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Moncut 40SC

- *Flutolanil* -

B.8 Environmental fate and behaviour and environmental exposure assessment

Rapporteur Member State: The Netherlands

June 2018

Renewal Assessment Report and Proposed decision of the Netherlands prepared in the context of the possible approval of flutolanil under Regulation (EC) 1107/2009

Version history page

Volume 3-CP, chapter B.8

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B.8 Environmental fate and behaviour and environmental exposure assessment

The notifier Nihon-Nohyaku provided a risk assessment for the product Moncut 40SC (460 g/L). The RMS made its own risk assessment based on the assessment provided by the Notifier. The representative GAP of the product considered for the renewal application is shown in Table B.8-1.

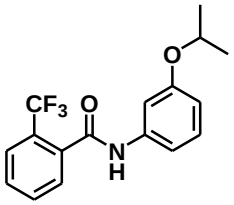
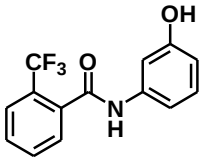
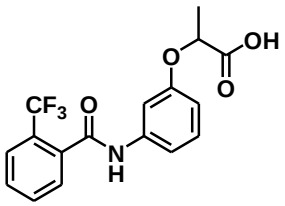
Table B.8-1: Representative GAP supported for EU renewal of Flutolanil

Use No.	Crop and/ or situation	F, G or I	Application					PHI min. (days)	Remarks
			method kind	growth stage & season (months)	Number min max	interval between appl.	kg a.s./ha min-max		
1	Potato Seed tuber treatment (ware, seed and starch potatoes)	F/ I	In store treatment Canopied hydraulic or spinning disc equipment	BBCH 00 – 03 (before planting)	1	-	0.368	-	Based on a planting rate of 4 t tubers/ha*
2	Potato Seed tuber treatment (ware, seed and starch potatoes)	F	On planter treatment as tuber falls into furrow	BBCH 00 – 03 (at planting)	1	-	0.368	-	Based on a planting rate of 4 t tubers/ha*
3	Potato Seed tuber treatment (ware, seed and starch potatoes)	F	In planter treatment before catching up by planting chains.	BBCH 00 – 03 (at planting)	1	-	0.368	-	Based on a planting rate of 4 t tubers/ha*
4	Tulip, Iris	F	Broadcast application with boom sprayer, followed by soil incorporation.	BBCH 00 Oct – Dec (pre-planting)	1	-	2.76	-	Incorporation into the soil, 10 – 15 cm

* please note that planting density of potatoes can vary by EU member state or whether the potato is being grown for consumption as ware potatoes or for the production of seed potatoes. The representative use in potatoes supported for the renewal of flutolanil is at a planting rate of 4 tonnes potatoes/ha since this is considered representative of the majority of intended EU uses. Especially for seed potatoes which are often planted at higher densities the proposed GAP is unlikely to be realistic for all member states.

In Volume 3-AS, chapter B.8.5, the RMS provided a paragraph indicating how the literature search was carried out.

A list of metabolites observed in environmental fate testing is included below.

No.	Name, IUPAC CAS name, [CAS number] Structure	Molecular formula molar mass Other names / codes	Occurrence Major/Minor Compartment(s)
AS 1	Flutolanil α,α,α-trifluoro-3'-isopropoxy-*o*toluanilide 	SN 84364 NNF-136 S-837	All compartments, 100%
2	M4 α,α,α-trifluoro-3'-hydroxy-*o*-toluanilide 	DIP	Major in water (5.2%), system (6.8%) Minor in soil (3.0%)
3	M11 2-[3-(α,α,α-trifluoro-*o*-toluoylamino) phenoxy]propionic acid 	-	Major in water (6.9%), system (8.3%) Minor in soil (4.9%)

Metabolites M4 and M11 were considered as major metabolites in the surface water, because they were observed at two consecutive time points > 5% in the system resp. water compartments (Wyss-Benz, M. (1993), Pond system).

Additionally, metabolites M-2 (HFT), M-3 (HIP), M-5 (HDP), M-6, MDP, M-7, M-101 and M-102 were found as minor / transient metabolites in soil and or water.

B.8.1 Fate and behaviour in soil

Data on the active substance are evaluated in Volume 3 B.8.1 (AS). A summary of this information is provided here to assist exposure assessment.

In aerobic soil flutolanil degrades by the following reactions:

- Hydrolysis of ether bond to phenol at 3'-position (M-4 production from flutolanil, M-5 from M-2).
- Hydroxylation to form phenol at 4'-position (M-2 from flutolanil, M-5 from M-4, M-7 from M-6).
- Methylation of phenol at 3'-position (M-6 from M-4, M-7 from M-5).

- Oxidation of terminal methyl moiety of isopropyl part (M-3 and M-11 from flutolanil). The proposed metabolic pathway is shown below:

