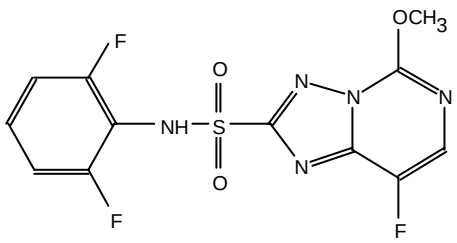
APPENDIX 3

LISTING OF END POINTS

Chapter 2.1: Identity, Physical and Chemical Properties, Details of Uses, Further Information, and Proposed Classification and Labelling

Active substance (ISO Common Name)	Florasulam
Function (*e.g.* fungicide)	Herbicide
Rapporteur Member State	Belgium

Identity (Annex IIA, point 1)

Chemical name (IUPAC)	2', 6', 8-Trifluoro-5-methoxy-s-triazolo [1,5-c] pyrimidine-2-sulfonanilide
Chemical name (CA)	N-(2,6-diflurophenyl)-8-fluoro-5 methoxy (1,2,4) triazolo (1,5-c)pyrimidine-2-sulphonamide
CIPAC No	616
CAS No	145701-23-1
EEC No (EINECS or ELINCS)	not available
FAO Specification (including year of publication)	not available
Minimum purity of the active substance as manufactured (g/kg)	970
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	No impurities are considered to be of toxicological, ecotoxicological or environmental significance.
Molecular formula	$C_{12}H_8O_3N_5F_3S$
Molecular mass	359.3
Structural formula	

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity)	193.5 to 230.5EC with decomposition
Boiling point (state purity)	Not required
Temperature of decomposition	approx. 202.5 °C
Appearance (state purity)	Purified a.s. : solid at 25°C. Technical material : also solid.
Relative density (state purity)(22°C)	1.53
Surface tension (21°C)	Φ = 71.5 mN/m (not surface active)
Vapour pressure (in Pa, state temperature)	1 x 10^{-5} Pa at 25°C
Henry's law constant (Pa m^3 mol^{-1})	3.29 x 10^{-5} Pa.m^3/mol (pH 5) at 20°C 4.35 x 10^{-7} Pa.m^3/mol (pH 7) at 20°C 2.94 x 10^{-8} Pa.m^3/mol (pH 9) at 20°C
Solubility in water (g/l or mg/l, state temperature) (20°C)	solubility in : purified water (pH 5.6-5.8) : 0.121 g/L pH 5.0 buffer : 0.084 g/L pH 7.0 buffer : 6.36 g/L pH 9.0 buffer : 94.2 g/L
Solubility in organic solvents (20°C)	solubility in : n-heptane* : 0.019x10^{-3} g/L xylene* : 0.227 g/L dichloroethane : 3.75 g/L methanol : 9.81 g/L n-octanol* : 0.184 g/L acetone : 123 g/L ethyl acetate : 15.9 g/L acetonitrile : 72.1 g/L * g/L solution (rest : g/L solvent)
Partition coefficient (log P_{OW}) (state pH and temperature)	pH 4.0: log P_{ow} = 1.00
	pH 7.0: log P_{ow} = -1.22
	pH 10.0: log P_{ow} = -2.06
Hydrolytic stability (DT_{50}) Test at 50°C	pH 4 and 7: less than 5% degradation after 7 d
Test at 50°C	pH 9: k = 0.378 d^{-1};$t_{1/2}$ = 2 d (triazole-label)
Test at 25°C	pH 5: no degradation observed after 30 d
Test at 25°C	pH 7: no degradation observed after 30 d
Test at 25°C	pH 9: k = 0.00692 d^{-1}; $t_{1/2}$ = 100 d (phenyl-label) k = 0.00706 d^{-1}; $t_{1/2}$ = 98 d (triazole-label)
Dissociation constant	pK_a = 4.54 (determined at 22-23°C)
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	8 (nm) γ (L.mol^{-1}.cm^{-1}) acidic (pH 0.75) : 259.8 1.22x10^4 basic (pH 13.21) : 262.4 2.36x10^4 methanolic (pH 12.60) : 204.1 2.74x10^4

	florasulam has no absorption max. above 290 nm, but γ > 10 $L.mol^{-1}.cm^{-1}$.
Photostability (DT_{50}) (aqueous, sunlight, state pH)	Further tests are required
Quantum yield of direct phototransformation in water at Σ > 290 nm	Φ= 0.074
Flammability	not highly flammable/ not self-heating substance
Explosive properties	not explosive

