Draft Assessment Report

Evaluation of Active Substances

Plant Protection Products

Prepared according to **Regulation (EC) 1107/2009**
as it applies in Great Britain

Flonicamid

List of Endpoints
Amendment to approval

(amendment of the ARfD)
Great Britain

April 2023

Version History

When	What
April 2023	Initial DAR
August 2023	Updated to reflect revised tox endpoints, changes highlighted in yellow.

List of end points

Competent Authority	Month and year	Active Substance (Name)
HSE	**April 2023**	**Flonicamid**

Background

An application was submitted by the producer of the approved active substance flonicamid to amend the ARfD (Acute Reference Dose) for flonicamid in Great Britain (GB).

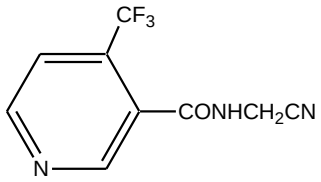
This document contains the endpoints for flonicamid from the previous EFSA conclusion from 2011 as well as the updated endpoints concluded for the amendment application.

The document complements the list of endpoints and DAR that supported the first inclusion of flonicamid in Annex I of Directive 91/414, dated February 2005 and final addenda to that DAR dated October 2009.

Identity, Physical and Chemical Properties, Details of Uses, Further Information (Regulation (EU) N° 283/2013, Annex Part A, points 1.3 and 3.2)

Active substance (ISO Common Name)	Flonicamid
Function (*e.g.* fungicide)	Insecticide / aphicide

Identity

Chemical name (IUPAC)	N-cyanomethyl-4-(trifluoromethyl)nicotinamide
Chemical name (CA)	N-(cyanomethyl)-4-(trifluoromethyl)-3pyridincarboxamide
CIPAC No	763
CAS No	158062-67-0
EC No (EINECS or ELINCS)	not allocated
FAO Specification (including year of publication)	No FAO specification is available
Minimum purity of the active substance as manufactured	960 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Toluene max 3g/kg
Molecular formula	C9H6F3N3O
Molar mass	229.16g/mol
Structural formula	

Physical and chemical properties (Annex IIA, point 2)

Melting point (purity)	157.5 °C (99.7%)
Boiling point (purity)	No boiling point observed (99.7%)
Temperature of decomposition (purity)	306-320°C (99.7%)

Appearance (purity)	PAI : off white: Solid powder, odourless TGAI : Light beige (21°C), Solid powder (24.9°C)
Vapour pressure (temperature, purity)	2.55×10^{-6} Pa at 25°C 9.43×10^{-7} Pa at 20°C (99.7)
Henry's law constant (temperature)	4.2×10^{-8} (20°C) (99.7%) calculation based
Solubility in water (temperature, purity and pH)	5.2 g/L at 20°C (99.7%)

Solubility in organic solvents (temperature, purity)

	PAI (99.7%) g/L at 20°C	TGAI (98. g/L at 20°C
Acetone	163.5	157.1
Ethyl acetate	34.2	34.9
Methanol	104.3	89.0
Dichloromethane	4.5	4.0
Toluene	0.55	0.30
Hexane	0.0002	0.0003
n-Octanol	3.0	2.6
Acetonitrile	132.8	111.4
Isopropyl alcohol	18.7	14.7

Surface tension (concentration and temperature, purity)	47.3 mN/m at 25±1°C 47.0 mN/m at 40±1°C Concentration tested 90 % of water solubility. Although the concentration tested is not correct as it is greater than 1 g/L it is clear that the material is surface active. Surface active (98.7%)
Partition coefficient (temperature, pH and purity)	Log Pow = -0.24 at 20°C (pH not measured) (calculated value)
Dissociation constant (purity)	pKa =-0.24 at 20°C (pH not measured) (calculated value)
UV/VIS absorption (max.) incl. ε (purity, pH)	λmax — ε (L/(cm x mol)) 265 nm in neutral solution (99.7%) — 3870 266 nm in acidic solution — 3890 204 and 270 nm in basic solution — 13200 and 4190 No significant absorption above 290 nm

Flammability (purity)	Not highly flammable (98.7%)
Explosive properties (purity)	Not explosive (expert statement)
Oxidising properties (purity)	Not oxidising (expert statement)

Summary of representative uses evaluated (name of active substance or the respective variant)*

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage&season (j)	number min/max (k)	interval between applications (min)	g as/hL min–max (l)	water L/ha min–max	g as/ha min–max (l)		
Potatoes	all EU countries	Teppeki	F	Aphids	50 WG	500 g/kg	foliar application	maturation of tubers (j). Late spring till early summer. BBCH 81-95	2	21 days	16 - 40	200 - 500	80	14	-
Wheat	all EU countries	Teppeki	F	Aphids	50 WG	500 g/kg	foliar application	ears stage (j) late spring till early summer. BBCH 51-85	2	21 days	14 - 35	200 - 500	70	28	-
Apples/ pears	all EU countries	Teppeki	F	Aphids	50 WG	500 g/kg	foliar application	maturation of fruits (j) early spring till early summer. BBCH 81-89	3	21 days	7 (4.7) – 35	200 - 1000 (1500 excep.)	70	21	-
Peaches	Southern countries	Teppeki	F	Aphids	50 WG	500 g/kg	foliar application	maturation of fruits (j) very early spring till early summer. BBCH 81-89	2	21 days	7 (4.7) – 35	200 - 1000 (1500 excep.)	70	14	-

* For uses where the column "Remarks" is marked in grey further consideration is necessar
Uses should be crossed out when the notifier no longer supports this use(s).

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)

(b) Outdoor or field use (F), greenhouse 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. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).

(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) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha (m) PHI - minimum pre-harvest interval

Methods of Analysis

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

Technical a.s. (analytical technique)	HPLC/UV
Impurities in technical a.s. (analytical technique)	HPLC/UV, GD/FID and Karl Fisher titration
Plant protection product (analytical technique)	HPLC/UV

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for enforcement purposes

Food of plant origin	Option 1: flonicamid Option 2: flonicamid, TFNA and TFNG expressed as flonicamid
Food of animal origin	Flonicamid and TFNA-AM expressed as flonicamid
Soil	Flonicamid
Water surface	Flonicamid
drinking/ground	flonicamid
Air	Flonicamid

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC-MS/MS LOQ : 0.01 mg/kg (wheat grain, tomatoes and apples) and 0.02 mg/kg in wheat straw for each compound (flonicamid and its metabolites TFNG, TFNA and TFNA-AM) And HPLC-MS/MS LOQ : 0.05 mg/kg (peach and potatoes) and 0.10 mg/kg (wheat straw) for each compound (flonicamid and its metabolites TFNG, TFNA and TFNA-AM)

Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC-MS/MS (an enforcement method is not required due to the fact that no MRLs are proposed) LOQ: 0.01 mg/L for milk LOQ: 0.01 mg/kg for bovine, poultry tissues and poultry eggs LOQ: 0.025 mg/kg for the other ruminant tissues For each compound (flonicamid and its metabolites OH-TFNA-AM, TFNA and TFNA-AM)
Soil (analytical technique and LOQ)	HPLC-MS/MS LOQ 0.005 mg/kg (flonicamid, TFNG, TFNG-AM, TFNA, TFNA-AM and TFNA-OH)
Water (analytical technique and LOQ)	HPLC-MS/MS LOQ: 0.1 µg/L (flonicasmid, TFNA, TFNG, TFNA-AM, TFNA-OH and TFNG-AM in drinking water and surface water)
Air (analytical technique and LOQ)	HPLC-UV LOQ:1.5 µg/m^3 (flonicamid)
Body fluids and tissues (analytical technique and LOQ)	Not required; the active substance is not classified as toxic or very toxic.

Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

	RMS/peer review proposal
Active substance	none

Impact on Human and Animal Health

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

Rate and extent of oral absorption/systemic bioavailability	Rapid and extensive >80% within 24 h Tmax = 0.4 h at low dose (2mg/kg
Distribution	Extensive with peak tissue concentrations ≤ peak blood concentrations except in liver, kidney, adrenals, thyroid and GI tract.
Potential for bioaccumulation	None
Rate and extent of excretion	Rapid mostly via urine 70 – 80% within 24 h; low biliary excretion (~ 5% AD).
Metabolism in animals	Proceeds in the rat by nitrile & amide hydrolysis, N-oxidation, hydroxylation of pyridine ring Main component in urine, faeces and bile: IKI-220 (up to 70% AD); main metabolite in urine and bile: TFNA-AM (up to 27% AD); minor metabolites: TFNA and conjugates, TFNG-AM, TFNA-AM N oxide conjugate, OH-TFNA-AM, TFNG
Toxicologically relevant compounds (animals and plants)	Parent substance
Toxicologically relevant compounds (environment)	Parent substance, impurity toluene

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral	884 – 1768 mg/kg bw (m – f)	**R22**
Rat LD_{50} dermal	> 2000 mg/kg bw	
Rat LC_{50} inhalation	> 5.5 mg/L air /4h (state way, e.g. nose only)	
Skin irritation	> 4.9 mg/L (4 h, nose-only aerosol)	
Eye irritation	(MMAD 4.8 µm)	
Skin sensitisation	non irritant	

Short-term toxicity (Annex IIA, point 5.3)

Target organ / critical effect	kidney (rat, dog), liver (mouse, rat), haematopoietic system (mouse, dog)	
Relevant oral NOAEL	8 mg/kg bw/d (dog 90-d and 52 w)	

	60 mg/kg bw/d (rat, 90-d) 15.3 mg/kg bw/d (mouse, 90-d)	
Relevant dermal NOAEL	1000 mg/kg bw/d (rat, 28-day study)	
Relevant inhalation NOAEL	no study – not required	

Genotoxicity (Annex IIA, point 5.4)

In vitro studies	No genotoxic potential	
In vivo studies	No genotoxic potential	
Photomutagenicity	No genotoxic potential	
Potential for genotoxicity	No genotoxic potential	

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

Target/critical effect	Rat: kidneys, liver, anaemia Mouse: lungs, liver, haemopoitec system.	
Relevant Noel	7.32 mg/kg bw/d (rat, 2-y) 10 mg/kg bw/d (mouse, 18 month)	
Carcinogenicity	Rat: nasal tumours not considered relevant for humans. Mouse: strain- and species-specific lung tumours of unknown relevance to humans.	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect	Reproduction: no adverse effect on reproductive parameters Parents: kidneys les ovary/adrenal weights Offspring: delayed vaginal opening and reduced uterus weight in F1 weanlings	
Relevant parental NOAEL	18 mg/kg bw/d	
Relevant reproductive NOAEL	109 mg/kg bw/d (highest dose tested)	
Relevant offspring NOAEL	30 mg/kg bw/d	

Developmental toxicity

Developmental target / critical effect	Development (rat): increased placental weight, increased skeletal variations (cervical ribs) Development (rabbit): increased visceral anomalies without maternal toxicity Parental : liver and kidney (rat), reduced weight gain and food consumption (rabbit)	
Relevant maternal NOAEL	Rat: 100 mg/kg bw/d Rabbit: 7.5 mg/kg bw/d	
Relevant developmental NOAEL	Rat: 100 mg/kg bw/d Rabbit: 25 mg/kg bw/dh	

Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)

Acute neurotoxicity	NOAEL 600 mg/kg bw (rat)	
Repeated neurotoxicity	NOAEL > 625 mg/kg bw/d (rat, 90-day)	
Delayed Neurotoxicity		

Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

Mechanism studies	Lung cell cycle analysis (BrdU index): dose response relationship in the mouse (NOEL 12.3 mg/kg bw/d); reversibility study; comparative study in the rat and the mouse Lung cell cycle analysis (BrdU index) with TFNG, TFNA, TFNA-AM: no effect on BrdU index after a 3 or 7-d treatment at 318-402 mg/kg bw/d Comparison of lung cell cycle analysis after flonicamid or isoniazid dietary exposure in 3 mouse strains: BrdU index increased in CD-1 mouse strain only after flonicamid and no strain specificity after isoniazid.

Endocrine disrupting properties	State which study was performed and in what species and the outcome, if applicable also the NOAEL and LOAEL.
Studies performed on metabolites or impurities	Acute oral toxicity of metabolites TFNA oral LD50: >2000 mg/kg. No clinical signs TFNA-AM oral LD50: >2000 mg/kg. No clinical signs TFNA-OH oral LD50: >2000 mg/kg. No clinical signs TFNG oral LD50: >2000 mg/kg. No clinical signs TFNG-AM oral LD50:>2000 mg/kg. No clinical signs Genotoxicity testing of metabolites Bacterial reverse mutation assays: negative for TFNA; TFNA-AM; TFNA-OH; TFNG and TFNG-AM. 90-day toxicity studies on metabolites TFNA: NOAEL 136 mg/kg bw/d TFNG: NOAEL 135 mg/kg bw/d

Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)

Not applicable. Flonicamid has not been marketed. No adverse health effects have been reported in manufacturing plant personnel

Summary[1] (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)	Value (mg/kg bw (per day))	Study	Uncertainty factor
ADI	0.025	rabbit, developmental	100
AOEL	0.025	rabbit, developmental	100
Acute Reference Dose (ARfD)	0.075	rabbit, developmental	100

[1] If available include also reference values for metabolites

Dermal absorption (Regulation (EU) N° 284/2013, Annex Part A, point 7.3)

