	
			R4 stream	1.167	6.46	
Spring use in winter cereals at rate 120 g a.s./ha, post emergence						
Flufenacet	P.subcapitata	7.55	D1 ditch	0.846	8.92	≥10
			D1 stream	0.629	12.0	
			D2 ditch	1.702	4.43	
			D2 stream	1.111	6.79	
			D3 ditch	0.760	9.93	
			D4 pond	0.0267	282.77	
			D4 stream	0.572	13.19	
			D5 pond	0.0289	261.24	
			D5 stream	0.614	12.29	
			D6 ditch	0.756	9.98	
			R1 pond	0.0687	109.89	
			R1 stream	0.764	9.98	
			R3 stream	1.080	6.99	
			R4 stream	0.501	15.06	
Autumn use in winter cereals at rate 160 g a.s./ha, post emergence						
Flufenacet	P.subcapitata	7.55	D1 ditch	4.328	1.74	≥10
			D1 stream	2.699	2.79	
			D2 ditch	3.957	1.90	
			D2 stream	2.480	3.04	
			D3 ditch	1.010	7.47	
			D4 pond	0.756	9.98	
			D4 stream	1.081	6.98	
			D5 pond	0.766	9.85	
			D5 stream	0.946	7.98	
			D6 ditch	3.732	2.02	
			R1 pond	0.0797	94.73	
			R1 stream	3.790	1.99	
			R3 stream	4.980	1.51	
			R4 stream	3.957	1.89	
Spring use in winter cereals at rate 160 g a.s./ha, post emergence						
Flufenacet	P.subcapitata	7.55	D1 ditch	1.129	6.68	≥10
			D1 stream	0.838	9.00	
			D2 ditch	2.412	3.13	
			D2 stream	1.574	4.79	
			D3 ditch	1.014	7.44	
			D4 pond	0.0357	211.48	

Compound	Species	E _r C ₅₀ (µg a.s. /L)	FOCUS Step 3	Max PEC _{sw} (µg a.s. /L)	TER _{LT}	Trigger
			D4 stream	0.763	9.89	
			D5 pond	0.0387	195.09	
			D5 stream	0.818	9.22	
			D6 ditch	1.009	7.48	
			R1 pond	0.0913	82.69	
			R1 stream	1.021	7.39	
			R3 stream	1.450	5.20	
			R4 stream	0.668	11.30	
Autumn use in winter cereals at rate 240 g a.s./ha, post emergence						
Flufenacet	P.subcapitata	7.55	D1 ditch	6.543	1.15	≥10
			D1 stream	4.082	1.84	
			D2 ditch	6.199	1.21	
			D2 stream	3.882	1.94	
			D3 ditch	1.514	4.98	
			D4 pond	1.168	6.46	
			D4 stream	1.647	4.58	
			D5 pond	1.170	6.45	
			D5 stream	1.420	5.31	
			D6 ditch	5.693	1.32	
			R1 pond	0.116	65.08	
			R1 stream	5.811	1.29	
			R3 stream	7.641	0.98	
			R4 stream	5.980	1.26	

Values in bold indicate unacceptable risk

In the table below are listed all the scenarios for which the TER_{LT} value did not meet the trigger.

Table 2.9.9-37: The FOCUS STEP 3 scenarios, for which the P.subcapitata TER_{LT} needs further refinement.

Scenario STEP 3	Winter cereals				
	Autumn use 120 g a.s./ha	Autumn use 160 g a.s./ha	Autumn use 240 g a.s./ha	Spring use 120 g a.s./ha	Spring use 160 g a.s./ha
D1 ditch	D1 ditch	D1 ditch	D1 ditch	D1 ditch	D1 ditch
D1 stream	D1 stream	D1 stream	D1 stream	-	D1 stream
D2 ditch	D2 ditch	D2 ditch	D2 ditch	D2 ditch	D2 ditch
D2 stream	D2 stream	D2 stream	D2 stream	D2 stream	D2 stream
D3 ditch	D3 ditch	D3 ditch	D3 ditch	D3 ditch	D3 ditch
D4 pond	-	D4 pond	D4 pond	-	-
D4 stream	-	D4 stream	D4 stream	-	D4 stream
D5 pond	-	D5 pond	D5 pond	-	-
D5 stream	-	D5 stream	D5 stream	-	D5 stream
D6 ditch	D6 ditch	D6 ditch	D6 ditch	D6 ditch	D6 ditch
R1 pond	-	-	-	-	-
R1 stream	R1 stream	R1 stream	R1 stream	R1 stream	R1 stream
R3 stream	R3 stream	R3 stream	R3 stream	R3 stream	R3 stream
R4 stream	R4 stream	R4 stream	R4 stream	-	-

- No further refinement is needed

Based on a comparison of the results of the standard laboratory toxicity studies with FOCUS Step 3 maximum PEC_{sw} values for flufenacet, the TER_{LT} values for algae meet the required trigger of 10, except the scenarios given in the Table 2.9.9-37. For those scenarios, P.subcapitata TER needs further refinement.

Therefore, the PEC_{sw} values for flufenacet were further refined at FOCUS Step 4 using 10-metres- and 20-metres-wide FOCUS buffer zones for mitigation of Spray Drift and Run-off.

STEP 4 – 10-metres wide FOCUS buffer zone for mitigation of Spray Drift and Run-off

TER_{LT} values for relevant scenarios based on worst case scenario PEC_{sw} from STEP 4 with 10 meter buffer zone FOCUS was presented in the Table 2.9.9-38 below:

Table 2.9.9-38: Chronic toxicity exposure ratios (TER_{LT}) for P.subcapitata based on worst case scenario PEC_{sw} from STEP 4 with 10 meter buffer zone FOCUS.

Compound	Species	E _r C ₅₀ (µg a.s./L)	FOCUS Step 4	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
Autumn use in winter cereals at rate 1 x 120 g a.s./ha, pre emergence						
Flufenacet	P.subcapitata	7.55	D1 ditch	2.680	2.81	≥10
			D1 stream	1.672	4.51	
			D2 ditch	3.227	2.33	
			D2 stream	2.021	3.73	
			D3 ditch	0.109	69.26	
			D6 ditch	2.764	1.84	
			R1 stream	1.354	6.94	
			R3 stream	1.728	4.36	
			R4 stream	0.527	14.32	
Spring use in winter cereals at rate 1 x 120 g a.s./ha, post emergence						
Flufenacet	P.subcapitata	7.55	D1 ditch	0.194	38.91	≥10
			D2 ditch	1.702	4.43	
			D2 stream	1.111	6.79	
			D3 ditch	0.109	69.26	
			D6 ditch	0.114	66.22	
			R1 stream	0.347	21.75	
			R3 stream	0.493	15.31	
Autumn use in winter cereals at rate 1 x 160 g a.s./ha, post emergence						
Flufenacet	P.subcapitata	7.55	D1 ditch	4.328	1.74	≥10
			D1 stream	2.699	2.79	
			D2 ditch	3.957	1.90	
			D2 stream	2.480	3.04	
			D3 ditch	0.145	52.00	
			D4 pond	0.750	10.06	
			D4 stream	1.081	6.98	
			D5 pond	0.761	9.92	
			D5 stream	0.812	9.29	
			D6 ditch	3.732	2.02	
			R1 stream	1.697	4.44	
			R3 stream	2.246	3.36	
			R4 stream	1.786	4.22	
Spring use in winter cereals at rate 1 x 160 g a.s./ha, post emergence						
Flufenacet	P.subcapitata	7.55	D1 ditch	0.259	29.15	≥10
			D1 stream	0.218	34.63	
			D2 ditch	2.412	3.13	
			D2 stream	1.574	4.79	
			D3 ditch	0.146	51.71	
			D4 stream	0.148	51.01	

Compound	Species	E _r C ₅₀ (µg a.s./L)	FOCUS Step 4	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
			D5 stream	0.160	47.18	
			D6 ditch	0.153	49.34	
			R1 stream	0.464	16.27	
			R3 stream	0.662	11.40	
Autumn use in winter cereals at rate 1x 240 g a.s./ha, post emergence						
Flufenacet	P.subcapitata	7.55	D1 ditch	6.543	1.15	≥10
			D1 stream	4.082	1.84	
			D2 ditch	6.199	1.21	
			D2 stream	3.882	1.94	
			D3 ditch	0.218	34.63	
			D4 pond	1.159	6.51	
			D4 stream	1.674	4.51	
			D5 pond	1.163	6.49	
			D5 stream	1.249	6.04	
			D6 ditch	5.693	1.32	
			R1 stream	2.602	2.90	
			R3 stream	3.446	2.19	
			R4 stream	2.699	2.79	

Values in bold indicate unacceptable risk

In the table below are listed all the scenarios for which the TER_{LT} value did not meet the trigger.

Table 2.9.9-39: The FOCUS STEP 4 scenarios with 10 m buffer, for P.subcapitata which the TER_{LT} needs further refinement.

Autumn use 120 g a.s./ha	Spring use 120 g a.s./ha	Autumn use 160 g a.s./ha	Spring use 160 g a.s./ha	Autumn use 240 g a.s./ha
D1 ditch	D 2 ditch	D1 ditch	D2 ditch	D1 ditch
D1 stream	D2 stream	D1 stream	D2 stream	D1 stream
D2 ditch		D2 ditch	-	D2 ditch
D2 stream	-	D2 stream	-	D2 stream
		D4 stream		D4 pond
		D5 pond		D4 stream
		D5 stream		D5 pond
D6 ditch	-	D6 ditch	-	D5 stream
	-		-	D6 ditch
	-	R1 stream	-	R1 stream
R1 stream	-	R3 stream	-	R3 stream
R3 stream	-	R4 stream	-	R4 stream

- No further refinement is needed

Based on a comparison of the results of the standard laboratory toxicity studies with FOCUS Step 4 PEC_{sw} values for flufenacet calculated assuming 10-metres buffer zone for mitigation of Spray Drift in all D scenarios and Spray Drift and Run-off in all R scenarios (for Run-off the adequate reduction factors given by FOCUS L&M Guideline for 10- metres wide vegetated buffer zone were used), the TER_{LT} values for algae meet the required trigger of 10, except the scenarios given in the Table 2.9.9-39.

For those scenarios, P.subcapitata TER needs further refinement.

As a result, PEC_{sw} values for flufenacet for autumn application to winter cereals were further refined using the FOCUS Step 4 with 20 meter buffer zone FOCUS.

STEP 4 – 20-metres wide FOCUS buffer zone for mitigation of Spray Drift and Run-off

TER_{Lt} values for relevant scenarios based on worst case scenario PEC_{sw} from STEP 4 with 20 meter buffer zone FOCUS was presented in table below.

Table 2.9.9-40: Chronic toxicity exposure ratios (TER_{Lt}) for P.subcapitata based on worst case scenario PEC_{sw} from STEP 4 with 20 meter buffer zone.

Compound	Species	E _r C ₅₀ (µg a.s./L)	FOCUS Step 4	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
Autumn use in winter cereals at rate 1 x 120 g a.s./ha, pre emergence						
Flufenacet	P.subcapitata	7.55	D1 ditch	2.680	2.81	≥10
			D1 stream	1.672	4.51	
			D2 ditch	3.227	2.33	
			D2 stream	2.021	3.73	
			D6 ditch	2.764	2.73	
			R1 stream	0.652	11.57	
			R3 stream	0.907	8.32	
Spring use in winter cereals at rate 1 x 120 g a.s./ha, post emergence						
Flufenacet	P.subcapitata	7.55	D2 ditch	1.702	4.43	≥10
			D2 stream	1.111	6.79	
Autumn use in winter cereals at rate 1 x 160 g a.s./ha, post emergence						
Flufenacet	P.subcapitata	7.55	D1 ditch	4.328	1.74	≥10
			D1 stream	2.699	2.79	
			D2 ditch	3.957	1.90	
			D2 stream	2.480	3.04	
			D5 pond	0.758	9.96	
			D5 stream	0.812	9.29	
			D6 ditch	3.732	2.02	
			D4 stream	1.081	6.98	
			R1 stream	0.883	8.55	
			R3 stream	1.173	6.43	
			R4 stream	0.993	7.60	
Spring use in winter cereals at rate 1 x 160 g a.s./ha, post emergence						
Flufenacet	P.subcapitata	7.55	D2 ditch	2.412	3.13	≥10
			D2 stream	1.574	4.79	
Autumn use in winter cereals at rate 1 x 240 g a.s./ha, post emergence						
Flufenacet	P.subcapitata	7.55	D1 ditch	6.543	1.15	≥10
			D1 stream	4.082	1.84	
			D2 ditch	6.199	1.21	
			D2 stream	3.882	1.94	
			D4 pond	1.154	6.54	
			D4 stream	1.674	4.51	
			D5 pond	1.159	6.51	
			D5 stream	1.249	6.04	
			D6 ditch	5.693	1.32	

Compound	Species	E _r C ₅₀ (µg a.s./L)	FOCUS Step 4	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
			R1 stream	1.354	5.57	
			R3 stream	1.799	4.19	
			R4 stream	1.41	5.35	

Values in bold indicate unacceptable risk

In the table below are listed all the scenarios for which the TER_{LT} value did not meet the trigger.

Table 2.9.9-41: The FOCUS STEP 4 scenarios with 20 m buffer, for P.subcapitata which the TER_{LT} needs further refinement.

Autumn use 120 g s.a./ha	Spring use 120 g s.a./ha	Autumn use 160 g a.s./ha	Spring use 160 g a.s./ha	Autumn use 240 g a.s./ha
D1 ditch	D2 ditch	D1 ditch	D2 ditch	D1 ditch
D1 stream	D2 stream	D1 stream	D2 stream	D1 stream
D2 ditch	-	D2 ditch	-	D2 ditch
D2 stream	-	D2 stream	-	D2 stream
D6 ditch	-	D5 pond	-	D6 ditch
-	-	D5 stream	-	D4 pond
R3 stream	-	D6 ditch	-	D4 stream
-	-	D4 stream	-	D5 pond
-	-	R1 stream	-	D5 stream
-	-	R3 stream	-	R1 stream
-	-	R4 stream	-	R3 stream
-	-	-	-	R4 stream

Based on a comparison of the results of the standard laboratory toxicity studies with FOCUS Step 4 PEC_{sw} values for flufenacet calculated assuming 20-metres buffer zone for mitigation of Spray Drift in all D scenarios and Spray Drift and Run-off in all R scenarios (for Run-off the adequate reduction factors given by FOCUS L&M Guideline for 20 –metres wide vegetated buffer zone were used), the TER_{LT} values for algae meet the required trigger of 10, except the scenarios given in the table 2.9.9-41.

The further refinement is required for these scenarios.

At the same time it shall be pointed out that in case of the scenarios D4-pond, D4-stream, D5-pond, D5-stream and D6-ditch, when the required trigger value for TER_{LT} was not met for applications in autumn, the risk may still be negligible. That is due to the fact that for those scenarios the predominant identified migration route was drainage occurring shortly after application and late in autumn and in winter, when algae are in dormant stage. It was also noticed that for these scenarios the concentrations of Flufenacet above the level of the safe PEC_{sw} values were obtained for the period between December and the end of February or the first days of March on the latest. Similar statement with regard to the temporal occurrence of modelled concentrations of Flufenacet in SW bodies may be drawn for all R scenarios.

Overall conclusion of algae' risk assessment:

Autumn Uses

The general conclusions drawn from the risk assessment for algae presented above, are provided below, individually for each use listed in the EU-representative GAP.

In case of the post-emergence use in Winter cereals in autumn, at application rate **240 g Flufenacet/ha**, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenarios:

- D1 ditch, D1 stream, D2 ditch, D2 stream, D4 pond, D4 stream, D5 pond, D5 stream, D6 ditch, R1 stream, R3 stream and R4 stream. In case of scenarios D4 pond, D4 stream, D5 pond, D5 stream and D6 ditch RMS noticed that although safe PEC_{sw} values were not reached at STEP 4, it may be stated that the risk for algae was not substantial due to the fact that they occurred late in autumn and in winter, when algae are in dormant period from December to February; also in none of these scenarios the PEC_{sw} values above the safe level were observed later than in the first days of March. Also in case of all R scenarios for which safe PEC_{sw} value was not reached, similar conclusion may be drawn.

The only safe scenario identified within that use was D3, assuming 10-metres wide buffer zone for mitigation of Spray Drift.

Therefore for that use it may be stated that one safe scenario was identified – D3 scenario assuming 10-metres wide non-spray buffer zone to mitigate the Spray drift.

In case of the post-emergence use in Winter cereals in autumn, at application rate **160 g Flufenacet/ha**, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenarios:

- D1 ditch, D1 stream, D2 ditch, D2 stream, D4 stream, D5 pond, D5 stream, D6 ditch, R1 stream, R3 stream and R4 stream. In case of scenarios D4 stream, D5 pond, D5 stream and D6 ditch RMS noticed that although safe PEC_{SW} values were not reached at STEP 4, it may be stated that the risk for algae was not substantial due to the fact that they occurred late in autumn and in winter, when algae are in dormant period from December to February; also in none of these scenarios the PEC_{SW} values above the safe level were observed later than in the first days of March. Also in case of all R scenarios for which safe PEC_{SW} value was not reached, similar conclusion may be drawn.

The only safe scenario identified within that use was D3, assuming 10-metres wide buffer zone for mitigation of Spray Drift.

Therefore for that use it may be stated that one safe scenario was identified – D3 scenario assuming 10-metres wide non-spray buffer zone to mitigate the Spray drift.

In case of the post-emergence use in Winter cereals in autumn, at application rate **120 g Flufenacet/ha**, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenarios:

- D1 ditch, D1 stream, D2 ditch, D2 stream, D6 ditch and R3 stream. In case of scenario D6 ditch RMS stated that although safe PEC_{SW} values were not reached at STEP 4, it may be stated that the risk for algae was not substantial due to the fact that they occurred late in autumn and in winter, when algae are in dormant period from December to February; also in none of these scenarios the PEC_{SW} values above the safe level were observed later than in the first days of March. Also in case of R3 scenario similar conclusion may be drawn.

The safe scenarios identified within that use were D4 and D5 – all three already at STEP 3 (hence no buffer zone needed to be implemented), D3 ditch assuming 10-metres wide non-spray buffer zone to mitigate Spray Drift, R1 assuming 20-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off and R4 assuming 10-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off.

Therefore, for that use it may be stated that the following safe scenarios were identified: scenarios D4 and D5 without any buffer zone (safe PEC_{SW} values were obtained already at STEP 3), D3 ditch assuming 10-metres wide non-spray buffer zone to mitigate Spray Drift, R1 scenario assuming 20-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off and R4 scenario assuming 10-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off.

SPRING USE

The general conclusions drawn from the risk assessment for algae presented above, are provided below, individually for each use listed in the EU-representative GAP.

In case of the post-emergence use in Winter cereals at spring, at application rate **160 g Flufenacet/ha**, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenarios:

- D2 ditch and D2 stream

In case of scenarios D4 pond, D5 pond, R1 pond and R4 stream safe PEC_{SW} values were obtained already at STEP 3 (so no buffer needed).

In case of the following scenarios: D1 ditch, D1 stream, D3 ditch, D4 stream, D5 stream and D6 ditch, safe PEC_{SW} values were obtained at STEP 4 after implementation of the 10-metres wide non-spray buffer zone for mitigation of the Spray Drift;

For scenarios R1 stream and R3 stream safe PEC_{SW} values were obtained at STEP 4 after implementation of 10-metres wide vegetated buffer zone for mitigation of the Spray Drift and Run-off.

Therefore for that application pattern only for scenario D2 safe use was not demonstrated. In case of scenario R4 it was demonstrated that implementation of the buffer zone mitigating Spray Drift and/or Run-off was not necessary. 10-metres wide non-spray buffer zone was demonstrated to be necessary to obtain safe PEC_{SW} values for scenarios D1, D3, D4, D5, D6, R1 and R3. In case of scenarios R1 and R3 that buffer zone has to be vegetated in order to mitigate the Run-off.

In case of the post-emergence use in Winter cereals at spring, at application rate **120 g Flufenacet/ha**, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenarios:

- D2 ditch and D2 stream

In case of scenarios D1 stream, D4 pond, D4 stream, D5 pond and D5 stream, R1 pond, and R4 stream safe PEC_{SW} values were obtained already at STEP 3.

In case of the scenarios D1 ditch, D3 ditch and D6 ditch safe PEC_{SW} values were obtained at STEP 4 after implementation of the 10-metres wide non-spray buffer zone for mitigation of the Spray Drift;

For scenarios R1 stream and R3 stream safe PEC_{SW} values were obtained at STEP 4 after implementation of 10-metres wide vegetated buffer zone for mitigation of the Spray Drift and Run-off.

Therefore for that application pattern only for scenario D2 safe use was not demonstrated. In case of scenarios D4, D5 and R4 it was demonstrated that implementation of the buffer zone mitigating Spray Drift and/or Run-off was not necessary. 10-metres wide non-spray buffer zone was demonstrated to be necessary to obtain safe PEC_{SW} values for scenario D1, D3, D6, R1 and R3. In case of scenarios R1 and R3 that buffer zone has to be vegetated in order to mitigate the Run-off.

As an additional refinement step RMS carried out the calculations using the VFS-mod option to mitigate run-off. The selected vegetated buffer zone was 10-metres wide. The same width of the buffer zone was used in function of the non-spray buffer zone for simultaneous mitigation of the Spray Drift.

The results of the calculations are presented below in the table 2.9.9-42. Only those scenarios are listed, for which a safe use was not obtained at STEP 4 assuming the maximum admissible reduction factors set by FOCUS.

As VFS-mod is a tool specific only for mitigating Run-off, and hence for R scenarios, in the table below only the results obtained for R scenarios, where relevant, are presented.

Table 2.9.9-42: Chronic toxicity exposure ratios (TER_{LT}) for based on worst case scenario PEC_{SW} from 10-metres buffer zone, VFS-mod.

Compound	Species	E _r C ₅₀ (µg a.s./L)	FOCUS Step 4	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
Autumn use in winter cereals at rate 1 x 120 g a.s./ha, pre emergence						
Flufenacet	P.subcapitata	7.55	R3 stream	1.275	5.92	≥10
Autumn use in winter cereals at rate 1 x 160 g a.s./ha, post emergence						
Flufenacet	P.subcapitata	7.55	R1 stream	0.129	58.52	≥10
			R3 stream	0.181	41.71	
			R4 stream	0.128	58.98	
Autumn use in winter cereals at rate 1 x 240 g a.s./ha, post emergence						
Flufenacet	P.subcapitata	7.55	R1 stream	0.194	38.91	≥10
			R3 stream	0.272	27.75	
			R4 stream	0.192	39.32	

Based on the results presented above it may be stated that the use of the VFS-mod for R scenarios assuming the 10-metres wide vegetated buffer zone resulted in reaching safe uses in all scenarios of concern in autumn post emergence use in winter cereals at 240 g Flufenacet/ha and 160 g Flufenacet/ha. In case however of autumn pre emergence use in winter cereals at 120 g/ha for R3 scenario a wider buffer zone than determined using VFS-mod will be needed to demonstrate the safe use also for that scenario and application pattern.

Risk assessment for aquatic macrophytes- Lemna gibba

The lowest toxicity endpoint 7-day E_rC₅₀ of 13.9 µg a.s./L performed for Lemna gibba was used in the risk assessment.

In addition, it should be noted that, the Applicant proposed to use the peak exposure study for Lemna sp. with E_rC₅₀> 126 µg a.s./L to refine the risk for R scenarios (Bruns 2013, see CA, Vol 3, B9).

RMS is of the opinion that although the study is valid it may be used in the refined risk assessment for macrophytes

only if:

- Further evidence is provided that rooted macrophytes are not more sensitive to flufenacet than Lemna sp.
- The peak exposure design of the study covers the peaks observed in the FOCUS scenarios.

Therefore, the study will not be used in the current risk assessment.

The risk assessment based on the 7-day E_rC_{50} of 13.9 µg a.s./L based on growth rate is presented below in Tables 2.9.9-43 - 2.9.9-50.

Table 2.9.9.43: TER_{LT} values for Lemna gibba exposed to flufenacet and its metabolites.

Compound	Species	E _r C ₅₀ (µg/L)	FOCUS STEP	Max PEC _{sw} (µg/L)	TER _A	Trigger
Autumn use in winter cereals at rate 120 g a.s./ha, pre emergence						
Flufenacet	Lemna gibba	13.9	Step1	31.227	0.44	≥10
			Step 2NE	13.797	1.00	
			Step 2SE	11.217	1.24	
FOE oxalate		>100 000	Step1	6.466	>15465.51	
FOE methylsulfide		106 000	Step1	0.084	1261904.76	
FOE methylsulfone		>100 000	Step1	1.896	>52742.61	
TFA		1990 000	Step1	10.228	194563.94	
FOE-Thiadone		18 320	Step1	1.464	12513.66	
FOE-Trifluoroethane sulfonic acid		>10 000	Step1	1.084	>9225.09	
Spring use in winter cereals at rate 120 g a.s./ha, post emergence						
Flufenacet	Lemna gibba	13.9	Step1	31.277	0.44	≥10
			Step2 NE	6.057	2.30	
			Step2 SE	11.217	1.23	
FOE oxalate		>100 000	Step 1	6.466	>15465.51	
FOE methylsulfide		106 000	Step 1	0.084	1261904.76	
FOE methylsulfone		>100 000	Step1	1.896	>52742.61	
TFA		1999 000	Step1	10.228	194563.94	
FOE-Thiadone		18.320	Step 1	1.464	12513.66	
FOE-Trifluoroethane sulfonic acid		>10 000	Step 1	1.084	>9225.09	
Autumn use in winter cereals at rate 160 g a.s./ha, post emergence						
Flufenacet	Lemna gibba	13.9	Step 1	41.636	0.33	≥10
			Step 2NE	18.395	0.76	
			Step 2SE	14.956	0.93	
FOE oxalate		>100 000	Step 1	8.622	11598.23	
FOE methylsulfide		106 000	Step1	0.111	>954954.95	
FOE methylsulfone		>100 000	Step1	2.528	>39556.69	
TFA		1990 000	Step1	13.638	145918.82	
FOE-Thiadone		18 320	Step1	1.952	9385.24	
FOE-Trifluoroethane sulfonic acid		>10 000	Step1	1.445	>6920.41	
Spring use in winter cereals at rate 160 g a.s./ha, post emergence						
Flufenacet	Lemna gibba	13.9	Step 1	41.636	0.33	≥10
			Step 2 NE	8.076	1.72	
			Step 2 SE	14.956	0.93	
FOE oxalate		>100 000	Step1	8.622	>11598.23	
FOE methylsulfide		106 000	Step1	0.111	954954.95	
FOE methylsulfone		>100 000	Step1	2.528	>39556.69	
TFA		1990 000	Step1	13.638	145918.82	
FOE-Thiadone		18 320	Step1	1.952	9385.24	
FOE-Trifluoroethanesulfonic acid		>10 000	Step1	1.445	>6920.41	
Autumn use in winter cereals at rate 240 g a.s./ha, post emergence						
Flufenacet	Lemna gibba	13.9	Step 1	62.454	0.22	10
				27.593	0.50	
				22.433	0.62	
FOE oxalate		>100 000	Step 1	12.933	>7732.16	
FOE methylsulfide		106 000	Step 1	0.167	634730.53	
FOE methylsulfone		>100 000	Step 1	3.792	>26371.30	
TFA		1990 000	Step 1	22.426 ¹	88736.28	
FOE-Thiadone		18 320	Step 1	2.928	6256.83	
FOE-Trifluoroethane sulfonic acid		>10 000	Step 1	2.168	>4612.54	

1) max PEC_{gw}

Values in bold indicate unacceptable risk

All TER_{LT} values calculated for metabolites of flufenacet with consideration of worst case exposure assumptions are far above the trigger of 10 indicating acceptable chronic risk to Lemna gibba.

However, the TER_{LT} values for flufenacet obtained by FOCUS Step 2 calculations are lower than the Annex VI

trigger value of 10 for all proposed uses in winter cereals and needs further refinement.

Table 2.9.9-44: Chronic toxicity exposure ratios (TER_{LT}) for Lemna gibba based on worst case scenario PEC_{sw} from STEP 3.

