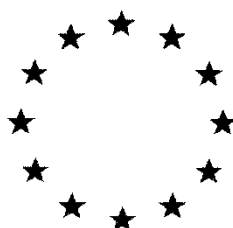


European Commission



**Draft Assessment Report prepared according to the Commission
Regulation (EU) N° 1107/2009**

BAS 750F

Volume 3 – B.8 (PPP) – BAS 750 01 F

Rapporteur Member State : United Kingdom
Co-Rapporteur Member State : France & Austria

Version History

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Table of contents

B.8. ENVIRONMENTAL FATE AND BEHAVIOUR	4
B.8.1. FATE AND BEHAVIOUR IN SOIL	4
B.8.1.1. Route and rate of degradation in soil	5
B.8.1.2. Mobility in soil	5
B.8.2. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SOIL (PEC_S)	5
B.8.2.1. BAS 750 F	5
B.8.2.2. 1,2,4- triazole	6
B.8.3. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN GROUND WATER (PEC_{GW})	7
B.8.4. FATE AND BEHAVIOUR IN WATER AND SEDIMENT	15
B.8.4.1. Aerobic mineralisation in surface water	15
B.8.4.2. Water/sediment study	15
B.8.4.3. Irradiated water/sediment study	15
B.8.5. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SURFACE WATER AND SEDIMENT (PEC_{SW}, PEC_{SED})	15
B.8.6. FATE AND BEHAVIOUR IN AIR	37
B.8.6.1. Route and rate of degradation in air and transport via air	37
B.8.6.2. Predicted environmental concentrations from airborne transport	37
B.8.7. PREDICTED ENVIRONMENTAL CONCENTRATIONS FROM OTHER ROUTES OF EXPOSURE	37
B.8.8. REFERENCES RELIED ON	37

B.8. ENVIRONMENTAL FATE AND BEHAVIOUR

BAS 750 01 F is the representative formulation supporting the application for the approval of the active substance BAS 750 F in Europe. Environmental exposure assessments were conducted for BAS 750 F based on the intended use pattern (table 8.1).

Table 8.1: Intended application pattern in EU member states

Crop	Wheat
Timing of Application (BBCH)	30 – 69
Max number of treatments	2
Min interval between applications (days)	14
Application rate (g/ha)	150

Based upon the Volume 3- B.8 (AS), the following endpoints have been determined to be appropriate for use within PEC calculations.

Table 8.2: Endpoints used for PEC calculations for BAS 750F and its metabolites 1,2,4- triazole

Input Parameter	Unit	BAS 750 F	1,2,4- triazole
Physio-Chemical Parameters			
Molar mass	g/ mol	397.8	69.1
Molar correction factor	-	-	0.174
Water Solubility (20 °C, pH 7)	mg/L	0.81	700000
Saturated Vapour pressure (20 °C)	Pa	3.2×10^{-6}	0.22
PEC_{soil} Calculations			
Max occurrence in soil	%	-	5.2
Soil DegT ₅₀ (SFO) longest non-normalised field value	d	846.6	
PEC_{gw} calculations			
Soil DegT ₅₀ (geometric mean of normalised field values)	d	200	
Soil degradation parameters for DFOP model			
DT ₅₀ fast phase	d		1.68 ^a
DT ₅₀ slow phase	d		60.5 ^a
g			0.489 ^b
PEC_{sw} calculations			
Soil DegT ₅₀ (geometric mean)	d	200	-
DT ₅₀ water, sediment (geometric mean)	d	163.4	1000
DT ₅₀ water (FOCUS default)	d	1000	1000
DT ₅₀ sediment (geometric mean)	d	163.4	1000

^a Geometric mean of normalised field DT₅₀ (20°C, pF2)

^b Arithmetic mean

Unless stated otherwise the calculations presented are considered to be acceptable by the RMS.

B.8.1. FATE AND BEHAVIOUR IN SOIL

Aerobic soil metabolism demonstrated a simple metabolic profile of BAS 750 F in soil. The degradation of BAS 750 F in aerobic soil systems shows little mineralisation. No major metabolites occurred in soil degradation

studies with the parent. Two minor metabolites, M750F001 (1,2,4-triazole) and M750F003, were observed during the aerobic soil metabolism studies in very low amounts. Both did not reach levels above 5% except for one single measurement in one soil, where 1,2,4-triazole reached a maximum level of 5.1% at day 90 (mean of two replicates) with subsequent decline. Hence, for metabolites of BAS 750 F, PEC_{soil} calculations are not required. However, because 1,2,4-triazole is a potential common metabolite of azole fungicides, it is included in the residue definition for risk assessment to address potential regulatory interest. For further information, see Volume 3CA, Section B-8 of the DAR.

B.8.1.1. Route and rate of degradation in soil

No formulation specific studies were performed. For details on the active substance and its metabolites, please refer to Volume 3CA, Section B-8.

B.8.1.2. Mobility in soil

No formulation specific studies were performed. For details on the active substance and its metabolites, please refer to Volume 3CA, Section B-8.

B.8.2. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SOIL (PEC_s)

B.8.2.1. BAS 750 F

B.8.2.1.1. PEC_{soil} -Initial

Report:	CP 9.13/1 Pape L., 2016a Predicted environmental concentrations of BAS 750F and its metabolite 1,2,4-triazole in soil following application to cereals 2015/1260841
Guidelines:	FOCUS Kinetics (2006) SANCO 10058/2005 version 1.1 of Dec. 2014, Generic Guidance for Tier 1 Ground Water Assessments version 2.2
GLP	No

The applicant performed first tier calculations of PEC_{soil} using Excel spreadsheets. The application scheme considered within the calculations is 2 x 150g a.s. /ha with a 14 day interval; this is in line with the proposed GAP. Within the calculations a crop interception of 80% was considered; as considered appropriate¹ for winter and spring cereals at the earliest proposed growth stage application (BBCH 30). The DegT50 value was set to 846.6 days (longest non-normalised field dissipation value).

Considering a soil bulk density of 1.5g/cm³ and a soil depth of 5cm the maximum PEC_{soil} for BAS 750 was calculated to be 0.080 mg/Kg; the full results are presented within table 8.2.1.1.1.

Table 8.2.1.1.1: PEC_{soil} (mg/kg) following application of 2 x 150g a.s./ ha to cereals at BBCH 30

Time (days)	After first application		After second application	
	$PEC_{soil, act}$	$PEC_{soil, twa}$	$PEC_{soil, act}$	$PEC_{soil, twa}$
	0.040	0.040	0.080	0.080
1	0.040	0.040	0.079	0.080
2	0.040	0.040	0.079	0.079
4	0.040	0.040	0.079	0.079
7	0.040	0.040	0.079	0.079

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

14	0.040	0.040	0.079	0.079
21	0.039	0.040	0.078	0.079
28	0.039	0.040	0.078	0.079
48	0.038	0.039	0.076	0.078
100	0.037	0.038	0.073	0.076

B.8.2.1.2. PEC_{soil} -Accumulation

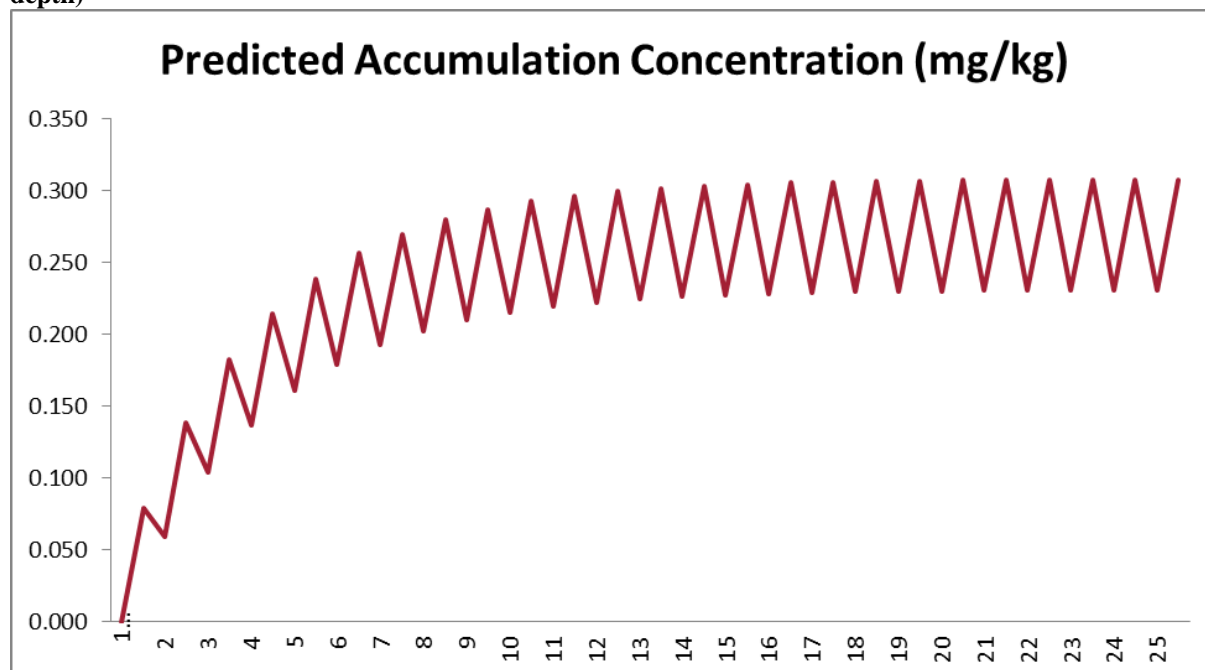
As the field dissipation DegT90 of BAS 750 F is greater than 1 year (365 days) PEC_{soil} accumulation values must be determined.

The applicant calculated the long term PEC_{soil} after repeated application, considering a mixing depth of 20cm. For this mixing depth to be considered the management of the crop must involve soil mixing to 20cm on an annual basis; this is not expected for cereal crops. Therefore calculations should consider accumulation in the top 5cm of soil.

As within the above calculation, the application scheme was set to 2 x 150g a.s. /ha (14 day interval) with 80% crop interception. Considering a soil bulk density of 1.5g/cm³ and a soil depth of 5cm the plateau peak concentration was calculated to be 0.308 mg/kg; reached after 23 years of continuous use, where the DegT50 value was set to 846.6 days (see figure 8.2.1.2.1).

The RMS rejected the applicants' calculations where a tillage depth of 20cm was considered as cereals are not routinely ploughed to 20cm on a yearly basis. In subsequent evaluations where national management of the required crop involves mixing to 20cm on an annual basis a mixing depth of 20cm could be considered as part of the assessment.

Figure 8.2.1.2.1: RMS predicted concentrations in the soil after repeated applications (assuming 5cm soil depth)



B.8.2.2. 1,2,4- triazole

Due to uncertainties surrounding the formation and decline of metabolites, it is considered appropriate to calculate metabolite PEC_{soil} values on the basis of a single application of the maximum total dose, taking into account peak occurrence, molecular weight correction and crop interception.

The applicant did not follow this approach within their submission. The RMS re-calculated the PEC value for 1,2,4 triazole following the total dose approach. The total dose was calculated to be 2.7 g/ha; based upon a.s. total dose of 300g a.s. /ha 5.1% maximum occurrence and a molar correction factor of 0.174. The resulting PEC_{soil} value, considering 80% crop interception; a soil bulk density of 1.5g/cm³ and a soil depth of 5cm the maximum was calculated to be 0.001 mg/kg.