TEPPEKI ® 50% WG	Concentrate: 7.46%; spray dilution: 13%

Exposure scenarios (Regulation (EU) N° 284/2013, Annex Part A, point 7.2)

Operators		Potato		Orchard	
		no PPE	PPE	no PPE	PPE
	UK POEM	324	90	421	283
	German	39	21	53	46
	PPE: gloves during mixing/loading and application				
Workers	Worst case exposure without PPE: 116% of AOEL; with PPE: 5.7% of AOEL				
Bystanders and residents	Potato scenario: exposure <1% of AOEL Orchard scenario: exposure is 14% of AOEL				

Classification with regard to toxicological data (Annex IIA, point 10)

	RMS/peer review proposal
Flonicamid	N/a

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

Plant groups covered	Cereals (wheat), Root vegetable (potato) and Fruit crop (perach,pepper)
Rotational crops	None
Plant residue defintion for monitoring	Option 1 : Flonicamid Option 2 : Flonicamid+TFNG+TFNA expressed as flonicamid
Plant residue definition for risk assessment	Flonicamid+TFNG+TFNA expressed as flonicamid
Conversion factor (monitoring to risk assessment)	Option 1: Yes, 2.5 apple/pear, 1.6 peach, 3.0 potato and 17.5 wheat grain Option 2 : None

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

Animals covered	Goat and hen

Animal residue definition for monitoring	Flonicamid+TFNA-AM expressed as Flonicamid
Animal residue definition for risk assessment	Flonicamid+TFNA-AM expressed as Flonicamid
Conversion factor (monitoring to risk assessment)	None
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue (yes/no)	No

Residues in succeeding crops

	Study not required

Stability of residues

Stable for at least a period of 18 months on crops (apple, potato, wheat) and for at least 15 months on cereal products (bread).
Stable for a period of at least 8 months in poultry matrices (meat, eggs, fat) and at least 9 month in goat matrices (meat, milk, fat).

Residues from livestock feeding studies

MRL calculations	Ruminant	Pig/Swine	Poultry
	Conditions of requirement of feeding studies		
Expected Intakes by livestock ≥0.1 mg/kg diet (dry weight basis) (yes/no – if yes, specify the level)	Yes 0.46 and 0.64 mg/kg DM (dairy& beef cattle)	Yes 0.37 mg/kg DM Pig	Yes 0.33 mg/kg DM Poultry
Potential for accumulation (Yes/No)	NO	Not applicable	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	No	Not applicable	No
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant Residue levels in matrices (flonicamid + TFNA-AM): Max . mg/kg		
Muscle	<0.025 (4 N)	Not required	0.050
Fat	<0.005 (6 N)	Not required	0.0226 (8 N)

Residues from livestock feeding studies

MRL calculations	Ruminant	Pig/Swine	Poultry
Kidney	<0.025 (4 N)	Not required	-
Liver	<0.025 (4 N)	Not required	0.058 (8 N)
Milk[(a)]	<0.01* (5 N)	-	-
Eggs	-	-	0.0735 (8 N)

Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern/ S outhern Region	Trials results relevant to the representative uses	Recommendations/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (d)
Option 1: Residue for monitoring defined as flonicamid only						
Apple/pear	N/S	2x <0.01; 4x 0.01; 4x 0.02; 2x 0.03; 0.045; 2x 0.08; 0.085	R_{ber}: 0.08, R_{max} 0.10	0.1	0.085	0.02
Peach	S	0.02; 3x 0.03; 0.04; 0.06; 0.08; 0.09; 0.18; 0.26	R_{ber}: 0.23, R_{max} 0.31	0.3	0.26	0.05
Potato	N/S	17x<0.01, 0.01		0.01*	0.01	0.01
Wheat	N/S	**Grain:** 14x <0.01;0.01; <0.02; 0.02; 0.04; 0.06	R_{ber}: 0.02, R_{max} 0.05	0.1	0.06	0.01
		Straw: 6x <0.02; 0.02; 2x 0.03; 2x 0.04; 2x 0.05. 0.08; 0.09; 0.11; 0.23; 0.39			0.39	0.03
Option 2: Residues for monitoring defined as sum flonicamid. TFNA. TFNG expressed as flonicamid						
Apple/pear	N/S	<0.03; 3x 0.03; 3x 0.04; 2x 0.044; 0.054; 0.064; 0.076; 0.115; 0.126; 0.15; 0.185	R_{ber}: 0.21, R_{max} 0.19	0.2	0.185	0.04
Peach	S	0.04; 3x 0.05; 0.06; 0.094; 0.10; 0.11; 0.208; 0.298	R_{ber}: 0.27, R_{max} 0.35	0.5	0.298	0.08
Potato	N/S	8x <0.03; 5x 0.03; 3x 0.044; 0.048; 0.056	R_{ber}: 0.09, R_{max} 0.06	0.1	0.056	0.03

Crop	Northern/ S outhern Region	Trials results relevant to the representative uses	Recommendations/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (d)
Wheat	N/S	**Grain:** 0.038; 0.075; 0.084; 0.117; 0.130; 0.149; 0.203; 0.227; 0.267; 0.350; 0.466; 0.517; 0.521; 0.552; 0.570; 0.585; 0.738; 1.124	R_{ber}: 1.11, R_{max} 1.07	2.0	1.124	0.31
		Straw: 4x< 0.06; 0.105; 0.106; 0.132; 0.144; 0.150; 0.162; 0.178; 0.179; 0.196; 0.268; 0.407; 0.422; 0.474; 0.477			0.477	0.156

(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 representative use
(c) Highest residue

Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9)
Including all uses (representative uses and uses related to an MRL application).

ADI	0.025mg/kg bw per day
TMDI (european diet) (%ADI)	**TMDI using EFSA PRIMO Model** **-Option 1:** 63% ADI (WHO Cluster diet B) using conversion factors of 2.5, 1.6, 3.0 and 17.5 for apple, peach, potato and wheat **-Option 2:** 72% ADI (WHO Cluster diet B)
NEDI (% ADI)	-
Factors included in NEDI	-
ARfD	0.075mg/kg bw
Acute exposure (% ARfD)	Revised ArfD represents a safer acute exposure than under previous assessment - acceptable

Processing factors

Crop/ processed fraction	Number of studies	Transfer factor
Wheat: bread (whole meal)	4	0.28 – 0.86 (mean: 0.58)
Plum/Prune	1	2.5

* Calculated on the basis of distribution in the different portions. Parts. Or products as determined through balance studies.