STEP 3:

Compound	Species	E _r C ₅₀ (µg a.s./L)	FOCUS Step 3	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
Autumn use in winter cereals at rate 120 g a.s./ha, pre emergence						
Flufenacet	Lemna gibba	13.9	D1 ditch	2.680	5.19	≥10
			D1 stream	1.672	8.31	
			D2 ditch	3.227	4.31	
			D2 stream	2.021	6.88	
			D3 ditch	0.758	18.34	
			D4 pond	0.398	34.92	
			D4 stream	0.658	21.12	
			D5 pond	0.560	24.82	
			D5 stream	0.710	19.58	
			D6 ditch	2.764	5.03	
			R1 pond	0.0609	228.24	
			R1 stream	2.800	4.96	
			R3 stream	3.783	3.67	
R4 stream	1.167	11.91				
Spring use in winter cereals at rate 120 g a.s./ha, post emergence						
Flufenacet	Lemna gibba	13.9	D1 ditch	0.846	16.43	≥10
			D1 stream	0.629	22.10	
			D2 ditch	1.702	8.17	
			D2 stream	1.111	12.51	
			D3 ditch	0.760	18.29	
			D4 pond	0.0267	520.60	
			D4 stream	0.572	24.30	
			D5 pond	0.0289	480.97	
			D5 stream	0.614	22.64	
			D6 ditch	0.756	18.39	
			R1 pond	0.0687	202.333	
			R1 stream	0.764	18.19	
			R3 stream	1.080	12.87	
R4 stream	0.501	27.74				
Autumn use in winter cereals at rate 160 g a.s./ha, post emergence						
Flufenacet	Lemna gibba	13.9	D1 ditch	4.328	3.21	≥10
			D1 stream	2.699	5.15	
			D2 ditch	3.957	3.51	
			D2 stream	2.480	5.60	
			D3 ditch	1.010	13.76	
			D4 pond	0.756	18.39	
			D4 stream	1.081	12.86	
			D5 pond	0.766	18.15	
			D5 stream	0.946	14.69	
			D6 ditch	3.732	3.72	
			R1 pond	0.0797	174.40	
			R1 stream	3.790	3.67	
			R3 stream	4.980	2.79	
R4 stream	3.957	3.51				

Table 2.9.9.43. Chronic toxicity exposure ratios (TER_{LT}) for Lemna gibba based on worst case scenario PEC_{sw} from STEP 3 (continued).

Compound	Species	E _r C ₅₀ (µg a.s./L)	FOCUS Step 3	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
Spring use in winter cereals at rate 160 g a.s./ha, post emergence						
Flufenacet	Lemna gibba	13.9	D1 ditch	1.129	12.31	
			D1 stream	0.838	16.59	
			D2 ditch	2.412	5.76	
			D2 stream	1.574	8.83	

Compound	Species	E _r C ₅₀ (µg a.s./L)	FOCUS Step 3	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
			D3 ditch	1.014	13.71	≥10
			D4 pond	0.0357	389.36	
			D4 stream	0.763	18.22	
			D5 pond	0.0387	359.17	
			D5 stream	0.818	16.99	
			D6 ditch	1.009	13.78	
			R1 pond	0.0913	152.25	
			R1 stream	1.021	13.61	
			R3 stream	1.450	9.59	
R4 stream	0.668	20.81				
Autumn use in winter cereals at rate 240 g a.s./ha, post emergence						
Flufenacet	Lemna gibba	13.9	D1 ditch	6.543	2.12	≥10
			D1 stream	4.082	3.41	
			D2 ditch	6.199	2.24	
			D2 stream	3.882	3.58	
			D3 ditch	1.514	9.18	
			D4 pond	1.168	11.90	
			D4 stream	1.647	8.44	
			D5 pond	1.170	11.88	
			D5 stream	1.420	9.79	
			D6 ditch	5.693	2.44	
			R1 pond	0.116	119.83	
			R1 stream	5.811	2.39	
			R3 stream	7.641	1.82	
			R4 stream	5.980	2.32	

*values in bold indicate unacceptable risk

In the table below are listed all the scenarios for which the TER_{LT} value did not meet the trigger.

Table 2.9.9-45: The FOCUS STEP 3 scenarios in winter cereals, for which the TER_{LT} Lemna gibba needs further refinement.

Scenario STEP 3	Winter cereals				
	Autumn use 120 g a.s./ha	Spring use 120 g a.s./ha	Autumn use 160 g a.s./ha	Spring use 160 g a.s./ha	Autumn use 240 g a.s./ha
D1 ditch	D1 ditch	-	D1 ditch	-	D1 ditch
D1 stream	D1 stream	-	D1 stream	-	D1 stream
D2 ditch	D2 ditch	D2 ditch	D2 ditch	D2 ditch	D2 ditch
D2 stream	D2 stream	-	D2 stream	D2 stream	D2 stream
D3 ditch	-	-	-	-	D3 ditch
D4 pond	-	-	-	-	-
D4 stream	-	-	-	-	D4 stream
D5 pond	-	-	-	-	-
D5 stream	-	-	-	-	D5 stream
D6 ditch	D6 ditch	-	D6 ditch	-	D6 ditch
R1 pond	-	-	-	-	-
R1 stream	R1 stream	-	R1 stream	-	R1 stream
R3 stream	R3 stream	-	R3 stream	R3 stream	R3 stream
R4 stream	-	-	R4 stream	-	R4 stream

- No further refinement is needed

Based on a comparison of the results of the standard laboratory toxicity studies with FOCUS Step 3 maximum PEC_{sw} values for flufenacet, the TER_{LT} values for Lemna gibba meet the required trigger of 10, except the scenarios given in the Table 2.9.9-45. For these scenarios Lemna sp. TER needs further refinement.

Therefore, the PEC_{sw} values for flufenacet were further refined at FOCUS Step 4 using 10-metres- and 20-metres-wide FOCUS buffer zones for mitigation of Spray Drift and Run-off. As an additional refinement step in Run-off mitigation were performed the calculations in VFS-mod assuming the 10-metres wide buffer zone for reducing migration with Spray Drift (D and R) scenarios and Run-off (for R scenarios only).

FOCUS STEP 4 -10-metres wide FOCUS buffer zone for mitigation of Spray Drift and Run-off

TER_{LT} values for relevant scenarios based on worst case scenario PEC_{sw} from STEP 4 with 10-meter buffer zone FOCUS were presented in the Table 2.9.9-46 below:

Table 2.9.9-46: Chronic toxicity exposure ratios (TER_{LT}) for Lemna gibba based on worst case scenario PEC_{sw} from STEP 4 with 10 meter buffer zone.

Compound	Species	E _r C ₅₀ (µg a.s./L)	FOCUS Step 4	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
Autumn use in winter cereals at rate 120 g a.s./ha, preemergence						
Flufenacet	Lemna gibba	13.9	D1 ditch	2.680	5.19	≥10
			D1 stream	1.672	8.31	
			D2 ditch	3.227	4.31	
			D2 stream	2.021	6.88	
			D6 ditch	2.764	5.03	
			R1 stream	1.354	10.27	
			R3 stream	1.728	8.04	
Spring in winter cereals at rate 120 g a.s./ha, post emergence						
Flufenacet	Lemna gibba	13.9	D2 ditch	1.702	8.17	≥10
Autumn use in winter cereals at rate 160 g a.s./ha, post emergence						
Flufenacet	Lemna gibba	13.9	D1 ditch	4.328	3.21	≥10
			D1 stream	2.699	5.15	
			D2 ditch	3.957	3.51	
			D2 stream	2.480	5.60	
			D6 ditch	3.732	3.72	
			R1 stream	1.697	8.19	
			R3 stream	2.246	6.19	
			R4 stream	1.786	7.78	
Spring use in winter cereals at rate 160 g a.s./ha, post emergence						
Flufenacet	Lemna gibba	13.9	D2 ditch	2.412	5.76	≥10
			D2 stream	1.574	8.83	
			R3 stream	0.662	21.00	
Autumn use in winter cereals at rate 240 g a.s./ha, post emergence						
Flufenacet	Lemna gibba	13.9	D1 ditch	6.543	2.12	≥10
			D1 stream	4.082	3.41	
			D2 ditch	6.199	2.24	
			D2 stream	3.882	3.58	
			D6 ditch	5.693	2.44	
			D3 ditch	0.218	63.76	
			D4 stream	1.674	8.30	
			D5 stream	1.249	11.13	
			R1 stream	2.602	5.34	
			R3 stream	3.446	4.03	
R4 stream	2.699	5.15				

*Values in bold indicate unacceptable risk

In the table below are listed all the scenarios for which the TER_{LT} value did not meet the trigger.

Table 2.9.9-47: The FOCUS STEP 4 scenarios with 10 m buffer, for which the TER_{LT} Lemna gibba needs further refinement.

Scenario STEP 4	Autumn use 120 g s.a./ha	Spring use 120 g s.a./ha	Winter cereals		
			Autumn use 160 g a.s./ha	Spring use 160 g s.a./ha	Autumn use 240 g a.s./ha
D1 ditch	D1 ditch	D2 ditch	D1 ditch	D2 ditch	D1 ditch
D1 stream	D1 stream	-	D1 stream	D2 stream	D1 stream
D2 ditch	D2 ditch	-	D2 ditch	-	D2 ditch
D2 stream	D2 stream	-	D2 stream	-	D2 stream
D6 ditch	D6 ditch	-	D6 ditch	-	D6 ditch
D4 stream	-	-	-	-	D4 stream
R1 stream		-	R1 stream	-	R1 stream
R3 stream	R3 stream	-	R3 stream	-	R3 stream
R4 stream	-	-	R4 stream	-	R4 stream

Based on a comparison of the results of the standard laboratory toxicity studies with FOCUS Step 4 with 10 meter buffer zone PEC_{sw} values for flufenacet, the TER_{LT} values for Lemna gibba meet the required trigger of 10, except the scenarios given in the Table 2.9.9-47. For these scenarios Lemna gibba TER needs further refinement. As a result, PEC_{sw} values for flufenacet for autumn and spring application to winter cereals were further refined using the FOCUS Step-4 with 20 meter buffer zone FOCUS.

STEP 4 – 20-metres wide FOCUS buffer zone for mitigation of Spray Drift and Run-off

Table 2.9.9-48: Chronic toxicity exposure ratios (TER_{LT}) for Lemna gibba based on worst-case scenario PEC_{sw} from STEP 4 with 20 meter buffer zone.

Compound	Species	E _r C ₅₀ (µg a.s./L)	FOCUS Step 4	Max PEC _{sw} (µg a.s./L)	TER _{L,T}	Trigger
Autumn use in winter cereals at rate 120 g a.s./ha, pre-emergence						
Flufenacet	Lemna gibba	13.9	D1 ditch	2.680	5.19	≥10
			D1 stream	1.672	8.31	
			D2 ditch	3.227	4.31	
			D2 stream	2.021	6.88	
			D6 ditch	2.764	5.03	
			R3 stream	0.907	15.33	
Spring use in winter cereals at rate 120 g a.s./ha, post-emergence						
Flufenacet	Lemna gibba	13.9	D2 ditch	1.702	8.17	≥10
Autumn use in winter cereals at rate 160 g a.s./ha, post emergence						
Flufenacet	Lemna gibba	13.9	D1 ditch	4.328	3.21	≥10
			D1 stream	2.699	5.15	
			D2 ditch	3.957	3.51	
			D2 stream	2.480	5.60	
			D6 ditch	3.732	3.72	
			R1 stream	0.883	15.74	
			R3 stream	1.173	11.85	
			R4 stream	0.933	14.90	
Spring use in winter cereals at rate 160 g a.s./ha, post emergence						
Flufenacet	Lemna gibba	13.9	D2 ditch	2.412	5.76	≥10
			D2 stream	1.574	8.83	
Autumn use in winter cereals at rate 240 g a.s./ha, post emergence						
Flufenacet Flufenacet	Lemna gibba	13.9	D1 ditch	6.543	2.12	≥10
			D1 stream	4.082	3.41	
			D2 ditch	6.199	2.24	
			D2 stream	3.882	3.58	
			D4 stream	1.674	8.30	
			D6 ditch	5.693	2.44	
			R1 stream	1.354	10.27	
			R3 stream	1.799	7.73	
			R4 stream	1.410	9.86	

*values in bold indicate unacceptable risk

In the table below are listed all the scenarios for which the TER_{LT} value did not meet the trigger.

Table 2.9.9-49: The FOCUS STEP 4 scenarios with 20 m buffer, for which the TER_{LT} Lemna gibba needs further refinement.

Scenario STEP 4	Autumn use 120 g s.a./ha	Spring use 120 g s.a./ha	Winter cereals		
			Autumn use 160 g a.s./ha	Spring use 160 g s.a./ha	Autumn use 240 g a.s./ha
D1 ditch	D1 ditch	D2 ditch	D1 ditch	D2 ditch	D1 ditch
D1 stream	D1 stream	-	D1 stream	D2 stream	D1 stream
D2 ditch	D2 ditch	-	D2 ditch	-	D2 ditch
D2 stream	D2 stream	-	D2 stream	-	D2 stream
D6 ditch	D6 ditch	-	D6 ditch	-	D6 ditch
D4 stream	-	-	-	-	D4 stream
R1 stream	-	-	R1 stream	-	-
R3 stream	-	-	R3 stream	-	R3 stream
R4 stream	-	-	R4 stream	-	R4 stream

Based on a comparison of the results of the standard laboratory toxicity studies with FOCUS Step 4 PEC_{sw} values for flufenacet calculated assuming 20-metres buffer zone for mitigation of Spray Drift in all D scenarios and Spray Drift and Run-off in all R scenarios (for Run-off the adequate reduction factors given by FOCUS L&M Guideline for 10-20 –metres wide vegetated buffer zone were used, the TER_{LT} values for algae meet the required trigger of 10, except the scenarios given in the Table 2.9.9-49.

For those scenarios, Lemna gibba TER needs further refinement.

At the same time it shall be pointed out that in case of the scenarios D4-pond, D4-stream, D5-pond, D5-stream and D6-ditch, when the required trigger value for TER_{LT} was not met for applications in autumn, the risk may still be negligible. That is due to the fact that for those scenarios the predominant identified migration route was drainage occurring shortly after application and late in autumn and in winter. It was also noticed that for these scenarios the concentrations of Flufenacet above the level of the safe PEC_{sw} values were obtained for the period between December and the end of February or the first days of March on the latest.

Similar statement with regard to the temporal occurrence of modelled concentrations of Flufenacet in SW bodies may be drawn for all R scenarios.

These conclusions were based on the thorough analysis of the TOXSWA concentration profiles in water phase

presented in graphical form in the Appendixes 3-5 of the document Vol. 3 B.8_CP of this RAR. Also these results were analysed using the E-PAT 1.0 tool (results not presented in the RAR).

Overall conclusion of Lemna gibba risk assessment

Autumn Uses:

The general conclusions drawn from the risk assessment for algae presented above are given, are provided below, individually for each use listed in the EU-representative GAP.

- In case of the post-emergence use in Winter cereals in autumn, at application rate **240 g Flufenacet/ha**, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenarios:
 - D1 ditch, D1 stream, D2 ditch, D2 stream, D4 stream, D6 ditch, R3 and R4. In case of scenarios D4 stream and D6 ditch RMS noticed that although safe PEC_{SW} values were not reached at STEP 4, it may be stated that the risk for Lemna spp. was not substantial due to the fact that they occurred late in autumn and in winter, when Lemna sp. in dormant period from December to February; also in none of these scenarios the PEC_{SW} values above the safe level were observed later than in the first days of March. Also in case of all R scenarios for which safe PEC_{SW} value was not reached, similar conclusion may be drawn.

The safe scenarios identified within that use were: D3 ditch assuming 10-metres wide buffer zone for mitigation of Spray Drift, D4 pond already at STEP 3 (hence no buffer zone needed to be implemented), D5 pond already at STEP 3 (hence no buffer zone needed to be implemented), D5 stream assuming 10-metres wide buffer zone for mitigation of Spray Drift, R1 pond already at STEP 3 (hence no buffer zone needed to be implemented), R1 stream assuming 20-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off;

Therefore, for that use it may be stated that three safe scenarios were identified: for the D3 scenario assuming 10-metres wide non-spray buffer zone to mitigate the Spray drift, for D5 scenario assuming 10-metres wide non-spray buffer zone to mitigate Spray Drift and R1 assuming 20-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off.

- In case of the post-emergence use in Winter cereals in autumn, at application rate **160 g Flufenacet/ha**, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenarios:
 - D1 ditch, D1 stream, D2 ditch, D2 stream, and D6 ditch. In case of scenario D6 ditch RMS noticed that although safe PEC_{SW} values were not reached at STEP 4, it may be stated that the risk for Lemna spp. was not substantial due to the fact that they occurred late in autumn and in winter, when Lemna sp. was in dormant period from December to February; also in none of these scenarios the PEC_{SW} values above the safe level were observed later than in the first days of March.

The safe scenarios identified within that use were: D3 ditch, D4 pond, D4 stream, D5 pond, D5 stream – all them already at STEP 3 (hence no buffer zone needed to be implemented), as well as R1 pond already at STEP 3 (hence no buffer zone needed to be implemented), R1 stream assuming 20-metres wide vegetated buffer zone for mitigation of Spray Drift and Run-off, R3 stream assuming 20-metres wide vegetated buffer zone for mitigation of Spray Drift and Run-off and R4 stream assuming 20-metres wide vegetated buffer zone for mitigation of Spray Drift and Run-off.

Therefore for that use it may be stated that the following safe uses were identified: for scenarios D3, D4 and D5 without any buffer zone (safe PEC_{SW} values were obtained already at STEP 3) as well as R1, R3 and R4 scenarios assuming 20-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off.

- In case of the post-emergence use in Winter cereals in autumn, at application rate **120 g Flufenacet/ha**, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenarios:
 - D1 ditch, D1 stream, D2 ditch, D2 stream and D6 ditch. In case of scenario D6 ditch RMS noticed that although safe PEC_{SW} values were not reached at STEP 4, it may be stated that the risk for Lemna spp.e was not substantial due to the fact that they occurred late in autumn and in winter, when Lemna sp. is in dormant period from December to February; also in none of these scenarios the PEC_{SW} values above the safe level were observed later than in the first days of March

The safe scenarios identified within that use were D3 ditch, D4 (pond and stream), D5 (pond and stream), R1 pond and R4 stream – all they already at STEP 3 (hence no buffer zone needed to be implemented), as well as R1 stream assuming 10-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off and R3 assuming 20-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off

Therefore for that use it may be stated that the following safe uses were identified: for scenarios D3, D4, D5 and R4 without any buffer zone (safe PEC_{SW} values were obtained already at STEP 3) as well as R1 scenario assuming 10-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off and R3 scenario assuming 20-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off.

SPRING USE

The general conclusions drawn from the risk assessment for algae presented above are given, are provided below, individually for each use listed in the EU-representative GAP.

- In case of the post-emergence use in Winter cereals at spring, at application rate **160 g Flufenacet/ha**, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenarios: D2 ditch and D2 stream;

In case of scenarios D1 ditch, D1 stream, D3 ditch, D4 pond, D4 stream, D5 pond and D5 stream, R1 pond, R1 stream and R4 stream safe PEC_{SW} values were obtained already at STEP 3.

For scenario R3 stream safe PEC_{SW} values were obtained at STEP 4 after implementation of 10-metres wide vegetated buffer zone for mitigation of the Spray Drift and Run-off.

Therefore for that application pattern only for scenarios D2 safe use was not demonstrated. In case of scenario R3 it was demonstrated that it was necessary to implement the buffer zone mitigating Spray Drift and Run-off. In all remaining scenarios identified as returning the safe PEC_{SW} values it was demonstrated that the implementation of any mitigation measures was not necessary as the assessment was finalised at Step 3.

- In case of the post-emergence use in Winter cereals at spring, at application rate **120 g Flufenacet/ha**, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenario D2 ditch.

In case of scenarios D1 ditch, D1 stream, D2 stream, D3 ditch, D4 pond, D4 stream, D5 pond and D5 stream, R1 pond, R1 stream, R3 stream and R4 stream safe PEC_{SW} values were obtained already at STEP 3. For that application pattern assessment at STEP 4 was not performed.

Therefore for that application pattern only for scenario D2 safe use was not demonstrated. In case of scenarios D1, D3, D4, D5, D6, R1, R3 and R4 it was demonstrated that implementation of the buffer zone mitigating Spray Drift and/or Run-off was not necessary.

As an additional refinement step RMS carried out the calculations using the VFS-mod option to mitigate run-off. The selected vegetated buffer zone was 10-metres wide. The same width of the buffer zone was used in function of the non-spray buffer zone for simultaneous mitigation of the Spray Drift.

The results of the calculations are presented below in the table 2.9.9-50. In it are listed only those scenarios, for which safe PEC_{SW} values were not obtained at STEP 4 assuming the maximum admissible reduction factors set by FOCUS.

As VFS-mod is a tool specific only for mitigating Run-off, and hence for R scenarios, in the table below only the results obtained for R scenarios, where relevant, were presented.

Table 2.9.9-50: Chronic toxicity exposure ratios (TER_{LT}) for *Lemna gibba* based on worst case scenario PEC_{SW} from 10-metres buffer zone, VFS-mod.

Infrared barrier zone, VRS-mold.						
Compound	Species	E _r C ₅₀ (µg a.s./L)	FOCUS Step 4	Max PEC _{Sw} (µg a.s./L)	TER _{LT}	Trigger
Autumn use in winter cereals at rate 1 x 160 g a.s./ha, post emergence						
Flufenacet	L.gibba	13.9	R1 stream	0.129	107.75	≥10
			R3 stream	0.181	79.80	
			R4 stream	0.128	108.60	
Autumn use in winter cereals at rate 1 x 240 g a.s./ha, post emergence						
Flufenacet	L.gibba	13.9	R1 stream	0.194	71.64	≥10
			R3 stream	0.272	51.10	
			R4 stream	0.192	72.40	

Based on the results presented above it may be stated that the use of the VFS-mod for R scenarios assuming the 10-metres wide vegetated buffer zone resulted in reaching safe PEC_{sw} values in all scenarios of concern in autumn post-emergence use in Winter cereals at 160 g a.s./ha and 240 g Flufenacet/ha.

The Applicant as a refinement provided the risk assessment based on microcosm study (Foekema 1997, see CA, Vol 3., B9). This study was re-evaluated by RMS and was considered valid in case of Macrophytes (Lemna sp. and Elodea sp.). The results of the study suggest that rooted plants are more sensitive than Lemna sp. Therefore, RMS would like to propose the $NOEC_{macrophytes}$ of 6 $\mu\text{g a.s./L}$ value with the Assessment Factor of 5 to refine the risk for aquatic macrophytes, including Lemna sp and Elodea sp. In addition, the peak exposure study for Lemna sp. with $E_rC_{50} > 126 \mu\text{g a.s./L}$ to refine the risk assessment for R scenarios (Bruns 2013, see CA, Vol 3, B9) was performed.

RMS is of the opinion that although the study is valid it may be used in the refined risk assessment for macrophytes only if:

- Further evidence is provided that rooted macrophytes are not more sensitive to flufenacet than Lemna sp.
- The peak exposure design of the study covers the peaks observed in the FOCUS scenarios.

Therefore, the study will not be used in the current risk assessment.

Risk assessment for Macrophytes including Lemna sp and Elodea sp

Consequently the risk assessment will be performed using the new $NOEC_{macrophytes} = 6 \mu\text{g a.s./L}$ obtained from Microcosm study (see Foekema 1997, see CA, Vol 3., B9) with AF of 5 and it is presented below in tables 2.9.9-51 – 2.9.9-58.

Table 2.9.9-51: TER_{LT} values for Macrophytes exposed to flufenacet.

Compound	Species	NOEC (µg a.s./L)	FOCUS STEP	Max PEC _{sw} (µg a.s./L)	TER _A	Trigger
Autumn use in winter cereals at rate 1 x 120 g a.s./ha, pre emergence						
Flufenacet	Microcosm (Lemna sp + Elodea sp.)	6	Step1	31.227	0.19	≥5
			Step 2NE	13.797	0.43	
			Step 2SE	11.217	0.53	
Spring use in winter cereals at rate 1 x 120 g a.s./ha, post emergence						
Flufenacet	Microcosm (Lemna sp + Elodea sp.)	6	Step1	31.277	0.19	≥5
			Step2 NE	6.057	0.99	
			Step2 SE	11.217	0.53	
Autumn use in winter cereals at rate 1 x 160 g a.s./ha, post emergence						
Flufenacet	Microcosm (Lemna sp + Elodea sp.)	6	Step 1	41.636	0.14	≥5
			Step 2NE	18.395	0.32	
			Step 2SE	14.956	0.40	
Spring use in winter cereals at rate 1 x 160 g a.s./ha, post emergence						
Flufenacet	Microcosm (Lemna sp + Elodea sp.)	6	Step 1	41.636	0.14	≥5
			Step 2 NE	8.076	0.74	
			Step 2 SE	14.956	0.40	
Autumn use in winter cereals at rate 1x 240 g a.s./ha, post emergence						
Flufenacet	Microcosm (Lemna sp + Elodea sp.)	6	Step 1	62.454	0.09	≥5
				27.593	0.21	
				22.433	0.26	

values in bold indicate unacceptable risk

TER_{LT} values for flufenacet obtained by FOCUS 1-2 calculations are lower than trigger value of 5 for all proposed uses in winter cereals and needs further refinement.

Table 2.9.9-52: Chronic toxicity exposure ratios (TER_{LT}) for Macrophytes based on worst case scenario PEC_{sw} from STEP 3.

Compound	Species	NOEC ($\mu\text{g a.s./L}$)	FOCUS Step 3	Max PEC_{sw} ($\mu\text{g a.s./L}$)	TER_{LT}	Trigger
Autumn use in winter cereals at rate 1 x 120 g a.s./ha, pre emergence						
Flufenacet	Microcosm (Lemna sp + Elodea sp.)	6	D1 ditch	2.680	2.23	≥ 5
			D1 stream	1.672	3.58	
			D2 ditch	3.227	1.85	
			D2 stream	2.021	2.96	
			D3 ditch	0.758	7.91	
			D4 pond	0.398	15.07	

Compound	Species	NOEC (µg a.s./L)	FOCUS Step 3	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
			D4 stream	0.658	9.11	
			D5 pond	0.560	10.71	
			D5 stream	0.710	8.45	
			D6 ditch	2.764	2.17	
			R1 pond	0.0609	98.52	
			R1 stream	2.800	2.14	
			R3 stream	3.783	1.58	
R4 stream	1.167	5.14				
Spring use in winter cereals at rate 1 x 120 g a.s./ha, post emergence						
Flufenacet	Microcosm (Lemna sp + Elodea sp.)	6	D1 ditch	0.846	7.09	≥5
			D1 stream	0.629	9.53	
			D2 ditch	1.702	3.52	
			D2 stream	1.111	5.40	
			D3 ditch	0.760	7.89	
			D4 pond	0.0267	224.71	
			D4 stream	0.572	10.48	
			D5 pond	0.0289	207.61	
			D5 stream	0.614	9.77	
			D6 ditch	0.756	7.93	
			R1 pond	0.0687	87.33	
			R1 stream	0.764	7.85	
			R3 stream	1.080	5.55	
R4 stream	0.501	11.97				
Autumn use in winter cereals at rate 1 x 160 g a.s./ha, post emergence						
Flufenacet	Microcosm (Lemna sp + Elodea sp.)	6	D1 ditch	4.328	1.38	≥5
			D1 stream	2.699	2.22	
			D2 ditch	3.957	1.51	
			D2 stream	2.480	2.41	
			D3 ditch	1.010	5.94	
			D4 pond	0.756	7.93	
			D4 stream	1.081	5.55	
			D5 pond	0.766	7.83	
			D5 stream	0.946	6.34	
			D6 ditch	3.732	1.60	
			R1 pond	0.0797	75.28	
			R1 stream	3.790	1.58	
			R3 stream	4.980	1.20	
			R4 stream	3.957	1.51	

*values in bold indicate unacceptable risk

Table 2.9.9-52. Chronic toxicity exposure ratios (TER_{LT}) for Macrophytes based on worst case scenario PEC_{sw} from STEP 3 (continued).