PEC_{soil} accumulation values are not required for the metabolite 1,2,4-triazole.

B.8.3. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN GROUND WATER (PEC_{gw})

Report:	CP 9.2.4.1/2 Pape L., 2016a Predicted environmental concentrations of BAS 750F and its metabolites in groundwater following application to cereals 2016/1237569
Guidelines:	FOCUS Ground Water Report SANCO/321/2000 rev. 2, FOCUS groundwater (2014): SANCO/13144/2010 v3 of 2014, Generic Guidance for Tier 1 FOCUS Ground Water Assessments version 2.2, FOCUS Kinetics (2006) SANCO/ 10058/2005 version 1.1 of Dec 14
GLP	No

Groundwater modelling was performed for use of BAS 750 F at all relevant scenarios for spring and winter cereals, using the models FOCUS-PEARL 4.4.4, FOCUS-PELMO 5.5.3 and FOCUS-MACRO5.5.4. Modelling was performed for the parent compound (BAS 750 F) and the soil metabolite 1,2,4,- triazole.

Within the modelling BAS 750 F was applied every year, for 20 years (with a 6-year warm up period). The application scheme considered within the calculations is 2 x 150g a.s. /ha with a 14 day interval; this is in line with the proposed GAP. Within the calculations a crop interception of 80% was considered; as considered appropriate² for winter and spring cereals at the earliest proposed growth stage application (BBCH 30). Within the modelling both spring and winter cereals are considered, this is appropriate for winter and spring wheat applications.

For spring cereals the first application date at BBCH 30 was set to 28 days after emergence, this is considered appropriate. For winter cereals the application dates, absolute values were required to be considered, the applicant considered these dates on a zonal basis (table 8.3.1). The applicant explained that for winter cereals the AppDate tool does not adequately reflect the dormancy period; due to the dormancy period it is considered that a harmonised relative application date could not be produced. The applicant elected to consider the dates on a zonal basis, to increase harmonisation with the dates considered within the surface water modelling (CP B.8.5) and assigning specific dates for each scenario is not proven to be more accurate and the exact application time can vary considerably between years depending on actual weather conditions. Overall the RMS is of the opinion that the dates selected and approach taken are acceptable.

The application scenario and application dates considered within the modelling are summarised within table 8.3.1.

Table 8.3.1: Application scenario for BAS 750 F applied to cereals considered within the PEC _{gw} calculations	
Crop	Cereals
FOCUS _{gw} crop	Spring and winter cereals
Crop growth stage at the first application [BBCH]	30
Max no. of applications [-]	2
Maximum interval [d]	14
Application rate [g a.s./ha]	150
Interception [%]	80/80

² 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

Amount reaching the soil surface [g a.s. /ha]	30/30	
Total yearly soil load [g a.s. /ha]	60	
Application dates Spring cereal		
	1 st application	2 nd application
Châteaudun	7 th April (97)*	21 st April (111)*
Hamburg	29 th April	13 th May
Jokioinen	15 th June	29 th June
Kremsmünster	29 th April	13 th May
Okehampton	29 th April	13 th May
Porto	7 th April	21 st April
Application dates winter cereals		
	1 st application	2 nd application
Châteaudun	1 st May (121)*	15 th May (135)*
Hamburg	1 st May	15 th May
Jokioinen	1 st June	15 th June
Kremsmünster	1 st May	15 th May
Okehampton	1 st May	15 th June
Piacenza	15 th March	29 th March
Porto	15 th March	29 th March
Sevilla	15 th March	29 th March
Thiva	15 th March	29 th March
* In brackets: Julian day used for FOCUS MACRO calculations		

The assessment has been categorised into four tiers, where the lowest tier results in the most conservative risk assessment, with the higher tiers being refined by optimising the input data by considering bi-phasic degradation of the metabolite 1,2,4- triazole and altering the formation fraction from the default value of 1. Considering the available data sets, the following formation fractions were calculated; for full details please refer to CA B.8.1.1.1.1.

Table 8.3.2: Estimated formation of 1,2,4-triazole	
Soil	Formation fraction of 1,2,4-triazole
LUFA 5M (loamy sand)	0.12
New Jersey (Loam)	0.65
Li 10 (Loam sand)	0.42
Indiana (Loam)	0.42
Arithmetic mean	0.40

The first tier was conducted by the RMS and does not take into account the bi-phasic behaviour of the metabolite 1,2,4 triazole nor any alteration to the default formation fraction (1). Within the modelling the 1,2,4-triazole DT₅₀ value was set to the slow phase DT₅₀ (60.5 days). The input parameters are summarised within table 8.3.5 and 8.3.6.

Tiers 2-4 take into account the bi-phasic degradation of 1,2,4-triazole, and introduce the formation fraction refinements in a stepwise process.

The degradation behaviour of 1,2,4-triazole is described with DFOP kinetics³. The fraction of the metabolite formed from the parent was divided into two compartments, i.e. one fast degrading and one slow degrading compartment. For each compartment, the corresponding rate of the DFOP model was considered as degradation endpoint. The formation fraction of the metabolite was multiplied with the parameter g of the DFOP model for fast degrading compartment and with (1-g) for the slow degrading compartment. The total PEC_{gw} of the

³ CRD (2014): Triazole Derived Metabolite: 1,2,4-Triazole. Proposed revision to DT₅₀ Summary, Scientific Evaluation and Assessment July 2011, revised September 2011 (after comments from MS and EFSA) and further revised January 2013 (minor clarifications added post-commenting)

metabolite was calculated by adding the PEC_{gw} of the two compartments. In order to minimise the influence of non-linear sorption of the metabolite, the amount of active substance applied was doubled and the predicted concentrations of parent and metabolite in leachate were divided by 2. The compartment model considered for the calculation is shown in Figure 8.3.1.

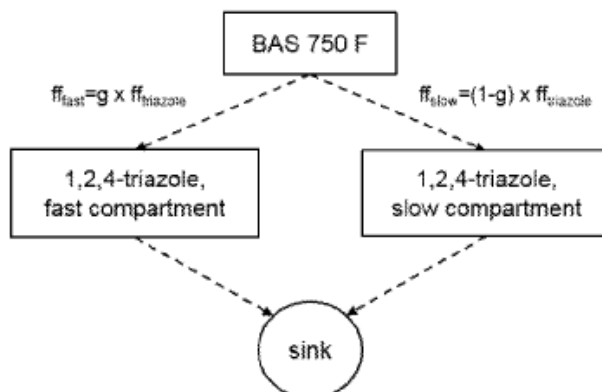


Figure 8.3.1: Compartment model of BAS 750 F and 1,2,4-triazole considered for the PEC_{gw} calculations.

For the FOCUS-PEARL and FOCUS-PELMO calculations, the parent substance and the metabolite were considered together in one run as describes above; the input parameters are summarised within table 8.3.5 and 8.3.6.

For the FOCUS-MACRO calculations, the metabolite was calculated as ‘parent equivalent’, i.e. the application rate of the parent was corrected taking into account the molar correction factor of the metabolite and formation fraction of the metabolite. In accordance with the above compartmental model two model runs were performed: one run corresponding to the fast degrading compartment where the metabolite application rate was multiplied with the parameter ‘g’ and corresponding to the slow degrading compartment where the metabolite application rate was multiplied with (1-g). As for the calculations with the other models, the metabolite application rate was doubled, and the concentration calculated by dividing the total metabolite concentration (fast + slow) by 2. The application rates considered within FOCUS-MACRO are summarised within table 8.3.4.

Table 8.3.4: MACRO Groundwater application rate calculations

Molecular Weight- BAS 750 F	397.8 g/mol	g	0.489
Molecular weight- 1,2,4 –triazole	69.1 g/mol	1-g	0.511
Formation Fraction	1	0.65	0.4
Equivalent application rate- Fast Phase	5.096516 g/ha	3.312735 g/ha	2.038606 g/ha
Equivalent application rate- Slow Phase	5.325807 g/ha	3.461775 g/ha	2.130323 g/ha

The results indicate that the tier 1 calculations conducted by the RMS are sufficient to indicate that risk of groundwater contamination of BAS 750 F and 1,2,4- triazole at $>0.1 \mu\text{g.L}$ from the proposed use of BAS 750 01 F is unlikely. However to aid the discussion on setting the formation fraction for 1,2,4-triazole (from BAS 750 F) the RMS have considered and validated the additional tiers presented by the applicant.

The input parameters considered within all modelling is presented within table 8.3.5 and 8.3.6.

Table 8.3.5: Overview of input parameters for BAS 750 F used for the leaching simulation models PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4

Input parameter	Unit	Value	Remarks
PHYSIO-CHEMICAL PARAMETERS			
Molecular mass	[g/ mol]	397.8	Phys-chem. properties
Water solubility (20 °C, pH 7)	[mg/ L]	0.81	Phys-chem. properties
Molar enthalpy of dissolution	[kJ/ mol]	27	FOCUS recommendation
Saturated Vapour pressure (20 °C)	[Pa]	3.2 x 10 ⁻⁶	Phys-chem. properties
Molar enthalpy of vaporization	[kJ/ mol]	95	FOCUS recommendation
Diffusion coefficient in water (20 °C)			FOCUS recommendation
PEARL	m ² /d	4.3 x 10 ⁻⁵	
MACRO	m ² /s	5 x 10 ⁻¹⁰	
Diffusion coefficient in gas (20 °C)			FOCUS recommendation
PEARL	m ² /d	0.43	
PELMO	cm ² /s	0.05	
DEGRADATION PARAMETERS			
DegT ₅₀ soil at reference conditions: geometric mean of normalised field values (20 °C, pF2)	[d]	200	Geometric mean of normalised field values (n=6)
PELMO transformation rate to 1,2,4- triazole			
No biphasic consideration	Tier 1	0.00346567	Calculated as ln(2)/DegT ₅₀ x metabolite formation fraction
To fast degrading compartment	Tier 2	0.00169474	Calculated as ln (2)/ DegT ₅₀ x metabolite formation fraction x parameter g
	Tier 3	0.00110158	
	Tier 4	0.00067790	
To slow degrading department	Tier 2	0.00177099	Calculated as ln (2)/ DegT ₅₀ x metabolite formation fraction x parameter (1- g)
	Tier 3	0.00115114	
	Tier 4	0.00070840	
PELMO transformation rate to SINK	Tier 1	0	Calculated as (ln(2)/ DegT ₅₀)– total metabolite transformation rate
	Tier 2	0	
	Tier 3	0.00121301	
	Tier 4	0.00207944	
Molar activation energy (PEARL)	[kJ/ mol]	65.4	EFSA recommendation
Q ₁₀ (PELMO)	[-]	2.58	EFSA recommendation
Temperature correction exponent (MACRO)	[K ⁻¹]	0.0948	EFSA recommendation
Exponent of moisture correction function			
PEARL, PELMO	[-]	0.7	FOCUS recommendation
MACRO		0.49	
SORPTION PARAMETERS			
K _{oc}	[mL/ g]	3455.6	Geometric mean (n=8)
K _{om}	[mL/ g]	2004.4	Calculated as K _{om} = K _{oc} / 1.724
Freundlich exponent 1/n	[-]	0.975	Arithmetic mean (n = 8)
Method of subroutine description	[-]	pH independent	-
CROP RELATED PARAMETERS			
TSCF (crop uptake)	[-]	0	FOCUS recommendation