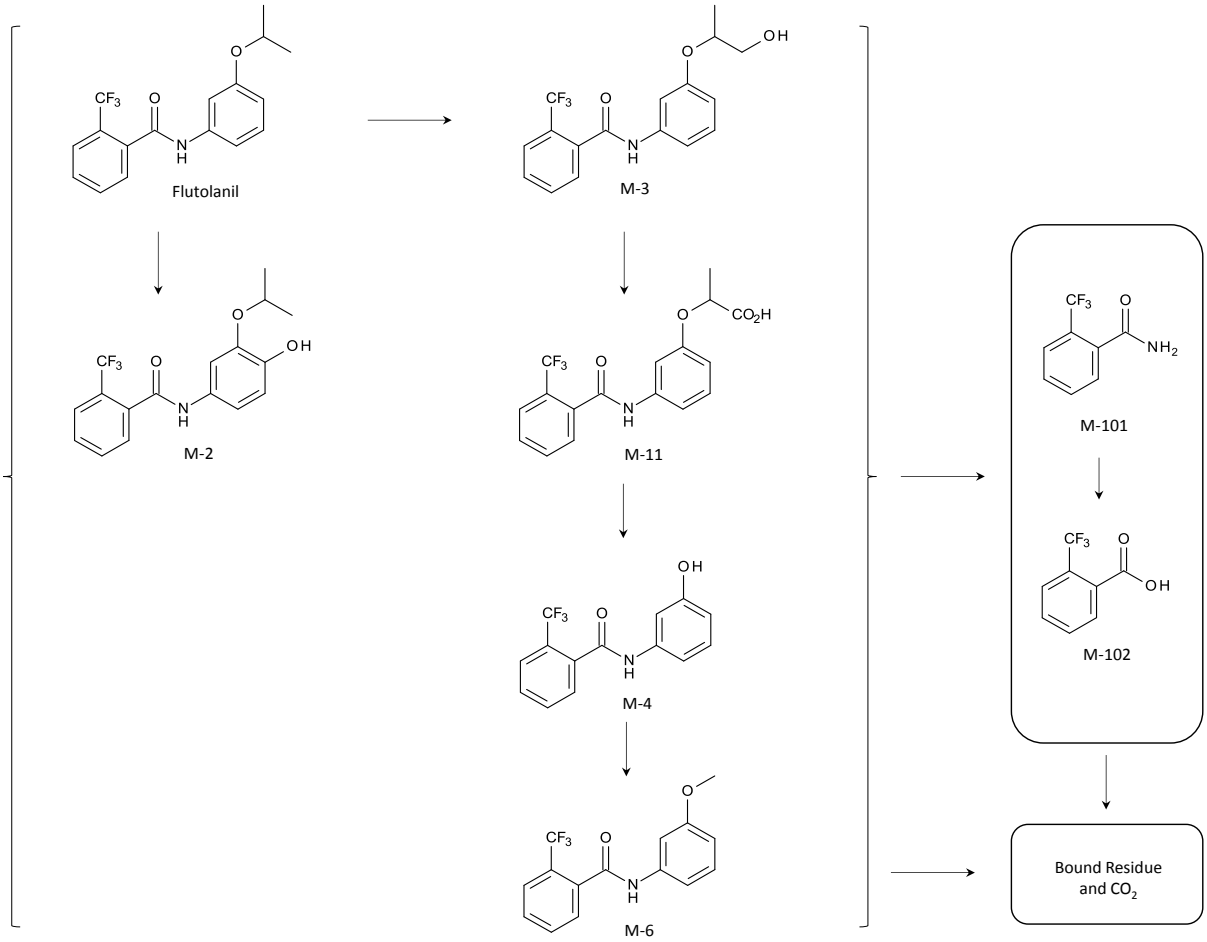


Figure 8.5.1-1 Aerobic route of degradation in soil

There were no major aerobic degradation metabolites at >10% or minor metabolites in soil >5% at 2 or more consecutive time points or >5% and increasing at the final timepoint in soil. Metabolite M4 was detected at max 3.0% and metabolite M11 was detected at max 4.9% AR (Takahashi, 2015).

RMS determined whether the databases of DegT50matrix values from laboratory and field studies can be treated as separate databases or whether they should be pooled. From the DegT50 excel sheet that is related to the EFSA guidance document[1] to obtain DegT50, the conclusion was that the test confirms that the field studies show shorter DegT50 than the laboratory studies. Therefore the field DegT50 results are used to derive the geometric mean modelling endpoint. It should be noted that tuber and spray application field DT_{50} values are combined. Based on the EFSA endpoint selector it has been established that these populations are statistically different (geomean tuber treatments is 148.5 days and geomean spray treatments is 74.9 days).

[1] European Food Safety Authority, 2014. EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662, 37 pp., doi:10.2903/j.efsa.2014.3662

The worst-case non-normalised field DT50 for tuber treatment was used for PEC soil calculation. If an authorisation with a spray application is requested, the worst-case spray non-normalised field DT50 of 211 days should be used.
Under anaerobic conditions only very limited degradation of flutolanil was observed.

Please refer to the table below for details.

Table B.8.1-1: EU endpoints for Flutolanil

Parameter	**Flutolanil**
Geometric mean field $DegT_{50}$ (days)	105
Maximum non-normalised field half-life (days) incorporation	342
Maximum non-normalised field half-life (days) spray	211
Geometric mean K_{FOC} (L/kg)	643
Arithmetic mean 1/n	0.9

B.8.2 Predicted environmental concentrations in soil (PEC_S)

For the PEC calculations, the following representative uses were considered.

Table B.8.2-1: Risk envelope representative GAP

Individual Crop	**FOCUS Crop Used for Interception**	**Application**				**Amount Reaching the Soil per Season**
		Rate per Season	**Frequency/Interval**	**Plant Interception[a]**	**BBCH Stage**	
		[g a.s. /ha]	**[days]**	**[%]**		**[g a.s. /ha]**
Potato	Potato	368	1/n.a.	0	00	368
Tulip & iris	Onions	2760	1/n.a.	0	00	2760

[a] Crop interception was included in line with Table 1.4 and 1.5 of EFSA Journal 2014 (3662), the DegT50 guidance document for evaluating laboratory and field dissipation studies. As application is before or at planting no interception is taken into account.
n.a. not applicable

The predicted environmental concentrations in soil (PEC_{soil}) for the active substance Flutolanil were calculated based on a simple first tier approach (Microsoft® Excel spreadsheet) assuming even distribution of the compound in the upper soil layer. A standard soil density of 1.5 g/cm^3 was assumed. The molecular weight, the maximum half-life and the maximum occurrence for Flutolanil are presented in Table B.8.2-2. The tuber half-life is applied for tulip and iris as well, this is conservative.
$PEC_{soil,\ actual}$ is presented using the default soil layer depth of 5 cm. Since the substance is incorporated over a 10-15 cm soil layer for the pre-planting use in tulips and iris, a PECsoil over 10 cm soil layer is also presented. See also Table B.8-1.

Table B.8.2-2: EU modelling endpoints for PEC_{soil} calculations

Parameter	Unit	Value	Comment
Flutolanil			
Molar mass	[g/mol]	323.3	-
Worst-case DT_{50}	[days]	342	Worst-case non-normalised field half-life in soil from treated tuber trials
Maximum occurrence in soil	[% AR]	n.a.	Parent substance
Molar mass correction factor	[-]	n.a.	-

The decline of Flutolanil following applications of the product was simulated using EXCEL spreadsheets according to FOCUS decline kinetics (Soil persistence models and EU Registration - The Final Report of the Soil Modelling Workgroup of FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use) – 29 February 1997). The following equations were applied.

[1] PEC_{soil} immediately after a single application ($PEC_{S,\ initial}$) was calculated using the following equation:

$$PEC_{S,\ initial}\ [mg/kg] = \frac{A[g/ha] \times (1 - F)}{100 \times d\ [cm] \times \rho\ [g/cm^3]}$$

Where:
A = Application rate

F = Fraction intercepted by crop

d = Depth of field soil layer (5 cm)

ρ = Dry bulk density (1.5 g/cm3)

This PEC value is used as the basis for the short and long term PEC calculations (after multiple applications). The $PEC_{S,\ initial}$ should not be confused with the actual PEC ($PEC_{s,actual}$, also expressed as PIEC), which is often used to describe the highest concentration. When only a single application takes place, the $PEC_{S,\ initial}$ is similar to the $PEC_{S,actual}$.

[2] The maximum ('moving window') time weighted average (TWA) PEC values are found by calculating a set of TWA PECs over a time window that is moved along the time axis. The average PEC within a day and the maximum average PEC over a timeframe are calculated by:

$$\text{Average PEC over a day [mg/kg]} = \frac{PEC_{S,\ initial} \times (1\text{-}e^{-kt})}{kt}$$

$$PEC_{twa,max}\ [mg/kg] = \frac{PEC_{S,\ actual,max} \times (1\text{-}e^{-kt})}{kt}$$

Where:
t = days after application
k = first order degradation/dissipation rate constant (ln(2)/half-life)
The maximum TWA over the moving window is calculated from the $PEC_{S,\ actual,max}$:

[3] The plateau concentration ($PEC_{S,plateau}$), i.e. the minimum concentration in soil before the first annual application, is provided for parent flutolanil. The persistence criterion has been triggered for this substance (max DT_{50} > 90 days), and hence the $PEC_{S,plateau}$ is provided. The $PEC_{S,plateau}$ is calculated as follows:

$$PEC_{S,plateau}\ [mg/kg] = PEC_{S,\ actual,max\ /}\ (1 - e^{(-365-((n-1)i)k)})$$

Where:
$PEC_{S,\ actual,max}$ = $PEC_{S,\ actual,max}$ calculated for 5 cm soil depth [mg/kg]
n = number of applications (-)
i = interval period between applications (days)

The plateau concentration in soil resulting from long-term use is calculated for a soil depth of 20 cm when soil incorporation by ploughing between application schemes could be expected (i.e. cereals).