Proposed MRLs

Plant products	Residues for monitoring defined as	
	Flonicamid	Flonicamid+TFNA+TFNG
Apple/Pears	0.1	0.2
Peaches	0.3	0.5
Potatoes	0.01*	0.1
Wheat	0.1	2

Animal Products	0.02* (residues defined as flonicamid

	+TFNA-AM)

Environmental fate and behaviour

Route of degradation (aerobic) in soil (Annex IIA. Point 7.1.1.1.1)

Mineralisation after 100 days	47-56.6 % after 30 d, (4 soils)
Non-extractable residues after 100 days	29.6-43.3 % after 30 d, (4 soils)
Relevant metabolites - name and/or code. % of applied (range and maximum)	TFNA : 12.2-36.4 % after 1-3 d TFNA-OH : 12.1-21.3 % after 2-7 d TFNG-AM : 7.8-10.2 % after 0.3-2 d TFNG : < 3.9 % TFNA-AM : 7.6 % after 7 d

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

Anaerobic degradation	No data provided. not required (April-July applications)
Soil photolysis	DT50 : 53 d (dark) and 22 d (continous artificial light) on dry soil TFNG-AM : 13.8 % (dark). 29.5 % (light) after 15 d Negligible role of photodegradation

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

Method of Calculation	1st order by linear regression. R2 > 0.94
Laboratory studies (range or median. With n value. With r^2 value)	1st order by linear regression. R2 > 0.94 DT50lab (20°C. aerobic): Flonicamid : 0.7-1.8 d (mean 1.1 d). 4 soils (pH 6.2-7.2) Flonicamid geometric mean 1 day TFNA : 0.29-0.46 d (mean 0.4 d). 3 soils (pH 5.76.8) TFNA-OH : 1.0-2.6 d (mean 1.6 d). 3 soils (pH 5.76.8) TFNG-AM : 0.2-1.0 (mean 0.5 d). 3 soils (pH 6.27.0) TFNG : 0.1-1.1 d (mean 0.5 d). 3 soils (pH 5.7-6.8)

	TFNA-AM : 1.0-2.6 d (mean 1.6 d). 3 soils (pH 6.2-7.0)
	DT90lab (20°C. aerobic): Flonicamid : 2.3-6.0 d (mean 3.5 d) TFNA : 1.0-1.5 d (mean 1.3 d) TFNA-OH : 3.4-8.7 d (mean 5.4 d) TFNG-AM : 0.6-3.3 (mean 1.6 d) TFNG : 0.4-3.5 d (mean 1.5 d) TFNA-AM : 3.4-8.5 d (mean 5.2 d)
	DT50lab (10°C. aerobic): Flonicamid : 2.4 d TFNA : 0.99 d TFNA-OH : 4.5 d TFNG-AM : 0.7 d TFNG : 0.3 d
	TFNA-AM : 4.8 d
	DT50lab (20°C. anaerobic): No data. not required (April-July applications)
	degradation in the saturated zone:

Field studies (state location. Range or median with n value)	DT50f: : no data. not required
	DT90f: : no data. not required
Soil accumulation and plateau concentration	No data. not required

Soil adsorption/desorption (Annex IIA. point 7.1.2)

K_f/K_{oc}	Flonicamid	Kd : 0.03-0.17 L/kg Kdoc : 2.5-8.7 L/kg (mean 5.9) 4 soils (pH 6.5-7.6)
K_d		
pH dependence (yes / no)(if yes type of dependence)	TFNA	Kd : < 0.02 L/kg Kdoc : < 3.0 L/kg (mean about 2.0) 4 soils (pH 5.7-7.2)
	TFNA-OH	Kd : < 0.06 L/kg

		Kdoc : < 4.4 L/kg (mean about 3.0)	
		4 soils (pH 5.7-7.2)	
	TFNG-AM	Kd : 0.04-0.32 L/kg	
		Kdoc : 5.5-13.2 L/kg (mean 9.2)	4 soils (pH 5.6-7.2)
	TFNG	Kd : < 0.03 L/kg	
		Kdoc : < 4.0 L/kg (mean about 1.6)	
		4 soils (pH 5.7-7.2)	
	TFNA-AM	Kd : 0.03-0.20 L/kg	
		Kdoc : 2.8-12.1 L/kg (mean 6.2)	9 soils (pH 5.6-8.1)
	No pH dependence for flonicamid or its metabolites.		

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

Column leaching	No data provided. not required
Aged residues leaching	No data provided. not required
Lysimeter/ field leaching studies	No data provided

PEC (soil) (Annex IIIA. point 9.1.3)

Method of calculation	5 cm soil layer. BD 1.5 Flonicamid : max. DT_{50lab} 1.8 d TFNA : max. 36.4 %. max. DT_{50lab} 0.5 d. MR 0.83 TFNA-OH : max. 21.3 %. max. DT_{50lab} 2.6 d. MR 0.90 TFNG-AM : max. 10.2 %. max. DT_{50lab} 1.0 d. MR 1.08 TFNG : max. 3.9 %. max. DT_{50lab} 1.1 d. MR 1.08 TFNA-AM : max. 7.6 %. max. DT_{50lab} 2.6 d. MR 0.83
Application rate	Single application at 80 g/ha (potatoes) or 70 g/ha (apples and cereals). Crop interception : 50 %

PECsoil (µg/kg) for single application at 80 g/ha to potatoes

Day	Flonicamid		TFNA		TFNA-OH		TFNA-AM		TFNG		TFNG-AM	
	Act	TWA	Act	TWA	Act	TWA	Act	TWA	Act	TWA	Act	TWA
Initial	53.3	53.3	16.1	16.1	10.2	10.2	3.4	3.4	2.2	2.2	5.9	5.9
1	36.3	44.2	4.0	8.7	7.8	9.0	2.6	3.0	1.2	1.6	3.0	4.3
2	24.7	37.2	1.0	5.4	6.0	7.9	2.0	2.6	0.6	1.3	1.5	3.2
4	11.4	27.2	0.1	2.9	3.5	6.3	1.2	2.1	0.2	0.8	0.4	2.0
7	3.6	18.4	-	1.7	1.6	4.6	0.5	1.5	-	0.5	-	1.2
28	-	4.9	-	0.4	-	1.4	-	0.5	-	0.1	-	0.3
50	-	2.8	-	0.2	-	0.8	-	0.3	-	0.1	-	0.2
100	-	1.4	-	0.1	-	0.4	-	0.1	-	-	-	0.1

PECsoil (µg/kg) for single application at 70 g/ha to cereals and orchards												
Day	Flonicamid		TFNA		TFNA-OH		TFNA-AM		TFNG		TFNG-AM	
	Act	TWA	Act	TWA	Act	TWA	Act	Act	TWA	Act	TWA	Act
Initial	46.7	46.7	14.1	14.1	8.9	8.9	2.94	2.94	1.97	1.97	5.14	5.14
1	31.7	38.8	3.5	7.6	6.8	7.8	2.25	2.58	1.05	1.46	2.57	3.71
2	21.6	32.6	0.9	4.8	5.2	6.9	1.72	2.28	0.56	1.12	1.28	2.78
4	10.0	23.8	0.1	2.5	3.1	5.5	1.01	1.81	0.16	0.72	0.32	1.74
7	3.2	16.1	-	1.5	1.4	4.0	0.45	1.33	-	0.44	0.04	1.05
28	-	4.3	-	0.4	-	1.1	-	0.39	-	0.11	-	0.26
50	-	2.4	-	0.2	-	0.7	-	0.22	-	0.06	-	0.15
100	-	1.2	-	0.1	-	0.3	-	0.11	-	-	-	0.07

For potato. 50 % interception is thought to be realistic for the current intended conditions of use (well developed plants). In case of earlier application (early stage of leaf development) 15 % interception could be realistic and PECs would be increased by a factor of 1.7. Such a particular condition of use should be dealt with at MS level if relevant. However with regard to safety margins. impact on the terrestrial risk assessment is not expected.