Table 8.3.6: Overview of input parameters for 1,2,4-triazole used for the leaching simulation models PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4				
Input parameter		Unit	Value	Remarks
PHYSIO-CHEMICAL PARAMETERS				
Molecular mass		[g/ mol]	69.1	Phys-chem. properties
Water solubility (20 °C, pH 7)		[mg/ L]	700000	Phys-chem. properties
Molar enthalpy of dissolution		[kJ/ mol]	27	FOCUS recommendation
Saturated Vapour pressure (20 °C)		[Pa]	0.22	Phys-chem. properties
Molar enthalpy of vaporization		[kJ/ mol]	95	FOCUS recommendation
Diffusion coefficient in water (20 °C)				
PEARL		m²/d	4.3 x 10 ⁻⁵	FOCUS recommendation
MACRO		m²/s	5 x 10 ⁻¹⁰	
Diffusion coefficient in gas (20 °C)				
PEARL		m²/d	0.43	FOCUS recommendation
PELMO		cm²/s	0.05	
DEGRADATION PARAMETERS				
DT ₅₀ soil at reference conditions: (20 °C, pF2)				
Fast degrading compartment		[d]	1.68	Geometric mean of normalised values (n=4) ⁴
Slow degrading compartment		[d]	60.50	
Fraction in fast degrading compartment (g)		[-]	0.489	Arithmetic mean (n=4)
Formation Fraction from parent				
Tier 1:		[-]	1	Default
Tier 2		[-]	1	Default
Tier 3		[-]	0.65	Worst case
Tier 4		[-]	0.40	Arithmetic mean (n=4)
PEARL formation fractions				
Tier 1		[-]	1	
To fast degrading compartment	Tier 2	[-]	0.489	Formation fraction x parameter (1*g)
	Tier 3		0.318	
	Tier 4		0.196	
To slow degrading compartment	Tier 2	[-]	0.511	Formation fraction x parameter (1-g)
	Tier 3		0.332	
	Tier 4		0.204	
MACRO formation fraction		[-]	-	Calculated as parent-equivalent
PELMO transformation rates to SINK				
Fast degrading compartment		[d ⁻¹]	0.412588	Calculated as ln(2)/DT ₅₀
Slow degrading compartment		[d ⁻¹]	0.011457	
Molar activation energy (PEARL)		[kJ/ mol]	65.4	EFSA recommendation
Q ₁₀ (PELMO)		[-]	2.58	EFSA recommendation
Temperature correction exponent (MACRO)		[K ⁻¹]	0.0948	EFSA recommendation

⁴ CRD (2014): Triazole Derived Metabolite: 1,2,4-Triazole. Proposed revision to DT₅₀ Summary, Scientific Evaluation and Assessment July 2011, revised September 2011 (after comments from MS and EFSA) and further revised January 2013 (minor clarifications added post-commenting)

Exponent of moisture correction function			
PEARL, PELMO	[-]	0.7	FOCUS
MACRO		0.49	recommendation
SORPTION PARAMETERS			
K _{oc}	[mL/ g]	89.0	Arithmetic mean (n=4)
K _{om}	[mL/ g]	51.6	Calculated as K _{om} = K _{oc} /1.724
Freundlich exponent 1/n	[-]	0.916	Arithmetic mean (n = 4)
Method of subroutine description	[-]	pH independent	-
CROP RELATED PARAMETERS			
TSCF (crop uptake)	[-]	0	FOCUS recommendation

Results

Considering the above input parameters, the RMS calculated PEC_{gw} modelling using FOCUS-PEARL 4.4.4, FOCUS-PELMO 5.5.3 and FOCUS-MACRO5.5.4. for both spring and winter cereals. The results are summarised below. The resulting groundwater concentrations for the parent compound were identical for all tiers of the modelling; these values are reported within table 8.3.7. and tier 1 1,2,4-triazole concentrations reported within table 8.3.8.

The 80th percentile annual average PEC_{gw} concentrations at 1m solid depth were calculated as <0.1µg/L for both BAS 750 F and the soil metabolite 1,2,4- triazole when applied to spring and winter cereals. Therefore, it is considered that risk of groundwater contamination at >0.1µg.L from the proposed use of BAS 750 01 F is unlikely.

As explained previous the subsequent tiers are to aid discussions on the setting of an appropriate formation fraction for the soil metabolite 1,2,4-triazole.

Table 8.3.7: Tier 1- 80th percentile annual leachate concentrations of BAS 750F following application to spring and winter cereals (2 x 150g a.s/ha; 14 day interval from BBCH 30)

Spring Cereals			
Scenario	PEC _{gw} (µg/L)		
	PEARL	PELMO	MACRO
Châteaudun	<0.000001	<0.001	<0.001
Hamburg	0.000001	<0.001	
Jokioinen	<0.000001	<0.001	
Kremsmünster	<0.000001	<0.001	
Okehampton	<0.000001	<0.001	
Porto	<0.000001	<0.001	
Winter Cereals			
Scenario	PEC _{gw} (µg/L)		
	PEARL	PELMO	MACRO
Châteaudun	<0.000001	<0.001	<0.001
Hamburg	<0.000001	<0.001	
Jokioinen	<0.000001	<0.001	
Kremsmünster	<0.000001	<0.001	
Okehampton	<0.000001	<0.001	
Piacenza	0.000001	<0.001	
Porto	<0.000001	<0.001	
Sevilla	<0.000001	<0.001	
Thiva	<0.000001	<0.001	

Table 8.3.8: Tier 1- 80th percentile annual leachate concentration of 1,2,4- triazole following application to spring and winter cereals (2 x 150g a.s/ha; 14 day interval with 80% crop interception).

Spring Cereals			
Scenario	PEC _{gw} (µg/L)		
	PEARL	PELMO	MACRO
Châteaudun	0.011702	0.006	0.0215
Hamburg	0.089997	0.075	
Jokioinen	0.025241	0.023	
Kremsmünster	0.054583	0.049	
Okehampton	0.075468	0.068	
Porto	0.043854	0.059	
Winter Cereals			
Scenario	PEC _{gw} (µg/L)		
	PEARL	PELMO	MACRO
Châteaudun	0.014478	0.009	0.0239
Hamburg	0.078986	0.085	
Jokioinen	0.025779	0.033	
Kremsmünster	0.052159	0.056	
Okehampton	0.079980	0.081	
Piacenza	0.043659	0.052	
Porto	0.040808	0.068	
Sevilla	<0.000001	<0.001	
Thiva	0.008704	0.003	

Tier 2-4

The applicant calculated PEC_{gw} modelling using FOCUS-PEARL 4.4.4, FOCUS-PELMO 5.5.3 and FOCUS-MACRO5.5.4. for both spring and winter cereals. The results are summarised below; unless noted otherwise the RMS agrees with the PEC values submitted by the applicant.

Table 8.3.9: Tier 2- 80th percentile annual leachate concentration of 1,2,4- triazole following application to spring and winter cereals (2 x 150g a.s/ha; 14 day interval with 80% crop interception).

Spring Cereals			
Scenario	PEC _{gw} (µg/L)		
	PEARL	PELMO	MACRO
Châteaudun	0.006	0.004	0.005*
Hamburg	0.046	0.039	
Jokioinen	0.013	0.012	
Kremsmünster	0.028	0.025	
Okehampton	0.039	0.035	
Porto	0.022	0.031	
Winter Cereal			
Scenario	PEC _{gw} (µg/L)		
	PEARL	PELMO	MACRO
Châteaudun	0.007	0.005	0.005*
Hamburg	0.041	0.044*	
Jokioinen	0.013	0.017	
Kremsmünster	0.027	0.029*	
Okehampton	0.041	0.042*	
Piacenza	0.022	0.027*	
Porto	0.021	0.035*	
Sevilla	<0.000001	<0.001	
Thiva	0.005	0.002	

* RMS value: During validation the concentration was calculated to be lower than the Applicants modelling by 0.001µg/L.

Table 8.3.10: Tier 3- 80 th percentile annual leachate concentration of 1,2,4- triazole following application to spring and winter cereals (2 x 150g a.s/ha; 14 day interval with 80% crop interception).			
Spring Cereals			
Scenario	PEC _{gw} (µg/L)		
	PEARL	PELMO	MACRO
Châteaudun	0.003	0.002	0.003
Hamburg	0.027	0.023	
Jokioinen	0.007	0.007	
Kremsmünster	0.016	0.015	
Okehampton	0.023	0.021	
Porto	0.013	0.018	
Winter Cereals			
Scenario	PEC _{gw} (µg/L)		
	PEARL	PELMO	MACRO
Châteaudun	0.004	0.003	0.003*
Hamburg	0.024	0.026	
Jokioinen	0.007	0.010	
Kremsmünster	0.016	0.017	
Okehampton	0.025 ^{\$}	0.025	
Piacenza	0.013	0.016	
Porto	0.012	0.020	
Sevilla	<0.000001	<0.001	
Thiva	0.002	0.001	
^{\$} RMS value: the applicant modelling reported a value of 0.024; it is expected this is a rounding error.			
* RMS value: During validation the concentration was calculated to be lower than the Applicants modelling by 0.001µg/L.			

Table 8.3.11: Tier 4- 80 th percentile annual leachate concentration of 1,2,4- triazole following application to spring and winter cereals (2 x 150g a.s/ha; 14 day interval with 80% crop interception).			
Spring Cereals			
Scenario	PEC _{gw} (µg/L)		
	PEARL	PELMO	MACRO
Châteaudun	0.002	0.001	0.002*
Hamburg	0.014	0.012	
Jokioinen	0.004	0.004	
Kremsmünster	0.009	0.008	
Okehampton	0.013	0.011	
Porto	0.007	0.010	
Winter Cereals			
Scenario	PEC _{gw} (µg/L)		
	PEARL	PELMO	MACRO
Châteaudun	0.002	0.002	0.002*
Hamburg	0.013	0.014	
Jokioinen	0.004	0.005	
Kremsmünster	0.009	0.009	
Okehampton	0.014	0.014	
Piacenza	0.007	0.009	
Porto	0.006	0.011	
Sevilla	<0.001	<0.001	
Thiva	0.001	0.001	
* RMS value: During validation the concentration was calculated to be lower than the Applicants modelling by 0.001µg/L.			

B.8.4. FATE AND BEHAVIOUR IN WATER AND SEDIMENT

Very little degradation of BAS 750 F was shown to occur in the hydrolysis, ready biodegradation and aerobic mineralisation studies. However, in the aqueous photolysis study, rapid degradation of BAS 750 F was shown to occur and four major metabolites were formed: M750F005, M750F006, M750F007 and M750F008. In the water/sediment study, BAS 750 F was shown to quickly partition to sediment which was determined to be the major degradation compartment. Two major metabolites were detected in the water/sediment study: 1,2,4-triazole and M750F003. For further information, see Volume 3CA, Section B-8 of the DAR.