[4] The peak accumulated PEC_S ($PEC_{S,peak\ accum}$) is calculated as the sum of the plateau concentration before the first annual application and the maximum actual PEC_S (calculated for 5 cm soil depth). This is often referred to as $PEC_{S,plateau,max.}$

$$PEC_{S,peak\ accum}\ [mg/kg] = PEC_{S,plateau} + PEC_{S,actual,max}$$

The results for Flutolanil ($PEC_{S,actual,max}$, $PEC_{S,TWA,}$ $PEC_{S,plateau\ and}$ $PEC_{S,peak\ accum}$) are shown in Table B.8.2-3.

Table B.8.2-3: Initial PEC, PEC_{TWA}, $PEC_{S,plateau}$ and $PEC_{S,peak\ accum}$ of Flutolanil (mg/kg) after application of Moncut 40SC

PECs (mg/kg)		Flutolanil					
		Potato (5 cm)		Tulip & iris (5 cm)		Tulip & iris (10 cm)	
Appl. rate		368		2760		2760	
Days after maximum		PEC	PEC_{TWA}	PEC	PEC_{TWA}	PEC	PEC_{TWA}
Initial	0	0.491	-	3.680	-	1.840	-
Short term	1	0.490	0.490	3.673	3.676	1.836	1.838
	2	0.489	0.490	3.665	3.673	1.833	1.836
	4	0.487	0.489	3.650	3.665	1.825	1.833
Long term	7	0.484	0.487	3.628	3.654	1.814	1.827
	14	0.477	0.484	3.577	3.628	1.789	1.814
	21	0.470	0.480	3.527	3.603	1.763	1.801
	28	0.464	0.477	3.477	3.578	1.738	1.789
	50	0.443	0.467	3.325	3.500	1.663	1.750
	100	0.401	0.444	3.005	3.331	1.502	1.666
$PEC_{S,plateau}$		0.112	-	0.840	-	0.840	-
$PEC_{S,peak\ accum}$		**0.603**	-	**4.520**	-	**2.641**	-

These PEC values are used as input for the ecotoxicological risk assessment in Volume 3-CP (PPP) B.9.

B.8.3 Predicted environmental concentrations in groundwater (PEC_{GW})

The predicted environmental concentrations in groundwater (PEC_{gw}) for the active substance Flutolanil were calculated using the simulation models PEARL (v4.4.4), PELMO (v5.5.3) and MACRO (v5.5.4) (scenario Châteaudun) following the recommendations of the FOCUS working group on groundwater scenarios.

The leaching calculations were run over 26 years, as proposed for pesticides which may be applied every year. The first six years are a 'warm up' period; only the last 20 years were considered for the assessment of the leaching potential. The 80th percentile of the average annual groundwater concentrations in the percolate at 1 m depth under a treated field were evaluated and were taken as the relevant PEC_{gw} values.

According to FOCUS, the calculations were conducted based on geometric mean soil half-lives, referenced to standard temperature and moisture conditions. Crop interception will reduce the amount of a compound reaching the soil and therefore this has been taken into account depending on the growth stage at application. The interception rates follow the FOCUS recommendations. The interception values as presented in the PECsoil section also apply for the groundwater PEC calculations. The amount reaching the soil is calculated by (100%-interception) x dosage and application is set to 'To the soil surface' as recommended in FOCUSgw guidance.

The representative GAP considered for the renewal application is shown in Table B.8-1

The compound-specific input parameters used in the assessments are fully justified in section Volume 3 B.8 (CA) and volume 1. These compound-specific inputs for PEC_{GW} are summarised in Table B.8.3-1.

Table B.8.3-1: Input parameters of Flutolanil for PEC_{gw} calculations

Parameter	Unit	Value	Comment
Flutolanil			
Molar mass	[g/mol]	323.3	-
Water solubility	[mg/L]	8.01	-
Vapour Pressure	[Pa]	4.1E-07	-
Plant uptake factor	[-]	0	Non-systemic
Walker Exponent	[-]	0.7	Default value
PEARL Parameters			
DT_{50}	[days]	105	Geometric mean field DT50, tuber and spray combined (n=8)
Molar Activation Energy	[kJ/mol]	65.4	Default
K_{foc}	[kg/L]	643	Geometric mean
Freundlich (1/n)	-	0.9	Default
PELMO Parameters			
Henry Coefficient	[J/mol]	1.65E-05	Henry = (VP)(MW)/(solubility)
Rate constant	[1/day]	0.00660	ln(2)/DT50
Q_{10}	[-]	2.58	Default value

The application pattern and application timings are described in Table B.8.3-2 and Table B.8.3-3 respectively. The dates of application for potatoes are based on the relative application scheme (FOCUS generic guidance 2.2, groundwater). The preferred application date of planting is not available in the groundwater models, and therefore the emergence – 15 days was selected as application date to define the planting date.

Since potatoes are incorporated into the soil, the corresponding application method is selected for modelling in PEARL. The incorporation depth is set at 10 cm.

Additionally, injection is selected for modelling. This method is normally selected to simulate application by fumigation, but the PEARL report [2] mentions that this method could be used to simulate the leaching of a treated planting material and/or in-furrow application. The injection depth is set at 10 cm. As this application method is not available in PELMO and MACRO only a PEARL simulation was done.

For flower bulbs, an absolute application date was selected: November 1st. This date is selected to represent the date of planting for most scenarios. A relative scheme, based on the emergence of the representative crop, was not realistic. Onions was chosen as surrogate FOCUS crop scenario for flower bulbs. This crop does not cover all scenarios, and hence no PECgw values are available for the proposed use in tulip and iris in Okehampton, Piacenza and Sevilla. For product registrations post-

[2] Alterra-rapport 013, Leistra et al., PEARL model for pesticide behaviour and emissions in soil-plant systems; Descriptions of the processes in FOCUS PEARL v 1.1.1.

Approval, MS might need to consider whether modelling using a (different) surrogate crop is required, if Okehampton, Piacenza and/or Sevilla is considered the relevant scenario for national assessments. Since this application concerns spraying and then immediate incorporation, the incorporation method was selected for modelling. The incorporation depth is set at 15 cm, since the substance is incorporated over a 10-15 cm soil layer for the pre-planting use in tulips and iris. This is conservative for the assessment of PECgw. See also Table B.8-1.