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 4 : flonicamid and TFNA are stable
	pH 7: flonicamid and TFNA are stable
	pH 9 : DT_{50} 204 d (25° C). 17.1 d (40° C). 9.0 d (50° C) (1st order. linear regression) TFNG-AM : 65.1 % after 20 d at 50° C TFNG : 85.7 % after 120 d at 50° C TFNA : stable
Photolytic degradation of active substance and relevant metabolites	pH 7 . 23° C : stable (dark). DT_{50} 267 d (continous artifical light). Negligible role of photodegradation (Φ = 0.000319)
Readily biodegradable (yes/no)	No
Degradation in – DT_{50} water Water/sediment – DT_{90} water	30.3-37.3 d (1st order. linear regression. n=2) 100.5-123.8 d
-DT_{50} whole system -DT_{90} whole system	35.7-43.6 d (1st order) 118.7-144.8 d
Mineralisation	15.6-59.1 % (136-145 d)
Non-extractable residues	38.4-75.4 % (136-145 d)
Distribution in water / sediment systems (active substance)	Max. 17.8-43.7 % after 3 d due to high sediment:water ratio (1:4) and to high OC content up to 10.2 % (DT50 41-69 d)
Distribution in water / sediment systems (metabolites)	TFNA : max. 9.6 % in water after 30 d (apparent DT50 60 d) and 9.2 % in sediment after 42 d (apparent DT50 59 d). TFNA-OH : max. 12.5 % in water after 42 d (apparent DT50 49 d) and < 2.2 % in sediment. TFNG : < 3.7 % in water and < 2.7 % in

	sediment. TFNA-AM : < 0.9 % in water and < 1.1 % in sediment.

PEC (surface water) (Annex IIIA. Point 9.2.3)

Method of calculation	FOCUS-SW step 1 Mean DT_{50} flonicamid in water/sediment : 39.7 d Mean Koc flonicamid : 19 (notifier proposal. 5.9 should be used) FOCUS-SW step 2 Soil : mean DT_{50lab} (flonicamid/TFNA/TFNA-OH/TFNA-AM/TFNG/TFNG-AM) = 1.1 /0.4 /1.6 /1.6 /0.5 /0.5 Soil : Max. amounts of metabolites (TFNA/TFNA-OH/TFNAAM/TFNG/TFNG-AM) = 36.4 /20.2 /6.9 /2.5 /9.6 (% of parent) Water/sed : mean DT_{50} whole system for both phases (flonicamid/TFNA/TFNA-OH/TFNA-AM/TFNG/TFNG-AM) = 39.7/ 69.3/ 69.3 / 69.3 / 69.3 / 69.3 (flonicamid : notifier proposal. 55 d should be used) Water : max. amounts of metabolites in whole system (TFNA/TFNAOH/TFNA-AM/TFNG/TFNG-AM) = 17.9 /13.2 /1.1 /3.5 /1.0 (% of parent) Koc : mean values (flonicamid/TFNA/TFNA-OH/TFNA-AM/TFNG/TFNG-AM) = 19 /1.6 /3.0 /4.6 /1.7 /5.3 (flonicamid: notifier proposal. 5.9 should be used)
Application rate	Apples : 3 x 70 g/ha. 21 d interval. 70 % interception Potatoes : 2 x 80 g/ha. 21 d interval. 50 % interception Wheat : 2 x 70 g/ha. 21 d interval. 70 % interception
Main routes of entry	Step 1 Spray drift : 15.7 % at 3 m for apples. 2.76 % at 1 m for potatoes and wheat Run-off/drainage : 10 % Step 2 Spray drift : overall 90th percentile (11 % at 3 m for apples. 2.44 % at 1 m for potatoes and wheat)

	Run-off/drainage : 3 % of soil residue 4 DALA

PEC_{SW} (µg/L) for flonicamid – step 1 calculation

Day	Apples		Potatoes		Wheat	
	Actual	TWA	Actual	TWA	Actual	TWA
Initial	79.2		53.4		46.8	
1	77.6	78.4	52.5	53.0	45.9	46.3
2	76.2	77.7	51.6	52.5	45.1	45.9
4	73.6	76.3	49.8	51.6	43.6	45.1
7	69.9	74.3	47.3	50.3	41.3	44.0
14	61.8	70.1	41.8	47.2	36.6	41.4
21	54.7	66.1	37.0	44.7	32.4	39.1
28	48.4	62.4	32.7	42.2	28.6	36.9
42	37.9	55.9	25.6	37.8	22.4	33.1
50	33.0	52.7	22.3	35.6	19.5	31.1
100	13.7	37.3	9.3	25.2	8.1	22.1

PEC_{SW} (µg/L) for flonicamid for multiple applications (worst case) – step 2 calculation

Day after max	Apples (max. at 42 d) [1]		Potatoes (max. at 25 d) [1]		Wheat (max. at 25 d) [1]	
	Actual	TWA	Actual	TWA	Actual	TWA
0	5.53		1.32		1.04	
1	5.39	5.46	1.29	1.30	1.02	1.03
2	5.30	5.40	1.26	1.29	1.00	1.02
4	5.28	5.32	1.22	1.27	0.97	1.00
7	4.97	5.23	1.16	1.23	0.92	0.98
14	4.40	4.96	1.02	1.16	0.81	0.92
21	3.89	4.68	0.91	1.10	0.72	0.87
28	3.44	4.43	0.80	1.04	0.63	0.82
42	2.70	3.97	0.63	0.93	0.49	0.73
50	2.34	3.74	0.54	0.87	0.43	0.69
100	0.98	2.65	0.22	0.62	0.18	0.49

[1] time for the max. concentration starting from the first application

PEC_{SW} (µg/L) for metabolites for multiple applications to apples (worst case) – step 2 calculation