Summary of intended uses

Crop and/ or situation	**Member State or Country**	**Product name**	**F G or I**	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI** (days)	**Remarks:**
					Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min)	g as/hL min max	water L/ha min max	g as/ha min max		
(a)			(b)	(c)	(d-f)	(i)	(f-h)	(j)	(k)					(l)	(m)
Winter cereals	N/S	EF-1343 or PRIMUS	F	Broadleaf weeds (mainly *Galium aparine, Stellaria media, Matricaria spp.*)	SC	50 g/L	Broadcast application with medium volume	BBCH 12 to 49 (2-3 leaves to stem elongation)	1 (2) : split treatment with a total rate of 7.5 g a.s./ha./ season	6-8 weeks	1.25-5.0	40-150	0.5-7.5	NA	-

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, 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)
(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
(f) All abbreviations used must be explained
(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated
(i) g/kg or g/l
(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
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

NA : Not applicable – PHI determined by the stage of application.

Classification and proposed labelling (Annex IIA, point 10)

with regard to physical/chemical data	-
with regard to toxicological data	-
with regard to fate and behaviour data	-
with regard to ecotoxicological data	N,R50/53

Chapter 2.2: Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (principle of method)	HPLC with UV detection at 260 nm for determination of florasulam.
Impurities in technical as (principle of method)	*HPLC with UV detection at 260 nm. *GC with FID for the determination of the process solvents.
Plant protection product (principle of method)	HPLC with UV detection at 260 nm for determination of florasulam content.

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	ERC 95.6 : HPLC with UV detection at 260 nm. LOQ for grain : 0.01 mg/kg, LOQ for straw and whole plant : 0.05 mg/kg.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	No methods required
Soil (principle of method and LOQ)	*<u>For determination of extractable residues</u> : -ESP LC-MS/MS – LOQ : 0.05 µg/kg for florasulam and 5-hydroxy metabolite. -ESP LC-MS – LOQ : 0.05 µg/kg for both compounds. -GC-MSD – LOQ : 0.05 µg/kg for florasulam residues. *<u>For determination of bioavailable residues</u> : -ESP LC-MS/MS – LOQ : 0.05 µg/kg for florasulam and 5-hydroxy metabolite. -A Magnetic Particle-based Immunoassay test kit for DE-570 determination - LOQ : 0.05 µg/kg for florasulam residues.
Water (principle of method and LOQ)	*<u>Drinking water</u> : -HPLC with UV detection at 260 nm for determination of florasulam and 5-hydroxy-metabolite. LOQ of 0.05

	µg/L for florasulam and 0.10 µg/L for the metabolite. - HPLC with UV detection at 260 nm involving derivatisation, determining florasulam residues – LOQ : 0.05 µg/L. *<u>Surface water</u> : HPLC with UV detection at 260 nm for determination of florasulam and 5-hydroxy-metabolite. LOQ of 0.10 µg/L for florasulam and 0.20 µg/L for the metabolite. *<u>Drinking water, surface water and ground water :</u> A Magnetic Particle-based immunoassay test kit for determination of florasulam residues – LOQ : 0.1 µg/L.
Air (principle of method and LOQ)	HPLC-UV method involving derivatisation of florasulam – LOQ : 1.5 µg/m³.
Body fluids and tissues (principle of method and LOQ)	HPLC-UV method involving derivatisation of florasulam – LOQ : 100 ηg/mL.

Chapter 2.3: Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism in mammals (Annex IIA, point 5.1)

Rate and extent of absorption:	85-91% within 24 h
Distribution:	Widely distributed at 1h; highest residues in skin and carcass at 168 h
Potential for accumulation:	No accumulation
Rate and extent of excretion:	76-88.9% in urine ; 3.2-15% in feces within 24 h
Metabolism in animals	limited; > 70% of dose excreted as parent compound ; ± 5% as phenyl hydroxyl; ± 3% as sulfate hydroxyphenyl
Toxicologically significant compounds (animals, plants and environment)	Parent compound

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral	> 5000 mg/kg bw
Rat LD_{50} dermal	> 2000 mg/kg bw
Rat LC_{50} inhalation	> 5 mg/l
Skin irritation	not irritant
Eye irritation	not irritant
Skin sensitization (test method used and result)	Maximisation test ; not sensitizer

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	Hepatotoxicity (dog) Kidney : hypertrophy epithelial cells, collecting ducts (dog)
Lowest relevant oral NOAEL / NOEL	5 mg/kg bw/d
Lowest relevant dermal NOAEL / NOEL	No treatment-related systemic effects at any dose level tested
Lowest relevant inhalation NOAEL / NOEL	-