MACRO cannot directly simulate soil incorporation of plant protection products. It requires a plant protection product to be applied in a minimal amount of irrigation water (suggested 0.1 mm) to the soil surface. Therefore RMS applied an application rate of 368 g a.s. for potatoes and 2.76 kg a.s. for flower bulbs so that it equals the application rate in kg/ha (from the GAP). The groundwater scenario in MACRO does not further account for adjustments in incorporation depth. Similarly to modelling in PEARL, onions was chosen as a surrogate crop for flower bulbs.

Table B.8.3-2: Application pattern used for PEC_{gw} calculations of Flutolanil

Individual Crop	FOCUS Crop		Application				Amount Reaching the Soil per Season
	Interception [a]	Representative modelling crop	Rate per Season	Frequency/Interval	Plant Interception	BBCH Stage	
			[g a.s. /ha]	[days]	[%]		[g a.s. /ha]
Potatoes	Potatoes	Potatoes	368	1/n.a.	0	00-03	368
Flower bulbs	Onions	Onions	2760	1/n.a.	0	00	2760

[a] Crop interception was included in line with Table 1.4 and 1.5 of EFSA Journal 2014 (3662), the DegT50 guidance document for evaluating laboratory and field dissipation studies. As application is before or at planting no interception is taken into account.
n.a. not applicable

Table B.8.3-3: Application dates used for the simulation runs with Flutolanil

Individual crop	**Potato**	**Flower bulbs**
Repeat Interval for App. Events	**Every Year**	**Every Year**
Application Technique	**Soil incorporation/injection**	**Soil incorporation**
Scenario	**1st App. Date (relative date)**	**1st App. Date (Julian day)**
Chateaudun	Emergence date -15	1 November (304)
Hamburg	Emergence date -15	1 November (304)
Jokioinen	Emergence date -15	1 November (304)
Kremsmuenster	Emergence date -15	1 November (304)
Okehampton	Emergence date -15	Not available
Piacenza	Emergence date -15	Not available
Porto	Emergence date -15	1 November (304)
Sevilla	Emergence date -15	Not available
Thiva	Emergence date -15	1 November (304)

PEC_{gw} were evaluated as the 80th percentile of the mean annual leachate concentration at 1 m soil depth. PEC_{gw} values obtained with FOCUS PEARL, PELMO and MACRO for Flutolanil are given in tables Table B.8.3-4 until Table B.8.3-6. Values > 0.1 µg/L are marked bold.

Table B.8.3-4: FOCUS PEARL, PELMO and MACRO PEC_{gw} results of Flutolanil potato incorporation at 0.1 m. Values in bold exceed the 0.1 µg/L criterion.

Scenario	**Flutolanil**		
	PEARL	**PELMO**	**MACRO**
	[µg/L]	**[µg/L]**	**[µg/L]**
Chateaudun	<0.001	<0.001	<0.001
Hamburg	0.004	0.001	n.a.
Jokioinen	<0.001	<0.001	n.a.
Kremsmuenster	0.002	0.001	n.a.
Okehampton	0.003	0.003	n.a.
Piacenza	0.003	0.002	n.a.
Porto	<0.001	<0.001	n.a.
Sevilla	<0.001	<0.001	n.a.
Thiva	<0.001	<0.001	n.a.

n.a.= not assessed

Table B.8.3-5: FOCUS PEARL, PELMO and MACRO PEC_{gw} results of Flutolanil potato injection at 0.1 m. Values in bold exceed the 0.1 µg/L criterion.

Scenario	Flutolanil		
	PEARL	PELMO	MACRO
	[µg/L]	[µg/L]	[µg/L]
Chateaudun	<0.001	n.a.	n.a.
Hamburg	0.012	n.a.	n.a.
Jokioinen	<0.001	n.a.	n.a.
Kremsmuenster	0.007	n.a.	n.a.
Okehampton	0.009	n.a.	n.a.
Piacenza	0.009	n.a.	n.a.
Porto	<0.001	n.a.	n.a.
Sevilla	<0.001	n.a.	n.a.
Thiva	<0.001	n.a.	n.a.

n.a.= not assessed since this application method is not available in PELMO and MACRO

Table B.8.3-6: FOCUS PEARL, PELMO and MACRO PEC_{gw} results of Flutolanil flower bulbs incorporation at 0.15 m (onion used as a surrogate crop). Values in bold exceed the 0.1 µg/L criterion.

Scenario	Flutolanil		
	PEARL	PELMO	MACRO
	[µg/L]	[µg/L]	[µg/L]
Chateaudun	0.005	<0.001	<0.001
Hamburg	**0.345**	0.001	n.a.
Jokioinen	<0.001	<0.001	n.a.
Kremsmuenster	**0.216**	0.001	n.a.
Okehampton	n.a.	n.a.	n.a.
Piacenza	n.a.	n.a.	n.a.
Porto	0.025	<0.001	n.a.
Sevilla	n.a.	n.a.	n.a.
Thiva	<0.001	<0.001	n.a.

n.a.= not assessed

In general, PEARL results show higher PEC_{GW} than PELMO results. For the use in potatoes, flutolanil PEC_{GW} values are < 0.1 µg/L.

For the use in tulips & iris, flutolanil PEC_{GW} values are < 0.1 µg/L for the scenarios Chateaudun, Jokioinen, Porto and Thiva. For Hamburg and Kremsmuenster, leaching above the parametric limit of 0.1 µg/L is expected.

B.8.4 Fate and behaviour in water and sediment

Data on the active substance are detailed in Volume 3 B.8 (CA). A summary of this information is provided here to assist exposure assessment.

The fate and behaviour of flutolanil in aquatic systems has been investigated under abiotic and biotic conditions. Some studies were already evaluated during the previous EU review.

Flutolanil is hydrolytically stable in buffers at pH 5, pH 7 and pH 9, independent of the temperature.

The photolytic degradation of flutolanil in water has been investigated under sterile conditions in acetate buffer solutions at pH 7 for up to 30 days. Photolysis accelerates the degradation of flutolanil in aqueous buffer solutions at pH 7. The DT50 value based on individual replicate data of Tanaka (2016) was 231 days. The other photolysis study (Carpenter, 1991) did not present half lives according to FOCUS kinetics, but similar half lives were observed. Two known degradates M-101 and M-102 were identified as minor degradates, which accounted for 2.6 and 1.3% of AR after 24 days irradiation, several unknown degradates were detected but none of these accounted for greater than 2% of AR.

In four water / sediment systems (pH of water phase 6.8 - 8.3) flutolanil did not significantly mineralize. Flutolanil partitioned from the water phase into the sediment. Once in the sediment, parent continued to degrade over time. Flutolanil reached a maximum of 78.4% of applied radioactivity in the sediment at the end of the incubation period 98 days. Kinetic modelling analysis according to FOCUS Kinetics of the data from four aquatic sediment systems treated with flutolanil provided acceptable model fits, giving a geometric mean total system DegT50 value of **224** days. Trigger DT50 values for whole system, water and sediment were in the range 88.7-413, 4.49-50.4 and 91.9-1000 days, respectively, and trigger DT90 values were in the range 295-1480, 86.2->10000 and 305-3320 days, respectively.