Day after max	TFNA		TFNA-OH		TFNA-AM		TFNG		TFNG-AM	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.94		0.79		0.076		0.24		0.068	
1	0.93	0.94	0.78	0.78	0.075	0.076	0.23	0.23	0.067	0.068
2	0.92	0.93	0.77	0.78	0.074	0.075	0.23	0.23	0.066	0.067
4	0.90	0.92	0.76	0.77	0.073	0.074	0.23	0.23	0.066	0.067
7	0.88	0.91	0.73	0.76	0.071	0.073	0.22	0.23	0.064	0.066
14	0.82	0.88	0.68	0.73	0.066	0.071	0.20	0.22	0.060	0.064
21	0.76	0.85	0.64	0.71	0.061	0.068	0.19	0.21	0.056	0.062
28	0.71	0.82	0.59	0.69	0.057	0.066	0.18	0.20	0.052	0.060
42	0.62	0.77	0.52	0.64	0.050	0.062	0.15	0.19	0.045	0.056
50	0.57	0.74	0.48	0.62	0.046	0.060	0.14	0.18	0.042	0.054
100	0.34	0.59	0.29	0.50	0.028	0.048	0.08	0.15	0.025	0.043

PEC (Sediment)

Method of calculation	See PECsw
Application rate	See PECsw

PEC_{sed} (µg/kg) for flonicamid – step 1 calculation

Day	Apples		Potatoes		Wheat	
	Actual	TWA	Actual	TWA	Actual	TWA
Initial	12.9		9.8		8.6	
1	14.7	13.8	9.9	9.9	8.7	8.6
2	14.4	14.2	9.8	9.9	8.5	8.6
4	13.9	14.2	9.4	9.7	8.2	8.5
7	13.2	13.9	8.9	9.5	7.8	8.3
14	11.7	13.2	7.9	9.0	6.9	7.8
21	10.4	12.5	7.0	8.4	6.1	7.4
28	9.2	11.8	6.2	8.0	5.4	7.0
42	7.2	10.6	4.8	7.1	4.2	6.2
50	6.2	9.9	4.2	6.7	3.7	5.9
100	2.6	7.0	1.7	4.8	1.5	4.2

PEC_{sed} (µg/kg) for flonicamid for multiple applications (worst case) – step 2 calculation

Day after max	Apples (max. at 47 d)		Potatoes (max. at 26 d)		Wheat (max. at 26 d)	
	Actual	TWA	Actual	TWA	Actual	TWA
0	0.97		0.24		0.19	

1	0.96	0.97	0.24	0.24	0.19	0.19
2	0.94	0.96	0.23	0.24	0.18	0.19
4	0.91	0.94	0.22	0.23	0.18	0.18
7	0.86	0.92	0.21	0.23	0.17	0.18
14	0.76	0.86	0.19	0.21	0.15	0.17
21	0.67	0.81	0.17	0.20	0.13	0.16
28	0.60	0.77	0.15	0.19	0.11	0.15
42	0.47	0.69	0.11	0.17	0.09	0.13
50	0.40	0.65	0.10	0.16	0.08	0.12
100	0.17	0.46	0.04	0.11	0.03	0.09

PECsed (µg/kg) for metabolites for multiple applications to apples (worst case) – step 2 calculation

Day after max	TFNA		TFNA-OH		TFNA-AM		TFNG		TFNG-AM	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
0	0.014		0.023		0.003		0.004		0.004	
1	0.014	0.014	0.023	0.023	0.003	0.003	0.004	0.004	0.003	0.004
2	0.014	0.014	0.023	0.023	0.003	0.003	0.004	0.004	0.003	0.003
4	0.013	0.014	0.022	0.023	0.003	0.003	0.004	0.004	0.003	0.003
7	0.013	0.013	0.021	0.022	0.003	0.003	0.004	0.004	0.003	0.003
14	0.012	0.013	0.020	0.021	0.003	0.003	0.003	0.004	0.003	0.003
21	0.011	0.013	0.019	0.021	0.003	0.003	0.003	0.004	0.003	0.003
28	0.010	0.012	0.017	0.020	0.003	0.003	0.003	0.003	0.003	0.003
42	0.009	0.011	0.015	0.019	0.002	0.003	0.003	0.003	0.002	0.003
50	0.008	0.011	0.014	0.018	0.002	0.003	0.002	0.003	0.002	0.003
100	0.005	0.009	0.008	0.014	0.001	0.002	0.001	0.003	0.001	0.002

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

Method of calculation and type of study (e.g. modelling, monitoring,lysimeter)	FOCUS-PELMO Flonicamid : mean DT50lab 1.1 d. mean Koc 1.6 (first rapporteur proposal. 5.9 should be used). 1/n 0.9 (default) Q10 2.2, Walker equation coefficient 0.7
Application rate	Apples : 3 x 70 g/ha. 21 d interval. interception 65-80 % Potatoes : 2 x 80 g/ha. 21 d interval. interception 15-50 % Wheat : 2 x 70 g/ha. 21 d interval. interception 70-90 %

$PEC_{(gw)}$

Maximum concentration	Value not produced by FOCUS shells.

	not required.
Average annual concentration	PECgw < 0.001 µg/L for flonicamid (all scenarios) No reliable PECgw available for metabolites. Concentrations are not expected to exceed those of flonicamid (lower amounts in soil. similar properties).

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

Direct photolysis in air	Not available. not required
Quantum yield of direct phototransformation	Not applicable
Photochemical oxidative degradation in air	DT50 ..13.7 d (12 h day) for KOH 0.779 x 10-12 cm3 molecule-1 sec-1 and [OH] 1.5 x 106 radicals per cm3
Volatilisation	from plant surfaces: no data provided
	from soil: no data provided

PEC (air)

Method of calculation	Expert judgement based on physico chemical properties

PEC(a)

Maximum concentration	Flonicamid has a low vapour pressure (9.43 x 10-7 Pa at 20° C) and a low Henry law constant (4.2 x 108 Pa m3 mole-1). Accordingly negligible concentrations are expected in air despite slow photo-oxidation in air.