STEP 3 (continued).						
Compound	Species	NOEC (µg a.s./L)	FOCUS Step 3	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
Spring use in winter cereals at rate 1 x 160 g a.s./ha, post emergence						
Flufenacet	Microcosm (Lemna sp + Elodea sp.)	6	D1 ditch	1.129	5.31	≥5
			D1 stream	0.838	7.15	
			D2 ditch	2.412	2.48	
			D2 stream	1.574	3.81	
			D3 ditch	1.014	5.91	
			D4 pond	0.0357	168.06	
			D4 stream	0.763	7.86	
			D5 pond	0.0387	155.03	
			D5 stream	0.818	7.33	
			D6 ditch	1.009	5.94	
			R1 pond	0.0913	65.71	
			R1 stream	1.021	5.87	
			R3 stream	1.450	4.13	
			R4 stream	0.668	8.98	
Autumn use in winter cereals at rate 1x 240 g a.s./ha, post emergence						
Flufenacet	Microcosm (Lemna sp + Elodea sp.)	6	D1 ditch	6.543	0.91	≥5
			D1 stream	4.082	1.46	
			D2 ditch	6.199	0.96	
			D2 stream	3.882	1.54	
			D3 ditch	1.514	3.96	
			D4 pond	1.168	5.13	
			D4 stream	1.647	3.64	
			D5 pond	1.170	5.12	

Compound	Species	NOEC (µg a.s./L)	FOCUS Step 3	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
			D5 stream	1.420	4.22	
			D6 ditch	5.693	1.05	
			R1 pond	0.116	51.72	
			R1 stream	5.811	1.03	
			R3 stream	7.641	0.78	
			R4 stream	5.980	1.00	

*values in bold indicate unacceptable risk

In the table below are listed all the scenarios for which the TER_{LT} value did not meet the trigger.

Table 2.9.9-53: The FOCUS STEP 3 scenarios in winter cereals, for which the TER_{LT} Macrophytes needs further refinement.

Scenario STEP 3	Winter cereals				
	Autumn use 120 g a.s./ha	Spring use 120 g a.s./ha	Autumn use 160 g a.s./ha	Spring use 160 g a.s./ha	Autumn use 240 g a.s./ha
D1 ditch	D1 ditch	-	D1 ditch	-	D1 ditch
D1 stream	D1 stream	-	D1 stream	-	D1 stream
D2 ditch	D2 ditch	D2 ditch	D2 ditch	D2 ditch	D2 ditch
D2 stream	D2 stream	-	D2 stream	D2 stream	D2 stream
D3 ditch	-	-	-	-	D3 ditch
D4 pond	-	-	-	-	-
D4 stream	-	-	-	-	D4 stream
D5 pond	-	-	-	-	-
D5 stream	-	-	-	-	D5 stream
D6 ditch	D6 ditch	-	D6 ditch	-	D6 ditch
R1 pond	-	-	-	-	-
R1 stream	R1 stream	-	R1 stream	-	R1 stream
R3 stream	R3 stream	-	R3 stream	R3 stream	R3 stream
R4 stream	-	-	R4 stream	-	R4 stream

- no further refinement is needed

Based on a comparison of the results of the standard laboratory toxicity studies with FOCUS Step 3 maximum PEC_{sw} values for flufenacet, the TER_{LT} values for Macrophytes meet the required trigger of 10, except the scenarios given in the Table 2.9.9-53. For these scenarios Macrophytes TER needs further refinement.

Therefore, the PEC_{sw} values for flufenacet were further refined at FOCUS Step 4 using 10-metres- and 20-metres-wide FOCUS buffer zones for mitigation of Spray Drift and Run-off. As an additional refinement step in Run-off mitigation were performed the calculations in VFS-mod assuming the 10-metres wide buffer zone for reducing migration with Spray Drift (D and R) scenarios and Run-off (for R scenarios only).

FOCUS STEP 4 -10-metres wide FOCUS buffer zone for mitigation of Spray Drift and Run-off

TER_{LT} values for relevant scenarios based on worst case scenario PEC_{sw} from STEP 4 with 10 meter buffer zone FOCUS were presented in the Table 2.9.9-54.

Table 2.9.9-54: Chronic toxicity exposure ratios (TER_{LT}) for Macrophytes based on worst case scenario PEC_{sw} from STEP 4 with 10 meter buffer zone.

Compound	Species	NOEC (µg a.s./L)	FOCUS Step 4	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
Autumn use in winter cereals at rate 1 x 120 g a.s./ha, pre-emergence						
Flufenacet	Microcosm (Lemna sp + Elodea sp.)	6	D1 ditch	2.680	2.23	≥5
			D1 stream	1.672	3.58	
			D2 ditch	3.227	1.85	
			D2 stream	2.021	2.96	
			D6 ditch	2.764	2.17	
			R1 stream	1.354	4.43	
			R3 stream	1.728	3.47	
Spring in winter cereals at rate 1 x 120 g a.s./ha, post-emergence						
Flufenacet	Microcosm (Lemna sp + Elodea sp.)	6	D2 ditch	1.702	3.52	≥5
Autumn use in winter cereals at rate 1 x 160 g a.s./ha, post emergence						
Flufenacet	Microcosm (Lemna sp + Elodea sp.)	6	D1 ditch	4.328	1.38	≥5
			D1 stream	2.699	2.22	
			D2 ditch	3.957	1.51	
			D2 stream	2.480	2.41	
			D6 ditch	3.732	1.60	
			R1 stream	1.697	3.53	

Compound	Species	NOEC (µg a.s./L)	FOCUS Step 4	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
			R3 stream	2.246	2.67	
			R4 stream	1.786	3.35	
Spring use in winter cereals at rate 1 x 160 g a.s./ha, post emergence						
Flufenacet	Microcosm (Lemna sp + Elodea sp.)	6	D2 ditch	2.412	2.48	≥5
			D2 stream	1.574	3.81	
			R3 stream	0.662	9.06	
Autumn use in winter cereals at rate 1 x 240 g a.s./ha, post emergence						
Flufenacet	Microcosm (Lemna sp + Elodea sp.)	6	D1 ditch	6.543	0.91	≥5
			D1 stream	4.082	1.46	
			D2 ditch	6.199	0.96	
			D2 stream	3.882	1.54	
			D6 ditch	5.693	1.05	
			D3 ditch	0.218	27.52	
			D4 stream	1.674	3.58	
			D5 stream	1.249	4.80	
			R1 stream	2.602	2.30	
			R3 stream	3.446	1.74	
			R4 stream	2.699	2.22	

*values in bold indicate unacceptable risk

In the table below are listed all the scenarios for which the TER_{LT} value did not meet the trigger.

Table 2.9.9-55: The FOCUS STEP 4 scenarios with 10 m buffer, for which the TER_{LT} Macrophytes needs further refinement.

Scenario STEP 4	Autumn use 120 g s.a./ha	Spring use 120 g s.a./ha	Winter cereals		
			Autumn use 160 g a.s./ha	Spring use 160 g s.a./ha	Autumn use 240 g a.s./ha
D1 ditch	D1 ditch	D2 ditch	D1 ditch	D2 ditch	D1 ditch
D1 stream	D1 stream	-	D1 stream	D2 stream	D1 stream
D2 ditch	D2 ditch	-	D2 ditch	-	D2 ditch
D2 stream	D2 stream	-	D2 stream	-	D2 stream
					D4 stream
D6 ditch	D6 ditch	-	D6 ditch	-	D5 stream
D4 stream	-	-	-	-	D6 ditch
R1 stream	R1 stream	-	R1 stream	-	R1 stream
R3 stream	R3 stream	-	R3 stream	-	R3 stream
R4 stream	-	-	R4 stream	-	R4 stream

- No further refinement is needed

Based on a comparison of the results of the standard laboratory toxicity studies with FOCUS Step 4 with 10 meter buffer zone PEC_{sw} values for flufenacet, the TER_{LT} values for Macrophytes meet the required trigger of 10, except the scenarios given in the Table 2.9.9-55. For these scenarios Macrophytes TER needs further refinement.

As a result, PEC_{sw} values for flufenacet for autumn and spring application to winter cereals were further refined using the FOCUS Step-4 with 20 meter buffer zone FOCUS.

STEP 4 – 20-metres wide FOCUS buffer zone for mitigation of Spray Drift and Run-off

Table 2.9.9-56: Chronic toxicity exposure ratios (TER_{LT}) for Macrophytes based on worst-case scenario PEC_{sw} from STEP 4 with 20 meter buffer zone.

Compound	Species	NOEC (µg a.s./L)	FOCUS Step 4	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
Autumn use in winter cereals at rate 1 x 120 g a.s./ha, pre-emergence						
Flufenacet	Microcosm (Lemna sp + Elodea sp.)	6	D1 ditch	2.680	2.23	≥5
			D1 stream	1.672	3.58	
			D2 ditch	3.227	1.85	
			D2 stream	2.021	2.96	
			D6 ditch	2.764	2.17	
			R1 stream	0.652	9.20	
			R3 stream	0.907	6.61	
Spring use in winter cereals at rate 1 x 120 g a.s./ha, post-emergence						
Flufenacet	Microcosm (Lemna sp + Elodea sp.)	6	D2 ditch	1.702	3.52	≥5
Autumn use in winter cereals at rate 1x 160 g a.s./ha, post emergence						
Flufenacet	Microcosm (Lemna sp + Elodea sp.)	6	D1 ditch	4.328	1.38	≥5
			D1 stream	2.699	2.22	
			D2 ditch	3.957	1.51	

Compound	Species	NOEC (µg a.s./L)	FOCUS Step 4	Max PEC _{sw} (µga.s./L)	TER _{LT}	Trigger
			D2 stream	2.480	2.41	
			D6 ditch	3.732	1.60	
			R1 stream	0.883	6.79	
			R3 stream	1.173	5.11	
			R4 stream	0.933	6.43	
Spring use in winter cereals at rate 1x 160 g a.s./ha, post emergence						
Flufenacet	Microcosm (Lemna sp + Elodea sp.)	6	D2 ditch	2.412	2.48	≥5
			D2 stream	1.574	3.81	
Autumn use in winter cereals at rate 1x 240 g a.s./ha, post emergence						
Flufenacet Flufenacet	Microcosm (Lemna sp + Elodea sp.)	6	D1 ditch	6.543	0.91	≥5
			D1 stream	4.082	1.46	
			D2 ditch	6.199	0.96	
			D2 stream	3.882	1.54	
			D4 stream	1.674	3.58	
			D5 stream	1.249	4.80	
			D6 ditch	5.693	1.05	
			R1 stream	1.354	4.43	
			R3 stream	1.799	3.33	
	R4 stream	1.410	4.25			

*values in bold indicate unacceptable risk

In the table below are listed all the scenarios for which the TER_{LT} value did not meet the trigger.

Table 2.9.9-57: The FOCUS STEP 4 scenarios with 20 m buffer, for which the TER_{LT} Macrophytes needs further refinement.

Scenario STEP 4	Autumn use 120 g s.a./ha	Spring use 120 g s.a./ha	Winter cereals		
			Autumn use 160 g a.s./ha	Spring use 160 g s.a./ha	Autumn use 240 g a.s./ha
D1 ditch	D1 ditch	D2 ditch	D1 ditch	D2 ditch	D1 ditch
D1 stream	D1 stream	-	D1 stream	D2 stream	D1 stream
D2 ditch	D2 ditch	-	D2 ditch	-	D2 ditch
D2 stream	D2 stream	-	D2 stream	-	D2 stream
					D5 stream
D6 ditch	D6 ditch	-	D6 ditch	-	D6 ditch
D4 stream	-	-	-	-	D4 stream
R1 stream	-	-	-	-	R1 stream
R3 stream	-	-	-	-	R3 stream
R4 stream	-	-	-	-	R4 stream

- No further refinement is needed

Based on a comparison of the results of the standard laboratory toxicity studies with FOCUS Step 4 PEC_{sw} values for flufenacet calculated assuming 20-metres buffer zone for mitigation of Spray Drift in all D scenarios and Spray Drift and Run-off in all R scenarios (for Run-off the adequate reduction factors given by FOCUS L&M Guideline for 10-20 –metres wide vegetated buffer zone were used, the TER_{LT} values for algae meet the required trigger of 10, except the scenarios given in the Table 2.9.9-57. For those scenarios, Macrophytes TER needs further refinement.

Overall conclusion

Macrophates including Lemna sp and Elodea sp.

Autumn Uses:

The general conclusions drawn from the risk assessment for Macrophytes including Lemna sp. and Elodea sp. presented above are given, are provided below, individually for each use listed in the EU-representative GAP.

- In case of the post-emergence use in Winter cereals in autumn, at application rate **240 g Flufenacet/ha**, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenarios:
 - D1 ditch, D1 stream, D2 ditch, D2 stream, D4 stream, D5 stream, D6 ditch, R1 stream, R3 stream and R4 stream.

The safe scenarios identified within that use were: D3 ditch assuming 10-metres wide buffer zone for mitigation of Spray Drift, D4 pond already at STEP 3 (hence no buffer zone needed to be implemented), D5 pond already at STEP 3 (hence no buffer zone needed to be implemented), R1 pond already at STEP 3 (hence no buffer zone needed to be implemented).

Therefore, for that use it may be stated that three safe scenarios were identified: for the D3 scenario assuming 10-metres wide non-spray buffer zone to mitigate the Spray drift

- In case of the post-emergence use in Winter cereals in autumn, at application rate **160 g Flufenacet/ha**, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenarios:
 - D1 ditch, D1 stream, D2 ditch, D2 stream, and D6 ditch.

The safe scenarios identified within that use were: D3 ditch, D4 pond, D4 stream, D5 pond, D5 stream – all them already at STEP 3 (hence no buffer zone needed to be implemented), as well as R1 pond already at STEP 3 (hence no buffer zone needed to be implemented), R1 stream assuming 20-metres wide vegetated buffer zone for mitigation of Spray Drift and Run-off, R3 stream assuming 20-metres wide vegetated buffer zone for mitigation of Spray Drift and Run-off and R4 stream assuming 20-metres wide vegetated buffer zone for mitigation of Spray Drift and Run-off.

Therefore for that use it may be stated that the following safe uses were identified: for scenarios D3, D4 and D5 without any buffer zone (safe PEC_{SW} values were obtained already at STEP 3) as well as R1, R3 and R4 scenarios assuming 20-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off.

- In case of the post-emergence use in Winter cereals in autumn, at application rate **120 g Flufenacet/ha**, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenarios:
 - D1 ditch, D1 stream, D2 ditch, D2 stream and D6 ditch.

The safe scenarios identified within that use were D3 ditch, D4 (pond and stream), D5 (pond and stream), R1 pond and R4 stream – all they already at STEP 3 (hence no buffer zone needed to be implemented), and R1 stream, R3 stream assuming 20-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off

Therefore for that use it may be stated that the following safe uses were identified: for scenarios D3, D4, D5 and R4 without any buffer zone (safe PEC_{SW} values were obtained already at STEP 3) and R1 and R3 scenarios assuming 20-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off.

SPRING USE

The general conclusions drawn from the risk assessment for Macrophytes presented above are given, are provided below, individually for each use listed in the EU-representative GAP.

- In case of the post-emergence use in Winter cereals at spring, at application rate **160 g Flufenacet/ha**, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenarios:
 - D2 ditch and D2 stream;
 -

In case of scenarios D1 ditch, D1 stream, D3 ditch, D4 pond, D4 stream, D5 pond and D5 stream, R1 pond, R1 stream and R4 stream safe PEC_{SW} values were obtained already at STEP 3.

For scenario R3 stream safe PEC_{SW} values were obtained at STEP 4 after implementation of 10-metres wide vegetated buffer zone for mitigation of the Spray Drift and Run-off.

Therefore for that application pattern only for scenarios D2 safe use was not demonstrated. In case of scenario R3 it was demonstrated that it was necessary to implement 10 meter buffer zone mitigating Spray Drift and Run-off. In all remaining scenarios identified as returning the safe PEC_{SW} values it was demonstrated that the implementation of any mitigation measures was not necessary as the assessment was finalised at Step 3.

- In case of the post-emergence use in Winter cereals at spring, at application rate **120 g Flufenacet/ha**, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenario D2 ditch.

In case of scenarios D1 ditch, D1 stream, D2 stream, D3 ditch, D4 pond, D4 stream, D5 pond and D5 stream, D6 ditch, R1 pond, R1 stream, R3 stream and R4 stream safe PEC_{SW} values were obtained already at STEP 3. For that application pattern assessment at STEP 4 was not performed.

Therefore, for that application pattern only for scenario D2 safe use was not demonstrated. In case of scenarios D1, D3, D4, D5, D6, R1, R3 and R4 it was demonstrated that implementation of the buffer zone mitigating Spray Drift and/or Run-off was not necessary.

As an additional refinement step RMS carried out the calculations using the VFS-mod option to mitigate run-off. The selected vegetated buffer zone was 10-metres wide. The same width of the buffer zone was used in function of the non-spray buffer zone for simultaneous mitigation of the Spray Drift.

The results of the calculations are presented below in the table 2.9.9-58. In it are listed only those scenarios, for which safe PEC_{sw} values were not obtained at STEP 4 assuming the maximum admissible reduction factors set by FOCUS.

As VFS-mod is a tool specific only for mitigating Run-off, and hence for R scenarios, in the table below only the results obtained for R scenarios, where relevant, were presented.

Table 2.9.9-58: Chronic toxicity exposure ratios (TER_{LT}) for Macrophytes based on worst case scenario PEC_{sw} from 10-metres buffer zone, VFS-mod.

Insectes buffer zone, VPS-mod.						
Compound	Species	NOEC (µg a.s./L)	FOCUS Step 4	Max PEC _{sw} (µg a.s./L)	TER _{LT}	Trigger
Autumn use in winter cereals at rate 1 x 160 g a.s./ha, post emergence						
Flufenacet	Microcosm (Lemna sp + Elodea sp.)	6	R1 stream	0.129	46.51	≥5
			R3 stream	0.181	33.14	
			R4 stream	0.128	46.87	
Autumn use in winter cereals at rate 1 x 240 g a.s./ha, post emergence						
Flufenacet	Microcosm (Lemna sp + Elodea sp.)	6	R1 stream	0.194	30.92	≥5
			R3 stream	0.272	22.05	
			R4 stream	0.192	31.25	

Based on the results presented above it may be stated that the use of the VFS-mod for R scenarios assuming the 10-metres wide vegetated buffer zone resulted in reaching safe PEC_{sw} values in all scenarios of concern in autumn post-emergence use in Winter cereals at 160 g a.s./ha and 240 g Flufenacet/ha.

Endocrine disruption

Population relevant effects of Flufenacet on fish were studied in an early life-stage test (ELS) with rainbow trout and Sheepshead minnow. The fish full life cycle test (FFLC) with fathead minnow (*P. promelas*) was also conducted. The lowest value of NOEC 49 based on the effects the length and dry weight was estimated for Sheepshead minnow. In the ELS test the for rainbow trout the NOEC of 334 µg/L was estimated based on growth, as length, on post-hatch Day 33 (66 day study)

In the FFLC after 279 days of flow-through exposure, a NOEC of 138 µg/L was obtained for effects on F0 adult weight (but not on male length, nor on female weight or length). For all other endpoints, such as survival, reproduction and growth (other than male weight) higher NOECs of either 600 or 1211 µg/L were established.

There are currently no defined criteria for indentifying endocrine disruptors or interpreting the significance of any effects in ecotoxicology studies under the Commission Regulation (EU) No. 2009/1107.

Therefore, it is difficult to conclude that endocrine disruptive effects are/are not taking place.

Bees

The risk assessment

The risk assessment for effects on bees was conducted by Applicant according to the existing in force at the time of the preparation and submission of the dossier namely the EU GD on Terrestrial Ecotoxicology under Council Directive 91/414/EEC (SANCO/10329/2002) and EPPO Standard PP 3/10.

The risk was performed based on results of laboratory studies on oral and contact toxicity to bees with representative formulation DFF+FFA SC 600 and with active substance flufenacet.

The studies did not reveal sensitivity differences between honey bee and bumble bee foragers.

The risk assessment according to EU GD on Terrestrial Ecotoxicology under Council Directive 91/414/EEC (SANCO/10329/2002) and EPPO Standard PP 3/10 was performed by calculation of HQ values with consideration of maximum single application rate of the active substance (240 g/ha, worst case application to cereals covering all other intended uses).

Calculated hazard quotients are presented in the Table 2.9.9-59 below:

Table 2.9.9-59: Acute risk to adult bees from oral and contact exposure to flufenacet following the use of in cereals.

Test Species	Test substance	Exposure route	Application rate (g a.s./ha)/ (g product/ha)	LD ₅₀ (µg a.s /bee) (g product/bee)	HQ	Trigger value
Honeybee (<i>Apis mellifera</i>)	Flufenacet tech.	Oral	240	>109.2	<2.2	50
Honeybee (<i>Apis mellifera</i>)		Contact	240	>100	<2.4	
Honeybee (<i>Apis mellifera</i>)	DFF+FFA 600 SC	Oral	750 g product/ha	>217.8	<3.44	
		Contact		>200	<3.75	

*formulation/ha, density= 1.25 g/mL

The acute oral and contact HQ value for the active substance flufenacet, representative formulation DDF+FFA SC 600 are below the trigger value of 50, indicating an acceptable risk to adult honey bees following the use in cereals.

Brood development and colony condition was carried out with the Bee brood study, (according to Oomen's methodology, 1992)

In course of its evaluation of this study RMS stated that there were discrepancies between the study protocol, numerical results and their graphical presentation. Additionally it was stated that there were no statistically significant differences between response in the negative control and positive control (reference) in case of eggs and young larvae, although that was observed for the old larvae. RMS indicated that problem to the Applicant receiving the information that the study will be updated and in that form it should be ready for commenting period. At the same time the Applicant informed RMS about the new, ongoing semi-field study performed fully in line with the requirements of the current OECD 75 Guideline, which should also be made available during the commenting period. Therefore, RMS would like to propose to include both studies into the assessment evaluating them during the peer-review stage of the assessment process.

The chronic 10- day feeding study to adult bees was also conducted. Therefore, based on the study results the chronic risk assessment to adults bees and acute risk for adult bees was presented by RMS according to recommendation given in the New EFSA Guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees), (EFSA Journal 2013;11 (7):3295) which was published already in July 2013, but it has not come into force yet.

Acute adult toxicity:

The acute risk to honeybees from the use of DFF+FFA 600 SC was assessed using the maximum single application rate of 750 g product/ha correspond to 240 g flufenacet/ha and the LD₅₀ value (expressed as µg/bee) to calculate the Hazard Quotient (HQ) for contact exposure and ETR (exposure toxicity ratio) for oral exposure. The results are presented in the table below.

Table 2.9.9-60: The acute risk assessment for bees

Test item	Route	LD ₅₀	Max. application rate g a.s./ha (g product/ha)	HQ/ETR	Trigger	Risk for adult bees acceptable?
Screening assessment						
Flufenacet tech.	Contact	>109.2	240	< 2.20	42	Yes
	oral	>100	240	<0.018	0.2	Yes
DFF+FFA SC 600	Contact	>200	750 ¹	<3.75	42	Yes
	oral	>217.8	750 ¹	<0.026	0.2	Yes

¹ Based on application rate of 600 mL product density 1.251 g/mL

The hazard quotients and ETRs are below the relevant trigger values, indicating acceptable acute risk to adult bees.

Chronic adult toxicity

A chronic laboratory test with adult honeybees was provided for flufenacet. The results of the study were used for calculation of the Exposure Toxicity Ratio (ETR_{adult}) between the amount of residues that may be ingested by an adult bee in 1 day and the LDD₅₀ value.

The chronic exposure-toxicity ratio (ETR_{chronic adult oral}) is calculated using the following formula:

Chronic oral toxicity - screening step:

$$ETR_{\text{chronic adult oral}} = AR * SV / 10 \text{ d LDD}_{50}$$

With

AR... Application rate [kg a.s./kg]

SV... Short-cut value for the respective kind of application

LDD₅₀... Lethal dietary dose [μg a.s./bee/day]**Table 2.9.9-61: Chronic risk to adult bees- Screening test.**

Crop	Chronic LDD ₅₀	Max. application kg a.s./ha	Scenario	ETR _{adult}	Trigger	Risk for adult bees acceptable
Screening assessment						
Cereals	4.42	0.240	-	0.41	0.03	No
		0.160	-	0.276	0.03	No
		0.120		0.207	0.03	No

The ETR_{chronic adult oral} for the active substance is above the trigger value of 0.03 indicating a potential chronic risk to adult honey-bees. Therefore, a refined chronic risk assessment (1st tier assessment) taking into account various exposure routes has to be conducted.

Chronic oral toxicity – 1 tier assessment

The chronic exposure-toxicity ratio (ETR_{chronic adult oral}) is calculated using the following formula:

$$ETR_{\text{chronic adult oral}} = AR * Ef * SV * twa / 10 \text{ d LDD}_{50}$$

With

AR... Application rate [kg a.s./ha]

Ef... Exposure factor

twa... Time weighted average

SV... Short-cut value for the respective kind of application

LDD₅₀... Lethal dietary dose [μg a.s./bee/day]**Table 2.9.9-62: Chronic risk to adult bees - Tier 1 test.**

Crop	Chronic LDD ₅₀	Max. application kg a.s./ha	Scenario	ETR _{adult}	Trigger	Risk for adult bees acceptable
1st tier assessment						
Bare soil, crop attractive for pollen only	4.42	0.120	Treated crop	0.00	0.03	Yes
	4.42	0.120	weeds	0.01	0.03	Yes
	4.42	0.120	Field margin	0.00	0.03	Yes
	4.42	0.120	Adjacent crop	0.00	0.03	Yes
	4.42	0.120	Next crop	0.00	0.03	Yes
Cereals BBCH <10	4.42	0.120	Treated crop	0.00	0.03	Yes
	4.42	0.120	weeds	0.06	0.03	No
	4.42	0.120	Field margin	0.00	0.03	Yes
	4.42	0.120	Adjacent crop	0.00	0.03	Yes
	4.42	0.120	Next crop	0.00	0.03	Yes
Cereals BBCH 10-29	4.42	0.120	Treated crop	0.02	0.03	Yes
	4.42	0.120	weeds	0.06	0.03	No
	4.42	0.120	Field margin	0.00	0.03	Yes
	4.42	0.120	Adjacent crop	0.00	0.03	Yes
	4.42	0.120	Next crop	0.00	0.03	Yes
Cereals BBCH 10-29	4.42	0.160	Treated crop	0.024	0.03	Yes
	4.42	0.160	weeds	0.075	0.03	No
	4.42	0.160	Field margin	0.0009	0.03	Yes

Crop	Chronic LDD ₅₀	Max. application kg a.s./ha	Scenario	ETR _{adult}	Trigger	Risk for adult bees acceptable
	4.42	0.160	Adjacent crop	0.0005	0.03	Yes
	4.42	0.160	Next crop	0.014	0.03	Yes
Cereals BBCH 10-29	4.42	0.240	Treated crop	0.036	0.03	No
	4.42	0.240	weeds	0.113	0.03	No
	4.42	0.240	Field margin	0.001	0.03	Yes
	4.42	0.240	Adjacent crop	0.00075	0.03	Yes
	4.42	0.240	Next crop	0.021	0.03	Yes

All the ETR_{chronic adult} values in the first tier assessment are below the relevant trigger, indicating acceptable chronic risk to adult bees, except the following scenarios:

- **cereals and scenario weeds at the rate 240 g a.s/ha**
- **scenario weeds at the rates 160 g a.s/ha and 120 g a.s/ha**

Further consideration is needed.

Treated crop – cereals

The trigger values for cereals (treated crop) are only slight above the trigger value of 0.03 (being 0.036).

Flufenacet can be considered as virtually non-systemic when early pre- or post-emergence spray application is done in winter cereals according to the studies of metabolism in plants (see CA 6.2 Metabolism, distribution and expression of residues, Section 6.2.1 Plants). In plant metabolism studies spray-applied flufenacet result in negligible uptake and movement from the roots into the straw and grain samples.

Consequently the theoretical exposure of bees to pollen containing residues of flufenacet due to early spray applications is considered to be negligible. In addition, the cereals are not attractive to honey bees as they not produce nectar so exposure for bees can only theoretically be to pollen.

The growth stage of crops treated with Flufenacet – BBCH 10-13 (early growth stages in autumn) and BBCH 10-12 (early post emergence in the spring) practically excludes any exposure of bees to the crop's pollen, because the cereals are not in flowering period. The potential exposure to metabolites of flufenacet in bee relevant matrices (pollen of cereals) is very unlikely and can be considered as negligible when taking into account the low systemicity of flufenacet.

The mainly possible exposure of bees to the pollen contaminated with Flufenacet may be related to the flowering weeds in cereal fields.

Considerations on potential exposure to flowering weeds

The whole assessment presented below is based on the data submitted by the Applicant (on RMS's request). RMS, after thorough examination, considers it valid. However, it shall be indicated that the assessment refers to autumn application. In RMS's opinion the EU-representative GAP lacked clarity, therefore spring applications in cereals at early growth stages (10-13 BBCH) cannot be excluded. Nevertheless, in the documents submitted by the Applicant it is indicated that the weeds attractive to bees are observed in fields on which cereals are grown at crop growth stages much higher than those indicated in the GAP. Therefore, the assessment may be considered acceptable.