B.8.4.1. Aerobic mineralisation in surface water

No formulation specific studies were performed. For details on the active substance and its metabolites, please refer to Volume 3CA, Section B-8.

B.8.4.2. Water/sediment study

No formulation specific studies were performed. For details on the active substance and its metabolites, please refer to Volume 3CA, Section B-8.

B.8.4.3. Irradiated water/sediment study

No formulation specific studies were performed. For details on the active substance and its metabolites, please refer to Volume 3CA, Section B-8.

B.8.5. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SURFACE WATER AND SEDIMENT (PEC_{SW}, PEC_{SED})

Report:	CP 9.2.5/1 Pape L., Imukova K., 2016 b Predicted environmental concentrations of BAS 750 F and its metabolites in surface water and sediment following application to cereals 2015/1260843
Guidelines:	FOCUS Surface Water Report SANCO/4802/2001 rev. 2, FOCUS (2015): Generic guidance for FOCUS surface water scenarios v 1.4, FOCUS (2007): Landscape And Mitigation Factors Volume 1 SANCO/10422/2005 v2.0., FOCUS (2007): Landscape And Mitigation Factors Volume 2 SANCO/10422/2005 v2.0.
GLP:	no

Introduction

PEC_{SW} and PEC_{sed} were calculated for the example product BAS 750 01 F; exposure calculations were undertaken for BAS 750 F and its aquatic metabolites 1,2,4-triazole (M750F001), M750F003, M750F005, M750F006, M750F007 and M750F008, according to the recommendations of the FOCUS working groups on surface water⁵ and on landscape and mitigation⁶. Exposure calculations have been provided by the Applicant and repeated by the RMS, unless stated otherwise.

⁵ FOCUS (2001): FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC; version 1.4, May 2015

⁶ FOCUS (2007): Landscape And Mitigation Factors In Aquatic Ecological Risk Assessment. Volume 1. Extended Summary and Recommendations. Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0, September 2007.

For BAS 750 F, entry pathways via spray drift, drainage and runoff were considered relevant. For 1,2,4-triazole and M750F003 (occurring in low amounts in soil and in higher amounts in water and sediment), the relevant entry pathways are drainage and runoff, as well as formation after spray drift, drainage and runoff of the parent substance. For the photolytic aquatic metabolites M750F005, M750F006, M750F007 and M750F008, the pathway formation after entry of the parent substance into the water body via spray drift, drainage or runoff was considered relevant.

For BAS 750 F, PEC_{SW} calculations were performed at Step 1 to Step 4. Maximum PEC_{sed} values were reported for calculations at Step 1 to Step 3. For the metabolites, maximum PEC_{SW} and PEC_{sed} values were reported for calculations at Step 1 to Step 2.

The software packages STEPS1-2 (version 3.2) (Step 1 and 2), SWASH 5.3 in combination with FOCUS-MACRO 5.5.4, FOCUS-PRZM 4.3.1 and FOCUS-TOXSWA 4.4.3 (Step 3), and SWAN 4.0 (Step 4) were used.

Application scenarios

The Applicant states that, according to Good Agricultural Practice (GAP), BAS 750 01 F is scheduled for two applications to cereals. The application scenarios considered for PEC_{SW} and PEC_{sed} calculations are given in Table 8.5-1. At Step 2 to Step 4, simulations were performed for single and multiple applications. At all steps, the worst-case application rates were considered.

Table 8.5-1: Worst-case application scenarios of BAS 750 01 F applied to spring and winter cereals considered for the PEC_{SW} and PEC_{sed} calculations

Crop	Cereals
FOCUS _{SW} crop	Spring and winter cereals
Crop growth stage [BBCH]	30-69
Max. no. of applications [-]	2
Minimum application interval [d]	14
Application rate [g a.s. ha ⁻¹]	150
Total yearly application rate [g a.s. ha ⁻¹]	300

Step 1 and 2 scenario settings

Step 1 and 2 calculations were carried out for BAS 750 F and its metabolites for both winter and spring cereals and for both North and South Europe. Single and multiple applications of 150 g a.s. ha⁻¹ were simulated with an application period of 'March - May' and with 'average crop cover' selected. The RMS deems the Applicant's Step 1 and 2 scenario settings as being acceptable.

Step 3 and 4: application timing

At Step 3, all FOCUS scenarios parameterised for spring and winter cereals were selected for the simulations. The application method 'ground spray' was chosen and the chemical application method (CAM) was set to option '2' (application to foliar linear) for the R scenarios.

The application windows that are required for the Pesticide Application Tool (PAT) to determine actual application dates were chosen by the Applicant to cover the whole application window based on the respective BBCH growth stage. For spring cereals, the first application date at BBCH 30 was set to 28 days after emergence. For winter cereals, the first application date was set to 1st of May for the scenarios in Central Europe, to 15th of March for the scenarios in Southern Europe and to 1st of June for the scenarios in Northern Europe. The last possible application date for spring and winter cereals at BBCH 69 was set to 42 days (six weeks) prior to harvest. The exception to this was the D4 scenario, whereby, the application window from 1st June to the 10th July (6 weeks prior to harvest) is less than the minimum application range of 44 days that can be input to the PAT calculator (for a 14 day interval multiple application scheme). As a result, the date of the first application for the D4 scenario was set to May 27th. Depending on the FOCUS scenario, the length of the application

window was 44-80 days.

The RMS has checked these application dates against those suggested by AppDate (version 2.0). Because, for some scenarios, the date of first application suggested by AppDate differed quite substantially to that proposed by the Applicant (see Tables 8.5-2 and 8.5-3), for expediency, the RMS ran Tier 1 (see below) Step 3 calculations using the AppDate suggested dates of first application (and a second application 6 weeks prior to harvest).

Although this meant the application windows were different, and therefore, the PAT dates selected by the model often differed slightly, the calculated PEC values were similar (there were two exceptions to this, further information is provided in the ‘results and discussion’ section below). Because of the similarity in PEC values obtained, the RMS accepts the Applicant’s application dates and their results are presented below.

Table 8.5-2: Application dates for spring cereals

Scenario	Spring cereals (BBCH 30)		
	Application window proposed by Applicant	AppDate suggested date of first application (last application in brackets)	PAT dates selected using Applicant’s window and AppDate window
D1	2 nd June - 24 th July	27 th May (- 24 th July)	Applicant: 17 th June / 2 nd July AppDate: 17 th June / 2 nd July
D2	n/a	n/a	n/a
D3	29 th April - 9 th July	28 th April (- 9 th July)	Applicant: 4 th May / 18 th May AppDate: 4 th May / 18 th May
D4	24 th May - 15 th July	18 th May (-15 th July)	Applicant: 30 th May / 4 th July RMS: 30 th May / 16 th June
D5	12 th April - 8 th June	15 th April (- 8 th June)	Applicant: 14 th April / 11 th May AppDate: 22 nd April / 11 th May
D6	n/a	n/a	n/a
R1	n/a	n/a	n/a
R2	n/a	n/a	n/a
R3	n/a	n/a	n/a
R4	12 th April - 8 th June	9 th April (- 8 th June)	Applicant: 4 th May / 27 th May AppDate: 4 th May / 20 th May

Table 8.5-3: Application dates for winter cereals

Scenario	Winter cereals (BBCH 30)		
	Application window proposed by Applicant	AppDate suggested date of first application (last application in brackets)	PAT dates selected
D1	1 st June - 15 th July	30 th April (- 15 th July)	Applicant: 17 th June / 2 nd July AppDate: 14 th May / 17 th June
D2	1 st May - 26 th June	9 th May (- 26 th June)	Applicant: 7 th May / 23 rd May AppDate: 9 th May / 23 rd May
D3	1 st May - 4 th July	26 th May (- 4 th July)	Applicant: 4 th May / 18 th May AppDate: 20 th May / 21 st June
D4	27 th May - 10 th July	25 th April (- 10 th July)	Applicant: 30 th May / 4 th July AppDate: 30 th May / 4 th July
D5	15 th March - 3 rd June	15 th April (- 3 rd June)	Applicant: 8 th April / 22 nd April AppDate: 22 nd March / 11 th May
D6	15 th March - 19 th May	5 th March (- 19 th May)	Applicant: 15 th March / 9 th April

			AppDate: 5 th March / 9 th April
R1	1 st May - 19 th June	15 th May (- 19 th June)	Applicant: 2 nd May / 13 th June AppDate: 9 th May / 13 th June
R2	n/a	n/a	n/a
R3	15 th March - 20 th May	10 th April (- 20 th May)	Applicant: 28 th March / 11 th April AppDate: 11 th April / 25 th April
R4	15 th March - 3 rd June	15 th April (- 3 rd June)	Applicant: 4 th May / 27 th May AppDate: 4 th May / 27 th May

Step 3 and 4: tiered approach

The Applicant has proposed a tiered approach for Steps 3 and 4, for which, they provide the following justification:

Tier 1 calculations were performed with standard input parameters according to FOCUS.

At **Tier 2**, the interception values implemented in FOCUS MACRO for all drainage scenarios considered were refined to be in agreement with the values recommended by EFSA [EFSA (2014): 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. 67 pp.] and FOCUS (2014) for the respective BBCH growth stages specified in the GAP.

According to GAP, application should take place when the recommended BBCH growth stage of the respective crop is reached. Depending on actual weather conditions, application timing may vary considerably between different years. Individual application dates are calculated in FOCUS surface water models with the PAT tool depending on the scenario-specific weather conditions. The aim of this procedure is to select realistic worst-case application dates with respect to precipitation. In contrast, in FOCUS surface water models, plant development is defined by fixed dates for the growth stages emergence, maximum leaf area index (LAI) and harvest regardless of the weather conditions specified in the FOCUS scenarios. Interception values are interpolated internally between these fixed growth stages.

As a consequence, the interpolated plant growth stage at the application date calculated by the PAT may not be in agreement with the BBCH growth stage recommended in the GAP and, consequently, calculated interception values may deviate considerably from interception values recommended by EFSA and FOCUS as appropriate input for exposure modelling.

In order to compensate this bias, calculated interception values were adjusted manually to be in agreement with the values recommended by EFSA (2014) and FOCUS (2014) for the BBCH growth stage according to GAP. This was done by changing the parameter ZFINT in the input files of FOCUS MACRO (*.par) as recommended by FOCUS. Data presented in the report of Saur [Saur et al. (2001)] show that the proposed application window corresponds to the crop growth stage recommended in the GAP. Hence, applied procedure is justified.

According to EFSA and FOCUS, for application to cereals after BBCH 30 recommended interception values are 80%. Hence, all interception values <80% were set to 80%. The actual interception values of the FOCUS drainage scenarios are summarized in Appendix 3 of the PEC report.

At **Tier 3**, the default foliar DT₅₀ of 10 days was refined for all scenarios considered by a conservative estimate of 5 days (**Tier 3a**) and by an experimentally determined value of 2.1 days (**Tier 3b**) (see M-CA 7.1.4). The use of three different foliar DT₅₀ values at Tier 3 provides a comprehensive picture of the sensitivity of PEC values to this parameter. In addition, the interception refinement was applied for the drainage scenarios, as described in Tier 2.