Genotoxicity (Annex IIA, point 5.4)	Not genotoxic

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect	Anemia, hepatotoxicity, renal hypertrophy epithelial cells, collecting duct (dog)
Lowest relevant NOAEL / NOEL	5 mg/kg bw/d; dog , 1 year study
Carcinogenicity	Not carcinogenic

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect	No reproductive toxicity
Lowest relevant reproductive NOAEL / NOEL	syst toxicity : NOAEL = 100 mg/kg bw/d reprotox : NOAEL > 500 mg/kg bw/d
Developmental target / critical effect	No teratogenicity
Lowest relevant developmental NOAEL / NOEL	NOAEL developmental > 500 mg/kg bw/d

Neurotoxicity / Delayed neurotoxicity (Annex IIA, point 5.7)

Perineal soiling ; minor transient depression of reactivity to noise stimulus, on day of dosing.
NOAEL acute = 200 mg/kg bw
Chronic study: NOAEL = 250 mg/kg bw/d

Other toxicological studies (Annex IIA, point 5.8)

..... Renal cells affected are probably Type A intercalated cells, involved in acid-base regulation

Medical data (Annex IIA, point 5.9)

No detrimental effects on health in manufacturing personnel

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI	0.05 mg/kg/bw/d	1 year dog study	100
AOEL	0.05 mg/kg/bw/d	90 day dog study	100
Drinking water limit	-		
ARfD (acute reference dose)	Not necessary		

Dermal absorption (Annex IIIA, point 7.3)

12% within 24 h, *in vivo* rat study

Acceptable exposure scenarios (including method of calculation)

Operator	UK-POEM and German models : acceptable for proposed uses
Workers	Acceptable for proposed uses
Bystanders	Acceptable for proposed uses

Chapter 2.4: Residues

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Winter wheat.
Rotational crops	Spring wheat, sunflower, cabbage, carrot.
Plant residue definition for monitoring	Parent compound.
Plant residue definition for risk assessment	Parent compound.
Conversion factor (monitoring to risk assessment)	None.

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Lactating goats and laying hens.
Animal residue definition for monitoring	Parent compound.
Animal residue definition for risk assessment	Parent compound.
Conversion factor (monitoring to risk assessment)	-Milk, liver and kidney : 1 -Eggs : 1.
Metabolism in rat and ruminant similar (yes/no)	Yes (although 2 metabolites are not present in rat metabolism, but at a very low concentration).
Fat soluble residue: (yes/no)	No.

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

.....	The uptake of florasulam in edible plant parts of leafy vegetables, root vegetables, oil seed crop and cereals installed as succeeding crops is not sufficient to reach measurable levels in monitoring.

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 introduction)

.....	No loss of florasulam residues during frozen storage over 683 days.

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

Intakes by livestock < 0.1 mg/kg diet/day:	Ruminant: yes	Poultry: yes	Pig: yes
Muscle	-	-	-
Liver	-	-	-
Kidney	-	-	-
Fat	-	-	-
Milk	-	-	-
Eggs	-	-	-

Note : Livestock feeding studies are not required since residues of florasulam fed to animals do not exceed 0.1 mg/kg of diet as received.

Summary of critical residues data (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL	STMR (b)
Winter wheat	North	11 x 0.002 mg/kg for grain, 11 x <0.01 mg/kg for straw.	Results from 11 residue trials carried out in UK, Germany and France and which support the critical GAP of 7.5 g a.s./ha, 1 application at BBCH 49.	0.01* for grain	0.01*
	South	<0.002, <0.002 mg/kg for grain. <0.01, <0.01 mg/kg for straw.	Results from 2 residue trials carried out in France, Italy and Spain and which support the critical GAP of 7.5 g a.s./ha, 1 application at BBCH 49.		
Durum wheat	South	<0.002, <0.002, <0.002 mg/kg for grain. <0.01, <0.01, <0.01 mg/kg for straw.	Results from 3 residue trials carried out in France, Italy and Spain and which support the critical GAP of 5.0 g a.s./ha, 1 application at BBCH 36.	0.01* for grain	0.01*
Winter barley	North	6 x 0.002 mg/kg for grain, 6 x <0.01 mg/kg for straw.	Results from 6 residue trials carried out in UK, Germany and France and which support the critical GAP of 7.5 g a.s./ha, 1 application at BBCH 49.	0.01* for grain	0.01*
	South	6 x 0.002 mg/kg for grain, 6 x <0.01 mg/kg for straw.	Results from 6 residue trials carried out in France, Italy and Spain and which support the critical GAP of 7.5 g a.s./ha, 1 application at BBCH 49.		