The Applicant's assessment is summarised below.

The potential exposure of honey bees via flowering weeds to an herbicide that is used during autumn at the pre-emergence stages of cereals is considered as low. The autumn period is in general of low activity of honey bee hives, given the development phase of the colony which is getting prepared for the overwintering period. Even, in the rare case that the activity of foragers would be high in a period of days with mild temperatures during autumn, a recent publication (Maynard et al., 2015) demonstrates that the availability of flowering weeds in cereal fields at relevant application times for herbicides is minimal.

To analyse the presence of weeds in agricultural crops the available data has been extracted from the database for the crops cereals, sugar beet, and potatoes. As a conservative assessment only the data in the control plots (i.e. no herbicide treatment) was considered to provide a worst-case situation.

All data originate from worldwide herbicide efficacy trials in cereals conducted between 2004 and 2014 has been compiled (Maynard, et al. 2015). The majority of the studies were carried out in Europe; however for completeness of the datasets trials performed outside Europe were also included. Information on weed species, weed growth stages (BBCH), weed diameter (cm), weed ground cover (%), and weed plants/m² were obtained. Each weed species per trial was recorded separately, thus there are several data set entries per trial.

In the analysis done for the data on cereal fields, flowering weeds exceeding 10% ground cover were only

observed in 14 out of 2327 observations (i.e. 0.6%) and out of these 14 only one observation was possibly relevant under certain circumstances. Hence, exposure via flowering weeds is confirmed not to be a relevant route of exposure for bees.

Further, the Applicant argued that the potential exposure to metabolites of flufenacet in bee relevant matrices (pollen and nectar of flowering weeds) is very unlikely and can be considered as negligible when taking into account the low systemicity of flufenacet and the unlikely exposure via flowering weeds.

In concluding remarks the Applicant however stated that low risk to bees foraging on flowering weeds can be confirmed with the results of the higher tier cage study OECD 75. The study was conducted in 2015 under forced/confined exposure conditions, by application of 240 g a.s./ha flufenacet SC 508.8 under tunnel conditions to the full flowering and highly bee attractive surrogate crop *Phacelia tanacetifolia* (Tätzler, 2016 M-553011-01-1). The colonies exposed to flufenacet SC 508.8 applied directly as a spray and as residues on flowers (nectar and pollen) exhibited equivalent performance in terms of mortality, foraging rate, behaviour, brood development, colony strength and food stores compared to colonies exposed to only water.

For this reason the RMS would ask during the Commenting Period for this study to the finalized the risk assessment to bees after exposure of flufenacet and its metabolites.

Risk assessment for bumble bees

In addition to acute laboratory studies with adult honey bees, flufenacet was further subjected to topical acute bumble bee testing. The study did not reveal sensitivity differences between honey bee and bumble bee foragers.

Moreover, the Hazard Quotient (HQ) between the application rate and the acute contact laboratory LD₅₀ toxicity values for bumble bees was calculated:

$$HQ = AR/LD_{50}$$

Where AR=application rate in kg a.s./ha

LD₅₀ is expressed in in µg a.s./bee

Table 2.9.9-63: Acute contact risk assessment for bumble bees.

Test item	Route	Oral LD ₅₀	Max. application rate g a.s./ha	Hazard quotient	Trigger	Risk for adults bees Acceptable?
Flufenacet tech.	Contact	>100	240	<2.40	7	Yes

The hazard quotients are below the trigger value of 50 for higher tier testing, indicating acceptable acute risk to adult bumble bees.

Larval toxicity

No laboratory larval toxicity test was submitted since one higher tier study focused on effects of flufenacet on immature honey bee life stage was available.

Table 2.9.9-64: Summary of effects of formulated ethofumesate (500 g/L, SC formulation) on honeybees and honeybee brood.

Organism	Test substance	Time scale	Endpoint
Honeybee (<i>Apis mellifera</i>)	Flufenacet SC 508.8	21 day, bee brood feeding test .	No adverse effects on mortality, bee brood development (eggs, young larvae, old larvae, pupae) and colony development by feeding honey bee colonies sugar syrup with a flufenacet -concentration typical for/exceeding the concentration of flufenacet in the spray tank (1500 ppm)

In course of its evaluation of this study RMS stated that there were discrepancies between the study protocol, numerical results and their graphical presentation. Additionally it was stated that there were no statistically significant differences between response in the negative control and positive control (reference) in case of eggs and young larvae, although that was observed for the old larvae. RMS indicated that problem to the Applicant receiving the information that the study will be updated and in that form it should be ready for commenting period. At the same time the Applicant informed RMS about the new, ongoing semi-field study performed fully in line with the requirements of the current OECD 75 Guideline, which should also be made available during the commenting period. Therefore, RMS would like to propose to include both studies into the assessment evaluating them during the peer-review stage of the assessment process.

Overall conclusion regarding bees

The acute risk assessment for adults' bees is acceptable. Although the exposure of bees from flowering weeds and pollen at the time of application of flufenacet and is negligible the new semifield study performed fully in line with the requirements of the current OECD 75 Guideline should be submitted.

The chronic risk for adults and the acute and chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behavior could be not finalized for all proposed uses.

Non target arthropods:

The risk assessment for non-target arthropods other than bees was performed according to requirements of the ESCORT 2 Guidance Document (Candolfi, M.P. et al., 2000).

In field risk

In-field and off field hazard quotient (HQ) was calculated for formulation DFF+FFA SC 600 using the maximum application rate in winter cereals of 0.6 L DFF+FFA SC 600 represents worst case and covers remaining intended uses (applications on winter cereals at rates 0.3 L product /ha and 0.4 L product/ha).

Table 2.9.9-65: In-field risk to non-target terrestrial arthropods based on laboratory studies (Tier I) from exposure to the formulation DFF+ FFA SC 600 following the use in winter cereals.

Test substance	Test species	LR ₅₀ :ER ₅₀ (mL/ha)	PER (mL/ha)	HQ	Trigger value
DFF+FFA SC 600	Typhlodromus pyri	81.8	600	7.30	2
	Aphidius rhopalosiphii	>700	600	0.85	

The results of the in-field tier 1 risk assessment for Typhlodromus pyri indicated that a higher tier in-field risk assessment is required. Extended laboratory studies have been conducted with Typhlodromus pyri and with two additional species Chrysoperla carnea and Aleochara bilineata.

In - field refinement

Based on the results of the tier 1 in-field risk assessment extended laboratory studies were conducted for T. pyri, C. carnea and A. bilineata.

Table 2.9.9-66: In-field risk to non-target terrestrial arthropods based on results from extended laboratory studies (Tier 2) with the standard species T. Pyri and two additional species Aleochara bilineata and Chrysoperla carnea from exposure to the formulation DFF+FFA SC 600 following the use in winter cereals.

Test species	In-field rate mL product/ha	LR ₅₀ :ER ₅₀ mL product/ha	Risk acceptable if	Refined assessment required ?
Typhlodromus pyri	600	>83.2	Effects <50%	Yes
Chrysoperla carnea	600	600	Effects <50%	No
Aleochara bilineata	600	600	Effects <50%	No

Under extended laboratory conditions *T. pyri* was found to be the most sensitive species.

In that study the 7 day LR₅₀ for *T.pyri* based on mortality was determined to be 110.2 mL/ha.

No effects on reproductions above 50% was observed including and up the highest tested rate of 83.2 mL /ha, resulting in an ER₅₀>83.2 mL/ha (lower rate than expected in- field habitats). The results of this study indicated potential harmful effects on *T.pyri* from the use of DFF+FFA SC 600 at maximum application rate of 600 mL product/ha.

Consequently, an aged residue studies has been conducted for DFF+FFA SC 600 with *T. pyri* to demonstrate the potential for recovery. The study was conducted on potted maize plants with a single application rate of 700 mL product/ha. Aging of the spray residues of the test item on the potted maize plants took place under semi-field condition with rain protection during the whole study.

In this study the mites have been exposed to fresh residues of DFF + FFA SC 600 and to residues aged for 14 and 28 days. Freshly dried residues of the test item resulted in 98.9% corrected mortality. A corrected mortality of 87.1% was observed after an aging time of 14 days. An aging time of 28 days resulted in a low corrected mortality of 9.5% and no statistically significant effects on reproduction occurred (8.4% reduction relative to control).

The result of this aged residue study (with application of 0.7 L product/ha) demonstrate that after an ageing time of 28 days the residues have no impact on predatory mites. It can be concluded that, the potential for recovery is given for in field area and no acceptable adverse effects on non target arthropods have be expected in the in –field.

In addition, an extended laboratory study with *Chrysoperla carnea* has been conducted on the natural substrate – deatched maize leaves and indicated 20% corrected mortality for this species and no effects >50 % on fertility at highest tested rate of 600 mL product/ha. For the second species –*Aleochara bilineata* the formulation DFF+FFA SC 600 has low effects on parasitation rate and reduction of reproductive capacity in comparison to the control. The highest reduction in capacity 7.9% was recorded at highest treatment rate of 600 mL product/ha.

Therefore, the ER₅₀ value was estimated to be >600 mL product/ha.

It can be concluded that the risk to non-target arthropods in the in-field habitats from flufenacet on is acceptable following the use of DFF+FFA SC 600 according to the proposed use pattern supported in this submission

Off-field risk

Hazard quotients off-field were calculated for the formulation following the use in winter cereals using the maximum application rate in winter cereals of 0.6 L DFF+FFA SC 600 represents worst case and covers remaining intended uses (applications on winter cereals at rates 1 x 0.3 L product /ha and 0.4 L product/ha).

According to the ESCORT II Guidance Document, the HQ trigger value for laboratory toxicity data Tier I is 2.

Table 2.9.9-67: Off-field risk to non-target terrestrial arthropods based on laboratory studies from exposure to the formulation DFF+FFA SC 600 following the use in winter cereals.

Test substance	Test species	LR ₅₀ :ER ₅₀ mLproduct/ha	Vdf	Corr. factor	MAF	Off-field		Trigger value
						PER ¹ mL product/ha	HQ	
DFF+FFA SC 600	Typhlodromus pyri	81.8	10	10	1	16.62	0.20	2
	Aphidius rhopalosiphi	>700	10	10	1	16.62	0.023	2

¹ BBA drift values- 2.77% (1 application, field crops).

Off-field HQ values based on the laboratory studies (Tier 1) for non-target arthropods were below the Annex VI trigger values of 2 indicated acceptable risk off field.

Due to that fact that HQ in field for *T.pyri* was above the trigger of 2, the additional extended lab studies (Tier 2) for *Chrysoperla carnea* and *Aleochara bilineata* and for *T.pyri* were performed.

The effects on reproduction were investigated in these studies. For *Chrysoperla carnea* no effects >50 % on fertility at highest tested rate of 600 mL product/ha were observed resulting an ER₅₀> 600 mL product/ha.

For the second species –*Aleochara bilineata* the highest reduction in capacity 7.9% was recorded at highest treatment rate of 600 mL product/ha. The ER₅₀ values > 600 mL product/ha estimated for both additional species were above the maximum PERoff-field indicated an acceptable off risk. The extended laboratory study were also performed with *T.pyri*, resulting in an ER₅₀> 83.2 mL product/ha and LR₅₀ value of 110 mL product /ha exceeding also maximum expected off field exposure.

Overall conclusion regarding non-target arthropods other than bees

According to the outcome of the risk assessment it may be concluded that application of formulation DFF+FFC 600 SC to winter cereals (120 g Flufenacet/ha, 160 g Flufenacet/ha and 240 g Flufenacet/ha) and pose no unacceptable risk to non-target arthropods other than bees. No risk mitigation measures are required.

Soil non-target macro- and mesofauna

The risk assessment for soil macro- and mesofauna was performed according to requirements of the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2 final of 17th October 2002).

Evaluation was performed by calculation of TER values on the basis of results of performed studies (point 2.9.4, table 2.9.4-1) and exposure estimates as presented in table 2.9.9-2.

Summary of calculated TER values is presented in table 2.9.9.68-2.9.9.70 below.

Risk assessment for earthworm

The risk was performed for each application rates of DFF+FFA SC 600 to winter cereals.

Table 2.9.9-68: Chronic risk (TER_{LT}) to earthworms for flufenacet and metabolites, formulation based on max PEC_{SOIL} values, for the intended uses in cereals.

Species	Test substance	Endpoint	max PEC _{SOIL} (mg/kg)	TER _{LT}	Trigger
Winter cereals, 120 ga.s./ha					
Eisenia fetida	DFF+FFA SC 600	NOEC 1.3 * mg form./kg s dw	0.500 mg product/kg dws	2.6	≥5
	Flufenacet (DFF+FFA SC 600)	NOAER 0.203 mg a.s./kg sdw (measured value)	0.160	1.26	≥1
	FOE oxalate	NOEC ≥100 mg p.m./kg sdw	0.0093	10752.68	≥5
	FOE sulfonic acid-Na-salt	NOEC 500 mg p.m./ kg sdw	0.0287 ¹	17421.60	≥5
	FOE methylsulfone	NOEC 125 mg p.m./kg sdw	0.0075 ¹	16666.66	≥5
	TFA	NOEC 320 mg p.m./kg sdw	0.3092 ¹	1034.92	≥5
	FOE 5043-trifluoroethane sulfonic acid	NOEC 100 mg p.m./kg sdw	0.0080	12500	≥5
	FOE-Thiadone	NOEC 3.2 mg p.m./kg sdw	0.0118	271.18	≥5

* Endpoints corrected to allow for log P_{ow} > 2

¹ Accumulated PEC_{soil}

sdw soil dry weight

a.s. flufenacet

in bold value not achieved the trigger

Table 2.9.9-69: Chronic risk (TER_{LT}) to earthworms for flufenacet and metabolites, formulation based on max PEC_{SOIL} values, for the intended uses in cereals.

Species	Test substance	Endpoint	max PEC _{SOIL} (mg/kg)	TER _{LT}	Trigger
Winter cereals, 160 ga.s./ha					
Eisenia fetida	DFF+FFA SC 600	NOEC 1.3* mg form./kg s dw	0.667 mg product/kg s dw	1.94	≥5
	Flufenacet (DFF+FFA SC 600)	NOAER 0.203 mg a.s./kg s dw (measured value)	0.2133	0.95	≥1
	FOE oxalate	NOEC ≥100 mg p.m./kg sdw	0.0124	8064.51	≥5
	FOE sulfonic acid-Na-salt	NOEC 500 mg p.m./kg sdw	0.0383 ¹	13054.83	≥5
	FOE methylsulfone	NOEC 125 mg p.m./kg sdw	0.010 ¹	12500	≥5
	TFA	NOEC 320 mg p.m./kg sdw	0.4122 ¹	776.32	≥5
	FOE 5043-trifluoroethane sulfonic acid	NOEC ≥ 100 mg p.m./kg s dw	0.0107	9345.79	≥5
	FOE-Thiadone	NOEC 3.2 mg p.m./ kg sdw	0.0157	203.82	≥5

* Endpoints corrected to allow for log Pow > 2

¹ Accumulated PEC_{soil}

dws soil dry weight

a.s.- flufenacet

in bold value not achieved the trigger

Table 2.9.9-70: Chronic risk (TER_{LT}) to earthworms for flufenacet and metabolites, formulation based on max PEC_{SOIL} values, for the intended uses in cereals.

Species	Test substance	Endpoint	max PEC _{SOIL} (mg/kg)	TER _{LT}	Trigger
Winter cereals, 240 g a.s./ha					
Eisenia fetida	DFF+FFA SC 600	NOEC 1.3* mg form./kg s dw	1.000 mg form./kg s dw	1.3	≥5
	Flufenacet (DFF+FFA SC 600)	NOAER 0.203 mg a.s./kg s dw (measured value)	0.32	0.63	≥1
	FOE oxalate	NOEC ≥100 mg p.m./ kg sdw	0.0186	5376.34	≥5
	FOE sulfonic acid-Na-salt	NOEC 500 mg p.m./ kg sdw	0.0574 ¹	8710.80	≥5
	FOE methylsulfone	NOEC 125 mg p.m./ kg sdw	0.0150 ¹	8333.33	≥5
	TFA	NOEC 320 mg p.m./ kg sdw	0.6184 ¹	517.46	≥5
	FOE 5043trifluoroethane sulfonic acid	NOEC 100 mg p.m./ kg sdw	0.0160	6250	≥5
	FOE Thiadone	NOEC 3.2 mg p.m./ kg sdw	0.0236	135.59	≥5

* Endpoints corrected to allow for log Pow > 2

¹ Accumulated PEC_{soil}

sdw soil dry weight

a.s.- flufenacet

in bold value not achieved the trigger

For all metabolites of flufenacet the TER values exceed the critical trigger value of 5 indicating low risk for earthworm. The critical trigger value of 5 is not passed for all proposed uses of DFF+FFA SC 600 indicating a potential risk of the mixture for earthworm populations.

Due to the fact that the endpoint for flufenacet obtained from laboratory study was not considered valid (see Kratz 1997, Vol. 3, B9 CA) the risk assessment for that compound was based on the NOAER = 0.203 mg Flufenacet/kg soil dw (measured value), determined in the field study for the representative formulation DFF+FFA SC 600, applied in amount 0.6 L/ha.

A one-year earthworm field study with the representative formulation DFF+FFA SC 600 was conducted in Southern under field conditions after one autumn application of Diflufenican SC 500A on bare soil at a rate of 243.75 g diflufenican/ha (application 1) on followed by once application of DFF+ FFA SC 200+400 G (diflufenican+flufenacet, application 2): at different rates (0.6 L product/ha, 1.2 L product/ha and 1.8 L product/ha. The control plots were sprayed once with tap water, the toxic reference item plots were treated with Twist WP® at rate 17152.66 g product/ha (equivalent to 10000 g a.s. carbendazim/ha).

Not statistically significant reduction in numbers and in biomass of total earthworms, total juveniles, total adults and single species occurred at any post treatment samplings after application of the test item at rates of 0.6, 1.2 and 1.8 L/ha following the plateau application of diflufenican at a rate of 243.77 g a.s./ha.

However, biological significant effects (19-33%) could still be observed on the population Octolasion lacteum after 364 d at rates of 1.2 and 1.8 L product/ha. At rate of 0.6 L product/ha biological significant but transient effects for this species were observed.

Based on all the study results it was concluded that there was no long term adverse effects from maximum application of 0.6 L product/ha (leading 0.203 mg flufenacet/kg soil dw) for population of earthworms.

Therefore, for the application rates resulting in concentrations higher than 0.203 mg flufenacet/kg dw, corresponding to the field application rate of the representative formulation of higher than 0.6 DFF+FFA SC 600 L/ha, the long-term risk for earthworms cannot be considered acceptable.

Risk for non-target soil meso- and macrofauna (other than earthworms)

The TER value was calculated for formulation DFF+FFA SC 600 using the maximum application rate in winter cereals of 0.6 L DFF+FFA SC 600 represents worst case and covers remaining intended uses (applications on winter cereals at rates 0.3 L product /ha and 0.4 L product/ha).

Table 2.9.9-71: Chronic risk (TER_{LT}) to non-target soil macro-organisms for representative formulation DFF+FFA SC 600, flufenacet and its metabolites based on max PEC_{SOIL} values, for the intended uses in cereals.

Test substance	Test organism	Endpoint	max PEC _{SOIL} (mg/kg)	TER _{LT}	Trigger
Winter cereals, 240 ga.s./ha					
DFF+FFA SC 600	Folsomia candida	NOEC 89 mg form. /kg dws*	1.000	89	5
	Hypoaspis aculeifer	NOEC ≥65.30 mg form./kg dws	1.000	65.30	
Flufenacet	Folsomia candida	NOEC 31.5 mg a.s./kg dws*	0.320	98.43	
	Hypoaspis aculeifer	NOEC 281 mg a.s./kg dws*		878.12	
FOE-oxalate	Folsomia candida	NOEC ≥100 mg p.m./kg dws	0.0186	5376.34	
	Hypoaspis aculeifer	NOEC ≥100 mg p.m./kg dws		5376.34	
FOE sulfonic acid-Na-salt	Folsomia candida	NOEC ≥100 mg p.m./kg dws	0.0574 ¹	1742.16	
	Hypoaspis aculeifer	NOEC ≥100 mg p.m./kg dws		1742.16	
FOE methylsulfone	Folsomia candida	NOEC ≥100 mg p.m./kg dws	0.0150 ¹	6666.66	
	Hypoaspis aculeifer	NOEC 500 mg p.m./kg dws		33333.33	
TFA	Folsomia candida	NOEC ≥100 mg p.m./kg dws	0.6184 ¹	161.70	
	Hypoaspis aculeifer	NOEC ≥100 mg p.m./kg dws		161.70	
FOE 5043-trifluoroethane sulfonic acid	Folsomia candida	NOEC ≥100 mg p.m./kg dws	0.0160	6250	
	Hypoaspis aculeifer	NOEC ≥100 mg p.m./kg dws		6250	
FOE-Thiadone	Folsomia candida	NOEC 1.8 mg p.m./kg dws	0.0236	76.27	
	Hypoaspis aculeifer	EC ₁₀ =28 mg p.m./kg dws		1186.44	

* Endpoints corrected to allow for log P_{ow} > 2

¹ Accumulated PEC_{soil}

sdw soil dry weight

a.s.- flufenacet

Based on the laboratory toxicity endpoints and maximum PEC_{SOIL} values the long-term TER values for Hypoaspis aculeifer and Folsomia candida are higher than the annex VI trigger value of 5, indicating an acceptable risk.

Overall conclusion regarding soil non-target macro - and mesofauna

According to the outcome of the risk assessment it may be concluded that application of DFF+FFA 600 SC cereals (120 g a.s./ha, 160 g a.s./ha and 240 g a.s./ha) pose no unacceptable risk to earthworms and other soil macro - and mesofauna.

Evaluation of acceptability of effects on soil nitrogen turnover was performed according to requirements of the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2 final of 17th October 2002). Evaluation was carried out by comparison of concentrations of particular compound considered in studies and resulting with effects <25% (endpoints are provided in point 2.9.5, table 2.9.5-1) with soil exposure expected after application of DFF+FFA 600 SC according to the intended use pattern (as presented in table 2.9.9-2). In evaluation

only maximum exposure predicted for application of the product to winter cereals (240 g a.s./ha) was taken into account as it represents worst case and covers application to remaining intended crops (120 g a.s./ha and 160 g a.s./ha). Results of the risk assessment are presented in table 2.9.9-72.

Table 2.9.9-72: Summary of the soil nitrogen transformation endpoints for the active substance and its metabolites, representative formulation DFF + FFA SC 600 and risk assessment based on max PEC_{SOIL} values, for the intended uses in winter cereals.

Test item	PEC _{soil} [mg/kg dw soil]	Max tested concentration	% effect on soil nitrogen transformation rate at 28 days after treatment compared to control	Trigger
Flufenacet a.s.	0.320	0.83 mg s.a./kg dws	+3.20	< 25%
		4.13 mg s.a./kg dws	-0.60	
Formulation DFF+FFA SC 600	1 mg form/kg dws	0.6 L form./ha (equiv 0.983 mg form./kg dws)*	-3	
		3.0 L product/ha (equiv. 4.916 mg form./kg soil dw	-8	
FOE oxalate	0.0186	2.48 mg p.m./kg dws (equiv. to 1.86 kg p.m. /ha)	+8	
FOE sulfonic acid-Na-salt	0.0574	3.27 mg p.m./kg dws (equiv. to 2.455 kg a.s./ha)	-8	
FOE methylsulfone	0.0150	0.60 mg p.m./kg dws	+4	
		6.01 mg p.m./kg dws (-5	
TFA	0.6184	0.32 mg p m /kg dws (+3.1	
		1.60 mg p.m./kg dws	+24.4	
FOE 5043-trifluoroethane sulfonic acid	0.0160	0.164 mg p.m./kg dws	-2.3	
		0.820 mg p.m./kg dws	+15.4	
FOE-Thiadone	0.0236	0.149 mg p.m./kg dws	+19.3	
		0.749 mg p.m./kg dws	-3.2	

*density=1.229 g/mL

sdw soil dry weight

a.s.- flufenacet

According to the current regulatory requirements, the risk is considered acceptable if the effect on nitrogen transformation at the recommended application rate of a compound/product is $\leq 25\%$ after 100 days. In none of the above presented studies, the deviations from the control exceed 25% 28 days after application of the recommended application rate. Therefore, the risk from the representative formulation DFF + FFA SC 600, flufenacet and its degradation products in soil can be considered to be low.

Non-target terrestrial plants

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area. Spray drift from the treated areas may lead to residues of a product in off-crop areas.

The corresponding off-field predicted environmental rates (PER) for three different use patterns of representative formulation DFF+ FFA 600 SC (360, 240 180 g sum of a.s./ha, corresponding to 0.6 L product/ha, 0.4 L product/L and 0.3 L product /ha) are presented in the 2.9.9-73.

Table 2.9.9-73: Predicted environmental rates (PER) at 1 m distance from edge of field for representative foemulatioid DDF+FFA SC 600.

Crop	Timing of application	No of app.	Maximum application rate g of sum a.s./ha	Drift	Maf	PER off-field (at 1 m distance) g of sum a.s./ha
Cereals	Post emergence 10-13	1	360	2.77%	1	9.972
Cereals	Post emergence 11-13	1	240	2.77%	1	6.648
Cereals	Pre-emergence 00-22 BBCH	1	180	2.77%	1	4.986

According to the Terrestrial Guidance Document the risk to non-target plants is evaluated by comparing the lowest ER_{50} observed in the laboratory studies with the drift rates ($PER_{off-field}$) as reported in table 2.9.9-73.

The TER values calculation are presented in the Tables below.

Table 2.9.9-74: Deterministic risk assessment for DFF+FFA SC 600 based on vegetative vigor test for one application of 360 g sum of a.s./ha.

Distance (m)	Drift rate (%) ¹	PER off-field (g sum of a.s./ha)	Toxicity (g of sum a.s./ha)	TER			
		no drift reduction		No drift reduction	50% drift reduction	75% drift reduction	90% drift reduction
1	2.77	9.972	$ER_{50}=27.75$ (Cucumis sativus)	2.78	5.56	11.13	27.82
5	0.57	2.052		13.52	27.05	54.09	135.23
10	0.29	1.044		26.58	26.58	106.32	265.80

¹ BBA drift values (1 application, field crops), see Terr. Guidance Doc. SANCO/10329/2002 rev 2 final .

Note: In bold the TER values above trigger value of 5.

Table 2.9.9-75: Deterministic risk assessment for DFF+FFA SC 600 based on vegetative vigor test for one application of 240 g sum of a.s./ha.

Distance (m)	Drift rate (%)	PER off-field (g sum of a.s./ha)	Toxicity (g of sum a.s./ha)	TER			
		no drift reduction		No drift reduction	50% drift reduction	75% drift reduction	90% drift reduction
1	2.77	6.648	$ER_{50}=27.75$ (Cucumis sativus)	4.174	8.34	16.69	41.36
5	0.57	1.368		20.28	40.57	81.14	202.85
10	0.29	0.696		39.87	79.74	159.48	398.70

¹ BBA drift values (1 application, field crops), see Terr. Guidance Doc. SANCO/10329/2002 rev 2 final .

Note: In bold the TER values above trigger value of 5.

Table 2.9.9-76: Deterministic risk assessment for DFF+FFA SC 600 based on vegetative vigor test for one application of 180 g sum of a.s./ha.

Distance (m)	Drift rate (%)	PER off-field (g sum of a.s./ha)	Toxicity (g of sum a.s./ha)	TER			
		no drift reduction		No drift reduction	50% drift reduction	75% drift reduction	90% drift reduction
1	2.77	4.986	ER₅₀=27.75 (Cucumis sativus)	5.565	11.13	22.26	55.61
5	0.57	1.026		27.04	54.03	108.18	270.46
10	0.29	0.522		53.16	106.32	212.64	531.60

¹ BBA drift values (1 application, field crops), see Terr. Guidance Doc. SANCO/10329/2002 rev 2 final.

Note: In bold the TER values above trigger value of 5.

Overall conclusion regarding non –target plants - representative formulation - DFF + FFA SC 600

According to EU requirements the risk for non-target terrestrial plants is considered acceptable, if a 5 m buffer zone is kept without drift reduction or no buffer zone and a 50% drift reducing spray equipment, if 600 mL product /ha (360 g sum of a.s./ha) is applied.