Considering this risk assessment, only refinements for the D2 scenario would be necessary. However, to provide a complete overview, Tier 2 and Tier 3 calculations were performed for all scenarios.

The refinements considered at the different tiers are summarized in Table 8.5-4.

Table 8.5-4: Overview of refinements of the tiered approach for PEC_{sw} calculations at Step 3 & 4

	Refinement	Details of the refinement	Scenarios
Tier 1	<i>None</i>	-	-
Tier 2	<i>Interception</i>	<i>1st and 2nd app. 80%</i>	<i>All relevant drainage scenarios</i>
Tier 3a	<i>Interception</i>	<i>1st and 2nd app. 80%</i>	<i>All relevant drainage scenarios</i>
	<i>Foliar DT_{50}</i>	<i>5 days</i>	<i>All relevant scenarios</i>
Tier 3b	<i>Interception</i>	<i>1st and 2nd app. 80%</i>	<i>All relevant drainage scenarios</i>
	<i>Foliar DT_{50}</i>	<i>2.1 days</i>	<i>All relevant scenarios</i>

The RMS accepts the Applicant's Tier 2 refinement justification. According to the FOCUS Ground Water Assessments guidance (version 2.2, May 2014), the appropriate crop interception for winter and spring cereals, with a BBCH code of 30, is 80%. Therefore, the RMS deems the Applicant's refinement acceptable.

During the initial evaluation however, the RMS noted that the process undertaken by the Applicant in altering the ZFINT parameters was incorrect; the Applicant only amended the ZFINT parameters which were <80%, thus keeping the parameters that were >80%. The RMS is of the opinion that, in this instance, all the ZFINT parameters should have been altered to the relevant crop interception value as only altering the values <80% will result in a more beneficial PEC value (see 'results and discussion' section below for further information). Therefore, the RMS did not repeat the Applicant's Tier 2 modelling at the time and the Tier 2 PEC values were not used further in the risk assessment.

Subsequently the Applicant supplied amended Tier 2 calculations, where all ZFINT parameters were altered to 80%. The RMS has validated the amended Tier 2 calculations and these are reported within Tables 8.5-16 to 20. It should be noted that whilst these PEC values have been included within this evaluation (to allow for discussion on the appropriateness of the proposed refinement), the PEC values have not been considered within the subsequent risk assessment (therefore, the tables have been 'greyed-out' to indicate this). For expediency, the Applicant's initial Tier 2 calculations are also included, however, these too are 'greyed-out' to indicate they are not considered further.

The RMS does not accept the Applicant's Tier 3a and 3b refinements due to the associated foliar DT_{50} study (see section B.8.1.3 of the DAR) being unacceptable. For information, the Applicant's Tier 3 $PEC_{sw/sed}$ values are also included below ('greyed-out'), but these have not been validated or used further in the risk assessment.

Summary of input parameters

The environmental fate parameters of BAS 750 F and its metabolites used for the PEC_{sw} and PEC_{sed} calculations are summarised in Table 8.5-5 and Table 8.5-6.

Because the water solubility of the metabolites is unknown (excluding 1,2,4-triazole), the Applicant has proposed to use a value of 1000 mg L⁻¹ for each metabolite as a conservative estimate. The RMS notes that a value of 1000 mg L⁻¹ may not necessarily be conservative. Therefore, the RMS has repeated the Steps 1 and 2 modelling three times using water solubility values of 1000 mg L⁻¹ (in line with the Applicant), 10000 mg L⁻¹ and 0.81 mg L⁻¹ (the same value as BAS 750 F); no differences in PEC_{sw} or PEC_{sed} values were noted.

For 1,2,4-triazole, the endpoints were taken from: "Triazole Derived Metabolite: 1,2,4-Triazole: Proposed revision to DT_{50} : Summary, Scientific Evaluation and Assessment: July 2011, revised September 2011 (after comments from MS and EFSA) and further revised January 2013 (minor clarifications added post-commenting)"; the document is available on CIRCABC at the following address: CIRCABC > PLANT PROTECTION PRODUCTS AND THEIR RESIDUES > Library > Archive individual substances > Triazole metabolites agreed endpoints

Table 8.5-5: Summary of input parameters for BAS 750 F used for PEC_{sw} and PEC_{sed} calculations

Input parameter	Unit	Value	Remarks
Molar mass	[g mol ⁻¹]	397.8	Phys.-chem. properties
Water solubility (20°C)	[mg L ⁻¹]	0.81	Phys.-chem. properties

Vapour pressure (20°C)	[Pa]	3.2 x 10-6	Phys.-chem. properties
DEGRADATION IN SOIL			
Half-life in soil at reference conditions (20°C, pF2)	[d]	200	Geometric mean of normalized field values (n = 6)
Temperature correction function			
Reference temperature	[°C]	20	FOCUS recommendation
MACRO	[K ⁻¹]	0.0948	
PRZM (Q10)	[-]	2.58	
Moisture correction function			
Reference moisture	[-]	pF 2	FOCUS recommendation
Moisture exponent (PRZM)	[-]	0.7	
Moisture exponent (MACRO)	[-]	0.49	
SORPTION TO SOIL			
K _{f,oc} value	[mL g ⁻¹]	3455.6	Geometric mean (n = 8)
Freundlich exponent 1/n	[-]	0.975	Arithmetic mean (n = 8)
DEGRADATION IN AQUATIC SYSTEMS			
DT50 water, sediment (Step 1 - 2)	[d]	163.4	Geometric mean of total system DT50 (Level P-I, n = 2)
DT50 water (Step 1 - 4)	[d]	1000	FOCUS recommendation
DT50 sediment (Step 1 - 4)	[d]	163.4	Geometric mean of total system DT50 (Level P-I, n = 2)
DT50 crop (Step 3 - 4)	[d]	10	FOCUS recommendation
Temperature correction function			
Reference temperature TOXSWA: activation energy	[°C] [J mol ⁻¹]	20 65400	FOCUS recommendation
MANAGEMENT RELATED PARAMETERS			
Crop uptake factor	[-]	0	FOCUS recommendation
Wash off coefficient			
PRZM:	[cm ⁻¹] [mm ⁻¹]	0.5	FOCUS recommendation
MACRO:		0.05	

Table 8.5-6: Summary of input parameters for the surface water and sediment relevant metabolites of BAS 750 F used for PEC_{SW} and PEC_{sed} calculations

Input parameter	Unit	1,2,4-triazole	M750F...				
			003	005	006	007	008
Molar mass	[g mol ⁻¹]	69.1	287.2	379.3	355.8	337.3	355.8
Water solubility (20°C)	[mg L ⁻¹]	700000	1000	1000	1000	1000	1000
DEGRADATION IN SOIL							
Half-life in soil at reference conditions (20°C, pH 7)	[d]	60.5	1000	1000	1000	1000	1000
Max. observed occurrence in soil	[%]	5.1	1.8	0.001	0.001	0.001	0.001
SORPTION TO SOIL							
K _{f,oc} value	[mL g ⁻¹]	89	597.6	7863	4919	3938	17240
DEGRADATION IN AQUATIC SYSTEMS							
DT ₅₀ water, sediment (Step 1 - 2)	[d]	1000	1000	1000	1000	1000	1000
Max. observed occurrence in water/sediment	[%]	15.1	8.5	32.2	30.7	43.9	7.3

Results and discussion

The predicted global maximum concentrations of BAS 750 F in surface water and sediment are presented in Tables 8.5-7 to 8.5-30 below.

Step 1 and 2

The RMS notes the Applicant appeared to conduct Steps 1 and 2 exposure calculations using a DT_{50} water value of 163.4 days for BAS 750 F, as opposed to the 1000 day default value they have used for Steps 3 and 4. The RMS deems the 1000 day water DT_{50} value as being appropriate for all steps; 163.4 days is appropriate for the sediment DT_{50} value and the water/sediment DT_{50} value. This resulted in minor differences in PEC values calculated by the Applicant and the RMS. As the RMSs exposure calculations are deemed appropriate, these are presented below and not the Applicant's. All maximum PEC values occurred at Time 0 unless stated otherwise in brackets.

The Step 1 and 2 results (using STEPS 1 and 2 v3.2 software) for the parent compound are provided in Table 8.5-7 and Table 8.5-8; the results for the metabolites are provided in Tables 8.5-9 and 8.5-10.

Table 8.5-7: Step 1 and 2: Maximum PEC_{SW} and PEC_{sed} values of BAS 750 F following application to winter cereals

Application rate, [g a.s. ha ⁻¹]	Compartment	PEC_{SW} [µg L ⁻¹] and PEC_{sed} [µg Kg ⁻¹]		
		Step 1	Step 2	
			South Europe, Mar – May, average crop cover	
			Single application	Multiple application
150	Surface water	20.592	3.156	6.080
	Sediment	630.572 (day 1)	105.191	203.511
North Europe, Mar – May, average crop cover				
150	Surface water	20.592	1.749	3.332
	Sediment	630.572 (day 1)	56.776	108.973

Table 8.5-8: Step 1 and 2: Maximum PEC_{SW} and PEC_{sed} values of BAS 750 F following application to spring cereals

Application rate, [g a.s. ha ⁻¹]	Compartment	PEC_{SW} [µg L ⁻¹] and PEC_{sed} [µg Kg ⁻¹]		
		Step 1	Step 2	
			South Europe, Mar – May, average crop cover	
			Single application	Multiple application
150	Surface water	20.592	3.156	6.080
	Sediment	630.572 (day 1)	105.191	203.511
North Europe, Mar – May, average crop cover				
150	Surface water	20.592	1.749	3.332
	Sediment	630.572 (day 1)	56.776	108.973

Table 8.5-9: Step 1 and 2: Maximum PEC_{SW} and PEC_{sed} values of the metabolites following application to winter cereals

Metabolite	Compartment	PEC_{SW} [µg L ⁻¹] and PEC_{sed} [µg Kg ⁻¹]		
		Step 1	Step 2	
			South Europe, Mar – May, average crop cover	
			Single application	Multiple application
1,2,4-triazole	Surface water	3.209	0.525	1.005
	Sediment	2.847 (day 1)	0.465	0.892

M750F003	Surface water	4.308	0.710	1.379
	Sediment	25.278 (day 1)	4.188	8.150
M750F005	Surface water	3.521	0.478	0.920
	Sediment	215.874 (day 1)	36.040	69.812
M750F006	Surface water	4.390	0.646	1.245
	Sediment	183.503 (day 1)	30.635	59.344
M750F007	Surface water	6.982	1.056	2.037
	Sediment	240.821	40.205	77.880
M750F008	Surface water	0.452	0.090	0.094
	Sediment	48.196 (day 1)	8.046	15.586
North Europe, Mar – May, average crop cover				
1,2,4-triazole	Surface water	3.209	0.279	0.532
	Sediment	2.847 (day 1)	0.247	0.471
M750F003	Surface water	4.308	0.382	0.738
	Sediment	25.278 (day 1)	2.234	4.322
M750F005	Surface water	3.521	0.424	0.508
	Sediment	215.874 (day 1)	19.465	37.448
M750F006	Surface water	4.390	0.379	0.685
	Sediment	183.503 (day 1)	16.546	31.832
M750F007	Surface water	6.982	0.586	1.120
	Sediment	240.821	21.714	41.775
M750F008	Surface water	0.452	0.090	0.084
	Sediment	48.196 (day 1)	4.346	8.360