No transformation products ≥10% AR were observed in the water or sediment layer for either radiolabel. Two major degradates of flutolanil were found: metabolite M-4, (α,α,α-trifluoro-3'-hydroxy-*o*-toluanilide) was found in the water at 5.2% AR%, without other timepoints at >5% and without an increasing tendency. However, the %AR for water + sediment (system) was >5% at two consecutive timepoints (max **6.8%**).

Metabolite M-11, (2-[3'-(α,α,α-trifluoro-*o*-toluamido)phenoxy]propionic acid) was found >5% at two consecutive timepoints (5.4% at day 61 and 6.9% AR at day 105) in the water compartment, and consequently >5% in the whole system as well (max **8.3**%). Additionally, very minor transformation products in the sediment were detected which reached maximum concentrations of < 5.0% AR.

B.8.5 Predicted environmental concentrations in surface water and sediment (PEC_{sw}, PEC_{sed})

B.8.5.1 PECsw modelling approach

The calculation of PEC values for the active substance was done according to FOCUS guidance.

$FOCUS_{sw}$ is a four step tiered approach:

Step 1: In this, the most conservative step, all inputs are considered as a single loading to the water body and a worst-case PEC_{sw} and PEC_{sed} is calculated.

Step 2: Individual loadings into the water body from different entry routes are considered. Scenarios are also considered for Northern and Southern Europe separately but no specific crop scenarios are defined.

Step 3: An exposure assessment using realistic worst-case scenarios is made. The scenarios are representative of agricultural conditions in Europe and consider weather, soil, crop and different water-bodies. Simulations use the models PRZM, MACRO and TOXSWA within the SWASH shell.

Step 4: PEC values are refined by considering mitigation measures or specific scenario descriptions on a case-by-case basis.

B.8.5.2 Predicted environmental concentrations in surface water (PEC_{SW}) and sediment (PEC_{SED})

For PEC_{sw} and PEC_{sed} calculations, the active substance flutolanil and its major metabolites M4 and M11 were considered.

The relevant entry routes of a compound into surface water were considered in these calculations. FOCUS Steps 1 & 2 (version 3.2) and SWASH 5.3 (including MACRO 5.5.4, PRIZM 4.3.1 and TOXSWA 4.4.3) are used to calculate PEC_{SW} and PEC_{SED} values for Flutolanil, M4 and M11.

Please refer to the tables below for the input parameters for Steps 1-2.

Table B.8.5-1: Substance parameters used for Flutolanil in surface water (and sediment) PEC calculations, STEPs 1-2.

Parameter	Unit	Value	Comment
Flutolanil			
Molar mass	[g/mol]	323.3	-
Water solubility	[mg/L]	8.01	-
K_{oc}	[mL/g]	643	Geometric mean
DT_{50} soil	[days]	105	Geometric mean field DT50
DT_{50} total system	[days]	224	Geometric mean whole system DT50
DT_{50} water	[days]	224	Geometric mean whole system DT50
DT_{50} sediment	[days]	224	Geometric mean whole system DT50
Maximum occurrence in water sediment systems	[% AR]	100	Parent substance
Maximum occurrence in soil	[% AR]	100	Parent substance

Table B.8.5-2: Substance parameters used for M4 in surface water (and sediment) PEC calculations, STEPs 1-2.

Parameter	Unit	Value	Comment
M4			
Molar mass	[g/mol]	281.2	-
Water solubility	[mg/L]	1000	Default not limiting

Parameter	Unit	Value	Comment
K_{oc}	[mL/g]	333	-
DT_{50} soil	[days]	1000	Default
DT_{50} total system	[days]	1000	Default
DT_{50} water	[days]	1000	Default
DT_{50} sediment	[days]	1000	Default
Maximum occurrence in water sediment systems	[% AR]	6.8	Maximum %AR of applied
Maximum occurrence in soil	[% AR]	3.0	Maximum % of observed (Takahashi).

Table B.8.5-3: Substance parameters used for M11 in surface water (and sediment) PEC calculations, STEPs 1-2.

Parameter	Unit	Value	Comment
M11			
Molar mass	[g/mol]	353.3	-
Water solubility	[mg/L]	1000	Default not limiting
K_{oc}	[mL/g]	1	worst-case for PECsw
DT_{50} soil	[days]	1000	Default
DT_{50} total system	[days]	1000	Default
DT_{50} water	[days]	1000	Default
DT_{50} sediment	[days]	1000	Default
Maximum occurrence in water sediment systems	[% AR]	8.3	Maximum %AR of applied
Maximum occurrence in soil	[% AR]	4.9	Maximum % of observed (Takahashi).

The following application pattern is evaluated: see table below.

Table B.8.5-2: General and FOCUS specific data on the use pattern of Flutolanil in Europe (for FOCUS Step 1&2)

Crop	Interval	Rate per Season	FOCUS crop (Crop group)	Season	Crop cover
	[days]	[g a.s. /ha]			
Potato	-	368	Potato	Mar-May	none
Tulip & iris	-	2760	Onion	Mar-May*	none

* the season Oct-Feb is more applicable for this use. Mar-May was suggested by the notifier. Since Step 3 was used for this assessment, it was not considered necessary to adjust.

FOCUS step 1 and 2

The maximum PEC_{sw} and PEC_{sed} values for FOCUS Step 1 and 2 (version 3.2) are given in the tables below for Flutolanil (Table B.8.5-3) and its metabolites M4 (Table B.8.5-4) and M11 (Table B.8.5-5).

Table B.8.5-3: PECsw and PECsed values for Flutolanil (FOCUS Steps 1-2)

Crop Usage	Scenario	Flutolanil					
		Initial		TWA			
		PEC_{sw}	PEC_{sed}	7d TWA_{sw}	7d TWA_{sed}	21d TWA_{sw}	21d TWA_{sed}
		[µg/L]	[µg/kg]	[µg/L]	[µg/kg]	[µg/L]	[µg/kg]
Potato 368 g a.s./ha No interception Spring (Mar. - May)	Step 1	66.04	424.67	65.33	420.10	63.94	411.16
	Step 2 N-EU	12.86	82.72	12.73	81.83	12.46	80.09
	Step 2 S-EU	25.73	165.44	25.45	163.66	24.91	160.18
Tulip & iris 2760 g a.s./ha No interception Spring (Mar. - May)	Step 1	495.33	3.18E+03	490.01	3.15E+03	479.58	3.08E+03
	Step 2 N-EU	96.49	620.40	95.45	613.73	93.42	600.67
	Step 2 S-EU	192.97	1.24E+03	190.90	1.23E+03	186.83	1.2E+03

Table B.8.5-4: PECsw and PECsed values for M4 (FOCUS Steps 1-2)

Crop Usage	Scenario	M4					
		Initial		TWA			
		PEC_{sw}	PEC_{sed}	7d TWA_{sw}	7d TWA_{sed}	21d TWA_{sw}	21d TWA_{sed}
		[µg/L]	[µg/kg]	[µg/L]	[µg/kg]	[µg/L]	[µg/kg]
Potato 368 g a.s./ha No interception Spring (Mar. - May)	Step 1	2.22	7.38	2.21	7.37	2.20	7.31
	Step 2 N-EU	0.44	1.47	0.44	1.47	0.44	1.46
	Step 2 S-EU	0.88	2.94	0.88	2.94	0.88	2.92
Tulip & iris 2760 g a.s./ha No interception Spring (Mar. - May)	Step 1	16.63	55.37	16.59	55.24	16.51	54.97
	Step 2 N-EU	3.32	11.04	3.31	11.02	3.29	10.96
	Step 2 S-EU	6.63	22.09	6.62	22.03	6.58	21.93