For application rates 400 ml product/ha, 240 g sum of a.s./ha a 5 m buffer zone without drift reduction or no buffer zone and 50% drift reducing spray equipment is sufficient in order to protect the non-target flora on field margins.

For application rates 300 mL product/ha, corresponding to 180 g sum of a.s./ha, no risk mitigation is required for non target flora.

It is worth noting that for the vegetative vigour study the phytotoxic effects were widespread in all dicot species, including the most sensitive species tested - Cucumis sativus with the lowest toxicity endpoint $EC_{50}=27.75$ g a.s./ha (based on foliar fresh weight). That could have resulted in a lower endpoint than that calculated based on foliar fresh weight (21 d visual $EC_{50} < 3.2$ g sum of a.s./ha - endpoints empirically estimated by RMS).

In addition, the phytotoxicity data in this study are not adequate to assess at what level there would be no effects for this particular formulation for the most sensitive species Cucumis sativus (visual 21 d NOEL < 3.2 g a.s./ha, endpoints empirically estimated by RMS).

Taking into consideration that the representative formulation consists of two active substances – flufenacet and diflufenican, the level of the caused by flufenacet alone, could not be possibly to determined based on phytotoxicity effects.

However, since the measurement of phytotoxicity effects is rather subjective the biomass reduction measurement is used in preference as a more quantitative assessment of the toxicological effect on non-target plant species.

In opinion of RMS, the MSs should note that the risk assessment based on the quantitative parameter EC_{50} of 27.75 g a.s./ha (fresh weight) will not cover the phytotoxic effects from this particular formulation.

For the probabilistic risk assessment for representative formulation not sufficient data are available.

Therefore, RMS considered, two additional studies conducted with sformulation Flufenacet 500 SC containing only flufenacet (42.3 %) to evaluate the intrinsic toxicity of the active substance –flufenacet.

The probabilistic assessment based on the data with Flufenacet 500 SC can be used as surrogate in a kind of bridging, since lower endpoints were obtained with this formulation.

For clarity of evaluation the risk assessment for Flufenacet 500 SC was presented separately.

Risk assessment for Flufenacet 500 SC

Probabilistic risk assessment

Table 2.9.9-77: Probabilistic off risk assessment for non-target terrestrial plants based on effects on seedling emergence test for formulation Flufenacet SC 500.

Cereals, one application, 240 g a.s./ha; HC5 = 8.34 g a.s./ha						
Distance	Drift ¹	PER	TER			
[m]	(%)	no drift reduction [g a.s./ha]	No drift reduction	50% drift reduction	75% drift reduction	90% drift reduction
1	2.77	6.648	1.25	2.51	5.02	12.55
5	0.57	1.368	6.10	12.19	24.39	60.96
10	0.29	0.696	11.98	23.97	47.93	119.83

^a a.s.: flufenacet

¹ BBA drift values (1 application, field crops), see Terr. Guidance Doc. SANCO/10329/2002 rev 2 final.

Note: In bold the TER values above trigger value of 1.

Table 2.9.9-78: Probabilistic off risk assessment for non-target terrestrial plants based on effects on seedling emergence test for formulation Flufenacet SC 500.

Cereals, one application, 160 g a.s./ha; HC5 = 8.34 g a.s./ha						
Distance	Drift ¹	PER	TER			
[m]	(%)	no drift reduction [g a.s./ha]	No drift reduction	50% drift reduction	75% drift reduction	90% drift reduction
1	2.77	4.432	1.88	3.76	7.52	18.81
5	0.57	0.912	9.14	18.28	36.57	91.44
10	0.29	0.464	17.98	35.95	71.89	179.74

*active substance: flufenacet

¹ BBA drift values (1 application, field crops), see Terr. Guidance Doc. SANCO/10329/2002 rev 2 final .

Note: In bold the TER values above trigger value of 1.

Table 2.9.9-79: Probabilistic off -risk assessment for non-target terrestrial plants based on effects on seedling emergence test for formulation Flufenacet SC 500.

Cereals, one application, 120 g a.s./ha; HC5 = 8.34 g a.s./ha						
Distance	Drift ¹	PER	TER			
[m]	(%)	no drift reduction [g a.s./ha]	No drift reduction	50% drift reduction	75% drift reduction	90% drift reduction
1	2.77	3.324	2.57	5.01	10.03	25.09
5	0.57	0.684	12.19	24.38	48.77	121.92
10	0.29	0.348	23.96	47.93	95.86	239.65

*active substance flufenacet

Note: In bold the TER values above trigger value of 1.

Since Flufenacet SC 500 has stronger effects on seedling emergence than on the vegetative vigor of young plants, seedling emergence data determine the risk assessment.

Based on the probabilistic risk assessment, the risk for non-target terrestrial plants is considered acceptable with no buffer zone or drift reducing spraying equipment.

Overall conclusion regarding soil non-target plants – Flufenacet 500 SC

Based on the probabilistic risk assessment, the risk for non-target terrestrial plants is considered acceptable with no buffer zone or drift reducing spraying equipment.

2.10. CLASSIFICATION AND LABELLING

Toxic effects leading to the classification.

The main target organs in mouse, rat, dog were liver, thyroid, kidney, the hematopoietic and nervous systems indicated by changes in clinical chemistry, organ weights and/or histopathological findings; Axonopathy and axon swelling observed in 1-year dog and sub-chronic neurotoxicity study in rats. The effects occurred at the LOAELs of 28/27 mg/kg bw/day (m/f dogs) and at 38/43 mg/kg bw/day (m/f rats). Effects occurred at high levels of flufenacet which saturated metabolic pathways.

Based on these effects the classification as Xn, R48/22 was derived.

According to the CLP Regulation the Xn, R48/22 classification is transferred to STOT RE classification. Based on the guidance values specified in Annex 3.9.2.9.7 Table 3.9.3 of the regulation the dose levels at which effects were observed (i.e. 38 / 43 mg/kg bw/day) fall in the criteria for classification into STOT RE category 2 (i.e. $10 < c \leq 100$ mg/kg bw/day). Thus, the classification STOT RE2, H373 has to be applied for flufenacet.

Proposed classification according to Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures.

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification ¹⁾	Reason for no classification ²⁾
2.1.	Explosives				
2.2.	Flammable gases				
2.3.	Flammable aerosols				
2.4.	Oxidising gases				
2.5.	Gases under pressure				
2.6.	Flammable liquids				
2.7.	Flammable solids				
2.8.	Self-reactive substances and mixtures				
2.9.	Pyrophoric liquids	-	-	-	
2.10.	Pyrophoric solids	-	-	-	

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification ¹⁾	Reason for no classification ²⁾
2.11.	Self-heating substances and mixtures				
2.12.	Substances and mixtures which in contact with water emit flammable gases				
2.13.	Oxidising liquids				
2.14.	Oxidising solids				
2.15.	Organic peroxides				
2.16.	Substance and mixtures corrosive to metals	-	-	-	
3.1.	Acute toxicity - oral	H302 Harmful if swallowed.	-	H302 Harmful if swallowed.	
	Acute toxicity - dermal	-	-	-	
	Acute toxicity - inhalation	-	-	-	
3.2.	Skin corrosion / irritation	-	-	-	
3.3.	Serious eye damage / eye irritation	-	-	-	
3.4.	Respiratory sensitisation	-	-	-	
3.4.	Skin sensitisation	H317 May cause an allergic skin		H317 May cause an allergic skin reaction	
3.5.	Germ cell mutagenicity				
3.6.	Carcinogenicity				
3.7.	Reproductive toxicity				

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification ¹⁾	Reason for no classification ²⁾
3.8.	Specific target organ toxicity – single exposure				
3.9.	Specific target organ toxicity – repeated exposure	H373 May cause damage to organs (Nervous system)		H373 May cause damage to organs (Nervous system)	
3.10.	Aspiration hazard				
4.1.	Hazardous to the aquatic environment	Aquatic acute 1 H 400 Aquatic chronic 1 H410		None	Classification proposed
5.1.	Hazardous to the ozone layer				

¹⁾ Including specific concentration limits (SCLs) and M-factors

²⁾ Data lacking, inconclusive, or conclusive but not sufficient for classification

Labeling:

Signal word: Warning

Hazard pictogram:



Hazard statements:

H302 Harmful if swallowed

H317 May cause an allergic skin reaction

H373 May cause damage to organs (not specified) through prolonged or repeated exposure

H410: Very toxic to aquatic life with long lasting effects

Precautionary statements:

P273: Avoid release to the environment.

P391: Collect spillage.

P501: Dispose of contents/ container to an approved incineration plant.

10.2.2.2. Proposed classification according to DSD

Not relevant

10.2.2.3. Formulated mixtures proposal according to the CLP regulation

According to provisions set in Annex 1 of Regulation (EC) No 1272/2008 as amended, the following classification and labelling should be applied for Diflufenican + Flufenacet SC 600.

Proposed classification:

Environmental effects: Aquatic Acute 1, H400
 Aquatic chronic, H410

Labeling:

Signal word: Warning

Hazard pictogram:

Signal word:

**Hazard statements:**

H410: Very toxic to aquatic life with long lasting effects

Precautionary statements:

P 501: Dispose of contents/container in accordance with applicable regulation

EUH 401: To avoid risks to human health and the environment, comply with the instructions for use

2.11. RELEVANCE OF METABOLITES IN GROUNDWATER

The assessment of the fate and behaviour of Flufenacet in soil resulted in the identification of the following degradation product which were classified as major in line with the provisions of the SANCO Guidance 221/2000:

- FOE Oxalate,
- FOE Sulfonic acid,
- FOE Methylsulfone,
- FOE Thiadone,
- FOE 5043-Trifluoroethanesulfonic acid (TFESA),
- Trifluoroacetic acid (TFA).

Additionally FOE Alcohol was indicated as a potentially major soil degradation product of Flufenacet, but assessment for it was proposed to be covered by that for FOE Oxalate.

STEP 1: Exclusion of degradation products of no concern

The model exposure assessment of the Groundwater compartment presented in the document Vol B.8._CP under the point B.8.3. and summarized in this document under the point 2.8.6 (the numerical results are provided in the tables B.8.2.6-10 – B.8.2.6.-14). As a result of that assessment FOE Thiadone was demonstrated to be a degradation product

of no concern – for that compound the calculated $PEC_{GW} < 0.1 \mu\text{g/L}$ in all scenarios and for all uses listed in the EU-representative GAP.

All other degradation products will require further assessment of their relevance because the calculated for them $PEC_{GW} \geq 0.1 \mu\text{g/L}$ in at least one scenario for at least one of the uses listed in the EU-representative GAP.

2.11.1. STEP 2: Quantification of potential groundwater contamination

For the following degradation products the further quantification of the potential groundwater contamination was performed:

- FOE Oxalate;
- FOE Sulfonic acid;
- FOE Methylsulfone
- FOE 5043-Trifluoroethanesulfonic acid;
- Trifluoroacetic acid – TFA.

The results of that assessment are presented below.

FOE Oxalate:

The compound was demonstrated in the model exposure assessment to leach to groundwater in amounts $\geq 0.1 \mu\text{g/L}$ in at least one of the FOCUS GW scenarios for calculations performed using FOCUS PEARL and FOCUS PELMO models in all uses identified within the EU-representative GAP. In case of the use in autumn in Winter cereals at application rate of 240 g Flufenacet/ha for some scenarios the calculated $PEC_{GW} \geq 0.75 \mu\text{g/L}$.

However, the lysimeter studies did not confirm that FOE Oxalate would leach to GW compartment in amounts $\geq 0.1 \mu\text{g/L}$.

FOE Sulfonic acid:

The compound was demonstrated in the model exposure assessment to leach to groundwater in amounts $\geq 0.1 \mu\text{g/L}$ in almost all of the FOCUS GW scenarios for calculations performed using FOCUS PEARL and FOCUS PELMO models in all uses identified within the EU-representative GAP. Additionally, in some of them, for all uses identified in the EU-representative GAP the calculated $PEC_{GW} \geq 0.75 \mu\text{g/L}$.

The high leaching potential of FOE Sulfonic acid to Groundwater was confirmed by the results of the lysimeter studies.

FOE Methylsulfone:

Only for the use in Winter cereals in autumn at application rate 240 g Flufenacet/ha FOE Methylsulfone in some scenarios was demonstrated to leach to GW compartment in amounts $\geq 0.1 \mu\text{g/L}$, but none of the calculated PEC_{GW} values was $\geq 0.75 \mu\text{g/L}$. In case of all remaining uses identified within the EU-representative GAP the calculated $PEC_{GW} < 0.1 \mu\text{g/L}$.

That relatively low leaching potential was confirmed by the results of the lysimeter studies.

FOE 5043-Trifluoroethanesulfonic acid:

The compound was demonstrated in the model exposure assessment to leach to groundwater in amounts $\geq 0.1 \mu\text{g/L}$ in at least one of the FOCUS GW scenarios for calculations performed using FOCUS PEARL and FOCUS PELMO models in all uses identified within the EU-representative GAP. In case of the following uses:

- Autumn application to Winter cereals at application rate of 240 g Flufenacet/ha;
- Autumn application to winter cereals at application rate 160 g Flufenacet/ha;
- Autumn application to Winter cereals at application rate 120 g Flufenacet/ha;

for some scenarios the calculated $PEC_{GW} \geq 0.75 \mu\text{g/L}$.

There are no results of the lysimeter studies that could address the issue of the leaching behavior of FOE 5043-Trifluoroethanesulfonic acid to the Groundwater compartment.

TFA:

The compound was demonstrated in the model exposure assessment to leach to groundwater in amounts $\geq 0.75 \mu\text{g/L}$ in all of the FOCUS GW scenarios for calculations performed using FOCUS PEARL and FOCUS PELMO models in all uses identified within the EU-representative GAP. Additionally, in some of them, for all uses identified in the EU-representative GAP the calculated $PEC_{GW} \geq 10 \mu\text{g/L}$.

There are no results of the lysimeter studies that could address the issue of the leaching behavior of TFA to the Groundwater compartment.

As a result, according to the provisions of the Guidance Document SANCO 221/2000 FOE Methylsulfone would require further assessment at STEP 3, while the remaining degradation products, in addition to that level of Assessment, at STEP 4 and STEP 5.

2.11.2. STEP 3: Hazard assessment – identification of relevant metabolites**2.11.3. STEP 4: Exposure assessment – threshold of concern approach****2.11.4. STEP 5: Refined risk assessment****2.11.5. Overall conclusion****2.12. CONSIDERATION OF ISOMERIC COMPOSITION IN THE RISK ASSESSMENT****2.12.1. Identity and physical chemical properties**

Flufenacet is an active substance that does not exist in isomeric forms. Therefore, the consideration of the isomeric composition and its change under various conditions is not relevant.

2.12.2. Methods of analysis

Flufenacet is an active substance that does not exist in isomeric forms. Therefore, the consideration of the isomeric composition and its change under various conditions is not relevant.

2.12.3. Mammalian toxicity

Flufenacet is an active substance that does not exist in isomeric forms. Therefore, the consideration of the isomeric composition and its change under various conditions is not relevant.

2.12.4. Operator, Worker, Bystander and Resident exposure

Flufenacet is an active substance that does not exist in isomeric forms. Therefore, the consideration of the isomeric composition and its change under various conditions is not relevant.

2.12.5. Residues and Consumer risk assessment

Flufenacet is an active substance that does not exist in isomeric forms. Therefore, the consideration of the isomeric composition and its change under various conditions is not relevant.

2.12.6. Environmental fate

Neither Flufenacet nor any of its major degradation products has isomers that may require consideration in the risk assessment and/or were not covered by that performed within the current evaluation of Flufenacet in the area of the environmental fate and behaviour

2.12.7. Ecotoxicology

Neither Flufenacet nor any of its major degradation products has isomers that may require consideration in the risk assessment and/or were not covered by that performed within the current evaluation of Flufenacet in the area of ecotoxicology.

2.13. RESIDUE DEFINITIONS

2.13.1. Definition of residues for exposure/risk assessment

Food of plant origin:

Flufenacet including all metabolites containing the *N*-fluorophenyl-*N*-isopropyl moiety, expressed as flufenacet

Food of animal origin:

Flufenacet including all metabolites containing the *N*-fluorophenyl-*N*-isopropyl moiety, expressed as flufenacet

Soil:

Flufenacet, FOE Oxalate, FOE Sulfonic acid, FOE Methylsulfone, FOE Thiadone, FOE 5043-Trifluoroethanesulfonic acid, Trifluoroacetic acid;

Justification: RMS with this confirms the Applicant's proposal. All listed degradation products are major soil degradation products.

Groundwater:

Flufenacet, FOE Oxalate, FOE Sulfonic acid, FOE Methylsulfone, FOE Thiadone, FOE Trifluoroethanesulfonic acid, Trifluoroacetic acid (same as for soil compartment); additional compounds that may require assessment (on the basis of the results of lysimeter studies) are FOE Alcohol and FOE TGS;

Justification: The proposed residue definition is the same as proposed by the Applicant and contains the degradation products classified as major soil metabolites and displaying high leaching potential (excluding FOE Thiadone). The reason for inclusion of FOE Alcohol and FOE TGS is that in the lysimeter studies despite being minor soil degradates they were detected in leachates in quantifiable amounts. Therefore it cannot be excluded that under unfavourable conditions they would pose a risk to GW compartment.

Surface water:

Flufenacet, FOE Oxalate, FOE Sulfonic acid, FOE Methylsulfide, FOE Methylsulfone, FOE Thiadone, FOE Trifluoroethanesulfonic acid, Trifluoroacetic acid;

Justification: The proposed residue definition is the same as proposed by the Applicant and contains the degradation products classified as major soil, aquatic or soil and aquatic metabolites. At the same time it shall be indicated that in case of FOE Trifluoroethanesulfonic acid and TFA the assessment in the aquatic environment could not be finalised due to the fact that there was no water/sediment study with Flufenacet radiolabelled in position enabling adequately address the problem.

Sediment:

Flufenacet;

Justification: only Flufenacet was included into that residue definition because of the degradation products listed above in the definition for SW compartment none displayed any significant affinity to the sediment compartment – if detected there they were found in low amounts, not surpassing 5%.

Air:

Flufenacet, FOE Thiadone and Trifluoroacetic acid;

Justification: Flufenacet was included by default, although it shall be indicated that it does not pose a serious threat to the atmosphere; the reason for including FOE Thiadone and TFA is that they are volatile (although in case of TFA it was demonstrated that, being dissociated, that compound when formed from Flufenacet is not expected to migrate to air in any significant amounts) and persistent in air, so they may pose a serious threat to the atmosphere.

2.13.2. Definition of residues for monitoring

Food of plant origin:

Flufenacet including all metabolites containing the *N*-fluorophenyl-*N*-isopropyl moiety, expressed as flufenacet

Food of animal origin:

Flufenacet including all metabolites containing the *N*-fluorophenyl-*N*-isopropyl moiety, expressed as flufenacet

Soil:

Flufenacet, FOE Sulfonic acid, FOE Methylsulfone, Trifluoroacetic acid;

Justification: all listed compounds, including Flufenacet, displayed some potential (in case of TFA significant) for accumulation in soil (conclusion based on the results of the calculations of PEC_{SOIL} values) ;

Groundwater:

Flufenacet, FOE Oxalate, FOE Sulfonic acid, FOE Methylsulfone, FOE Trifluoroethanesulfonic acid and Trifluoroacetic acid;

Justification: the parent compound was included by default. In case of the degradation products listed above the reason for their inclusion was that for the proposed EU-representative application pattern in the GW model exposure assessment they were demonstrated to leach to the groundwater recharge in amounts $> 0.1 \mu\text{g/L}$. In many cases the calculated $PEC_{GW} > 0.75 \mu\text{g/L}$ and in case of TFA the calculated $PEC_{GW} > 10 \mu\text{g/L}$. The high leaching potential of FOE Sulfonic acid was confirmed in regulatory lysimeter studies. Finally, it shall be indicated that FOE Oxalate and FOE Sulfonic acid were detected in Groundwater in some monitoring studies, the results of which were presented in the publications summarised under the point B.8.5.

Surface water:

Flufenacet, FOE Oxalate, FOE Sulfonic acid, FOE Methylsulfide, FOE Thiadone and Trifluoroacetic acid

Justification: the parent compound was included by default. In case two degradation products – FOE Methylsulfide and FOE Thiadone, they were included into the definition due the fact that they are major aquatic degradation products (additionally FOE Thiadone was identified as major soil degradation product) with not defined persistence in natural water. The reason for including FOE Oxalate and FOE Sulfonic acid was that they are major soil degradation products and potentially major aquatic degradation products (in the water/sediment studies their formation potential was not fully assessed) with unknown persistence in water and highly mobile. Additionally in some monitoring studies, summarised below under the point B.8.5, they were detected in SW bodies in quite significant amounts, as was Flufenacet. The reason for including TFA is that it is very persistent and common pollutant. Additionally the problem of its formation from Flufenacet in SW compartment was not satisfactorily addressed.

Sediment:

Flufenacet;

Justification: the definition comprises the parent compound only, which was included by default, but also because the degradation in the SW bodies will comprise the migration from water phase to sediment (main dissipation process for Flufenacet in water), where it will undergo degradation. None of the degradation products listed for SW compartment were included due to the fact that they were either not detected in sediment or found in that compartment in very low amounts ($< 5\%$ of the initial amount of Flufenacet).

Air:

Flufenacet, FOE Thiadone and Trifluoroacetic acid;

Justification: the parent compound was included by default. In case two degradation products – FOE Thiadone and TFA they were included because of they high volatility and persistence in air, what results in a high level of risk they pose to the atmosphere.

Level 3

FLUFENACET

3. PROPOSED DECISION WITH RESPECT TO THE APPLICATION

3.1. BACKGROUND TO THE PROPOSED DECISION

3.1.1. Proposal on acceptability against the approval criteria – Article 4 and annex II of regulation (EC) No 1107/2009

3.1.1.1. Article 4			
		Yes	No
i)	It is considered that Article 4 of Regulation (EC) No 1107/2009 is complied with. Specifically the RMS considers that authorisation in at least one Member State is expected to be possible for at least one plant protection product containing the active substance for at least one of the representative uses.	X	
			It is considered that Article 4 of Regulation(EC) No 1107/2009 is complied with Flufenacet for the representative uses. A safe use has been demonstrated for the products containing Diflufenican + Flufenacet SC 600 (200+400 g/L) for the pre- and early post emergence use in cereals (wheat, barley, rye). No further representative uses were considered.
3.1.1.2. Submission of further information			
		Yes	No
i)	It is considered that a complete dossier has been submitted	X	
ii)	It is considered that in the absence of a full dossier the active substance may be approved even though certain information is still to be submitted because: (a) the data requirements have been amended or refined after the submission of the dossier; or (b) the information is considered to be confirmatory in nature, as required to increase confidence in the decision.		
			Not applicable
3.1.1.3. Restrictions on approval			
		Yes	No
	It is considered that in line with Article 6 of Regulation (EC) No 1107/2009 approval should be subject to conditions and restrictions.	X	
			The minimum concentration of the active substance in technical flufenacet is set to 970 g/kg based on the new material accountability study. The minimum purity as specified for the first inclusion was 950 g/kg. Some adjustments in the specification for the impurities was introduced.

				The active substance as manufactured does not contain any impurities requiring toxicological/ecotoxicological relevance.
3.1.1.4. Criteria for the approval of an active substance				
Dossier				
		Yes	No	
	It is considered the dossier contains the information needed to establish, where relevant, Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL) and Acute Reference Dose (ARfD).	X		-
	<p>It is considered that the dossier contains the information necessary to carry out a risk assessment and for enforcement purposes (relevant for substances for which one or more representative uses includes use on feed or food crops or leads indirectly to residues in food or feed). In particular it is considered that the dossier:</p> <p>(a) permits any residue of concern to be defined;</p> <p>(b) reliably predicts the residues in food and feed, including succeeding crops</p> <p>(c) reliably predicts, where relevant, the corresponding residue level reflecting the effects of processing and/or mixing;</p> <p>(d) permits a maximum residue level to be defined and to be determined by appropriate methods in general use for the commodity and, where appropriate, for products of animal origin where the commodity or parts of it is fed to animals;</p> <p>(e) permits, where relevant, concentration or dilution factors due to processing and/or mixing to be defined.</p>	X		<p>The submitted metabolism data in crops together with the available residue trials allow to confirm the existing residue definition in plants.</p> <p>A sufficient number of residue trials as the representative use have been submitted</p> <p>The data necessary to maintain currently binding MRLs and consumer risk assessment were submitted and are considered as sufficient for the current approval process.</p> <p>Residue levels in livestock commodities are expected to remain below the enforcement LOQ of 0.01 mg/kg in milk, 0.02 mg/kg in liver and 0.05 mg/kg in fat, eggs, kidney and muscle.</p> <p>Processing studies were sufficient to calculate processing factors.</p> <p>Residues of flufenacet are not expected in rotational crops.</p> <p>No risk for consumers could be identified with respect to the representative uses.</p>
	It is considered that the dossier submitted is sufficient to permit, where relevant, an estimate of the fate and distribution of the active substance in the environment, and its impact on non-target species.			
Efficacy				
		Yes	No	
	It is considered that it has been established for one or more representative uses that the plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use is sufficiently effective.	X		
Relevance of metabolites				
		Yes	No	

	It is considered that the documentation submitted is sufficient to permit the establishment of the toxicological, ecotoxicological or environmental relevance of metabolites.	X		The documentation submitted is sufficient to permit the establishment of the toxicological relevance of metabolites.
Composition				
		Yes	No	
	It is considered that the specification defines the minimum degree of purity, the identity and maximum content of impurities and, where relevant, of isomers/diastereo-isomers and additives, and the content of impurities of toxicological, ecotoxicological or environmental concern within acceptable limits.	X		Sufficient information has been presented by notifier to support the declared technical specification of flufenacet with respect to the identity and content of impurities in the respective technical specifications. The analytical methods provided are acceptable.
	It is considered that the specification is in compliance with the relevant Food and Agriculture Organisation specification, where such specification exists.	-		No FAO specification is available.
	It is considered for reasons of protection of human or animal health or the environment, stricter specifications than that provided for by the FAO specification should be adopted	-		Not applicable.
Methods of analysis				
		Yes	No	
	It is considered that the methods of analysis of the active substance, safener or synergist as manufactured and of determination of impurities of toxicological, ecotoxicological or environmental concern or which are present in quantities greater than 1 g/kg in the active substance, safener or synergist as manufactured, have been validated and shown to be sufficiently specific, correctly calibrated, accurate and precise.	X		Adequate analytical methods are available for the determination of flufenacet and all significant impurities in the technical material. Analytical methodology is available for the technical compound as well as for the formulated product.
	It is considered that the methods of residue analysis for the active substance and relevant metabolites in plant, animal and environmental matrices and drinking water, as appropriate, shall have been validated and shown to be sufficiently sensitive with respect to the levels of concern.		X	Adequate methods are available and sufficiently sensitive to monitor the respective current residue definition in plant material, soil, drinking water, surface water. Air method does not fulfil requirements.
	It is confirmed that the evaluation has been carried out in accordance with the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) of Regulation 1107/2009	X		Please refer to Level 2 Section 2.2 for further details The information submitted with regards to methods of analysis is sufficient to support approval. Refer also to Level 2, Section 2.5.
Impact on human health				
Impact on human health - ADI, AOEL, ARfD				
		Yes	No	

	It is confirmed that (where relevant) an ADI, AOEL and ARfD can be established with an appropriate safety margin of at least 100 taking into account the type and severity of effects and the vulnerability of specific groups of the population.	X		Please refer to Volume 3CA B.6 Toxicology and metabolism Point B.6.9.7 for further details
Impact on human health – proposed genotoxicity classification				
		Yes	No	
	It is considered that, on the basis of assessment of higher tier genotoxicity testing carried out in accordance with the data requirements and other available data and information, including a review of the scientific literature, reviewed by the Authority, the substance SHOULD BE classified or proposed for classification , in accordance with the provisions of Regulation (EC) No 1272/2008, as mutagen category 1A or 1B.		X	FOE 5043 is not mutagenic, clastogenic or genotoxic

Impact on human health – proposed carcinogenicity classification			
		Yes	No
i)	It is considered that, on the basis of assessment of the carcinogenicity testing carried out in accordance with the data requirements for the active substances, safener or synergist and other available data and information, including a review of the scientific literature, reviewed by the Authority, the substance SHOULD BE classified or proposed for classification , in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B .		X
ii)	Linked to above classification proposal. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.		
Impact on human health – proposed reproductive toxicity classification			
		Yes	No
i)	It is considered that, on the basis of assessment of the reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, the substance SHOULD BE classified or proposed for classification , in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B .		X

ii)	<p>Linked to either i) or ii) immediately above.</p> <p>It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.</p>			
Impact on human health – proposed endocrine disrupting properties classification				

		Yes	No	
i)	It is considered that the substance SHOULD BE classified or proposed for classification in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogenic category 2 and toxic for reproduction category 2 and on that basis shall be considered to have endocrine disrupting properties		X	Flufenacet is not a reproductive or developmental toxicant and endocrine disrupting substance
ii)	It is considered that the substance SHOULD BE classified or proposed for classification in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 2 and in addition the RMS considers the substance has toxic effects on the endocrine organs and on that basis shall be considered to have endocrine disrupting properties		X	Flufenacet is not a reproductive or developmental toxicant and endocrine disrupting substance
iii)	Linked to either i) or ii) immediately above. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005			
Fate and behaviour in the environment				
Persistent organic pollutant (POP)				
		Yes	No	
	It is considered that the active substance FULFILLS the criteria of a persistent organic pollutant (POP) as laid out in Regulation 1107/2009 Annex II Section 3.7.1.		X	<u>Persistence:</u> In water the determined DT ₅₀ was in range 16.98 – 58.72 days, what is below the regulatory threshold of 2 months (60 days). In soil the normalised geomean DT ₅₀ = 17.89 days (range: 7.04 – 37.40 days), what is well below the regulatory threshold of 6 months (180 days). In sediment the determined DT ₅₀ was in range 17.64 – 140.50 days, what is below the regulatory threshold value of 6 months (180 days). On that basis it may be stated that Flufenacet does not fulfill the regulatory criteria laid out in Regulation 1107/2009, Annex II, Section 3.7.1. <u>Bioaccumulation:</u> The determined BCF = 71.4, what is well below the regulatory threshold of 5000. On that basis it may be stated that Flufenacet does not fulfill the regulatory criterion laid out in Regulation 1107/2009, Annex II, Section 3.7.1.