Table 8.5-10: Step 1 and 2: Maximum PEC_{sw} and PEC_{sed} values of the metabolites following application to spring cereals

Metabolite	Compartment	PEC _{sw} [µg L ⁻¹] and PEC _{sed} [µg Kg ⁻¹]		
		Step 1	Step 2	
			South Europe, Mar – May, average crop cover	
			Single application	Multiple application
1,2,4-triazole	Surface water	3.209	0.525	1.005
	Sediment	2.847 (day 1)	0.465	0.892
M750F003	Surface water	4.308	0.710	1.379
	Sediment	25.278 (day 1)	4.188	8.150
M750F005	Surface water	3.521	0.478	0.920
	Sediment	215.874 (day 1)	36.040	69.812
M750F006	Surface water	4.390	0.646	1.245
	Sediment	183.503 (day 1)	30.635	59.344
M750F007	Surface water	6.982	1.056	2.037
	Sediment	240.821	40.205	77.880
M750F008	Surface water	0.452	0.090	0.094
	Sediment	48.196 (day 1)	8.046	15.586
North Europe, Mar – May, average crop cover				
1,2,4-triazole	Surface water	3.209	0.279	0.532
	Sediment	2.847 (Day 1)	0.247	0.471
M750F003	Surface water	4.308	0.382	0.738
	Sediment	25.278 (day 1)	2.234	4.322
M750F005	Surface water	3.521	0.424	0.508

	Sediment	215.874 (day 1)	19.465	37.448
M750F006	Surface water	4.390	0.379	0.685
	Sediment	183.503 (day 1)	16.546	31.832
M750F007	Surface water	6.982	0.586	1.120
	Sediment	240.821	21.714	41.775
M750F008	Surface water	0.452	0.090	0.084
	Sediment	48.196 (day 1)	4.346	8.360

Steps 3 and 4

Tier 1

As a first tier, the Applicant has completed $PEC_{SW/sed}$ calculations assuming standard FOCUS input parameters for BAS 750 F. The substance input parameters are summarised in Table 8.5-5 and the application details in Tables 8.5-2 and 8.5-3.

The Applicant conducted the Step 3 calculations using SWASH v5.3 and the modelling has been repeated by the RMS using the same modelling programs. The RMS was able to replicate all the Applicant's Step 3 and 4 modelling; the results are presented below. For Step 4, the RMS only ran the scenarios which were greater than the RAC (1 $\mu\text{g/L}$) at Step 3. However, because the RMS obtained the same values as the Applicant, all of the Applicant's Step 4 PEC values are included below and deemed appropriate.

Table 8.5-11: Step 3 and 4, Tier 1: $PEC_{SW,max}$ of BAS 750 F following application of 150 g a.s. ha^{-1} to spring cereals

Location	Water body	$PEC_{SW,max}$ [$\mu\text{g L}^{-1}$] and main entry route			
		Single application		Multiple application	
		Step 3	Step 4	Step 3	Step 4
		Edge-of-Field	5mD	Edge-of-Field	5mD
D1	ditch	1.328 Drift	0.692 Drainage	1.703 Drift	1.237 Drainage
D1	stream	0.846 Drift	0.434 Drainage	0.775 Drainage	0.775 Drainage
D3	ditch	0.948 Drift	0.257 Drift	0.830 Drift	0.215 Drift
D4	pond	0.050 Drainage	0.049 Drainage	0.089 Drainage	0.088 Drainage
D4	stream	0.775 Drift	0.283 Drift	0.707 Drift	0.292 Drainage
D5	pond	0.035 Drift	0.031 Drift	0.048 Drift	0.042 Drift
D5	stream	0.796 Drift	0.291 Drift	0.715 Drift	0.253 Drift
R4	stream	0.627 Drift	0.549 Runoff	0.599 Runoff	0.599 Runoff

5mD = Drift mitigation by no-spray buffer zone of 5 m

Table 8.5-12: Step 3 and 4, Tier 1: $PEC_{SW,max}$ of BAS 750 F following application of 150 g a.s. ha^{-1} to winter cereals

Location	Water body	PEC _{SW,max} [$\mu\text{g L}^{-1}$] and main entry route			
		Single application		Multiple application	
		Step 3	Step 4	Step 3	Step 4
		Edge-of-Field	5mD	Edge-of-Field	5mD
D1	ditch	1.198 Drift	0.718 Drainage	1.558 Drift	1.250 Drainage
D1	stream	0.841 Drift	0.451 Drainage	0.784 Drainage	0.784 Drainage
D2	ditch	1.215 Drift	1.195 Drainage	2.456 Drainage	2.456 Drainage
D2	stream	0.989 Drift	0.747 Drainage	1.533 Drainage	1.533 Drainage
D3	ditch	0.948 Drift	0.257 Drift	0.830 Drift	0.215 Drift
D4	pond	0.040 Drainage	0.039 Drainage	0.075 Drainage	0.073 Drainage
D4	stream	0.791 Drift	0.289 Drift	0.709 Drift	0.250 Drift
D5	pond	0.035 Drift	0.031 Drift	0.052 Drift	0.045 Drift
D5	stream	0.756 Drift	0.276 Drift	0.723 Drift	0.255 Drift
D6	ditch	0.952 Drift	0.402 Drainage	0.833 Drift	0.626 Drainage
R1	pond	0.077 Runoff	0.075 Runoff	0.153 Runoff	0.151 Runoff
R1	stream	0.622 Drift	0.399 Runoff	0.684 Runoff	0.684 Runoff
R3	stream	0.877 Drift	0.384 Runoff	0.779 Runoff	0.779 Runoff
R4	stream	0.627 Drift	0.505 Runoff	0.545 Runoff	0.545 Runoff

5mD = Drift mitigation by no-spray buffer zone of 5 m

Table 8.5-13: Step 3, Tier 1: PEC_{sed,max} of BAS 750 F following application of 150 g a.s. ha⁻¹ to spring cereals

Location	Water body	PEC _{sed,max} [$\mu\text{g kg}^{-1}$]	
		Single application	Multiple application
D1	ditch	11.440	21.900
D1	stream	5.866	11.580
D3	ditch	0.639	0.769
D4	pond	0.474	0.814
D4	stream	0.167	0.299
D5	pond	0.281	0.484
D5	stream	0.036	0.054
R4	stream	2.186	4.221

Table 8.5-14: Step 3, Tier 1: PEC_{sed,max} of BAS 750 F following application of 150 g a.s. ha⁻¹ to winter cereals

Location	Water body	PEC _{sed,max} [µg kg ⁻¹]	
		Single application	Multiple application
D1	ditch	12.110	20.660
D1	stream	6.251	10.670
D2	ditch	11.050	21.990
D2	stream	6.120	12.120
D3	ditch	0.630	0.763
D4	pond	0.413	0.731
D4	stream	0.128	0.244
D5	pond	0.291	0.510
D5	stream	0.030	0.062
D6	ditch	1.098	1.406
R1	pond	1.036	2.040
R1	stream	1.270	3.162
R3	stream	1.338	2.800
R4	stream	2.053	4.127

As mentioned in the ‘application scenarios’ section above, for completeness, the RMS also simulated PEC_{SW/SED} calculations using a date of first application provided by AppDate (version 2.0). The results were similar between the two sets of modelling, with two notable exceptions. Firstly, for winter cereals with multiple applications, in addition to the D1 ditch scenario, the D1 stream scenario also resulted in a PEC_{SW} value >1 µg/L (see Table 8.5-15). The RMS notes that this is not expected to cause any significant issues because mitigation measures are already required for the D1 ditch scenario.

Secondly, for spring cereals with multiple applications, the R4 scenario resulted in a PEC_{SW} value >1 µg/L. It is not clear why the PEC_{SW} value was so considerably higher when compared to the Applicant’s modelling; the application dates selected by the PAT were identical for the first application and only 7 days different for the second application (see Table 8.5-3). Given this sensitivity of the R4 scenario, the RMS is of the opinion that, where the R4 scenario is ‘relevant’ for the Member State, the Member State should pay particular consideration to the application timings of BAS 750 F to spring cereals. However, these are not considered further in this environmental risk assessment at this stage; the Applicant’s values are used in the environmental risk assessment.

Table 8.5-15: Step 3 and 4, Tier 1: RMS’s PEC_{SW,max} of BAS 750 F using suggested AppDate dates of first application

Application window	Loc- ation	Water body	PEC _{SW,max} [µg L ⁻¹]						
			Single application			Multiple application			
			PAT date	Step 3	Step 4	PAT dates	Step 3	Step 4	
				Edge-of-Field	5mD		Edge-of-Field	5mD	5mD+R
			Spring cereals						
09/04 – 08/06	R4	stream	04/05	0.6269	n.p.	04/05, 20/05	1.059	1.059	0.2674
			Winter cereals						
30/04 – 15/07	D1	Stream	14/05	1.422	0.5041	14/05, 17/06	1.122	0.8442	n.p.

5mD = Drift mitigation by no-spray buffer zone of 5 m

5mD + R = Drift mitigation by no-spray buffer zone of 5 m and vegetated buffer strip of 5 m

n.p. = Calculations not performed

The Applicant also conducted further Step 4 analysis, assuming no spray and vegetated buffer strips of up to 20 meters. However, these have not been reported as they did not further reduce the 5mD PEC_{SW} values >1 µg/L in Tables 8.5-11 to 8.5-14.

Tier 2 – amended calculations

The Applicant provided updated Tier 2 calculations whereby all ZFINT parameters had been altered to 80%. The RMS deems this approach acceptable and has validated the Applicant's Tier 2 modelling; all other input parameters and application scenarios were the same as at Tier 1. The RMS agrees with the Applicant's Tier 2 calculations. The results are presented below, however, these have been 'greyed-out' to indicate the values are not considered within the subsequent risk assessment.