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the critical GAP

Appendix 3 **Listing of End Points**

Belgium **August 2000** **Florasulam**

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.05 mg/kg b.w./day.
TMDI (European Diet) (% ADI)	0.07%
TMDI (German 4 to 6 years old girl) (% ADI)	0.16%
TMDI (UK toddler) (% ADI)	0.17%
TMDI (UK infant) (% ADI)	0.20%
NEDI (% ADI)	-
Factors included in NEDI	-
ARfD	-
Acute exposure (% ARfD)	-

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/processed crop	Number of studies	Transfer factor	% Transference *
No processing data are required.			

* Calculated on the basis of distribution in the different portions, parts or products as determined through balance studies

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Cereal grain	0.01* mg/kg.

Chapter 2.5: Fate and Behaviour in the Environment

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization after 100 days	4.8-13.5% after 100 d
Non-extractable residues after 100 days	29.6-57.1% after 100 d
Relevant metabolites - name and/or code, % of applied (range and maximum)	5-OH (max 71.6 %) , DFP-ASTCA (max 17.8%) , ASTCA (max 40.0%), TSA (max 15.9%)

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation	Degradation to metabolite 5-OH (max 87%) Low mineralization (1.3% max) Bound residue (max 11.2% after 365 d)
Soil photolysis	DT50 of 44 and 158 d , respectively under light and in the dark 5-OH and unknown 1 at maximum level of 2.1 and 2.8%; 27.7% bound residue

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Method of calculation	First order kinetics
Laboratory studies (range or median, with n value,with r^2 value)	DT_{50lab} (20°C, aerobic, a.s.): 0.7-4.5 days (4 soils) DT_{50lab} (20°C, aerobic, field cap, a.s.): 7.4-10 days (2 soils) DT_{90lab} (20°C, aerobic, a.s.): 2.2-15 days (4 soils)
	DT_{50lab} (20°C, aerobic, 5-OH): 10-31 days (5 soils) DT_{90lab} (20°C, aerobic, 5-OH): 34-102 days (5 soils)
	DT_{50lab} (20°C, aerobic, DFP-ASTCA): 8-25 days (2 soils)
	DT_{50lab} (20°C, aerobic, ASTCA): 158-502 days (2 soils)
	DT_{50lab} (5°C, aerobic, a.s.): 19-45 days (2 soils)
	DT_{50lab} (20°C, anaerobic, a.s.): 11-14 days (2 labellings)
	degradation in the saturated zone: -
Field studies (state location, range or median with n value)	DT_{50f}: a.s. = 2-18 days, 6 locations in France, UK, Germany, Greece
	DT_{90f}: a.s. = 23-61 days, 6 locations in France, UK, Germany, Greece
	DT_{50f}: 5-OH = 9-95 days, 6 locations in France, UK, Germany, Greece
	DT_{90f}: 5-OH = 41-209 days, 6 locations in France, UK, Germany, Greece
Soil accumulation and plateau concentration	-

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f /K_{oc} K_d	Koc (a.s.) = 4-54; Kf (a.s.) = 0.13-1.88 Koc (5-OH) = 7-32; Kf (5-OH) = 0.07-1.73 Koc (DFP-ASTCA) = 24-110; Kd (DFP-ASTCA) = 0.26-1.10 Koc (ASTCA) = 27-159; Kd (ASTCA) = 0.30-1.87

pH dependence (yes / no) (if yes type of dependence)	no

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching	15 g a.s./ha, 2 days, 200 mm rainfall : 67.7-92.1% applied radioactivity in the leachate
Aged residues leaching	-
Lysimeter/ field leaching studies	1 appl at 5 g a.s./ha on sand : total residue of 1 year = 0.03-0.05 µg /l 1 appl at 5 g a.s./ha on loam : total residue of 1 year < 0.01 to 0.01 µg /l 1 appl at 25 g a.s./ha on sand (exaggerated rate) : total residue of 1 year = 0.27µg /l = metabolites 5-OH, ASTCA, DFP-TSA, polar compounds, a.s. is absent

PEC (soil) (Annex IIIA, point 9.1.3)

Method of calculation	First order kinetics
Application rate	0.0075 kg a.s./ha, no crop interception, DT50 (a.s.) = 18 d (very conservative assumption)