				<p><u>Potential for long-range environmental transport:</u> The examination of the fate and behaviour of Flufenacet in air showed that the compound will not be persistent in that compartment, with $DT_{50} = 6.8$ hours, well below the regulatory threshold value of 2 days. It will be therefore not prone to the long-range transport in the atmosphere.</p> <p>It may be therefore stated that Flufenacet shall not be classified as POP as it does not fulfill any of the regulatory criterion laid out in Regulation 1107/2009, Annex II, Section 3.7.1.</p>
Persistent, bioaccumulative and toxic substance (PBT)				
		Yes	No	
	It is considered that the active substance FULFILS the criteria of a persistent, bioaccumulative and toxic (PBT) substance as laid out in Regulation 1107/2009 Annex II Section 3.7.2.		X	<p><u>Persistence:</u> In water the determined DT_{50} was in range 16.98 – 58.72 days, what is below the regulatory threshold of 40 - 60 days. In soil the normalised geomean $DT_{50} = 17.89$ days (range: 7.04 – 37.40 days), what is well below the regulatory threshold of 120 days. In sediment the determined DT_{50} was in range 17.64 – 140.50 days, what is below the regulatory threshold value of 120 - 180 days. On that basis it may be stated that Flufenacet does not fulfill the regulatory criteria laid out in Regulation 1107/2009, Annex II, Section 3.7.2.</p> <p><u>Bioaccumulation:</u> The determined $BCF = 71.4$ what is well below the regulatory threshold of 2000. On that basis it may be stated that Flufenacet does not fulfill the regulatory criterion laid out in Regulation 1107/2009, Annex II, Section 3.7.2.</p> <p><u>Toxicity:</u> Long term ni observed effect concentration for aquatic orgaism are in range of 0.000138 mg -5 mg/L which indictes that toxicity criteria are fulfilled.</p>
Very persistent and very bioaccumulative substance (vPvB).				
		Yes	No	
	It is considered that the active substance FULFILS the criteria of a a very persistent and very bioaccumulative substance (vPvB) as laid out in Regulation 1107/2009 Annex II Section 3.7.3.		X	<p><u>Persistence:</u> In water the determined DT_{50} was in range 16.98 – 58.72 days, what is below the regulatory threshold of 60 days. In soil the normalised geomean $DT_{50} = 17.89$ days (range: 7.04 – 37.40 days), what is well below the regulatory threshold of 180 days. In sediment the determined DT_{50} was in range 17.64 – 140.50 days, what is</p>

				<p>below the regulatory threshold value of 180 days. On that basis it may be stated that Flufenacet does not fulfill the regulatory criteria laid out in Regulation 1107/2009, Annex II, Section 3.7.3.</p> <p><u>Bioaccumulation:</u> The determined BCF = 71.4 what is well below the regulatory threshold of 5000. On that basis it may be stated that Flufenacet does not fulfill the regulatory criterion laid out in Regulation 1107/2009, Annex II, Section 3.7.3.</p> <p>It may be therefore stated that Flufenacet shall not be classified as vPvB as it does not fulfill any of the regulatory criterion laid out in Regulation 1107/2009, Annex II, Section 3.7.3.</p>
Ecotoxicology				
			No	
	<p>It is considered that the risk assessment demonstrates risks to be acceptable in accordance with the criteria laid down in the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) under realistic proposed conditions of use of a plant protection product containing the active substance, safener or synergist. The RMS is content that the assessment takes into account the severity of effects, the uncertainty of the data, and the number of organism groups which the active substance, safener or synergist is expected to affect adversely by the intended use.</p>			<p>In general the risk assessment to all groups of organisms was performed with consideration of each application rate to winter cereals (1 x 120 g a.s./ha, 1 x 160 g a.s./ha and 1 x 240 a.s./ha, respectively).</p> <p>The only exception was the risk assessment for non target arthropods and aute risk for honeybees performed consideration of the worst case exposure identified for autumn application to winter cereals (1 x 240 g a.s./ha).</p> <p>Performed evaluation covers therefore all intended uses (1 x 120 g a.s./ha and 1 x 160 g a.s./ha).</p> <p>The risk assssment performed at screening step demonstrated that acute exposure of birds and mammals to flufenacet applied according to the intended use pattern, will not pose an unacceptable acute risk to species believed to be at risk.</p> <p>The risk assessment performed at the Tier 1 demonstrated that long-term exposure of birds and mammals to flufenacet applied according to the intended use pattern, will not pose an unacceptable the long-term risk to species believed to be at risk.</p> <p>However, the TER_{LT} value for generic species- Pink-footed goose for the highest autumn application rate of 1 x 240 g a.s./ha, was only below trigger value of 5. (being 4.56). It should be note, that flufenacet at this rate is applied outside the breeding season of geese and for this reason; the risk may be considered acceptable.</p> <p>The approach of the refinement of the long-term risk assessment for herbivorous bird, considering the refined ftwa value of 0.3302, based on the longest DT₅₀ of 5.101 days value for flufenacet resulting in TER_{LT} value above the Annex VI trigger of 5, should be decided at MS level.</p>

				<p>Exposure to flufenacet metabolites TFA and FOE oxalate was also considered. Based on the toxicity data of active substance and its TFA metabolite from mammalian section it was concluded that toxicity of active substance covers the toxicity of TFA metabolite. In addition, the calculation of uptake by skylark the TFA residues' found in grain and straw after application of 270 g a.s./ha, indicated that exposure by diet may be acceptable.</p> <p>No toxicity endpoints is performed for FOE oxalate.</p> <p>In the studies performed on mammals – rats and lactating goats (representing livestock) it was demonstrated that FOE Oxalate was not a product of metabolism of Flufenacet. It shall be therefore stated that, as it was in case of mammals, the sole route of exposure to it was via food.</p> <p>FOE Oxalate was demonstrated not to be metabolized within the body once absorbed from the digestive track. At the same time it shall be indicated that the level of absorption was low – 61 – 80% was removed with faeces and 19-37% of the administered dose with urine. The depuration was fast – it occurred within 24 hours after uptake of the contaminated food. The accumulation of FOE Oxalate within the tissues was not observed. These results were obtained for the dose level of 1 mg/kg body weight (in studies with rats). Taking into account that FOE-oxalate metabolite does not bioaccumulate and is quickly excreted a chronic exposure of mammals can be considered negligible.</p> <p>That indicates that the risk to wild mammals resulting from the consumption of food containing that compound is expected to be minimal, if not negligible.</p> <p>The metabolism studies performed for laying hens, showed that FOE Oxalate, when administered to the test animals with food was minimally absorbed. The absorbed FOE Oxalate was not metabolized and the tissue analysis showed that it was retained predominantly in liver. It may be assumed that from there it would be depurated with urine. Low levels of that compound in muscles and fat indicate that FOE Oxalate uptaken with food will not be cumulated in the organism.</p> <p>At the same time it shall be indicated that these results were obtained for FOE Oxalate administered at the level 5 mg/kg body weight, corresponding to approximately 350 times of exposure of poultry.</p> <p>That indicates that the risk to wild bird resulting from the consumption of food containing that compound is expected to be minimal, if not negligible.</p> <p>The lack of chronic/reproductive effects cannot be deduced from the short term study conducted with laying hens. However, taking into account that FOE-oxalate metabolite does not bioaccumulate and is quickly excreted a chronic exposure of birds can be considered negligible.</p>
--	--	--	--	--

				<p>The risk resulting from drinking of contaminated water is considered to be low. The risk of secondary poisoning was demonstrated for compound with log Pow >3 (flufenacet).</p> <p>Risk from secondary poisoning for earthworm-eating birds/mammals for the active substance is considered acceptable.</p> <p>Risk from secondary poisoning for fish-eating birds/mammals for the active substance is considered acceptable for all proposed uses.</p> <p>Risk from secondary poisoning for fish-eating mammals for the active substance is considered acceptable for all proposed uses.</p> <p>Risk from secondary poisoning for earthworm-eating mammals for the active substance is considered acceptable for all proposed uses.</p> <p>On the basis of results of endocrine disruption specific studies performed with mammals it is concluded that flufenacet is not an endocrine disruptor.</p> <p>The risk assessment for aquatic organisms was performed for flufenacet and its aquatic as well as soil metabolites. Separate risk assessment for the formulated product was not performed.</p> <p>The results determined in studies with the formulated product should be reanalysed based on measure concentration.</p> <p>Acceptable acute risk to fish and H.azteca (the most sensitive aquatic invertebrates) exposed to flufenacet was concluded for calculations performed with consideration of Step 2 PEC_{sw} for all intended uses, except the highest application rate of 1 x 240 g a.s./ha for autumn application in winter cereals. Acceptable acute risk was concluded for exposure calculated at STEP 3.</p> <p>Acceptable risk to fish and aquatic invertebrates for metabolites of flufenacet was acceptable for STEP1 PEC_{sw}.</p> <p>The long-term risk assessment performed for fish exposed to flufenacet passed the respective triggers for PEC_{sw} values calculated at Step 3 except the application rates 1 x 160 g a.s./ha and 1 x 240 g a.s./ha for autumn use in winter cereals.</p> <p>PEC_{sw} values with 10 m vegetated buffer zone for R3 scenario at rate 1x 160 g a.s./ha and for R1, R3 and R4 scenarios at rate 1x 240 g a.s./ha indicated acceptable long-term risk for fish. However for D1 (ditch), D2 (ditch) and D6 (ditch) values with 20 m buffer zone for mitigation of Spray Drift and Run-off for application rate of 1 x 240 g a.s./ha, indicated an unacceptable long-term risk for fish. However, taking into account the geometric mean NOEC of 131</p>
--	--	--	--	---

				<p>(µg a.s./L) value obtained from additional studies on fish all TER_{LT} values calculated for flufenacet with consideration of calculation STEP 3 PEC_{sw} are above the trigger of 10 indicating acceptable long-term risk to fish.</p> <p>The long-term risk assessment performed for aquaic invertebrates exposed to flufenacet passed the respective triggers for PEC_{sw} values calculated at Step 2 except the application rate of 1 x 240 g a.s./ha for autumn use in winter cereals. Acceptable long-term risk was concluded for exposure calculated at STEP 3 for these uses.</p> <p>Acceptable long-term risk to sediment dwelling organisms exposed via water column was concluded for exposure calculated at Step 1.</p> <p>Study on bioconcentration of flufenacet in fish resulted of 71.4 which is below trigger of 100 indicating low potential for bioaccumulation.</p> <p>The risk assessment for algae:</p> <p>The long-term risk assessment performed to algae exposed fo flufenacet metabolites: FOE methylosulfide, FOE-methylosulfone, FOE oxalate, FOE trifluoroethane sulfonic acid,, TFA passed the respective triggers for PEC_{sw} values calculated at Step 1.</p> <p>The long- term risk performed to algae exposed fo flufenacet did not passed the respective triggers for PEC_{sw} values calculated at STEP1 and STEP 2. Therefore the long - term risk was performed based on PEC_{sw} values calculated at STEP 3 and STEP 4.</p> <p>The summary of the results are presented below:</p> <p><u>Autumn Uses:</u></p> <p>In case of the post-emergence use in Winter cereals in autumn, at application rate 240 g Flufenacet/ha, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenarios:</p> <ul style="list-style-type: none"> - D1 ditch, D1 stream, D2 ditch, D2 stream, D4 pond, D4 stream, D5 pond, D5 stream, D6 ditch, R1 stream, R3 stream and R4 stream. In case of scenarios D4 pond, D4 stream, D5 pond, D5 stream and D6 ditch RMS noticed that although safe PEC_{sw} values were not reached at STEP 4, it may be stated that the risk for algae was not substantial due to the fact that they occurred late in autumn and in winter, when algae are in dormant period from December to February; also in none of these
--	--	--	--	--

				<p>scenarios the PEC_{SW} values above the safe level were observed later than in the first days of March. Also in case of all R scenarios for which safe PEC_{SW} value was not reached, similar conclusion may be drawn.</p> <p>The only safe scenario identified within that use was D3, assuming 10-metres wide buffer zone for mitigation of Spray Drift.</p> <p>Therefore for that use it may be stated that one safe scenario was identified – D3 scenario assuming 10-metres wide non-spray buffer zone to mitigate the Spray drift.</p> <p>In case of the post-emergence use in Winter cereals in autumn, at application rate 160 g Flufenacet/ha, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenarios:</p> <ul style="list-style-type: none"> - D1 ditch, D1 stream, D2 ditch, D2 stream, D4 stream, D5 pond, D5 stream, D6 ditch, R1 stream, R3 stream and R4 stream. In case of scenarios D4 stream, D5 pond, D5 stream and D6 ditch RMS noticed that although safe PEC_{SW} values were not reached at STEP 4, it may be stated that the risk for algae was not substantial due to the fact that they occurred late in autumn and in winter, when algae are in dormant period from December to February; also in none of these scenarios the PEC_{SW} values above the safe level were observed later than in the first days of March. Also in case of all R scenarios for which safe PEC_{SW} value was not reached, similar conclusion may be drawn. <p>The only safe scenario identified within that use was D3, assuming 10-metres wide buffer zone for mitigation of Spray Drift.</p> <p>Therefore for that use it may be stated that one safe scenario was identified – D3 scenario assuming 10-metres wide non-spray buffer zone to mitigate the Spray drift.</p> <p>In case of the post-emergence use in Winter cereals in autumn, at application rate 120 g Flufenacet/ha, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenarios:</p> <ul style="list-style-type: none"> - D1 ditch, D1 stream, D2 ditch, D2 stream, D6 ditch and R3 stream. In case of scenario D6 ditch RMS stated that although safe PEC_{SW} values were not reached at STEP 4, it may be stated that the risk for algae was not substantial due to the fact that they occurred late in autumn and in winter, when algae are in dormant period from December to February;
--	--	--	--	---

				<p>also in none of these scenarios the PEC_{SW} values above the safe level were observed later than in the first days of March. Also in case of R3 scenario similar conclusion may be drawn.</p> <p>The safe scenarios identified within that use were D4 and D5 – all three already at STEP 3 (hence no buffer zone needed to be implemented), D3 ditch assuming 10-metres wide non-spray buffer zone to mitigate Spray Drift, R1 assuming 20-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off and R4 assuming 10-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off.</p> <p>Therefore, for that use it may be stated that the following safe scenarios were identified: scenarios D4 and D5 without any buffer zone (safe PEC_{SW} values were obtained already at STEP 3), D3 ditch assuming 10-metres wide non-spray buffer zone to mitigate Spray Drift, R1 scenario assuming 20-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off and R4 scenario assuming 10-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off.</p> <p><u>SPRING USE</u></p> <p>In case of the post-emergence use in Winter cereals at spring, at application rate 160 g Flufenacet/ha, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenarios:</p> <ul style="list-style-type: none"> - D2 ditch and D2 stream <p>In case of scenarios D4 pond, D5 pond, R1 pond and R4 stream safe PEC_{SW} values were obtained already at STEP 3 (so no buffer needed).</p> <p>In case of the following scenarios: D1 ditch, D1 stream, D3 ditch, D4 stream, D5 stream and D6 ditch, safe PEC_{SW} values were obtained at STEP 4 after implementation of the 10-metres wide non-spray buffer zone for mitigation of the Spray Drift;</p> <p>For scenarios R1 stream and R3 stream safe PEC_{SW} values were obtained at STEP 4 after implementation of 10-metres wide vegetated buffer zone for mitigation of the Spray Drift and Run-off.</p> <p>Therefore for that application pattern only for scenario D2 safe use was not demonstrated. In case of scenario R4 it was demonstrated that implementation of the buffer zone mitigating Spray Drift and/or Run-off was not necessary. 10-metres wide non-spray buffer zone was demonstrated to be necessary to obtain safe PEC_{SW} values for scenarios</p>
--	--	--	--	---

				<p>D1, D3, D4, D5, D6, R1 and R3. In case of scenarios R1 and R3 that buffer zone has to be vegetated in order to mitigate the Run-off.</p> <p>In case of the post-emergence use in Winter cereals at spring, at application rate 120 g Flufenacet/ha, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenarios:</p> <ul style="list-style-type: none"> - D2 ditch and D2 stream <p>In case of scenarios D1 stream, D4 pond, D4 stream, D5 pond and D5 stream, R1 pond, and R4 stream safe PEC_{SW} values were obtained already at STEP 3.</p> <p>In case of the scenarios D1 ditch, D3 ditch and D6 ditch safe PEC_{SW} values were obtained at STEP 4 after implementation of the 10-metres wide non-spray buffer zone for mitigation of the Spray Drift;</p> <p>For scenarios R1 stream and R3 stream safe PEC_{SW} values were obtained at STEP 4 after implementation of 10-metres wide vegetated buffer zone for mitigation of the Spray Drift and Run-off.</p> <p>Therefore, for that application pattern only for scenario D2 safe use was not demonstrated. In case of scenarios D4, D5 and R4 it was demonstrated that implementation of the buffer zone mitigating Spray Drift and/or Run-off was not necessary. 10-metres wide non-spray buffer zone was demonstrated to be necessary to obtain safe PEC_{SW} values for scenario D1, D3, D6, R1 and R3. In case of scenarios R1 and R3 that buffer zone has to be vegetated in order to mitigate the Run-off.</p> <p>The risk assessment for Lemna sp</p> <p>The long risk assessment performed to Lemna sp. exposed fo flufenacet metabolites : FOE methylosulfide, FOE-methylosulfone, FOE- oxalate, FOE-Thiadone, TFA passed the respective triggers for PEC_{sw} values calculated at Step 1. However for FOE sulfonic acid the data GAP was estimated.</p> <p>The long- term risk performed to Lemna sp. exposed fo flufenacet did not passed the respective triggers for PEC_{sw} values calculated at STEP1 and STEP 2. Therefore the long - term risk was performed based on PEC_{sw} values calculated at STEP 3 and STEP 4.</p> <p>The summary of the results are presented below:</p>
--	--	--	--	--

			<p>Lemna gibba</p> <p>Autumn Uses:</p> <p>In case of the post-emergence use in Winter cereals in autumn, at application rate 240 g Flufenacet/ha, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenarios:</p> <ul style="list-style-type: none"> - D1 ditch, D1 stream, D2 ditch, D2 stream, D4 stream, D6 ditch, R3 and R4. In case of scenarios D4 stream and D6 ditch RMS noticed that although safe PEC_{SW} values were not reached at STEP 4, it may be stated that the risk for Lemna spp. was not substantial due to the fact that they occurred late in autumn and in winter, when Lemna sp. in dormant period from December to February; also in none of these scenarios the PEC_{SW} values above the safe level were observed later than in the first days of March. Also in case of all R scenarios for which safe PEC_{SW} value was not reached, similar conclusion may be drawn. <p>The safe scenarios identified within that use were: D3 ditch assuming 10-metres wide buffer zone for mitigation of Spray Drift, D4 pond already at STEP 3 (hence no buffer zone needed to be implemented), D5 pond already at STEP 3 (hence no buffer zone needed to be implemented), D5 stream assuming 10-metres wide buffer zone for mitigation of Spray Drift, R1 pond already at STEP 3 (hence no buffer zone needed to be implemented), R1 stream assuming 20-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off;</p> <p>Therefore, for that use it may be stated that three safe scenarios were identified: for the D3 scenario assuming 10-metres wide non-spray buffer zone to mitigate the Spray drift, for D5 scenario assuming 10-metres wide non-spray buffer zone to mitigate Spray Drift and R1 assuming 20-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off.</p> <p>In case of the post-emergence use in Winter cereals in autumn, at application rate 160 g Flufenacet/ha, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenarios:</p> <ul style="list-style-type: none"> - D1 ditch, D1 stream, D2 ditch, D2 stream, and D6 ditch. In case of scenario D6 ditch RMS noticed that although safe PEC_{SW} values were not reached at STEP 4, it may be stated that the risk for Lemna spp. was not substantial due to the fact that they occurred late in autumn and in winter, when Lemna sp. was in dormant period from December to February; also in none of these scenarios the PEC_{SW} values above the safe level were observed later than in the first days of March. <p>The safe scenarios identified within that use were: D3 ditch, D4 pond, D4</p>
--	--	--	---

				<p>stream, D5 pond, D5 stream – all them already at STEP 3 (hence no buffer zone needed to be implemented), as well as R1 pond already at STEP 3 (hence no buffer zone needed to be implemented), R1 stream assuming 20-metres wide vegetated buffer zone for mitigation of Spray Drift and Run-off, R3 stream assuming 20-metres wide vegetated buffer zone for mitigation of Spray Drift and Run-off and R4 stream assuming 20-metres wide vegetated buffer zone for mitigation of Spray Drift and Run-off</p> <p>Therefore for that use it may be stated that the following safe uses were identified: for scenarios D3, D4 and D5 without any buffer zone (safe PEC_{SW} values were obtained already at STEP 3) as well as R1, R3 and R4 scenarios assuming 20-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off.</p> <p>In case of the post-emergence use in Winter cereals in autumn, at application rate 120 g Flufenacet/ha, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenarios:</p> <ul style="list-style-type: none"> - D1 ditch, D1 stream, D2 ditch, D2 stream and D6 ditch. In case of scenario D6 ditch RMS noticed that although safe PEC_{SW} values were not reached at STEP 4, it may be stated that the risk for Lemna spp.e was not substantial due to the fact that they occurred late in autumn and in winter, when Lemna sp. is in dormant period from December to February; also in none of these scenarios the PECSW values above the safe level were observed later than in the first days of March <p>The safe scenarios identified within that use were D3 ditch, D4 (pond and stream), D5 (pond and stream), R1 pond and R4 stream – all they already at STEP 3 (hence no buffer zone needed to be implemented), as well as R1stream assuming 10-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off and R3 assuming 20-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off</p> <p>Therefore for that use it may be stated that the following safe uses were identified: for scenarios D3, D4, D5 and R4 without any buffer zone (safe PEC_{SW} values were obtained already at STEP 3) as well as R1 scenario assuming 10-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off and R3 scenario assuming 20-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off.</p>
--	--	--	--	--

			<p><u>SPRING USE</u></p> <p>The general conclusions drawn from the risk assessment for Lemna gibba presented above are given, are provided below, individually for each use listed in the EU-representative GAP.</p> <p>In case of the post-emergence use in Winter cereals at spring, at application rate 160 g Flufenacet/ha, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenarios:</p> <ul style="list-style-type: none"> - D2 ditch and D2 stream; <p>In case of scenarios D1 ditch, D1 stream, D3 ditch, D4 pond, D4 stream, D5 pond and D5 stream, R1 pond, R1 stream and R4 stream safe PEC_{SW} values were obtained already at STEP 3.</p> <p>For scenario R3 stream safe PEC_{SW} values were obtained at STEP 4 after implementation of 10-metres wide vegetated buffer zone for mitigation of the Spray Drift and Run-off.</p> <p>Therefore for that application pattern only for scenarios D2 safe use was not demonstrated. In case of scenario R3 it was demonstrated that it was necessary to implement 10 meter buffer zone mitigating Spray Drift and Run-off. In all remaining scenarios identified as returning the safe PEC_{SW} values it was demonstrated that the implementation of any mitigation measures was not necessary as the assessment was finalised at Step 3.</p> <p>In case of the post-emergence use in Winter cereals at spring, at application rate 120 g Flufenacet/ha, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenario D2 ditch.</p> <p>In case of scenarios D1 ditch, D1 stream, D2 stream, D3 ditch, D4 pond, D4 stream, D5 pond and D5 stream, D6 ditch, R1 pond, R1 stream, R3 stream and R4 stream safe PEC_{SW} values were obtained already at STEP 3. For that application pattern assessment at STEP 4 was not performed.</p> <p>Therefore for that application pattern only for scenario D2 safe use was not demonstrated. In case of scenarios D1, D3, D4, D5, D6, R1, R3 and R4 it was demonstrated that implementation of the buffer zone mitigating Spray Drift and/or Run-off was not necessary.</p> <p>The Applicant as a refinement provided the risk assessment based on microcosm study (Foekema 1997, see CA, Vol 3., B9). This study was re-evaluated by RMS and was considered valid in case of Macrophytes (Lemna sp. and Elodea sp.). The results of the study suggest that rooted plants are</p>
--	--	--	--

			<p>more sensitive than Lemna sp.</p> <p>Therefore, RMS would like to propose the $\text{NOEC}_{\text{macrophytes}}$ of $6 \mu\text{g a.s./L}$ value with the Assessment Factor of 5 to refine the risk for aquatic macrophytes, including Lemna sp and Elodea sp.</p> <p>In addition, the peak exposure study for Lemna sp. with $\text{E}_\text{r}\text{C}_{50} > 126 \mu\text{g a.s./L}$ to refine the risk assessment for R scenarios (Bruns 2013, see CA, Vol 3, B9) was performed.</p> <p>RMS is of the opinion that although the study is valid it may be used in the refined risk assessment for macrophytes only if:</p> <ul style="list-style-type: none"> • Further evidence is provided that rooted macrophytes are not more sensitive to flufenacet than Lemna sp. • The peak exposure design of the study covers the peaks observed in the FOCUS scenarios. <p>Therefore, the study will not be used in the current risk assessment.</p> <p><u>Risk assessment for Macrophytes including Lemna sp and Elodea sp.</u></p> <p>Consequently the risk assessment was based on $\text{NOEC}_{\text{macrophytes}} = 6 \mu\text{g a.s./L}$ with AF of 5</p> <p>The long- term risk performed with Macrophytes including Lemna sp. and Elodea sp., exposed to flufenacet did not pass the respective triggers for PEC_{sw} values calculated at STEP1 and STEP 2. Therefore the long - term risk was performed based on PEC_{sw} values calculated at STEP 3 and STEP 4</p> <p>The summary of the results are presented below:</p> <p><u>Autumn Uses:</u></p> <p>The general conclusions drawn from the risk assessment for Macrophytes including Lemna sp. and Elodea sp. presented above are given, are provided below, individually for each use listed in the EU-representative GAP.</p> <p>In case of the post-emergence use in Winter cereals in autumn, at application rate 240 g Flufenacet/ha, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenarios:</p> <ul style="list-style-type: none"> - D1 ditch, D1 stream, D2 ditch, D2 stream, D4 stream, D5 stream, D6 ditch, R1 stream, R3 stream and R4 stream. <p>The safe scenarios identified within that use were: D3 ditch assuming 10-metres wide buffer zone for mitigation of Spray Drift, D4 pond already at STEP 3 (hence no buffer zone needed to be implemented), D5 pond already at STEP 3 (hence no buffer zone needed to be implemented), R1 pond already at STEP 3 (hence no buffer zone needed to be implemented).</p>
--	--	--	---