Step 3 and 4, Tier 2

Table 8.5-16: Step 3 and 4, Tier 2: $PEC_{sw,max}$ of BAS 750 F following application of 150 g a.s. ha⁻¹ to spring cereals

Location	Water body	PEC _{sw,max} [µg L ⁻¹] and main entry route			
		Single application		Multiple application	
		Step 3	Step 4	Step 3	Step 4
		Edge-of-Field	5mD	Edge-of-Field	5mD
D1	ditch	1.279 Drift	0.598 Drainage	1.680 Drift	1.101 Drainage
D1	stream	0.845 Drift	0.375 Drainage	0.736 Drift	0.689 Drainage
D3	ditch	0.948 Drift	0.257 Drift	0.830 Drift	0.215 Drift
D4	pond	0.035 Drainage	0.034 Drainage	0.072 Drainage	0.071 Drainage
D4	stream	0.775 Drift	0.283 Drift	0.707 Drift	0.250 Drift
D5	pond	0.034 Drift	0.030 Drift	0.047 Drift	0.041 Drift
D5	stream	0.796 Drift	0.291 Drift	0.715 Drift	0.253 Drift

5mD = Drift mitigation by no-spray buffer zone of 5 m

Table 8.5-17: Step 3 and 4, Tier 2: PEC_{sw,max} of BAS 750 F following application of 150 g a.s. ha⁻¹ to winter cereals

Location	Water body	PEC _{sw,max} [µg L ⁻¹] and main entry route			
		Single application		Multiple application	
		Step 3	Step 4	Step 3	Step 4
		Edge-of-Field	5mD	Edge-of-Field	5mD
D1	ditch	1.201 Drift	0.687 Drainage	1.573 Drift	1.266 Drainage
D1	stream	0.842 Drift	0.431 Drainage	0.793 Drainage	0.793 Drainage
D2	ditch	1.122 Drift	0.748 Drainage	1.757 Drainage	1.757 Drainage
D2	stream	0.937 Drift	0.467 Drainage	1.096 Drainage	1.096 Drainage
D3	ditch	0.948 Drift	0.257 Drift	0.830 Drift	0.215 Drift
D4	pond	0.034 Drainage	0.033 Drainage	0.070 Drainage	0.069 Drainage
D4	stream	0.791 Drift	0.289 Drift	0.709 Drift	0.250 Drift
D5	pond	0.034 Drift	0.030 Drift	0.050 Drift	0.043 Drift
D5	stream	0.756 Drift	0.276 Drift	0.723 Drift	0.255 Drift
D6	ditch	0.952 Drift	0.271 Drainage	0.833 Drift	0.531 Drainage

5mD = Drift mitigation by no-spray buffer zone of 5 m

Step 3, Tier 2

Table 8.5-18: Step 3, Tier 2: PEC_{sed,max} of BAS 750 F following application of 150 g a.s. ha⁻¹ to spring cereals

Location	Water body	PEC _{sed,max} [µg kg ⁻¹]	
		Single application	Multiple application
D1	ditch	10.430	20.030
D1	stream	5.044	10.500
D3	ditch	0.639	0.769
D4	pond	0.373	0.706
D4	stream	0.110	0.237
D5	pond	0.260	0.434
D5	stream	0.035	0.053

Table 8.5-19: Step 3, Tier 2: PEC_{sed,max} of BAS 750 F following application of 150 g a.s. ha⁻¹ to winter cereals

Location	Water body	PEC _{sed,max} [µg kg ⁻¹]	
		Single application	Multiple application
D1	ditch	11.760	21.070
D1	stream	6.040	10.890

D2	ditch	6.905	15.740
D2	stream	3.968	8.679
D3	ditch	0.630	0.763
D4	pond	0.373	0.701
D4	stream	0.105	0.227
D5	pond	0.263	0.441
D5	stream	0.023	0.061
D6	ditch	1.089	1.403

As can be seen by the above, the Tier 2 exposure calculations had a relatively minor effect of reducing the Tier 1 PEC values, with some scenarios resulting in increased PEC values. Should this refinement be deemed acceptable after the peer-review stage, the results will be considered in more detail.

For information, the Applicant's initial Tier 2 PEC values are presented below; note, they too are 'greyed-out' to highlight they are not used further in the risk assessment.

Step 3 and 4, Tier 2 – initial calculations by the Applicant

Table 8.5-20: Step 3 and 4, Tier 2: PEC_{sw,max} of BAS 750 F following application of 150 g a.s. ha⁻¹ to spring cereals

Location	Water body	PEC _{sw,max} [µg L ⁻¹] and main entry route			
		Single application		Multiple application	
		Step 3	Step 4	Step 3	Step 4
		Edge-of-Field	5mD	Edge-of-Field	5mD
D1	ditch	1.271	0.583	1.659	1.052
		Drift	Drainage	Drift	Drainage
D1	stream	0.845	0.365	0.736	0.659
		Drift	Drainage	Drift	Drainage
D3	ditch	0.948	0.257	0.830	0.215
		Drift	Drift	Drift	Drift
D4	pond	0.035	0.034	0.069	0.068
		Drainage	Drainage	Drainage	Drainage
D4	stream	0.775	0.283	0.707	0.250
		Drift	Drift	Drift	Drift
D5	pond	0.034	0.030	0.047	0.041
		Drift	Drift	Drift	Drift
D5	stream	0.796	0.291	0.715	0.253
		Drift	Drift	Drift	Drift

5mD = Drift mitigation by no-spray buffer zone of 5 m

Table 8.5-21: Step 3 and 4, Tier 2: PEC_{sw,max} of BAS 750 F following application of 150 g a.s. ha⁻¹ to winter cereals

Location	Water body	PEC _{sw,max} [µg L ⁻¹] and main entry route			
		Single application		Multiple application	
		Step 3	Step 4	Step 3	Step 4
		Edge-of-Field	5mD	Edge-of-Field	5mD
D1	ditch	1.191	0.667	1.552	1.196
		Drift	Drainage	Drift	Drainage
D1	stream	0.841	0.418	0.750	0.750
		Drift	Drainage	Drainage	Drainage
D2	ditch	1.122	0.748	1.757	1.757
		Drift	Drainage	Drainage	Drainage
D2	stream	0.937	0.467	1.096	1.096
		Drift	Drainage	Drainage	Drainage
D3	ditch	0.948	0.257	0.830	0.215
		Drift	Drift	Drift	Drift
D4	pond	0.034	0.033	0.068	0.066
		Drainage	Drainage	Drainage	Drainage
D4	stream	0.791	0.289	0.709	0.250
		Drift	Drift	Drift	Drift
D5	pond	0.034	0.030	0.050	0.043
		Drift	Drift	Drift	Drift
D5	stream	0.756	0.276	0.723	0.255
		Drift	Drift	Drift	Drift
D6	ditch	0.952	0.271	0.833	0.492
		Drift	Drainage	Drift	Drainage

5mD = Drift mitigation by no-spray buffer zone of 5 m

Step 3, Tier 2**Table 8.5-22: Step 3, Tier 2: PEC_{sed,max} of BAS 750 F following application of 150 g a.s. ha⁻¹ to spring cereals**

Location	Water body	PEC _{sed,max} [µg kg ⁻¹]	
		Single application	Multiple application
D1	ditch	10.240	19.220
D1	stream	4.899	10.040
D3	ditch	0.639	0.769
D4	pond	0.373	0.687
D4	stream	0.110	0.226
D5	pond	0.260	0.432
D5	stream	0.035	0.053

Table 8.5-23: Step 3, Tier 2: PEC_{sed,max} of BAS 750 F following application of 150 g a.s. ha⁻¹ to winter cereals

Location	Water body	PEC _{sed,max} [µg kg ⁻¹]	
		Single application	Multiple application
D1	ditch	11.450	19.980
D1	stream	5.877	10.280

D2	ditch	6.905	15.740
D2	stream	3.968	8.679
D3	ditch	0.630	0.763
D4	pond	0.373	0.684
D4	stream	0.105	0.217
D5	pond	0.263	0.440
D5	stream	0.023	0.061
D6	ditch	1.088	1.398

Tier 3

The RMS does not accept the Applicant's Tier 3 refinements due to the related foliar DT₅₀ study being unacceptable. However for information, the Applicant's Tier 3a and 3b PEC_{sw/ed} values are as follows; note, they are 'greyed-out' to highlight they are not used further in the risk assessment.

Step 3 and 4, Tier 3a

Table 8.5-24: Step 3 and 4, Tier 3a: PEC_{sw,max} of BAS 750 F following application of 150 g a.s. ha⁻¹ to spring cereals

Location	Water body	PEC _{sw,max} [µg L ⁻¹] and main entry route			
		Single application		Multiple application	
		Step 3	Step 4	Step 3	Step 4
		Edge-of-Field	5mD	Edge-of-Field	5mD
D1	ditch	1.159	0.461	1.524	0.702
		Drift	Drift	Drift	Drainage
D1	stream	0.843	0.310	0.732	0.440
		Drift	Drift	Drift	Drainage
D3	ditch	0.948	0.257	0.830	0.215
		Drift	Drift	Drift	Drift
D4	pond	0.033	0.028	0.050	0.048
		Drift	Drift	Drainage	Drainage
D4	stream	0.775	0.283	0.707	0.250
		Drift	Drift	Drift	Drift
D5	pond	0.034	0.029	0.046	0.040
		Drift	Drift	Drift	Drift
D5	stream	0.796	0.291	0.715	0.253
		Drift	Drift	Drift	Drift
R4	stream	0.627	0.375	0.543	0.414
		Drift	Runoff	Drift	Runoff

5mD = Drift mitigation by no-spray buffer zone of 5 m

Table 8.5-25: Step 3 and 4, Tier 3a: PEC_{sw,max} of BAS 750 F following application of 150 g a.s. ha⁻¹ to winter cereals

Location	Water body	PEC _{sw,max} [µg L ⁻¹] and main entry route			
		Single application		Multiple application	
		Step 3	Step 4	Step 3	Step 4
		Edge-of-Field	5mD	Edge-of-Field	5mD

Table 8.5-25: Step 3 and 4, Tier 3a: PEC_{sw,max} of BAS 750 F following application of 150 g a.s. ha⁻¹ to winter cereals

Location	Water body	PEC _{sw,max} [µg L ⁻¹] and main entry route			
		Single application		Multiple application	
		Step 3	Step 4	Step 3	Step 4
		Edge-of-Field	5mD	Edge-of-Field	5mD
D1	ditch	1.104	0.430	1.453	0.795
		Drift	Drainage	Drift	Drainage
D1	stream	0.840	0.308	0.728	0.498
		Drift	Drift	Drift	Drainage
D2	ditch	1.069	0.521	1.251	1.251
		Drift	Drainage	Drainage	Drainage
D2	stream	0.908	0.370	0.888	0.780
		Drift	Drift	Drift	Drainage
D3	ditch	0.948	0.257	0.830	0.215
		Drift	Drift	Drift	Drift
D4	pond	0.033	0.028	0.050	0.048
		Drift	Drift	Drainage	Drainage
D4	stream	0.791	0.289	0.709	0.250
		Drift	Drift	Drift	Drift
D5	pond	0.034	0.029	0.049	0.042
		Drift	Drift	Drift	Drift
D5	stream	0.756	0.276	0.723	0.255
		Drift	Drift	Drift	Drift
D6	ditch	0.952	0.258	0.833	0.344
		Drift	Drift	Drift	Drainage
R1	pond	0.064	0.062	0.116	0.114
		Runoff	Runoff	Runoff	Runoff
R1	stream	0.622	0.319	0.542	0.509
		Drift	Runoff	Drift	Runoff
R3	stream	0.877	0.320	0.763	0.598
		Drift	Drift	Drift	Runoff
R4	stream	0.627	0.314	0.543	0.341
		Drift	Runoff	Drift	Runoff

5mD = Drift mitigation by no-spray buffer zone of 5 m

*Step 3 and 4, Tier 3b***Table 8.5-26:** Step 3 and 4, Tier 3b: $PEC_{sw,max}$ of BAS 750 F following application of 150 g a.s. ha⁻¹ to spring cereals