Table B.8.5-5: PECsw and PECsed values for M11 (FOCUS Steps 1-2)

Crop Usage	Scenario	M11					
		Initial		TWA			
		PEC_{sw}	PEC_{sed}	7d TWA_{sw}	7d TWA_{sed}	21d TWA_{sw}	21d TWA_{sed}
		[µg/L]	[µg/kg]	[µg/L]	[µg/kg]	[µg/L]	[µg/kg]
Potato 368 g a.s./ha No interception Spring (Mar. - May)	Step 1	5.36	0.05	5.34	0.05	5.28	0.05
	Step 2 N-EU	1.07	0.01	1.07	0.01	1.06	0.01
	Step 2 S-EU	2.14	0.02	2.13	0.02	2.12	0.02
Tulip & iris 2760 g a.s./ha No interception Spring (Mar. - May)	Step 1	40.16	0.40	40.07	0.40	39.87	0.40
	Step 2 N-EU	8.01	0.08	7.99	0.08	7.95	0.08
	Step 2 S-EU	16.02	0.16	15.98	0.16	15.91	0.16

Step 3

Since the established Koc for flutolanil amounted to 643 mL/g, two sets of evaluations were conducted according to FOCUS requirements. One evaluation considered a DegT50water 1000 days and DegT50sed 225 days (total system) and the other considered a DegT50water of 225 days (total system) and DegT50sed of 1000 days. From the two sets of results, the combined worst-case PEC for each compartment is reported.

Table B.8.5-6: **Chemical input parameters of Flutolanil for STEP 3.**

Step 3 assessment		
Parameter	Flutolanil	Remarks/reference
Physico-chemical parameters		
Molecular weight (g/mol)	323.3	-
Vapour pressure (Pa; 20°C)	4.1E-07	-
Solubility in water (mg/L; 20°C)	8.01	-
Degradation in soil		
$DegT_{50}$ soil (days; normalised to 20°C and pF2)	105	Geometric mean
Temperature correction function: Reference temperature (°C) TOXSWA activation energy (kJ/mol) MACRO exponent (1/K) PRZM Q_{10}	 20 65.4 0.0948 2.58	 FOCUS recommendation. EFSA recommendation. EFSA recommendation. EFSA recommendation.
Moisture correction function: Reference moisture Walker exponent (PRZM) Calibrated exponent (MACRO)	 pF2 0.7 0.7	FOCUS recommendation.
Degradation in water/sediment systems		
$DegT_{50}$ water (days)	224/1000	Geometric mean Level P-I whole system value
$DegT_{50}$ sediment (days)	1000/224/	
Sorption to soil, suspended solids and sediment		
K_{foc} (mL/g)	643	Geometric mean
K_{fom} (mL/g)	373	K_{foc} / 1.724
1/n	0.9	default
Crop parameters		
Crop uptake factor	0	FOCUS recommendation; worst-case default value.
Foliar half-life (days)	10	FOCUS default value.
Foliar washoff coefficient (m^{-1})	50	FOCUS default value.

The two major water metabolites were included in the simulations. These substances M4 and M11 were added via the metabolite scheme of SWASH.

Table B.8.5-7: **Chemical input parameters of metabolite M4 for STEP 3.**

Step 3 assessment		
Parameter	M4	Remarks/reference
Physico-chemical parameters		
Molecular weight (g/mol)	281.2	-
Vapour pressure (Pa; 20°C)	4.1E-07	parent value
Solubility in water (mg/L; 20°C)	1000	non-limiting default
Degradation in soil		
$DegT_{50}$ soil (days; normalised to 20°C and pF2)	1000	default
Temperature correction function: Reference temperature (°C) TOXSWA activation energy (kJ/mol) MACRO exponent (1/K) PRZM Q_{10}	 20 65.4 0.0948 2.58	 FOCUS recommendation. EFSA recommendation. EFSA recommendation. EFSA recommendation.
Moisture correction function: Reference moisture Walker exponent (PRZM) Calibrated exponent (MACRO)	 pF2 0.7 0.7	FOCUS recommendation.
Degradation in water/sediment systems		
$DegT_{50}$ water (days)	1000	Geometric mean Level M-I whole system value
$DegT_{50}$ sediment (days)	1000	
Occurrence		
Fraction transformed in soil compartment	0.03	Maximum occurrence soil
Fraction transformed in water compartment	0.068	Maximum occurrence water/sediment attributed to water
Fraction transformed in sediment compartment	0	
Sorption to soil, suspended solids and sediment		
K_{foc} (mL/g)	333	Geometric mean
K_{fom} (mL/g)	193	K_{foc} / 1.724
1/n	0.9	default
Crop parameters		
Crop uptake factor	0	FOCUS recommendation; worst-case default value.
Foliar half-life (days)	10	FOCUS default value.
Foliar washoff coefficient (m^{-1})	50	FOCUS default value.

Table B.8.5-8: **Chemical input parameters of metabolite M11 for STEP 3.**

Step 3 assessment		
Parameter	M11	Remarks/reference
Physico-chemical parameters		
Molecular weight (g/mol)	353.3	-
Vapour pressure (Pa; 20°C)	4.1E-07	parent value
Solubility in water (mg/L; 20°C)	1000	non-limiting default
Degradation in soil		
$DegT_{50}$ soil (days; normalised to 20°C and pF2)	1000	default
Temperature correction function: Reference temperature (°C) TOXSWA activation energy (kJ/mol) MACRO exponent (1/K) PRZM Q_{10}	 20 65.4 0.0948 2.58	 FOCUS recommendation. EFSA recommendation. EFSA recommendation. EFSA recommendation.
Moisture correction function: Reference moisture Walker exponent (PRZM) Calibrated exponent (MACRO)	 pF2 0.7 0.7	FOCUS recommendation.
Degradation in water/sediment systems		
$DegT_{50}$ water (days)	1000	Geometric mean Level M-I whole system value
$DegT_{50}$ sediment (days)	1000	
Occurrence		
Fraction transformed in soil compartment	0.049	Maximum occurrence soil
Fraction transformed in water compartment	0.083	Maximum occurrence water/sediment attributed to water
Fraction transformed in sediment compartment	0	
Sorption to soil, suspended solids and sediment		
K_{foc} (mL/g)	1	Worst-case for water compartment
K_{fom} (mL/g)	1	
1/n	1.0	
Crop parameters		
Crop uptake factor	0	FOCUS recommendation; worst-case default value.
Foliar half-life (days)	10	FOCUS default value.
Foliar washoff coefficient (m^{-1})	50	FOCUS default value.

Application scheme

For potatoes, incorporation was selected, at a depth of 10 cm. CAM 8 was selected (incorporation in soil at one depth).