Definition of the Residue (Annex IIA. point 7.3)

Relevant to the environment	Soil : flonicamid. TFNA. TFNA-OH. TFNG-AM. TFNG. TFNAAM Residue for monitoring : flonicamid Groundwater : flonicamid. TFNA. TFNA-OH. TFNG-AM. TFNG. TFNA-AM Residue for monitoring : flonicamid Surface water : flonicamid. TFNA. TFNA-OH. (TFNG-AM originating from soil) Residue for monitoring : flonicamid Sediment flonicamid Air : flonicamid

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

Soil (indicate location and type of study)	No data
Surface water (indicate location and type of study)	No data
Ground water (indicate location and type of study)	No data
Air (indicate location and type of study)	No data

Classification and proposed labelling (Annex IIA. point 10)

With regard to fate and behaviour data	Candidate for R53

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

Toxicity to mammals	Short-term LD50 = 884 mg a.s./kg bw
Acute toxicity to birds	Long-term NOEL (teratogenicity) = 25 mg a.s./kg bw/d
Dietary toxicity to birds	LD50 (quail. boths sexes) > 2000 mg a.s./kg bw
Reproductive toxicity to birds	LD50 (duck. male) = 2621 mg a.s./kg bw

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

Exposure assessment according to SANCO/4145/2000 (25.09.02)

Birds

Application rate (kg as/ha)	Crop	Category *(feed item)*	Time-scale	TER	Annex VI Trigger
0.08	potatoes	medium herbivorous bird insectivorous bird	acute	251 368	10
0.07	wheat. apples. pears. peaches	insectivorous bird	acute	420	10
0.08	potatoes	medium herbivorous bird insectivorous bird	short-term	> 103 > 125	10
0.07	wheat. apples. pears. peaches	insectivorous bird	short-term	> 143	10
0.08	potatoes	medium herbivorous bird insectivorous bird	long-term	38 24	5
0.07	wheat. apples. pears. peaches	insectivorous bird	long-term	28	5

Small mammals: Tier 1

Application rate (kg as/ha)	Crop	Category *(feed item)*	Time-scale	TER	Annex VI Trigger
0.08	potatoes	medium herbivorous mammal	acute	378	10
0.07	wheat	insectivorous mammal	acute	1433	10

0.07	apples. pears	small herbivorous mammal	acute	77	10
0.07	peaches	small herbivorous mammal	acute	89	10
0.08	potatoes	medium herbivorous mammal	long-term	42.9	5
0.07	wheat	insectivorous mammal	long-term	111	5
0.07	apples. pears	small herbivorous mammal	long-term	8.23	5
0.07	peaches	small herbivorous mammal	long-term	8.60	5

Toxicity data for aquatic species (Annex IIA. point 8.2. Annex IIIA. point 10.2)

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/L)
Laboratory tests				
O. mykiss	a.s.	acute	LC50-96 h	> 100 mg a.s./L
O. mykiss	IKI-220 50%WG	acute	LC50-96 h	> 51 mg a.s./L
L. macrochirus	a.s.	acute	LC50-96 h	> 100 mg a.s./L
P. promelas	a.s.	chronic	NOEC-33 d	10 mg a.s./L
D. magna	a.s.	acute	EC50-48 h	> 100 mg a.s./L
D. magna	IKI-220 50%WG	acute	EC50-48 h	> 51 mg a.s./L
D. magna	a.s.	chronic	NOEC-21 d	3.1 mg a.s./L
Ps. subcapitata	a.s.		EbC50-72 h ErC50-72 h	> 100 mg a.s./L > 100 mg a.s./L
Ps. subcapitata	IKI-220 50%WG		EbC50-72 h ErC50-72 h	43 mg a.s./L > 51 mg a.s./L
L. gibba	a.s.		EC50 biomass and growth-7 d	119 mg a.s./L
C. riparius	a.s.	acute	LC50-48 h	> 200 mg a.s./L
C. riparius	a.s.	chronic	NOEC-28 d	25 mg a.s./L
O. mykiss	TFNA	acute	LC50-96 h	> 100 mg a.s./L
D. magna		acute	EC50-48 h	> 100 mg a.s./L
Ps. subcapitata			EbC50-72 h ErC50-72 h	> 100 mg a.s./L > 100 mg a.s./L
O. mykiss	TFNA-OH	acute	LC50-96 h	> 100 mg a.s./L
D. magna		acute	EC50-48 h	> 100 mg a.s./L
Ps. subcapitata			EbC50-72 h ErC50-72 h	29 mg a.s./L > 100 mg a.s./L
O. mykiss	TFNA-AM	acute	LC50-96 h	> 100 mg a.s./L
D. magna		acute	EC50-48 h	> 100 mg a.s./L
Ps. subcapitata			EbC50-72 h ErC50-72 h	> 100 mg a.s./L > 100 mg a.s./L
O. mykiss	TFNG-AM	acute	LC50-96 h	> 100 mg a.s./L
D. magna		acute	EC50-48 h	> 100 mg a.s./L
Ps. subcapitata			EbC50-72 h ErC50-72 h	> 100 mg a.s./L > 100 mg a.s./L

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

Active substance (exposure assessment according to FOCUS-Step 1)

Application rate (kg as/ha)	Crop	Organism	Timescale	Distance (m)	TER	Annex VI Trigger
0.08	apples (worst case)	fish	acute	3	> 643	100
		fish	chronic		126	10
		aquatic invertebrates	acute		> 643	100
		aquatic invertebrates	chronic		39	10
		algae			542	10
		aquatic plants			> 1501	10
		sed^{t} dwell^{ng} org^{ms}	chronic		315	10

Metabolites (exposure assessment according to FOCUS-Step 2)

Substance	Crop	Organism	Time-scale	Distance (m)	TER	Annex VI Trigger
TFNA	apples case) (worst	fish	acute	3	> 105 708	100
		aquatic invertebrates	acute		> 105 708	100
		algae			> 105 708	10
TFNA-OH	apples case) (worst	fish	acute	3	> 126 582	100
		aquatic invertebrates	acute		> 126 582	100
		algae			36 709	10
TFNA-AM	apples case) (worst	fish	acute	3	> 1.3 x 10^6	100
		aquatic invertebrates	acute		> 1.3 x 10^6	100
		algae			> 1.3 x 10^6	10
TFNG-AM	apples case) (worst	fish	acute	3	> 1.47 x 10^6	100
		aquatic invertebrates	acute		> 1.47 x 10^6	100
		algae			> 1.47 x 10^6	10

Bioconcentration

Bioconcentration factor (BCF)	logPow = 0.3 (i.e.. < 3)
Annex VI Trigger:for the bioconcentration factor	

Clearance time (CT50) (CT_{90})	
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	> 104.3 mg IKI-220 50% WG (TEPPEKI) / bee i.e.. > 53.3 mg a.s./bee
Acute contact toxicity	> 100.0 mg IKI-220 50% WG (TEPPEKI) / bee i.e.. > 51.1 mg 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				
0.08	all crops	oral contact	< 1.5 < 1.6	50 50
Field or semi-field tests: Six tunnel tests were performed. Test item: TEPEKI (0.07-0.14 kg a.s./ha). One test with winter wheat. two tests with white mustard. three tests with oil seed rape. Only slight and transient effects were observed in some tests.				