Location	Water body	$PEC_{sw,max}$ [$\mu\text{g L}^{-1}$] and main entry route			
		Single application		Multiple application	
		Step 3	Step 4	Step 3	Step 4
		Edge-of-Field	5mD	Edge-of-Field	5mD
D1	ditch	1.059	0.360	1.402	0.462
		Drift	Drift	Drift	Drift
D1	stream	0.841	0.308	0.729	0.260
		Drift	Drift	Drift	Drift
D3	ditch	0.948	0.257	0.830	0.215
		Drift	Drift	Drift	Drift
D4	pond	0.033	0.028	0.043	0.037
		Drift	Drift	Drift	Drift
D4	stream	0.775	0.283	0.707	0.250
		Drift	Drift	Drift	Drift
D5	pond	0.033	0.029	0.046	0.039
		Drift	Drift	Drift	Drift
D5	stream	0.796	0.291	0.715	0.253
		Drift	Drift	Drift	Drift
R4	stream	0.627	0.243	0.543	0.275
		Drift	Runoff	Drift	Runoff

5mD = Drift mitigation by no-spray buffer zone of 5 m

Table 8.5-27: Step 3 and 4, Tier 3b: $PEC_{sw,max}$ of BAS 750 F following application of 150 g a.s. ha⁻¹ to winter cereals

Location	Water body	$PEC_{sw,max}$ [$\mu\text{g L}^{-1}$] and main entry route			
		Single application		Multiple application	
		Step 3	Step 4	Step 3	Step 4
		Edge-of-Field	5mD	Edge-of-Field	5mD
D1	ditch	1.025	0.326	1.356	0.417
		Drift	Drift	Drift	Drift
D1	stream	0.840	0.307	0.727	0.257
		Drift	Drift	Drift	Drift
D2	ditch	1.032	0.365	1.102	0.842
		Drift	Drainage	Drift	Drainage
D2	stream	0.888	0.349	0.841	0.525
		Drift	Drift	Drift	Drainage
D3	ditch	0.948	0.257	0.830	0.215
		Drift	Drift	Drift	Drift
D4	pond	0.033	0.028	0.044	0.037
		Drift	Drift	Drift	Drift
D4	stream	0.791	0.289	0.709	0.250
		Drift	Drift	Drift	Drift
D5	pond	0.033	0.029	0.048	0.042
		Drift	Drift	Drift	Drift

Table 8.5-27: Step 3 and 4, Tier 3b: $PEC_{sw,max}$ of BAS 750 F following application of 150 g a.s. ha⁻¹ to winter cereals

Location	Water body	$PEC_{sw,max}$ [$\mu\text{g L}^{-1}$] and main entry route			
		Single application		Multiple application	
		Step 3	Step 4	Step 3	Step 4
		Edge-of-Field	5mD	Edge-of-Field	5mD
D5	stream	0.756	0.276	0.723	0.255
		Drift	Drift	Drift	Drift
D6	ditch	0.952	0.258	0.833	0.219
		Drift	Drift	Drift	Drainage
R1	pond	0.050	0.048	0.085	0.080
		Runoff	Runoff	Runoff	Runoff
R1	stream	0.622	0.230	0.542	0.303
		Drift	Runoff	Drift	Runoff
R3	stream	0.877	0.320	0.763	0.410
		Drift	Drift	Drift	Runoff
R4	stream	0.627	0.229	0.543	0.192
		Drift	Drift	Drift	Drift

5mD = Drift mitigation by no-spray buffer zone of 5 m

Step 3, Tier 3a**Table 8.5-28: Step 3, Tier 3a: $PEC_{sed,max}$ of BAS 750 F following application of 150 g a.s. ha⁻¹ to spring cereals**

Location	Water body	$PEC_{sed,max}$ [$\mu\text{g kg}^{-1}$]	
		Single application	Multiple application
D1	ditch	7.772	13.400
D1	stream	3.188	6.772
D3	ditch	0.639	0.769
D4	pond	0.316	0.562
D4	stream	0.077	0.155
D5	pond	0.254	0.418
D5	stream	0.035	0.053
R4	stream	1.469	2.778

Table 8.5-29: Step 3, Tier 3a: $PEC_{sed,max}$ of BAS 750 F following application of 150 g a.s. ha⁻¹ to winter cereals

Location	Water body	$PEC_{sed,max}$ [$\mu\text{g kg}^{-1}$]	
		Single application	Multiple application
D1	ditch	7.691	13.840
D1	stream	3.791	6.866
D2	ditch	4.830	11.370
D2	stream	3.365	6.248
D3	ditch	0.630	0.763
D4	pond	0.322	0.570
D4	stream	0.075	0.158
D5	pond	0.256	0.426
D5	stream	0.023	0.060
D6	ditch	1.074	1.381

R1	pond	0.856	1.580
R1	stream	1.029	2.339
R3	stream	1.070	2.223
R4	stream	1.255	2.626

*Step 3, Tier 3b***Table 8.5-30: Step 3, Tier 3b: PEC_{sed,max} of BAS 750 F following application of 150 g a.s. ha⁻¹ to spring cereals**

Location	Water body	PEC _{sed,max} [µg kg ⁻¹]	
		Single application	Multiple application
D1	ditch	5.576	9.515
D1	stream	1.691	3.737
D3	ditch	0.639	0.769
D4	pond	0.272	0.468
D4	stream	0.053	0.142
D5	pond	0.249	0.408
D5	stream	0.035	0.052
R4	stream	0.915	1.466

Table 8.5-31: Step 3, Tier 3b: PEC_{sed,max} of BAS 750 F following application of 150 g a.s. ha⁻¹ to winter cereals

Location	Water body	PEC _{sed,max} [µg kg ⁻¹]	
		Single application	Multiple application
D1	ditch	5.249	8.895
D1	stream	1.928	3.510
D2	ditch	3.954	7.842
D2	stream	2.946	4.287
D3	ditch	0.630	0.763
D4	pond	0.282	0.485
D4	stream	0.073	0.158
D5	pond	0.251	0.416
D5	stream	0.022	0.060
D6	ditch	1.063	1.365
R1	pond	0.660	1.057
R1	stream	0.784	1.400
R3	stream	0.816	1.627
R4	stream	0.632	1.285

Formulated product – BAS 750 01 F

For a formulated product and an application rate of 1.5 L ha⁻¹, the maximum initial PEC_{sw} value from entry through spray-drift, after a single application, was calculated. The FOCUS drift calculator implemented in SWASH (v5.3) was used. Standard calculations and mitigation measures (a no-spray buffer zone of 5 m and 50% drift reducing nozzles) were undertaken for the FOCUS ditch, stream and pond waterbodies. The results for a single application are presented in Tables 8.5-32 to 8.5-34 below because a single application resulted in larger, and therefore more conservative, PEC_{sw} values.

Table 8.5-32: $PEC_{SW,ini}$ from spray-drift entry to FOCUS ditch following application of 1.5 L ha⁻¹ of BAS 750 01 F to both winter and spring cereals

Crop	Application rate [kg product ha ⁻¹] ^a	Mitigation measures	Drift rate [%] ^b	$PEC_{SW,ini}$ [µg product L ⁻¹]
Cereals	1.4895	--	1.9274	9.5695
		5 m drift buffer	0.5224	2.5939
		50% drift reducing nozzles	0.9637	4.7848

^a Calculated from application rate of 1.5 L ha⁻¹ by multiplication with the product density of 0.993 kg L⁻¹

^b Areic mean percentage of application rate

Table 8.5-33: $PEC_{SW,ini}$ from spray-drift entry to FOCUS pond following application of 1.5 L ha⁻¹ of BAS 750 01 F to both winter and spring cereals

Crop	Application rate [kg product ha ⁻¹] ^a	Mitigation measures	Drift rate [%] ^b	$PEC_{SW,ini}$ [µg product L ⁻¹]
Cereals	1.4895	--	0.2191	0.3263
		5 m drift buffer	0.1896	0.2823
		50% drift reducing nozzles	0.10955	0.16315

^a Calculated from application rate of 1.5 L ha⁻¹ by multiplication with the product density of 0.993 kg L⁻¹

^b Areic mean percentage of application rate

Table 8.5-34: $PEC_{SW,ini}$ from spray-drift entry to FOCUS stream following application of 1.5 L ha⁻¹ of BAS 750 01 F to both winter and spring cereals

Crop	Application rate [kg product ha ⁻¹] ^a	Mitigation measures	Drift rate [%] ^b	$PEC_{SW,ini}$ [µg product L ⁻¹]
Cereals	1.4895	--	1.4304	7.1017
		5 m drift buffer	0.5224	2.5939
		50% drift reducing nozzles	0.7152	3.55085

^a Calculated from application rate of 1.5 L ha⁻¹ by multiplication with the product density of 0.993 kg L⁻¹

^b Areic mean percentage of application rate

Conclusion

Appropriate input parameters and application schemes were used by the Applicant. The Applicant proposed 3 tiers of FOCUS Step 3 modelling, however, the Tier 3 calculations were deemed unacceptable in this instance. Also, as the suitability of the Tier 2 exposure calculations are to be agreed with the other member states, only the Tier 1 calculations have been considered further in the aquatic risk assessment.

B.8.6. FATE AND BEHAVIOUR IN AIR

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

The Applicant states that no studies were performed with BAS 750 01 F and that the route and rate of degradation in air, as well as transport via air, is sufficiently addressed in Sections B.8.3.1 and B.8.3.2 of the DAR.

The Applicant goes on to state that the vapour pressure of BAS 750 F was determined as 3.2×10^{-6} Pa at 20°C and 6.5×10^{-6} Pa at 25°C, respectively. Therefore, the potential for deposition following volatilisation is considered negligible. The RMS accepts the Applicant's justification.

B.8.6.2. Predicted environmental concentrations from airborne transport

The Applicant states that, due to the low vapour pressure and the DT₅₀ in air being below 2 days (see Section B.8.3.1 of the DAR), no exposure and long-range transport of BAS 750 F in air is expected. Thus, no calculation of PEC from airborne transport was conducted. The RMS accepts the Applicant's justification.

B.8.7. PREDICTED ENVIRONMENTAL CONCENTRATIONS FROM OTHER ROUTES OF EXPOSURE

Other than the exposure routes summarised above, no further relevant routes of exposure are expected for BAS 750 F.

B.8.8. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 9.1.3/1	Pape L.	2016 a	Predicted environmental concentrations of BAS 750 F and its metabolite 1,2,4-Triazole in soil following application to cereals 2015/1260841 BASF SE, Limburgerhof, Germany Fed.Rep.	No	No	Not applicable	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			no Unpublished				
KCP 9.2.4.1/1	Pape L. Imukova K.	2016 a	Predicted environmental concentrations of BAS 750 F and its metabolites in groundwater following application to cereals 2015/1260842 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCP 9.2.4.1/2	Pape L.	2016 a	Predicted environmental concentrations of BAS 750 F and its metabolites in groundwater following application to cereals BASF SE, Limburgerhof, Germany Fed.Rep. 2016/1237568 no Unpublished	No	Yes	Not applicable	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 9.2.5/1	Pape L. Imukova K.	2016 b	Predicted environmental concentrations of BAS 750 F and its metabolites in surface water and sediment following application to cereals 2015/1260843 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 9.2.5/2	Pape L.	2017a	<p>Predicted environmental concentrations of BAS 750 F and its metabolites in surface water and sediment following application to cereals – Updated Tier 2 calculations</p> <p>2017/1002935</p> <p>BASF SE, Limburgerhof, Germany Fed.Rep.</p> <p>no</p> <p>Unpublished</p>	No	No	Not applicable	BASF