For tulips, the crop vegetables – bulb, was selected for modelling. The application scheme of incorporation was selected as well, at a depth of 10 cm. CAM 4 was selected (uniform incorporation in soil). Additionally, in TOXSWA, the drift calculator was used to determine drift percentages following in-spray application/incorporation to flower bulbs. Runoff was not considered a significant route to include due to the application method.

The application timing used in the modelling are summarised in the tables below.

Table B.8.5-9: Application timing

Application timing	Parent factor	Number of applications	Application rate (g a.s./ha)	Interval (days)
-		1	368	-
		1	2760	-

For potatoes, the start of the application window is set 30 days prior to the emergence day of the crop. The end of the window is set at the emergence day.

For flower bulbs, the application window for all scenarios is set at the last three months of the year. Therefore the application window for the two D6 scenarios of tulips (flower bulbs) is identical.

Table B.8.5-10: Application dates potato and flower bulbs (Julian days in brackets)

Crop scenario	**Step 3 scenario**	**Application window**		
		Emergence day	**Start of application window**	**End of application window**
Potato 1x368 g a.s/ha	D3	10 May (130)	10 April (100)	10 May (130)
	D4	22 May (142)	21 April (111)	22 May (142)
	D6	10 April (100)	11 March (70)	10 April (100)
	D6	5 August (217)	6 July (187)	5 August (217)
	R1	5 May (125)	5 April (95)	5 May (125)
	R2	15 March (74)	13 February (44)	15 March (74)
	R3	10 April (100)	11 March (70)	10 April (100)
Flower bulbs 1x2760 g a.s/ha	D3	25 April	1 October (274)	31 December (365)
	D4	23 April	1 October (274)	31 December (365)
	D6	10 May	1 October (274)	31 December (365)
	D6	20 October	1 October (274)	31 December (365)
	R1	20 April	1 October (274)	31 December (365)
	R2	28 February	1 October (274)	31 December (365)
	R3	1 March	1 October (274)	31 December (365)
	R4	1 March	1 October (274)	31 December (365)

Step 3 results

The maximum PEC_{sw} and PEC_{sed} values for flutolanil, M4 and M11 for the relevant FOCUS Step 3 scenarios following application to potatoes are given below.

Table B.8.5-11: Step 3 PEC_{sw} and PEC_{sed} of flutolanil following seed treatment application to potatoes at 368 g ha^{-1}: $DegT_{50water}$ 224 days and $DegT_{50sed}$ 1000days

Application scenario	Scenario	Waterbody	Water DT_{50} = 224 d Sediment DT_{50} = 1000 d					
			Parent		M4		M11	
			PEC_{sw}, max [µg/L]	PEC_{sed}, max [µg/kg]	PEC_{sw}, max [µg/L]	PEC_{sed}, max [µg/kg]	PEC_{sw}, max [µg/L]	PEC_{sed}, max [µg/kg]
Potatoes	D3	ditch	<1E-06	<1E-06	1.E-06	1.E-05	1.814	1.209
1 x 368 g a.s/ha	D4	pond	0.027	0.224	0.013	0.088	2.795	1.994
BBCH 00	D4	stream	0.048	0.078	0.014	0.031	1.174	0.699
	D6 early	ditch	0.035	0.047	0.011	0.021	1.256	0.746
	D6 late	ditch	0.091	0.109	0.012	0.022	1.277	0.762
	R1	pond	<1E-06	<1E-06	<1E-06	<1E-06	<1E-06	<1E-06
	R1	stream	<1E-06	<1E-06	<1E-06	<1E-06	<1E-06	<1E-06
	R2	stream	<1E-06	<1E-06	<1E-06	<1E-06	<1E-06	<1E-06
	R3	stream	<1E-06	<1E-06	<1E-06	<1E-06	<1E-06	<1E-06

Table B.8.5-12: Step 3 PEC_{sw} and PEC_{sed} of flutolanil following seed treatment application to potatoes at 368 g ha^{-1}: $DegT_{50water}$ 1000 days and $DegT_{50sed}$ 224days

Application scenario	Scenario	Waterbody	Water DT_{50} = 1000 d Sediment DT_{50} = 224 d					
			Parent		M4		M11	
			PEC_{sw}, max [µg/L]	PEC_{sed}, max [µg/kg]	PEC_{sw}, max [µg/L]	PEC_{sed}, max [µg/kg]	PEC_{sw}, max [µg/L]	PEC_{sed}, max [µg/kg]
Potatoes	D3	ditch	<1E-06	<1E-06	2.E-06	1.E-05	1.814	1.209
1 x 368 g a.s/ha	D4	pond	0.027	0.222	0.013	0.088	2.795	1.994
BBCH 00	D4	stream	0.048	0.077	0.014	0.031	1.174	0.699
	D6 early	ditch	0.035	0.043	0.011	0.021	1.256	0.746
	D6 late	ditch	0.091	0.100	0.012	0.022	1.277	0.762
	R1	pond	<1E-06	<1E-06	<1E-06	<1E-06	<1E-06	<1E-06
	R1	stream	<1E-06	<1E-06	<1E-06	<1E-06	<1E-06	<1E-06
	R2	stream	<1E-06	<1E-06	<1E-06	<1E-06	<1E-06	<1E-06
	R3	stream	<1E-06	<1E-06	<1E-06	<1E-06	<1E-06	<1E-06

Table B.8.5-13: Maximum Step 3 PEC_{sw} and PEC_{sed} of flutolanil following seed treatment application to potatoes at 368 g ha^{-1}

Application scenario	Scenario	Waterbody	Combination of Table B.8.5-11 & Table B.8.5-12					
			Parent		M4		M11	
			PEC_{sw}, max [µg/L]	PEC_{sed}, max [µg/kg]	PEC_{sw}, max [µg/L]	PEC_{sed}, max [µg/kg]	PEC_{sw}, max [µg/L]	PEC_{sed}, max [µg/kg]
Potatoes	D3	ditch	<1E-06	<1E-06	2.E-06	1.E-05	1.814	1.209
1 x 368 g a.s/ha	D4	pond	0.027	0.224	0.013	0.088	2.795	1.994
BBCH 00	D4	stream	0.048	0.078	0.014	0.031	1.174	0.699
	D6 early	ditch	0.035	0.047	0.011	0.021	1.256	0.746
	D6 late	ditch	0.091	0.109	0.012	0.022	1.277	0.762
	R1	pond	<1E-06	<1E-06	<1E-06	<1E-06	<1E-06	<1E-06
	R1	stream	<1E-06	<1E-06	<1E-06	<1E-06	<1E-06	<1E-06
	R2	stream	<1E-06	<1E-06	<1E-06	<1E-06	<1E-06	<1E-06
	R3	stream	<1E-06	<1E-06	<1E-06	<1E-06	<1E-06	<1E-06

TOXWA drift calculator (version 1, from the SWASH GUI) was used to determine drift percentages following in-spray application/incorporation to flower bulbs. These drift percentages were added to the application schemes in TOXSWA.

Table B.8.5-14: Application patterns for $PEC_{sw/sed}$ calculations accounting for drift following in-spray application/incorporation to flower bulbs.