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

Laboratory tests:

Species	Stage	Test Substance	Dose (g a.s./ha)	Endpoint	Effect	Annex VI Trigger
Laboratory tests						
A. rhopalosiphi (standard test)	adults	IKI-220 50% WG	80 210	mortality	22.2% 55.5%	30%
T. pyri (standard test)	protonymphs		80 210	mortality	100% 100%	30%
C. 7-punctata (standard test)	larvae		80 210	mortality	30% 30%	30%

Tier-1 risk assessment for flonicamid:

Test species	Toxicity endpoint	Lethal effect	Crop	Application rate in-field	HQ in-field
A. rhopalosiphi	LR50 > 80 g a.s./ha	22.2%	Potatoes	80	< 1
T. pyri	LR50 < 80 g a.s./ha	100	Potatoes	80	> 1
A. rhopalosiphi	LR50 > 80 g a.s./ha	22.2%	Wheat	70	< 0.88
T. pyri	LR50 < 80 g a.s./ha	100	Wheat	70	> 0.88
A. rhopalosiphi	LR50 > 80 g a.s./ha	22.2%	Apples/pears	70	< 0.88
Test species	Toxicity endpoint	Lethal effect	Crop	Application rate in-field	HQ in-field
T. pyri	LR50 < 80 g a.s./ha	100	Apples/pears	70	> 0.88
A. rhopalosiphi	LR50 > 80 g a.s./ha	22.2%	Peaches	70	< 0.88
T. pyri	LR50 < 80 g a.s./ha	100	Peaches	70	> 0.88

Tier 2 studies:

Species	Stage	Test Substance	Dose (g a.s. /ha)	Endpoint	Effect	Annex VI Trigger
Extended laboratory tests						
A. rhopalosiphi (ext[d] test)	Adults		85	mortality reproduction	4.4% 9.5%	30%
T. pyri (ext[d] test)	Protonymphs		85	mortality reproduction	23.3% 5.5%	30%
C. 7-punctata (ext[d] test)	larvae		85	mortality reproduction	6.1% 14.3%	30%
C. carnea (ext[d] test)	Larvae		85	mortality reproduction	18.8% 18.5%	30%
P. cupreus (standard test)	adults		45	mortality food consumption	3.8% 0.8%	30%
E. balteatus (ext[d] test)	Larvae		85	mortality reproduction	2.3% 30.2%	30%
O. laevigatus (lab test)	2[nd] stage nymph		161 (dry residues)	mortality reproduction	22% 11%	30%
Field or semi-field tests: no data						

* reduction.

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

Acute toxicity	flonicamid > 1000 mg a.s./kg soil TFNA > 100 mg a.s./kg soil TFNA-OH > 100 mg a.s./kg soil TFNG-AM > 100 mg a.s./kg soil TFNA-AM > 100 mg a.s./kg soil
Reproductive toxicity	not required

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

Substance	Crop	Time-scale	TER	Annex VI Trigger
Flonicamid [0.08 kg a.s./ha]	All crops	Acute	>1876	10
TFNA		Acute	>6211	10
TFNA-OH		Acute	>9804	10
TENG-AM		Acute	>16950	10
TFNA-AM		Acute	>29411	10

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

Nitrogen transformation	0.105 kg a.s./ha: no effect > 25%
Carbon mineralisation	0.105 kg a.s./ha: no effect > 25%

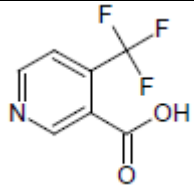
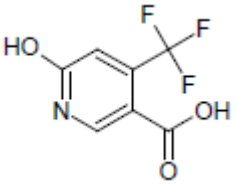
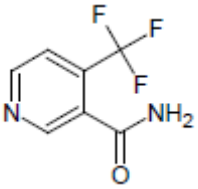
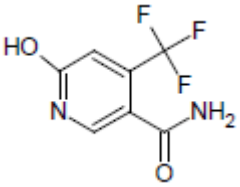
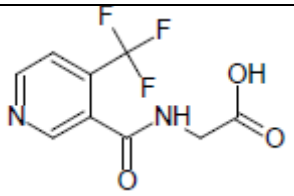
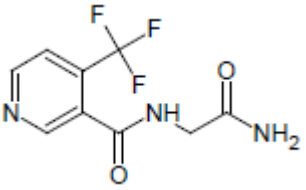
Effects on terrestrial plants (Annex IIA 8.6; Annex IIIA 10.8)

Foliar treatment	Eleven species. No effect in a screening test
Soil treatment	Seventeen species. No effect in a screening test

Classification and proposed labelling (Annex IIA. point 10)

With regard to exotoxicological data	Not classified

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name*	Structural formula*
TFNA	4-(trifluoromethyl)pyridine-3-carboxylic acid or 4-trifluoromethylnicotinic acid	
TFNA-OH	6-hydroxy-4-(trifluoromethyl)pyridine-3carboxylic acid or 6-hydroxy-4-trifluoromethylnicotinic acid	
TFNA-AM	4-(trifluoromethyl)pyridine-3-carboxamide or 4-trifluoromethylnicotinamide	
OH-TFNA-AM	6-hydroxy-4-(trifluoromethyl)pyridine-3carboxamide or 6-hydroxy-4-trifluoromethylnicotinamide	
TFNG	*N*-{[4-(trifluoromethyl)pyridin-3yl]carbonyl}glycine or *N*-(4-trifluoromethylnicotinoyl)glycine	
TFNG-AM	*N*-(2-amino-2-oxoethyl)-4-(trifluoromethyl)pyridine-3-carboxamide or *N*-(4-trifluoromethylnicotinoyl)glycinamide	

* ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008)

Abbreviations

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CA	Chemical Abstract
CAS	Chemical Abstract Service
CIPAC	Collaborative International Pesticide Analytical Council Limited
d	day

DAR	draft assessment report
DM	dry matter
DT_{50}	period required for 50 percent dissipation (define method of estimation)
DT_{90}	period required for 90 percent dissipation (define method of estimation)
ε	decadic molar extinction coefficient
EC_{50}	effective concentration
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GS	growth stage
h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HR	hazard rate
IESTI	international estimated short term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	organic carbon adsorption coefficient
kg	kilogram
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
µg	microgram
mg	milligram
mN	milli-Newton
MRL	maximum residue limit or level
MS	mass spectrometry
NESTI	national estimated short term intake
NIR	near-infrared-(spectroscopy)
nm	nanometer
NOAEL	no observed adverse effect level
NOEL	no observed effect level
OECD	Organisation for Economic Co-operation and Development
PEC	predicted environmental concentration

List of end points

PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
water PEC_{GW}	predicted environmental concentration in ground water
pH	pH-value
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
PELMO	Pesticides leaching model
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
r^2	coefficient of determination
RPE	respiratory protective equipment
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
TRR	Total radioactive residues
UDS	unscheduled DNA synthesis
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
yr	year