				<p>Therefore for that use it may be stated that one safe scenario was identified – D3 scenario assuming 10-metres wide non-spray buffer zone to mitigate the Spray drift.</p> <p>In case of the post-emergence use in Winter cereals in autumn, at application rate 160 g Flufenacet/ha, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenarios:</p> <ul style="list-style-type: none"> - D1 ditch, D1 stream, D2 ditch, D2 stream, and D6 ditch. <p>The safe scenarios identified within that use were: D3 ditch, D4 pond, D4 stream, D5 pond, D5 stream – all them already at STEP 3 (hence no buffer zone needed to be implemented), as well as R1 pond already at STEP 3 (hence no buffer zone needed to be implemented), R1 stream assuming 20-metres wide vegetated buffer zone for mitigation of Spray Drift and Run-off, R3 stream assuming 20-metres wide vegetated buffer zone for mitigation of Spray Drift and Run-off and R4 stream assuming 20-metres wide vegetated buffer zone for mitigation of Spray Drift and Run-off.</p> <p>Therefore for that use it may be stated that the following safe uses were identified: for scenarios D3, D4 and D5 without any buffer zone (safe PEC_{SW} values were obtained already at STEP 3) as well as R1, R3 and R4 scenarios assuming 20-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off.</p> <p>In case of the post-emergence use in Winter cereals in autumn, at application rate 120 g Flufenacet/ha, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenarios:</p> <ul style="list-style-type: none"> - D1 ditch, D1 stream, D2 ditch, D2 stream and D6 ditch. <p>The safe scenarios identified within that use were D3 ditch, D4 (pond and stream), D5 (pond and stream), R1 pond and R4 stream – all they already at STEP 3 (hence no buffer zone needed to be implemented), and R1 stream, R3 stream assuming 20-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off</p> <p>Therefore for that use it may be stated that the following safe uses were identified: for scenarios D3, D4, D5 and R4 without any buffer zone (safe PEC_{SW} values were obtained already at STEP 3) and R1 and R3 scenarios assuming 20-metres wide vegetated buffer zone to mitigate Spray Drift and Run-off.</p>
--	--	--	--	---

				<p><u>SPRING USE</u></p> <p>The general conclusions drawn from the risk assessment for Macrophytes presented above are given, are provided below, individually for each use listed in the EU-representative GAP.</p> <p>In case of the post-emergence use in Winter cereals at spring, at application rate 160 g Flufenacet/ha, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenarios:</p> <ul style="list-style-type: none"> - D2 ditch and D2 stream; <p>In case of scenarios D1 ditch, D1 stream, D3 ditch, D4 pond, D4 stream, D5 pond and D5 stream, R1 pond, R1 stream and R4 stream safe PEC_{SW} values were obtained already at STEP 3.</p> <p>For scenario R3 stream safe PEC_{SW} values were obtained at STEP 4 after implementation of 10-metres wide vegetated buffer zone for mitigation of the Spray Drift and Run-off.</p> <p>Therefore for that application pattern only for scenarios D2 safe use was not demonstrated. In case of scenario R3 it was demonstrated that it was necessary to implement 10 meter buffer zone mitigating Spray Drift and Run-off. In all remaining scenarios identified as returning the safe PEC_{SW} values it was demonstrated that the implementation of any mitigation measures was not necessary as the assessment was finalised at Step 3.</p> <p>In case of the post-emergence use in Winter cereals at spring, at application rate 120 g Flufenacet/ha, after application of the highest admissible mitigation measures – buffer zone of 20 metres for mitigation of Spray Drift and Run-off safe use was not demonstrated in case of scenario D2 ditch.</p> <p>In case of scenarios D1 ditch, D1 stream, D2 stream, D3 ditch, D4 pond, D4 stream, D5 pond and D5 stream, D6 ditch, R1 pond, R1 stream, R3 stream and R4 stream safe PEC_{SW} values were obtained already at STEP 3. For that application pattern assessment at STEP 4 was not performed.</p> <p>Therefore, for that application pattern only for scenario D2 safe use was not demonstrated. In case of scenarios D1, D3, D4, D5, D6, R1, R3 and R4 it was demonstrated that implementation of the buffer zone mitigating Spray Drift and/or Run-off was not necessary.</p> <p>The risk to bees resulting from their acute oral and contact exposure to Fufenacet and formulation DFF+FFA SC 600 is considered to be acceptable.</p> <p>The acute risk for adult bees is considered acceptable. The chronic risk for</p>
--	--	--	--	--

			<p>adults and the acute and chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behavior could be not finalized for all proposed uses until the semi-field study will be performed.</p> <p>Exposure of non-target arthropods other than bees to formulation DFF+FFA 600 SC applied according to the intended use pattern will not result with an unacceptable risk. No risk mitigation measures are required.</p> <p>Based on all the study results it was concluded that there was no long term adverse effects on reproduction for population of earthworms from maximum application of 0.6 L DFF+FFA SC 600 /ha (leading 0.203 mg flufenacet/kg soil dw). Therefore, for the application rates resulting in concentrations higher than 0.203 mg flufenacet/kg dw, corresponding to the field application rate of the representative formulation of 0.6 L DFF+FFA SC 600 /ha /ha, the long-term risk for earthworms cannot be considered acceptable.</p> <p>Acceptable long-term risk to other soil macro- and mesofauna may be concluded for all considered compounds.</p> <p>Available data indicated that the soil nitrogen transformation as well as soil short-term respiration will not be adversely affected following exposure of microorganisms to flufenacet , its soil metabolites and formulation DFF+FFA SC 600.</p> <p>Test concentrations at which effects were < 25% were significantly higher than exposure predicted after the application of DFF+FFA SC 600 according to the intended use pattern.</p> <p>Performed deterisk assessment demonstrated acceptable risk to non-target terrestrial plants following application of DFF+FFA SC 600 if:</p> <ul style="list-style-type: none"> - 5 m buffer zone is kept without drift reduction or no buffer zone and a 50% drift reducing spray equipment is applied, for application rate of 600 mL product /ha (360 g sum of a.s. /ha) - 5 m buffer zone without drift reduction or no buffer zone and 50% drift reducing spray equipment is applied, for application rate of 400 mL product/ha (240 g sum of a.s./ha) - no risk mitigation is required for 300 ml product/ha (180 g sum a.s./ha). <p>The risk assessment based on the lowest value of $ER_{50}=27.75$ g total active substances/ha (based on fresh weight) for most sensitive plants Cucumis sativa will not cover the phytotoxic visual effects caused by representative formulation DFF+FFA 600 SC/ha.</p> <p>The risk assessment for non-target plants was performed for formulation</p>
--	--	--	--

				<p>Flufenacet 500 SC to indicate the intrinsic toxicity of the active substance – flufenacet.</p> <p>Since Flufenacet SC 500 has stronger effects on seedling emergence than on the vegetative vigor of young plants seedling emergence data determine the risk assessment.</p> <p>Based on the probabilistic risk assessment for solo formulation Flufenacet 500 SC (containing 42.3% a.s.-flufenacet), the risk for non-target terrestrial plants is considered acceptable with no buffer zone or drift reducing spraying equipment.</p> <p>Study on the herbicidal activity of soil metabolites of flufenacet indicated significantly lower biological activity of metabolites compared to the parent compound.</p> <p>Available data enabled to conclude that flufenacet will not adversely affect the biological methods for sewage treatment.</p>
	It is considered that, on the basis of the assessment of Community or internationally agreed test guidelines, the substance HAS endocrine disrupting properties that may cause adverse effects on non-target organisms.		N	<p>The potential for endocrine disruption was investigated in specific studies with mammals. Results of these studies were negative indicating that flufenacet has no endocrine disruption potential.</p> <p>The same conclusion was taken with regard to birds, since there is no specific and validated guideline nor criteria for evaluation of endocrine disruption with birds.</p> <p>No specific studies were provided for fish, nevertheless taking into account that results of endocrine disruption specific studies in mammals indicated that flufenacet is not an endocrine disruptor, testing of aquatic organisms in this area was deemed not necessary.</p>
	<p>Linked to the consideration of the endocrine properties immediately above.</p> <p>It is considered that the exposure of non-target organisms to the active substance in a plant protection product under realistic proposed conditions of use is negligible.</p>			
	It is considered that it is established following an appropriate risk assessment on the basis of Community or internationally agreed test guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance, safener or synergist:		N	<p>The acute risk for adult bees is considered acceptable. The chronic risk for adults and the acute and chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behavior could be not finalized for all proposed uses until the semi-field study will be performed by Applicant (the study is available for request).</p>

Residue definition			
		Yes	No
	It is considered that, where relevant, a residue definition can be established for the purposes of risk assessment and for enforcement purposes.	X	<p>The data were sufficient to confirm the following residue definition for Enforcement and risk assessment:</p> <p>Food of plant origin: Flufenacet including all metabolites containing the <i>N</i>-fluorophenyl-<i>N</i>-isopropyl moiety, expressed as flufenacet</p> <p>Food of animal origin: Flufenacet including all metabolites containing the <i>N</i>-fluorophenyl-<i>N</i>-isopropyl moiety, expressed as flufenacet</p> <p>In the area of the environmental fate and behaviour the full residue definition for exposure assessment and monitoring is provided at Level 2 under the point 2.13. It looks as follows:</p> <p><u>Definition of residues for exposure/risk assessment</u></p> <p>Soil: Flufenacet, FOE Oxalate, FOE Sulfonic acid, FOE Methylsulfone, FOE Thiadone, FOE 5043-Trifluorethanesulfonic acid, Trifluoroacetic acid;</p> <p>Groundwater: Flufenacet, FOE Oxalate, FOE Sulfonic acid, FOE Methylsulfone, FOE Thiadone, FOE Trifluorethanesulfonic acid, Trifluoroacetic acid (same as for soil compartment); additional compounds that may require assessment (on the basis of the results of lysimeter studies) are FOE Alcohol and FOE TGS;</p> <p>Surface water: Flufenacet, FOE Oxalate, FOE Sulfonic acid, FOE Methylsulfide, FOE Methylsulfone, FOE Thiadone, FOE Trifluorethanesulfonic acid, Trifluoroacetic acid;</p> <p>Sediment: Flufenacet;</p> <p>Air: Flufenacet, FOE Thiadone and Trifluoroacetic acid;</p> <p><u>Definition of residues for monitoring</u></p> <p>Soil: Flufenacet, FOE Sulfonic acid, FOE Methylsulfone, Trifluoroacetic acid;</p> <p>Groundwater: Flufenacet, FOE Oxalate, FOE Sulfonic acid, FOE Methylsulfone, FOE Trifluorethanesulfonic acid and Trifluoroacetic acid;</p> <p>Surface water: Flufenacet, FOE Oxalate, FOE Sulfonic acid, FOE Methylsulfide, FOE</p>

				Thiadone and Trifluoroacetic acid <u>Sediment:</u> Flufenacet; <u>Air:</u> Flufenacet, FOE Thiadone and Trifluoroacetic acid;.
Fate and behaviour concerning groundwater				
		Yes	No	
	It is considered that it has been established for one or more representative uses, that consequently after application of the plant protection product consistent with realistic conditions on use, the predicted concentration of the active substance or of metabolites, degradation or reaction products in groundwater complies with the respective criteria of the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) of Regulation 1107/2009.		X	<p>The model exposure assessment of the Groundwater compartment presented in the document Vol B.8._CP under the point B.8.3. and summarized in this document at Level 2 under the point 2.8.6 (the numerical results are provided in the tables B.8.2.6-10 – B.8.2.6.-14). As a result of that assessment Flufenacet and FOE Thiadone were demonstrated to be compounds of no concern – for them the calculated $PEC_{GW} < 0.1 \mu\text{g/L}$ in all scenarios and for all uses listed in the EU-representative GAP.</p> <p>All other degradation products are identified as requiring further assessment of their relevance because the calculated for them $PEC_{GW} \geq 0.1 \mu\text{g/L}$ in at least one scenario for at least one of the uses listed in the EU-representative GAP.</p> <p><u>FOE Oxalate:</u> The compound was demonstrated in the model exposure assessment to leach to groundwater in amounts $\geq 0.1 \mu\text{g/L}$ in at least one of the FOCUS GW scenario for calculations performed using FOCUS PEARL and FOCUS PELMO models in all uses identified within the EU-representative GAP. In case of the use in autumn in Winter cereals at application rate of 240 g Flufenacet/ha for some scenarios the calculated $PEC_{GW} \geq 0.75 \mu\text{g/L}$. However, the lysimeter studies did not confirm that FOE Oxalate would leach to GW compartment in amounts $\geq 0.1 \mu\text{g/L}$.</p> <p><u>FOE Sulfonic acid:</u> The compound was demonstrated in the model exposure assessment to leach to groundwater in amounts $\geq 0.1 \mu\text{g/L}$ in almost all of the FOCUS GW scenarios for calculations performed using FOCUS PEARL and FOCUS PELMO models in all uses identified within the EU-representative GAP. Additionally, in some of them, for all uses identified in the EU-representative GAP the calculated $PEC_{GW} \geq 0.75 \mu\text{g/L}$. The high leaching potential of FOE Sulfonic acid to Groundwater was confirmed by the results of the lysimeter studies.</p> <p><u>FOE Methylsulfone:</u></p>

				<p>Only for the use in Winter cereals in autumn at application rate 240 g Flufenacet/ha FOE Methylsulfone in some scenarios was demonstrated to leach to GW compartment in amounts $\geq 0.1 \mu\text{g/L}$, but none of the calculated PEC_{GW} values was $\geq 0.75 \mu\text{g/L}$. In case of all remaining uses identified within the EU-representative GAP the calculated $\text{PEC}_{\text{GW}} < 0.1 \mu\text{g/L}$.</p> <p>That relatively low leaching potential was confirmed by the results of the lysimeter studies.</p> <p><u>FOE 5043-Trifluoroethanesulfonic acid:</u></p> <p>The compound was demonstrated in the model exposure assessment to leach to groundwater in amounts $\geq 0.1 \mu\text{g/L}$ in at least one of the FOCUS GW scenarios for calculations performed using FOCUS PEARL and FOCUS PELMO models in all uses identified within the EU-representative GAP. In case of the following uses:</p> <ul style="list-style-type: none"> - Autumn application to Winter cereals at application rate of 240 g Flufenacet/ha; - Autumn application to winter cereals at application rate 160 g Flufenacet/ha; - Autumn application to Winter cereals at application rate 120 g Flufenacet/ha; <p>for some scenarios the calculated $\text{PEC}_{\text{GW}} \geq 0.75 \mu\text{g/L}$.</p> <p>There are no results of the lysimeter studies that could address the issue of the leaching behavior of FOE 5043-Trifluoroethanesulfonic acid to the Groundwater compartment.</p> <p><u>TFA:</u></p> <p>The compound was demonstrated in the model exposure assessment to leach to groundwater in amounts $\geq 0.75 \mu\text{g/L}$ in all of the FOCUS GW scenarios for calculations performed using FOCUS PEARL and FOCUS PELMO models in all uses identified within the EU-representative GAP. Additionally, in some of them, for all uses identified in the EU-representative GAP the calculated $\text{PEC}_{\text{GW}} \geq 10 \mu\text{g/L}$.</p> <p>There are no results of the lysimeter studies that could address the issue of the leaching behavior of TFA to the Groundwater compartment.</p>
--	--	--	--	---

3.1.2. Proposal – Candidate for substitution

Candidate for substitution

Flufenacet**Volume 1 – Level 3**

		Yes	No	
	It is considered that the active substance shall be approved as a candidate for substitution		X	Substance flufenacet does not qualify as a candidate for substitution

3.1.3. Proposal – Low risk active substance

Low-risk active substances			
	Yes	No	
<p>It is considered that the active substance shall be considered of low risk.</p> <p>In particular it is considered that the substance should NOT be classified or proposed for classification in accordance with Regulation (EC) No 1272/2008 as at least one of the following:</p> <ul style="list-style-type: none"> — carcinogenic, — mutagenic, — toxic to reproduction, — sensitising chemicals, — very toxic or toxic, — explosive, — corrosive. <p>In addition it is considered that the substance is NOT:</p> <ul style="list-style-type: none"> — persistent (half-life in soil more than 60 days), — has a bioconcentration factor higher than 100, — is deemed to be an endocrine disrupter, or — has neurotoxic or immunotoxic effects. 		X	Due to substance sensitization potential, flufenacet should not be considered as a low risk

3.1.4. List of studies to be generated, still ongoing or available but not peer reviewed

Data gap	Relevance in relation to representative use(s)	Study status		
		No confirmation that study available or on-going.	Study on-going and anticipated date of completion	Study available but not peer-reviewed
3.1.4.1. Identity of the active substance or formulation				
None				
3.1.4.2. Physical and chemical properties of the active substance and physical, chemical and technical properties of the formulation				
None				
3.1.4.3. Data on uses and efficacy				
None				
3.1.4.4. Data on handling, storage, transport, packaging and labelling				
None				
3.1.4.5. Methods of analysis				
Method for monitoring of flufenacet in air		X		

3.1.4.6. Toxicology and metabolism				
None				
3.1.4.7. Residue data				
None				
3.1.4.8 Environmental fate and behaviour				
Examination of the fate and behaviour of Flufenacet radiolabelled in C5 position of thiadiazole ring in water/sediment system to determine the level of formation of TFA in the aquatic environment.	Data gap relevant for all representative uses listed in the EU-representative GAP	X		
3.1.4.9 Ecotoxicology				
Lack of toxicity data for the second representative species of the aquatic macrophytes – the study addressing the problem was rejected as not meeting the validity criteria.	It cannot be stated whether in light of the current Guidelines that data gap shall be considered relevant for the uses encompassed by the EU-representative GAP.	X		
The acute risk for adult bees is considered acceptable. The chronic risk for adults and the acute and chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behavior could be not finalized for all proposed uses until the semi-field study will be performed.	In light of the new EFSA's Guidance document on the risk assessment for bees (EFSA; 2013) the data gap relevant for all representative uses listed in the EU-representative GAP.		X – end of May 2016; The Applicant is carrying out new, updated calculations to the existing and evaluated bee brood test.	X; The Applicant declared that the new semi-field study covering this issue was available and could have been submitted on request.

3.1.5. Issues that could not be finalized

An issue is listed as an issue that could not be finalized where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles, as laid out in Commission Regulation (EU) No 546/2011, and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

Area of the risk assessment that could not be finalised on the basis of the available data	Relevance in relation to representative use(s)
Bees: The chronic risk for adults and the acute and chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behavior could be not finalized for all proposed uses until the semi-field study will be submitted.	All uses
Algae- The risk could be not finalized for the following scenarios: - D1 ditch, D1 stream, D2 ditch, D2 stream, D4 pond, D4 stream, D5 pond, D5 stream, D6 ditch, R1 stream, R3 stream and R4 stream	Autumn use to winter cereals at rate of 240 g a.s./ha
Algae- The risk could be not finalized for the following scenarios: -D1 ditch, D1 stream, D2 ditch, D2 stream, D4 stream, D5 pond, D5 stream, D6 ditch, R1 stream, R3 stream and R4 stream	Autumn use to winter cereals at rate of 160 g a.s./ha
Algae- The risk could be not finalized for the following scenarios: -D1 ditch, D1 stream, D2 ditch, D2 stream, D6, ditch and R3 stream	Autumn use to winter cereals at rate of 120 g a.s./ha
Algae- The risk could be not finalized for the following scenarios: -D2 ditch and D2 stream	Spring use to winter cereals at rates: 160 g a.s./ha and 160 g a.s./ha
Algae- The risk could be not finalized for the following scenarios: -D2 ditch and D2 stream	Spring use to winter cereals at rates: 120 g a.s./ha and 160 g a.s./ha
Lemna sp: - The risk could be not finalized for the following scenarios: -D1 ditch, D1 stream, D2 ditch, D2 stream, D4 stream, D6 ditch, R3 and R4	Autumn use to winter cereals at rate of 240 g a.s./ha
Lemna sp: - The risk could be not finalized for the following scenarios: - D1 ditch, D1 stream, D2 ditch, D2 stream and D6 ditch	Autumn use to winter cereals at rate of 160 g a.s./ha
Lemna sp: - The risk could be not finalized for the following scenarios: -D1 ditch, D1 stream, D2 ditch, D2 stream and D6 ditch	Autumn use to winter cereals at rate of 120 g a.s./ha
Lemna sp: - The risk could be not finalized for the following scenarios: - D2 ditch and D2 stream	Spring use to winter cereals at rate of 160 g a.s./ha
Lemna sp: - The risk could be not finalized for the following scenarios: - D2 ditch	Spring use to winter cereals at rate of 120 g a.s./ha
Macrophytes: - The risk could be not finalized for the following scenarios: -D1 ditch, D1 stream, D2 ditch, D2 stream, D4 stream, D5 stream, D6 ditch, R1 stream R3 stream and R4 stream	Autumn use to winter cereals at rate of 240 g a.s./ha

Macrophytes: - The risk could be not finalized for the following scenarios: - D1 ditch, D1 stream, D2 ditch, D2 stream and D6 ditch	Autumn use to winter cereals at rate of 160 g a.s./ha
Macrophytes: - The risk could be not finalized for the following scenarios: -D1 ditch, D1 stream, D2 ditch, D2 stream and D6 ditch	Autumn use to winter cereals at rate of 120 g a.s./ha
Macrophytes: - The risk could be not finalized for the following scenarios - D2 ditch and D2 stream	Spring use to winter cereals at rate of 160 g a.s./ha
Macrophytes: - The risk could be not finalized for the following scenarios - D2 ditch	Spring use to winter cereals at rate of 120 g a.s./ha
It is expected the long-term risk for earthworms	160 g a.s./ha and 240 g a.s./ha

3.1.6. Critical areas of concern

An issue is listed as a critical area of concern:

- (a) where the substance does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II of Regulation (EC) No 1107/2009 and the applicant has not provided detailed evidence that the active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, taking into account risk mitigation measures to ensure that exposure of humans and the environment is minimized, or
- (b) where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles, as laid out in Commission Regulation (EU) 546/2011, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

Critical area of concern identified	Relevance in relation to representative use(s)
None identified in the renewal assessment	Not applicable

3.1.7. Overview table of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in 3.3.1, has been evaluated as being effective, then 'risk identified' is not indicated in this table)

Representative use		Cereals pre-emergence	Cereals post-emergence
Operator risk	Risk identified	None	None
	Assessment not finalised	None	None
Worker risk	Risk identified	None	None
	Assessment not finalised	None	None
Bystander risk	Risk identified	None	None
	Assessment not finalised	None	None
Consumer risk	Risk identified	None	None
	Assessment not finalised	None	None

Representative use		Post-emergence use in Winter cereals (BBCH 11-13) in autumn at application rate 240 g Flufenacet/ha	Post-emergence use in Winter cereals (BBCH 10-13) in autumn, at application rate 160 g Flufenacet/ha	Pre- and post-emergence use in Winter cereals (BBCH 00-22) in autumn at application rate 120 g Flufenacet/ha
Risk to wild non target terrestrial vertebrates	Risk identified	X		
	Assessment not finalised	X		
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified	X	X	X
	Assessment not finalised	X	X	X
Risk to aquatic organisms	Risk identified	X	X	X
	Assessment not finalised	X	X	X
Groundwater exposure active substance	Legal parametric value breached			
	Assessment not finalised			
Groundwater exposure metabolites	Legal parametric value breached	X	X	X
	Parametric value of 10µg/L ^(a) breached	X	X	X
	Assessment not finalised			
Comments/Remarks				

The superscript numbers in this table relate to the numbered points indicated within chapter 3.1.5 and 3.1.6. Where there is no superscript number, see level 2 for more explanation.

(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

3.1.8. Area(s) where expert consultation is considered necessary

It is recommended to organise a consultation of experts on the following parts of the assessment report:

Area(s) where expert consultation is considered necessary	Justification
None	-

3.1.9. Critical issues on which the Co RMS did not agree with the assessment by the RMS

Issue on which Co-RMS disagrees with RMS	Opinion of Co-RMS	Opinion of RMS
E-fate: none identified		
Ecotox: none identified (not discussed).		

Points on which the co-rapporteur Member State did not agree with the assessment by the rapporteur member state. Only the points relevant for the decision making process should be listed.

██████████

114

113

██████████

[REDACTED]	[REDACTED]
[REDACTED] [REDACTED] [REDACTED] [REDACTED]	[REDACTED] [REDACTED]
[REDACTED] [REDACTED] [REDACTED]	
[REDACTED] [REDACTED] [REDACTED]	

[illegible]

[illegible]

[illegible]

<div><div></div><div></div><div></div><div></div><div></div></div>	
--	--

APPENDIX 1. GUIDANCE DOCUMENTS USED IN THIS ASSESSEMENT

EFSA. Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (OJ L 309, 24.11.2009, p. 1-50). EFSA Journal 2011;9(2):2092. [49 pp.]. doi:10.2903/j.efsa.2011.2092

EC (European Commission). Guidance document on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) No 844/2012 (the Renewal Regulation). SANCO/2012/11251 rev.1.2, July 2012.

EC (European Commission). Guidance document for applicants on preparing dossiers for the approval of a chemical new active substance and for the renewal of approval of a chemical active substance according to Regulation (EU) 283/2013 and Regulation (EU) No 284/2013. SANCO/10181/2013– rev. 2, May 2013.

EC (European Commission). Guidance document on rules for revision of assessment reports. SANCO/10180/2013– rev. 1, March 2013.

EC (European Commission). Template to be used for Assessment Reports. SANCO/12592/2012– rev. 0, November 2012.

EC (European Commission). Template to be used for the List of Endpoints. SANCO/12483/2014– rev. 3, 29 May 2015.

Volume 3 – B1: Identity

None

Volume 3 - B2: Physicochemical properties

None

Volume 3 - B5: Analytical methods

EC (European Commission). Technical Material and Preparations: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. SANCO/3029/99 rev.4, 11/07/00.

EC (European Commission). Residues: Guidance for generating and reporting methods of analysis in support of preregistration data requirements for Annex II (part A, section 4) and Annex III (part A, Section 5) of directive 91/414. SANCO/3029/99 rev. 4, 11/07/00.

EC (European Commission).: Guidance document on pesticide residues analytical methods. SANCO/825/00 rev.8.1, 16/11/2010.

Volume 3 - B6: Toxicology and metabolism of the active substance

Guidance document for WHO monographers and reviewers; **WHO/HSE/FOS/2015.1; Part 3: General criteria for interpretation of toxicological data.**

Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data; EFSA Journal 2012;10(3):2579

Commission Communication in the framework of the implementation of Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

Volume 3 - B7: Residues

EC (European Commission), Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs; SANCO 7525/VI/95 - rev.9 March 2011.

OECD (Organisation for Economic Co-operation and Development), OECD MRL Calculator: User Guide. In: Series on Pesticides No 56. ENV/JM/MONO(2011)2, 01 March 2011.

Uwe Meier (editor), Growth Stages of mono-and dicotyledonous plants. BBCH Monograph, 2. Edition. Federal Biological Research Centre for Agriculture and Forestry, 2001

EC (European Commission), Working document on the nature of residue in fish. SANCO/1187/2013, rev. 3, 31 January 2013.

OECD (Organisation for Economic Co-operation and Development), Guidance document on residues in livestock. In: Series on Pesticides No 73. ENV/JM/MONO(2013)8, 04-Sep-2013.

OECD (Organisation for Economic Co-operation and Development), Metabolism in Crops. OECD guideline for the testing of chemicals No 501, 8 January 2007.

OECD (Organisation for Economic Co-operation and Development), Metabolism in Rotational Crops. OECD guideline for the testing of chemicals No 502, 8 January 2007.

OECD (Organisation for Economic Co-operation and Development), Metabolism in Livestock. OECD guideline for the testing of chemicals No 503, 8 January 2007.

OECD (Organisation for Economic Co-operation and Development), Residues in Rotational Crops (Limited Field Studies). OECD guideline for the testing of chemicals No 504, 8 January 2007.

OECD (Organisation for Economic Co-operation and Development), Residues in Livestock. OECD guideline for the testing of chemicals No 505, 8 January 2007.

OECD (Organisation for Economic Co-operation and Development), Stability of Pesticide Residues in Stored Commodities. OECD guideline for the testing of chemicals No 506, 16 October 2007.

OECD (Organisation for Economic Co-operation and Development), Nature of the Pesticide Residues in Processed Commodities – High Temperature Hydrolysis. OECD guideline for the testing of chemicals No 507, 16 October 2007.

OECD (Organisation for Economic Co-operation and Development), Magnitude of the pesticide residues in processed commodities. OECD guideline for the testing of chemicals No 508, 3 October 2008.