PEC$_{(s)}$		Single Application Actual	Single Application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.0100 mg a.s./kg soil	0.0100 mg a.s./kg soil	-	-
Short term	24h	0.0096	0.0098	-	-
	2d	0.0093	0.0096		
	4d	0.0086	0.0093		
Long term	7d	0.0076	0.0088	-	-
	28d	0.0034	0.0061		
	50d	0.0015	0.0044		
	100d	0.0002	0.0025		

Method of calculation	First order kinetics
Application rate	0.0075 kg a.s./ha, no crop interception, DT50 (5-OH) = 95 d (very conservative assumption)

PEC$_{(s)}$		Single Application Actual	Single Application Time weighted average	Multiple application Actual	Multiple Application Time weighted average
Initial		0.0100 mg a.s./kg soil	0.0100 mg a.s./kg soil	-	-
Short term	24h	0.0099	0.0100	-	-
	2d	0.0099	0.0099		
	4d	0.0097	0.0099		
Long term	7d	0.0095	0.0097	-	-
	28d	0.0081	0.0090		
	50d	0.0069	0.0084		
	100d	0.0048	0.0071		

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	pH 5, 25 °C: no hydrolysis after 30 d
	pH 7, 25°C: no hydrolysis after 30 d
	pH 9, 25°C: t1/2 = 98-100 d major metabolite : 5-OH
Photolytic degradation of active substance and relevant metabolites	A new study is required
Readily biodegradable (yes/no)	No
Degradation in water/sediment - DT_{50} water - DT_{90} water - DT_{50} whole system - DT_{90} whole system	DT50 (a.s., water) ≈ DT50 whole system DT90 (a.s., water) ≈ DT90 whole system DT50 (a.s., whole system) = 8.7-18.0 d DT90 (a.s., whole system) = 28.7-59.7 d DT50 (5-OH, whole system) = 68.59-243.96 d
Mineralization	0-3.7% after 100 days
Non-extractable residues	4.5-11.2% after 100 days
Distribution in water / sediment systems (active substance)	Mainly present in water phase
Distribution in water / sediment systems (metabolites)	5-OH distributed in water and sediment phases

PEC (surface water) (Annex IIIA, point 9.2.3)

Method of calculation	First order kinetics
Application rate	0.0075 kg a.s./ha
Main routes of entry	Spray drift at 1 m (4%), DT50 a.s. = 18 d

PEC$_{(sw)}$		Single application Actual	Single Application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.100 µg/l	0.100	-	-
Short term	24h	0.096	0.098	-	-
	2d	0.093	0.096		
	4d	0.086	0.093		
Long term	7d	0.076	0.088	-	-
	14d	0.058	0.077		
	21d	0.045	0.069		
	28d	0.034	0.061		
	42d	0.020	0.050		

Method of calculation	First order kinetics
Application rate	0.0075 kg a.s./ha
Main routes of entry	Spray drift at 1 m (4%), DT50 5-OH = 244 d

PEC$_{(sw)}$		Single application Actual	Single Application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.100 µg/l	0.100	-	-
Short term	24h	0.100	0.100	-	-
	2d	0.099	0.100		
	4d	0.099	0.099		
Long term	7d	0.098	0.099	-	-
	14d	0.096	0.098		
	21d	0.094	0.097		
	28d	0.092	0.096		
	42d	0.089	0.094		

PEC (sediment)

Method of calculation	-
Application rate	Not relevant : a.s. mainly distributed in water phase

PEC$_{(sed)}$	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	-	-	-	-
Short term	-	-	-	-
Long term	-	-	-	-

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	Modelling with PELMO 3.0; DT50 =2.1 d, Koc = 18
Application rate	0.0075 g a.s./ha, 50% crop interception, 1 appl. on 15 April, Borstel and Parabraunerde soils, Hamburg average climate

PEC$_{(gw)}$

Maximum concentration	-
Average annual concentration	a.s. : 0.000 µg/l 5-OH : 0.060 µg/l DFP-ASTCA : 0.019 µg/l ASTCA : 0.273 µg/l

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air	-
Quantum yield of direct phototransformation	ϕ = 0.074
Photochemical oxidative degradation in air	Latitude: ..... Season: ..... DT_{50} .-
Volatilization	from plant surfaces: -0.8h volatilization within 24 h
	from soil: 1.3% volatilization within 24 h

PEC (air)

Method of calculation	Not relevant : no volatilization from plant or soil

PEC$_{(a)}$

Maximum concentration	-

Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environment	Water and soil : florasulam and metabolite 5-OH