Waterbody	Drift %
Ditch	2.7593
Pond	0.8106
Stream	1.8562

Table B.8.5-15: Step 3 PEC_{sw} and PEC_{sed} of flutolanil following in-spray application/incorporation to flower bulbs at 2760g ha^{-1}: $DegT_{50water}$ 224 days and $DegT_{50sed}$ 1000 days

Application scenario	Scenario	Waterbody	Water DT_{50} = 224 d Sediment DT_{50} = 1000 d					
			Parent		M4		M11	
			PEC_{sw}, max [µg/L]	PEC_{sed}, max [µg/kg]	PEC_{sw}, max [µg/L]	PEC_{sed}, max [µg/kg]	PEC_{sw}, max [µg/L]	PEC_{sed}, max [µg/kg]
Flower bulbs	D3	ditch	24.99	10.11	0.001	0.002	12.750	8.883
1x2760 g a.s/ha	D4	pond	2.241	9.854	0.163	1.009	20.740	14.890
BBCH 00	D4	stream	14.95	0.748	0.158	0.339	8.330	5.148
	D6 early	ditch	25.25	33.74	0.097	0.219	7.209	4.037
	D6 late	ditch	25.25	33.74	0.097	0.219	7.209	4.037
	R1	pond	2.763	19.13	0.008	0.117	0.011	0.012
	R1	stream	12.51	4.648	0.014	0.009	0.045	0.002
	R2	stream	16.53	18.90	0.010	0.035	0.096	0.005
	R3	stream	17.49	6.009	0.021	0.018	0.055	0.003
	R4	stream	13.81	10.13	0.013	0.011	0.056	0.003

Table B.8.5-16: Step 3 PEC_{sw} and PEC_{sed} of flutolanil following in-spray application/incorporation to flower bulbs at 2760g ha^{-1}: $DegT_{50water}$ 1000 days and $DegT_{50sed}$ 224 days

Application scenario	Scenario	Waterbody	Water DT_{50} = 1000 d Sediment DT_{50} = 224 d					
			Parent		M4		M11	
			PEC_{sw}, max [µg/L]	PEC_{sed}, max [µg/kg]	PEC_{sw}, max [µg/L]	PEC_{sed}, max [µg/kg]	PEC_{sw}, max [µg/L]	PEC_{sed}, max [µg/kg]
Flower bulbs	D3	ditch	24.99	10.11	3.E-04	0.002	12.750	8.883
1x2760 g a.s/ha	D4	pond	2.242	9.899	0.161	0.986	20.740	14.880
BBCH 00	D4	stream	14.95	0.739	0.158	0.339	8.330	5.148

	D6 early	ditch	25.250	33.59	0.097	0.216	7.209	4.037
	D6 late	ditch	25.250	33.59	0.097	0.216	7.209	4.037
	R1	pond	1.965	11.36	0.004	0.034	0.004	0.002
	R1	stream	8.244	4.475	0.012	0.008	0.042	0.002
	R2	stream	3.032	18.650	0.009	0.034	0.096	0.005
	R3	stream	8.443	5.597	0.015	0.016	0.051	0.003
	R4	stream	13.81	10.01	0.008	0.008	0.048	0.003

Table B.8.5-17: Maximum Step 3 PEC_{sw} and PEC_{sed} of flutolanil following in-spray application/incorporation to flower bulbs at 2760g ha^{-1}

Application scenario	**Scenario**	**Waterbody**	**Combination of Table B.8.5-15& Table B.8.5-16**					
			Parent		**M4**		**M11**	
			PEC_{sw}, max [µg/L]	**PEC_{sed}, max [µg/kg]**	**PEC_{sw}, max [µg/L]**	**PEC_{sed}, max [µg/kg]**	**PEC_{sw}, max [µg/L]**	**PEC_{sed}, max [µg/kg]**
Flower bulbs	D3	ditch	24.99	10.11	0.001	0.002	12.75	8.883
1x2760 g a.s/ha	D4	pond	2.242	9.899	0.163	1.009	20.74	14.89
BBCH 00	D4	stream	14.95	0.748	0.158	0.339	8.33	5.148
	D6 early	ditch	25.25	33.74	0.097	0.219	7.209	4.037
	D6 late	ditch	25.25	33.74	0.097	0.219	7.209	4.037
	R1	pond	2.763	19.13	0.008	0.117	0.011	0.012
	R1	stream	12.51	4.648	0.014	0.009	0.045	0.002
	R2	stream	16.53	18.9	0.01	0.035	0.096	0.005
	R3	stream	17.49	6.009	0.021	0.018	0.055	0.003
	R4	stream	13.81	10.13	0.013	0.011	0.056	0.003

For M11, the step 3 results are higher than the step 2 results. This is due to the unknown sorption of this substance which was set at 1 L/kg, enabling high drainage.

These PEC values are used as input for the ecotoxicological risk assessment in Volume 3-CP (PPP) B.9.

B.8.6 Fate and behaviour in air

B.8.6.1 Route and rate of degradation in air and transport via air

B.8.6.2 Predicted environmental concentrations from airborne transport

No PEC_{AIR} is calculated for Flutolanil since it is not volatile. Due to the predicted rapid degradation of Flutolanil in air there is low potential for long-range transport via air. The concentrations of Flutolanil in air is likely to be negligible.

No further work is necessary.

B.8.7 Predicted environmental concentrations from other routes of exposure

There are no other routes of exposure if the product is used according to good agricultural practice. Therefore no further estimations are considered necessary.

B.8.8 References relied on

Scientific peer-reviewed open literature search

Please refer to Volume 3 CA, B.8.5.1

Reference list

Reference	Author	Year	Title	Vertebrate Study [Y/N]	Data Protection claimed [Y/N]	Justification	Owner
CP 9.2.4.1-01	Hardy, I., & Jastrzebski, N.	2016b	Predicted Environmental Concentrations in Groundwater (PECgw) for Flutolanil Following Application to Potatoes and Flower Bulbs Report: XG/15/023E	N	N	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co., Ltd
CP 9.2.5-01	Hardy, I., & Agostini, F.	2016a	Predicted Environmental Concentrations in Surface Water (PECsw) and Sediment (PECsed) for Flutolanil Following Seed Treatment Application to Potatoes - Steps	N	N	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co., Ltd
CP 9.2.5-02	Hardy, I., & Agostini, F.	2016b	Predicted Environmental Concentrations in Surface Water (PECsw) and Sediment (PECsed) for Flutolanil Following Seed Treatment Application to Potatoes - FOCUSsw Step 3	N	N	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co., Ltd
CP 9.2.5-03	Hardy, I., & Agostini, F.	2016c	Predicted Environmental Concentrations in Surface Water (PECsw) and Sediment (PECsed) for Flutolanil Following Spray Application/Incorporation to Bulbs - Steps	N	N	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co., Ltd
CP 9.2.5-04	Hardy, I., & Agostini, F.	2016d	Predicted Environmental Concentrations in Surface Water (PECsw) and Sediment (PECsed) for Flutolanil Following Spray Application/Incorporation to flower bulbs -	N	N	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nihon Nohyaku Co., Ltd