OECD (Organisation for Economic Co-operation and Development), Crop Field Trial. OECD guideline for the testing of chemicals No 509, 7 September 2009.

EC (European Commission), Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev.3, 1997.

EC (European Commission), Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev.6, 1997.

EC (European Commission), Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev.2, 1997.

EC (European Commission), Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev.3, 1997.

EC (European Commission), Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95, 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010.

Official spreadsheets for the calculation of EU MRLs in plant and animal commodities released on the DG SANTE website, Estimation of animal intakes and HR, STMR and MRL calculations for products of animal origin, September 2015

Guidance documents used in the assessment in the area of the environmental fate and behaviour:

General guidance Documents:

- Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning placing of the plant protection products on the market, OJ L309/1 of 24. 11. 2009, CELEX_32009R1107_EN;
- Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning placing of the plant protection products on the market, OJ L93/1, of 3.4.2013, CELEX-32013R0283_EN;
- Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning placing of the plant protection products on the market, OJ L93/85, of 3.4.2013, CELEX_32013R0284_EN;
- Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorization of the plant protection products, OJ L155/127, of 11.6.2011, CELEX_32011R0546_EN;
- European Commission, Health & Consumer Protection Directorate – General: “Template to be used for Assessment Reports”, SANCO/12592/2012 – rev.0, November 2012;
- European Commission, Health & Consumer Protection Directorate – General: “Template to be used for Assessment Reports regarding Level 3 of Volume 1”, SANCO/11114/2012 – rev.0, 1 June 2012;
- European Commission, Health & Consumer Protection Directorate – General: “Template to be used for the List of Endpoints”, SANCO/12483/2014 – rev.2, 12 December 2014;
- European Commission, Health & Consumer Protection Directorate – General: “Guidance Document on Preparing Lists of Test and Study Reports According to Article 60 of Regulation (EC) No 1107/2009.”, SANCO/12580/2012 – rev.3.1, 17 May 2013;
- European Commission, Health & Consumer Protection Directorate – General: “Guidance Document on Rules for Revision of Assessment Reports”, SANCO/10180/2013 – rev.1, March 2013;
- European Commission, Health & Consumer Protection Directorate – General: “Guidance Document on Data Protection”, SANCO/12576/2012 – rev.1.1, 1 February 2013;
- European Commission, Health & Consumer Protection Directorate – General: “Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater of substances Regulated under Council Directive 91/414/EEC”, SANCO/221/2000 – rev.10-final, 25 February 2003;

Specific Guidelines, related to the specific areas of Assessment:

Vol. 3. CA, B.8.1.1.1.1. – Route of degradation in soil, aerobic degradation:

- OECD Guideline for Testing Chemicals No. 307, Aerobic and Anaerobic Transformation in Soil, 2002;
- US EPA OCSPP Fate, Transport and Transformation Test Guidelines, OPPTS 835.4100 and OPPTS 835.4200, Aerobic and Anaerobic Soil Metabolism, 2008;
- US EPA Guidelines for Pesticide Registration, Subdivision N, Section 162-1, Aerobic Soil Metabolism;
- M. Lynch (ed.): “Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides.”; SETAC 1985, Part 1: Fate and Behaviour in the Environment, chapter 1: Laboratory Soil Degradation Studiespoint 1.1: Aerobic Degradation;

Vol. 3. CA, B.8.1.1.1.2. – Route of degradation in soil, anaerobic degradation:

- OECD Guideline for Testing Chemicals No. 307, Aerobic and Anaerobic Transformation in Soil, 2002;
- US EPA OCSPP Fate, Transport and Transformation Test Guidelines, OPPTS 835.4100 and OPPTS 835.4200, Aerobic and Anaerobic Soil Metabolism, 2008;
- US EPA Guidelines for Pesticide Registration, Subdivision N, Section 162-2, Anaerobic Soil Metabolism;
- M. Lynch (ed.): “Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides.”; SETAC 1985,, Part 1: Fate and Behaviour in the Environment, chapter 1: Laboratory Soil Degradation Studies, point 1.2: Anaerobic Degradation;

Vol. 3. CA, B.8.1.1.1.3. – Route of degradation in soil, soil photolysis:

- OECD Guidelines for Testing Chemicals, Proposal for a New Guideline – Phototransformation of Chemicals on Soil Surface, Draft Document January 2002;
- US EPA OCSPP Fate, Transport and Transformation Test Guidelines, OPPTS 835.2410 – Photodegradation on Soil;
- US EPA Guidelines for Pesticide Registration, Subdivision N, Section 161-3, Soil Photolysis Study;
- M. Lynch (ed.): “Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides.”; SETAC 1985,, Part 1: Fate and Behaviour in the Environment, chapter 2: Soil Photolysis;

Vol. 3. CA, B.8.1.1.2.1. – Rate of degradation, laboratory studies:

- OECD Guideline for Testing Chemicals No. 307, Aerobic and Anaerobic Transformation in Soil, 2002;
- US EPA OCSPP Fate, Transport and Transformation Test Guidelines, OPPTS 835.4100 and OPPTS 835.4200, Aerobic and Anaerobic Soil Metabolism, 2008;
- US EPA Guidelines for Pesticide Registration, Subdivision N, Section 162-1, Aerobic Soil Metabolism;
- M. Lynch (ed.): “Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides.”; SETAC 1985,, Part 1: Fate and Behaviour in the Environment;
- FOCUS (2006): “Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies in EU Registration.”, Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference SANCO/10058/2005, version 2.0, 434 pp.;
- FOCUS (2011): “Generic Guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in the EU Registration.”, version 1.0, 23 November 2011;
- FOCUS (2014): “Generic Guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in the EU Registration.”, version 1.1, 18 December 2014;
- FOCUS (2002): “FOCUS groundwater scenarios in the EU review of active substances.”, Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference SANCO/321/2000 rev. 2, 202 pp;

Vol. 3. CA, B.8.1.1.2.2. – Rate of degradation, field studies:

- M. Lynch (ed.): “Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides.”; SETAC 1985., Part 1: Fate and Behaviour in the Environment, chapter 3.1 – Soil Dissipation Study;
- US EPA OCSPP Fate, Transport and Transformation Test Guidelines, OPPTS 835.6100 – Terrestrial Field Dissipation;
- NAFTA Guidance Document for Conducting Terrestrial Field Dissipation Studies, 31 March 2006;
- US EPA Guidelines for Pesticide Registration, Subdivision N, Section 164-1, Terrestrial Field Dissipation;
- FOCUS (2006): “Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies in EU Registration.”, Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference SANCO/10058/2005, version 2.0, 434 pp.;
- FOCUS (2011): “Generic Guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in the EU Registration.”, version 1.0, 23 November 2011;
- FOCUS (2014): “Generic Guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in the EU Registration.”, version 1.1, 18 December 2014;
- FOCUS (2002): “FOCUS groundwater scenarios in the EU review of active substances.”, Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference SANCO/321/2000 rev. 2, 202 pp.;
- European Commission (2014): “Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU.”, Report of FOCUS Ground Water Work Group, EC Document Reference SANCO/13144/2010 version 3, 613 pp.
- “The Application of Inverse Modelling Techniques to Pesticide Leaching Models.”; SSLRC support for PSC data evaluation and Risk Assessment activities; MAFF project code PL0528, pp. 12-23, available on-line on DEFRA webpage, folder “Science and Research Projects”;

Vol. 3. CA, B.8.1.2.1. – Adsorption and desorption:

- OECD Guideline for Testing Chemicals 106 – Adsorption-Desorption Using a Batch Equilibrium Method;
- US EPA OCSPP Fate, Transport and Transformation Test Guideline OPPTS 835.1230 – Adsorption/Desorption (Batch Equilibrium);
- US EPA OCSPP Fate, Transport and Transformation Test Guideline OPPTS 835.1220 – Sediment and Soil Adsorption/Desorption Isotherm;
- US EPA Guidelines for Pesticide Registration, Subdivision N, Section 163-1, Adsorption/Desorption;
- M. Lynch (ed.): “Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides.”; SETAC 1985, Part 1: Fate and Behaviour in the Environment, Chapter 4: Soil adsorption/Desorption;

Vol. 3. CA, B.8.1.3.1. – Column Leaching Studies:

- OECD Guideline for Testing Chemicals No. 312 – Leaching in Soil Columns;
- US EPA OCSPP Fate, Transport and Transformation Test Guideline OPPTS 835.1240 – Leaching Studies;

Vol. 3. CA, B.8.1.3.2. – Aged Residues Column Leaching:

- OECD Guideline for Testing Chemicals No. 312 – Leaching in Soil Columns;
- US EPA OCSPP Fate, Transport and Transformation Test Guideline OPPTS 835.1240 – Leaching Studies;

Vol. 3. CA, B.8.1.3.3. – Lysimeter Studies and/or Field Leaching:

- BBA Guidelines for the Testing of Plant Protection Products in Registration Procedure, Part IV, 4-3 (February 1990) – “Lysimeter tests for the translocation of plant protection products into the subsoil.”;

Vol. 3. CA, B.8.1.3.4. – Other studies:

- FOCUS (2014): “Generic Guidance for Tier 1 FOCUS Ground Water Assessments.” version 2.2, May 2014;

Vol. 3. CA, B.8.2.1.1. – Hydrolytic Degradation:

- OECD Guideline for Testing Chemicals No. 111 – Hydrolysis as a function of pH;

Vol. 3. CA, B.8.2.1.2. – Photochemical Degradation:

- OECD Guideline for Testing Chemicals No. 316 – Phototransformation of Chemicals in Water – Direct Photolysis;
- US EPA OCSPP Fate, Transport and Transformation Test Guideline OPPTS 835.2210 – Direct Photolysis Rate in Water by Sunlight;
- US EPA OCSPP Fate, Transport and Transformation Test Guideline OPPTS 835.2240 – Photodegradation in Water;
- US EPA Guidelines for Pesticide Registration, Subdivision N, Section 161-2, Aqueous Photolysis Studies;
- OECD Guidelines for the Testing of Chemicals, Proposal for a New Guideline – Phototransformation of Chemicals in Water – Direct and Indirect Photolysis (draft document, August 2000);
- ECETOC, Technical Report No. 12 The Phototransformation of Chemicals in Water: Results of a Ring-Test. Brussels June 1994.

Vol. 3. CA, B.8.2.2.2. – Aerobic Mineralisation in Surface Water:

- OECD Guideline for the Testing of Chemicals No. 309 – Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test;
- FOCUS (2006): “Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies in EU Registration.”, Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference SANCO/10058/2005, version 2.0, 434 pp.;
- FOCUS (2011): “Generic Guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in the EU Registration.”, version 1.0, 23 November 2011.

Vol. 3. CA, B.8.2.2.3. – Water/Sediment Study:

- OECD Guideline for the Testing of Chemicals No. 308 – Anaerobic and aerobic Transformation in Aquatic Sediment Systems;
- FOCUS (2006): “Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies in EU Registration.”, Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference SANCO/10058/2005, version 2.0, 434 pp.;
- FOCUS (2011): “Generic Guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in the EU Registration.”, version 1.0, 23 November 2011;
- European Commission Communication 2013/C95/01;

Vol. 3. CA, B.8.2.6. – Impact on Water Treatment Procedures:

No specific guidelines were used in that area of the assessment.

Vol. 3. CA, B.8.3. – Fate and Behaviour in Air:

- FOCUS (2008): “Pesticides in Air: Considerations for Exposure Assessment.”, Report of the FOCUS Working group on Pesticides in Air, EC Document Reference SANCO/10553/2006 Rev. 2, June 2008; 327 pp.;

Vol. 3. CA, B.8.4. – Definition of the Residue:

No specific guidelines were used in that area of the assessment.

Vol. 3. CA, B.8.5. – Monitoring Data Concerning Fate and Behaviour of the Active Substance, Metabolites, Degradation and Reaction Products:

No specific guidelines were used in that area of the assessment.

Vol. 3. CA, B.8.6. – Open Literature Review:

- EFSA (2011): “Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No. 1107/2009.”, EFSA Journal, 2011, 9 (2), 2092;

Vol. 3. CP, B.8.2. – Predicted Environmental Concentrations in Soil (PEC_s):

- FOCUS (2006): “Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies in EU Registration.”, Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference SANCO/10058/2005, version 2.0, 434 pp.;
- FOCUS (2014): “Generic Guidance for Tier 1 FOCUS Ground Water Assessments.” version 2.2, May 2014;

Vol. 3. CA, B.8.3. – Predicted Environmental Concentrations in Ground Water (PEC_{GW}):

- FOCUS (2006): “Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies in EU Registration.”, Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference SANCO/10058/2005, version 2.0, 434 pp.;
- FOCUS (2000): “FOCUS groundwater scenarios in the EU review of active substances.”, Report of the FOCUS Ground Water Scenarios Workgroup, EC Document Reference SANCO/321/2000, rev. 2, 202 pp.;
- FOCUS (2009): “Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU”; Report of the FOCUS Ground Water Work Group, EC Document Reference SANCO/13144/2010, version 1, 604 pp.
- FOCUS (2014): “Generic Guidance for Tier 1 FOCUS Ground Water Assessments.” version 2.2, May 2014;

Vol. 3. CA, B.8.5. – Predicted Environmental Concentrations in Surface Water and Sediment (PEC_{SW}, PEC_{SED}):

- FOCUS (2006): “Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies in EU Registration.”, Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference SANCO/10058/2005, version 2.0, 434 pp.;
- FOCUS (2003): “FOCUS Surface Water Scenarios in the Evaluation Process under 91/414/EC.”, Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001 –rev.2, 245 pp.;
- FOCUS (2007): “Landscape and Mitigation Factors in Aquatic Risk Assessment.”, Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2015, ver.2.0.

Appendix 2 Reference list

Reference list in the area of the environmental fate and behaviour:

The lists of references relied upon, including original studies provided by the Applicant and the open-source publications considered relevant for the present assessment are presented in the Vol. 2 as well as separate sections in the documents Vol. 3, B.8._CA and Vol.3, B.8._CP.

Ecotoxicology:

1. Risk Assessment for Birds and Mammals, EFSA Journal 2009;7(12):1438
2. Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC, SANCO/3268/2001 rev. 4 (final), 17 October 2002.
3. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013;11(7):3290.
4. EPPO/OEPP (2003). Environmental risk assessment scheme for plant protection products, Chapter 10: Honeybees (PP 3/10(2)). Bulletin OEPP/EPPO Bulletin 33: 141-145
5. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees), EFSA Journal 2013;11(7):3295

6. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/141/EEC, SANCO/10329/2002, 17 October 2002 rev. 2 final
7. Candolfi et al., 2000, Guidance Document on Regulatory Testing and Risk Assessment Procedures for Plant Protection Products with Non-Target Arthropods, ESCORT 2 SETAC Workshop
8. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/141/EEC, SANCO/10329/2002, 17 October 2002 rev. 2 final
9. O 11268-3 / 2014/ Soil quality - Effects of pollutants on earthworms - Part 3: Guidance on the determination of effects in field situations", 2nd edition
10. ISO 23611-2 (2007). Soil quality - Sampling of soil invertebrates - Part 2: Sampling and extraction of micro-arthropods (Collembola and Acarina).
11. Kula C. et al. (2006) Technical recommendations for the update of the ISO Earthworm Test Guideline (ISO 12268-3). Journal of Soils and Sediments 6: 182-186.
12. de Jong F.M.W. et al. (2010) Guidance for summarising and evaluation field studies with non-target arthropods. A guidance document of Dutch Platform for the Assessment of Higher Tier Studies Test Organisms. RIVM, Bilthoven, Netherlands.
13. EFSA (2011). Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (OJ L 309, 24.11.2009, p. 1-50). EFSA Journal 2011;9(2):2092. [49 pp.]. doi:10.2903/j.efsa.2011.2092
14. Guidance document for applicants on preparing dossiers for the approval of a chemical new active substance and for the renewal of approval of a chemical active substance according to Regulation (EU) 283/2013 and Regulation (EU) No 284/2013 (SANCO/10181/2013– rev. 2, May 2013).

Volume 4 Annex C:

SANCO/10597/2003 –rev. 10.1, 13 July 2012. Guidance document on the assessment of the equivalence of technical materials of substances regulated under regulation (EC) No 1107/2009.

SANCO/12638/2011 20 November 2012 rev. 2. Guidance document on significant and non-significant changes of the chemical composition of authorised plant protection products under Regulation (EC) No 1107/2009 of the EU Parliament and Council on placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

APPENDIX 2. REFERENCE LIST

No references specifically cited in Volume 1

APPENDIX 3. CONSUMER RISK ASSESSMENT

<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;"> Flufenacet </div> <div style="border: 1px solid black; padding: 5px; background-color: #f0f0f0;"> Prepare workbook for refined calculations </div> </div>											
Status of the active substance:					Code no.						
LOQ (mg/kg bw):					proposed LOQ:						
Toxicological end points											
ADI (mg/kg bw/day):					0,005		ARID (mg/kg bw):			0,017	
Source of ADI:					Source of ARID:						
Year of evaluation:					Year of evaluation:						
Explain choice of toxicological reference values. The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL). The pTMRLs have been submitted to EFSA in September 2006.											
Chronic risk assessment											
TMDI (range) in % of ADI minimum - maximum <div style="text-align: center;">22</div>											
No of diets exceeding ADI: ---											
	Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)		
	21,9	WHO Cluster diet B	17,1	Wheat	1,0	Poultry: Meat	0,8	Bovine: Meat			
	19,8	NL child	9,5	Wheat	5,9	Milk and milk products: Cattle	1,6	Swine: Meat			
	16,6	WHO cluster diet D	13,0	Wheat	0,9	Milk and milk products: Cattle	0,6	Bovine: Meat			
	16,3	DK child	11,0	Wheat	4,4	Rye	0,9	Birds' eggs			
	16,3	ES child	8,9	Wheat	2,5	Milk and milk products: Cattle	1,4	Bovine: Meat			
	14,4	DE child	8,2	Wheat	2,9	Milk and milk products: Cattle	1,1	Birds' eggs			
	13,8	WHO cluster diet E	7,9	Wheat	1,6	Barley	1,0	Poultry: Meat			
	13,3	IT kids/toddler	13,3	Wheat	0,0	Barley		FRUIT (FRESH OR FROZEN)			
	13,1	WHO Cluster diet F	7,2	Wheat	1,2	Barley	1,2	Swine: Meat			
	11,8	WHO regional European diet	5,9	Wheat	1,3	Swine: Meat	1,1	Bovine: Meat			
	10,1	SE general population 90th percentile	6,4	Wheat	2,5	Milk and milk products: Cattle	0,9	Birds' eggs			
	9,7	IE adult	4,6	Wheat	2,5	Barley	0,6	Milk and milk products: Cattle			
	9,5	ES adult	4,7	Wheat	1,0	Milk and milk products: Cattle	1,0	Barley			
	8,8	FR all population	6,6	Wheat	0,6	Poultry: Meat	0,5	Milk and milk products: Cattle			
	8,8	UK Toddler	7,8	Wheat	0,9	Birds' eggs	0,0	Barley			
	8,8	FR toddler	5,2	Wheat	1,3	Bovine: Meat	1,0	Birds' eggs			
	8,6	NL general	4,1	Wheat	1,3	Milk and milk products: Cattle	0,9	Swine: Meat			
	8,5	FR infant	5,1	Milk and milk products: Cattle	1,7	Wheat	0,6	Bovine: Meat			
	8,3	IT adult	8,3	Wheat	0,0	Barley		FRUIT (FRESH OR FROZEN)			
	8,0	PT General population	7,8	Wheat	0,1	Rye	0,1	Barley			
	6,6	UK Infant	5,2	Wheat	1,3	Birds' eggs	0,0	Bovine: Liver			
	6,1	LT adult	2,1	Wheat	1,1	Rye	1,0	Swine: Meat			
	5,7	DK adult	4,0	Wheat	0,7	Rye	0,6	Bovine: Meat			
	4,5	UK vegetarian	4,1	Wheat	0,3	Birds' eggs	0,0	Barley			
	3,7	UK Adult	3,4	Wheat	0,3	Birds' eggs	0,1	Barley			
	2,9	FI adult	2,0	Wheat	0,7	Rye	0,2	Birds' eggs			
		PL general population		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)			
Conclusion: The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Flufenacet is unlikely to present a public health concern.											

Acute risk assessment /children						Acute risk assessment / adults / general population						
The acute risk assessment is based on the ARfD.												
For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.												
In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.												
In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.												
Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.												
Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):			No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):		
	---			---			---			---		
	IESTI 1	*)	**) pTMRL/ threshold MRL (mg/kg)	IESTI 2	*)	**) pTMRL/ threshold MRL (mg/kg)	IESTI 1	*)	**) pTMRL/ threshold MRL (mg/kg)	IESTI 2	*)	**) pTMRL/ threshold MRL (mg/kg)
	Highest % of ARfD/ADI	Commodities		Highest % of ARfD/ADI	Commodities		Highest % of ARfD/ADI	Commodities		Highest % of ARfD/ADI	Commodities	
	7,3	Milk and milk	0,01 / -	7,3	Milk and milk	0,01 / -	3,5	Poultry: Meat	0,05 / -	3,5	Poultry: Meat	0,05 / -
	4,2	Wheat	0,05 / -	4,2	Wheat	0,05 / -	2,3	Wheat	0,05 / -	2,3	Wheat	0,05 / -
	3,8	Bovine: Meat	0,05 / -	3,8	Bovine: Meat	0,05 / -	2,1	Barley	0,05 / -	2,1	Barley	0,05 / -
	3,7	Birds' eggs	0,05 / -	3,7	Birds' eggs	0,05 / -	1,8	Bovine: Meat	0,05 / -	1,8	Bovine: Meat	0,05 / -
	3,3	Poultry: Meat	0,05 / -	3,3	Poultry: Meat	0,05 / -	1,4	Rye	0,05 / -	1,4	Rye	0,05 / -
No of critical MRLs (IESTI 1)			---			No of critical MRLs (IESTI 2)			---			
Processed commodities	No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:		
	---			---			---			---		
	Highest % of ARfD/ADI	Processed commodities	***) pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	***) pTMRL/ threshold MRL (mg/kg)			
	3,5	Wheat flour	0,05 / -				1,3	Bread/pizza	0,05 / -			
*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.												
**) pTMRL: provisional temporary MRL												
***) pTMRL: provisional temporary MRL for unprocessed commodity												
Conclusion:												
For Flufenacet IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.												
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.												
For processed commodities, no exceedance of the ARfD/ADI was identified.												

<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="background-color: #90EE90; padding: 10px; border: 1px solid black; text-align: center;"> TFA-Na from Flufenacet </div> <div style="background-color: #D3D3D3; padding: 10px; border: 1px solid black; text-align: center;"> Prepare workbook for refined calculations </div> </div>									
Status of the active substance:					Code no.				
LOQ (mg/kg bw):					proposed LOQ:				
Toxicological end points									
ADI (mg/kg bw/day):					ARfD (mg/kg bw):				
0,05 EFSA					0,75 proposal coRMS				
Source of ADI:					Source of ARfD:				
2014					2017				
<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="background-color: #90EE90; padding: 5px;"> Explain choice of toxicological reference values. </div> <div style="background-color: #D3D3D3; padding: 10px; border: 1px solid black; text-align: center;"> Undo refined calculations </div> </div>									
<p>The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL). The pTMRLs have been submitted to EFSA in September 2006.</p>									
Chronic risk assessment									
TMDI (range) in % of ADI									
minimum - maximum									
1 24									
No of diets exceeding ADI: ---									
	Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
	23,7	WHO Cluster diet B	13,0	Wheat	3,8	Maize	0,9	Soya bean	
	16,9	DK child	8,4	Wheat	6,7	Rye	0,6	Oats	
	16,6	WHO cluster diet D	9,9	Wheat	1,5	Brassica vegetables	0,8	Rice	
	16,4	NL child	7,2	Wheat	2,0	Milk and milk products: Cattle	1,6	Brassica vegetables	
	15,0	IE adult	3,5	Maize	3,5	Maize	1,9	Barley	
	14,4	IT kids/toddler	10,1	Wheat	2,3	Other cereal	0,5	Lettuce and other salad plants	
	14,4	WHO cluster diet E	6,0	Wheat	1,2	Barley	1,1	Brassica vegetables	
	13,7	PT General population	6,0	Wheat	3,3	Brassica vegetables	1,2	Rice	
	12,4	WHO Cluster diet F	5,5	Wheat	1,2	Rye	1,0	Soya bean	
	12,2	ES child	6,7	Wheat	0,8	Milk and milk products: Cattle	0,7	Rice	
	12,0	UK Toddler	6,0	Wheat	2,3	Sugar beet (root)	1,2	PULSES, DRY	
	11,9	DE child	6,2	Wheat	1,2	Rye	1,0	Milk and milk products: Cattle	
	11,6	FR toddler	4,0	Wheat	1,9	Legume vegetables (fresh)	1,1	Brassica vegetables	
	10,9	UK Infant	4,0	Wheat	1,6	Maize	1,0	Sugar beet (root)	
	10,2	WHO regional European diet	4,5	Wheat	0,9	Brassica vegetables	0,8	Legume vegetables (fresh)	
	10,2	SE general population 90th percentile	4,9	Wheat	1,4	Brassica vegetables	0,8	Milk and milk products: Cattle	
	9,6	IT adult	6,3	Wheat	1,1	Other cereal	0,7	Lettuce and other salad plants	
	7,9	NL general	3,2	Wheat	0,9	Brassica vegetables	0,6	Legume vegetables (fresh)	
	7,8	FR infant	1,8	Milk and milk products: Cattle	1,4	Legume vegetables (fresh)	1,3	Wheat	
	7,8	ES adult	3,6	Wheat	0,7	Barley	0,7	Lettuce and other salad plants	
	7,1	FR all population	5,0	Wheat	0,4	Lettuce and other salad plants	0,2	Brassica vegetables	
	6,1	UK vegetarian	3,1	Wheat	0,6	PULSES, DRY	0,6	Rice	
	5,8	LT adult	1,6	Rye	1,6	Wheat	0,5	Brassica vegetables	
	5,4	DK adult	3,1	Wheat	1,0	Rye	0,2	Brassica vegetables	
	4,9	UK Adult	2,5	Wheat	0,6	Rice	0,4	Sugar beet (root)	
	3,5	FI adult	1,5	Wheat	1,0	Rye	0,2	Brassica vegetables	
	1,3	PL general population	0,6	Brassica vegetables	0,3	Potatoes	0,1	PULSES, DRY	
Conclusion: The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of TFA-Na from Flufenacet is unlikely to present a public health concern.									

Acute risk assessment /children						Acute risk assessment / adults / general population						
The acute risk assessment is based on the ARfD.												
For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.												
In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.												
In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.												
Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.												
Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):			No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):		
	IESTI 1			IESTI 2			IESTI 1			IESTI 2		
	Highest % of ARfD/ADI			Highest % of ARfD/ADI			Highest % of ARfD/ADI			Highest % of ARfD/ADI		
	Commodities			Commodities			Commodities			Commodities		
	pTMRL/ threshold MRL (mg/kg)			pTMRL/ threshold MRL (mg/kg)			pTMRL/ threshold MRL (mg/kg)			pTMRL/ threshold MRL (mg/kg)		
	7,5			7,5			3,0			3,0		
	5,8			5,6			2,7			2,7		
	5,6			4,3			2,7			1,8		
	5,0			4,1			2,2			1,6		
	5,0			3,9			2,0			1,6		
No of critical MRLs (IESTI 1)												
No of critical MRLs (IESTI 2)												
Processed commodities	No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:		
	IESTI 1			IESTI 2			IESTI 1			IESTI 2		
	Highest % of ARfD/ADI			Highest % of ARfD/ADI			Highest % of ARfD/ADI			Highest % of ARfD/ADI		
	Processed commodities			Processed commodities			Processed commodities			Processed commodities		
	pTMRL/ threshold MRL (mg/kg)			pTMRL/ threshold MRL (mg/kg)			pTMRL/ threshold MRL (mg/kg)			pTMRL/ threshold MRL (mg/kg)		
	1,2			0,4			0,4			0,4		
	0,4			0,0			0,0			0,0		
	0,3			0,0			0,0			0,0		
	0,1			0,0			0,0			0,0		
	0,1			0,0			0,0			0,0		
*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.												
**) pTMRL: provisional temporary MRL												
***) pTMRL: provisional temporary MRL for unprocessed commodity												
Conclusion:												
For TFA-Na from Flufenacet IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.												
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.												
For processed commodities, no exceedance of the ARfD/ADI was identified.												