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	-
Surface water (indicate location and type of study)	-
Ground water (indicate location and type of study)	-
Air (indicate location and type of study)	-

Chapter 2.6: Effects on Non-target Species

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Acute toxicity to mammals	LD50 = 5000 mg a.s./kg bw
Reproduction toxicity to mammals	NOAEL = 2000 mg a.s./kg food
Acute toxicity to birds	LD50 = 1046 mg a.s./kg bw
Dietary toxicity to birds	LC50 > 5000 mg a.s./kg food
Reproductive toxicity to birds	NOEC = 1500 mg a.s./kg food

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Application rate (kg as/ha)	Crop	Category (*e.g.* insectivorous bird)	Time-scale	TER	Annex VI Trigger
0.0075	cereals	Small insectivorous bird	Acute	5669	10
		Small grass eating bird	Acute	16031	10
		Small insectivorous bird	Short term	8130	10
		Small grass eating bird	Short term	22989	10
		Small insectivorous bird	Long term	2439	5
		Small grass eating bird	Long term	6897	5
0.0075	cereals	Small insectivorous mammal	Acute	76628	10
		Small grass eating mammal	Acute	27100	10
		Small insectivorous bird	Long term	9195	5
		Small grass eating bird	Long term	3252	5

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Laboratory tests				
Fish	A.s.	96 h	LC50	> 100
Daphnia		48 h	LC50	> 292
Algae		72 h	ErC50	0.00894
Fish		28 d	NOEC	119
Daphnia		21 d	NOEC	38.9
Lemna gibba		14 d	EC50	0.00118
Fish	Metabolite 5-OH	96 h	LC50	> 91
Daphnia		48 h	LC50	>96.7
Algae		72 h	EbC50	21.32
Microcosm or mesocosm tests				
Not required				

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

Appendix 3 **Listing of End Points**

Belgium **August 2000** **Florasulam**

Application rate (kg as/ha)	Crop	Organism	Time-scale	Distance (m)	TER	Annex VI Trigger
0.0075	Cereals	Fish	Acute	1	1000000	100
		Daphnia	Acute	1	2920000	100
		Algae	Acute	1	89	10
		Lemna	Acute	1	12	10
		Fish	Chronic	1	1190000	10
		Daphnia	Chronic	1	389000	10

Bioconcentration

Bioconcentration factor (BCF)	0.8-2.2
Annex VI Trigger for the bioconcentration factor	100
Clearance time (CT_{50}) (CT_{90})	6.4-5.9 d -
Level of residues (%) in organisms after the 14 day depuration phase	-

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Acute oral toxicity	LD50 > 100 µg a.s./bee
Acute contact toxicity	LD50 > 100 µg a.s./bee

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Application rate (kg as/ha)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests				
0.0075	cereals	Oral	< 0.075	50
		Contact	< 0.075	50

Field or semi-field tests
- not required

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Appendix 3 **Listing of End Points**

Belgium **August 2000** **Florasulam**

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect	Annex VI Trigger
Laboratory tests						
Typhlodromus pyri	protonymphs	formulation	0.0075	beneficial capacity	12.3%	30%
			0.015		43.6 %	
Aphidius rhopalosiphi	adults	formulation	0.0075	beneficial capacity	25.2%	30%
			0.015		49.7%	
Poecilus cupreus	adults	formulation	0.0075	mortality	0%	30%
			0.015		0%	
Chrysoperla carnea	first instar larvae	formulation	0.0075	beneficial capacity	77.55%	30%
			0.015		100%	
Extended laboratory test						
Chrysoperla carnea	first instar larvae	formulation	0.0075	beneficial capacity	0%	30%

Field or semi-field tests
- not required

Effects on earthworms (Annex IIA, point 8.4, Annex IIIA, point 10.6)

Acute toxicity	LC50 > 1320 mg a.s./kg soil
Reproductive toxicity	-

Toxicity/exposure ratios for earthworms (Annex IIIA, point 10.6)

Application rate (kg as/ha)	Crop	Time-scale	TER	Annex VI Trigger
0.0075	cereals	acute	> 132000	10

Effects on soil micro-organisms (Annex IIA, point 8.5, Annex IIIA, point 10.7)

Nitrogen mineralization	Negligible effects at application rate equivalent to 0.0075 and 0.0375 kg a.s./kg soil
Carbon mineralization	Negligible effects at application rate equivalent to 0.0075 and 0.0375 kg a.s./kg soil