European Commission

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

TRITICONAZOLE

Volume 3 – B.8 (PPP) – Premis 25 FS (Triticonazole 25 g/L)

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

Version History

When	What
September/2003	Initial DAR
September/2004	Addendum 1
January/2005	Addendum 2
July/2018	DRAR

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B.8. ENVIRONMENTAL FATE AND BEHAVIOUR

Premis 25 FS (BAS 595 01 F, Triticonazole 25 g/L) is the representative formulation (seed treatment, FS) supporting the application for renewing the approval of the active substance triticonazole (BAS 595 F) in Europe. Exposure assessments were conducted for triticonazole based on the following intended use pattern.

Crop	Application method/time (BBCH growth stage)	Number of applications	Maximum seeding rate [kg/ha]	Application rate per treatment			
				Triticonazole		BAS 595 01 F	
				[g a.s./100 kg seeds]	[g a.s./ha]	[L/100 kg seeds]	[L/ha]
Cereals (winter/spring)	Seed treatment (BBCH 00)	1	250	5	12.5	0.2	0.5

Based on this GAP, an appropriate application scenario was defined using worst-case assumptions regarding application rate and timing. Thus, seed treatment in cereals corresponding to a maximum application rate of 12.5 g a.s./ha was simulated. Crop interception was assumed to be 0 % yielding a total annual soil load of 12.5 g a.s./ha.

No formulation specific studies were performed. Only results and endpoints are presented below that are relevant for conducting a complete exposure assessment for triticonazole according to latest guidance documents.

Compartment	Residue Definition
Soil	Triticonazole, RPA 406341 (Trans-diol), RPA 404766 (Cis-diol), RPA 406203 (Z-isomer)(a), 'Met 6 (MWT 333)'(b), 'Met 7 (MWT 315)'(b)
Groundwater	Triticonazole, RPA 406341 (Trans-diol), RPA 404766 (Cis-diol), RPA 406203 (Z-isomer)(a), 'Met 6 (MWT 333)'(b), 'Met 7 (MWT 315)'(b)
Surface Water	Triticonazole, RPA 406341 (Trans-diol), RPA 404766 (Cis-diol), RPA 406203 (Z-isomer)(c), 'Met 6 (MWT 333)'(b), 'Met 7 (MWT 315)'(b)
Sediment	Triticonazole, RPA 406341 (Trans-diol), RPA 404766 (Cis-diol), RPA 406203 (Z-isomer)(c), 'Met 6 (MWT 333)'(b), 'Met 7 (MWT 315)'(b)
Air	Triticonazole

(a) RPA 406203 (Z-isomer) has to be included in the exposure assessment in case of spray applications only (exposure to irradiation at the soil surface)
(b) Metabolite fraction > 5 % AR at two consecutive sampling points in a legacy soil degradation study (Ayliffe & Austin, 1993)
(c) Above 10 % AR in aquatic photolysis

B.8.1. FATE AND BEHAVIOUR IN SOIL

B.8.1.1. Rate of degradation in soil

B.8.1.1.1. Laboratory studies

Studies on rate of degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

The rate of degradation in soil of triticonazole and metabolites has been assessed in laboratory studies and is summarised in the tables below. Notice that the kinetic assessment provided by the RMS AT is based on the entire period of incubation (so one year in most cases). Metabolite RPA 407922 is not considered to occur at significant amounts in soil degradation studies. Therefore degradation data obtained for RPA 407922 in a dedicated soil degradation study are not considered further. Conservative degradation rates and formation fractions for the two metabolite fractions 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)' have been obtained in a separate position paper (Szegedi, 2018).

Table B.8.1.1.1-1 Summary on aerobic degradation rates of <u>triticonazole</u> in laboratory soil degradation studies conducted at <u>20 - 25 °C</u> - <u>trigger & modelling endpoints</u>

Soil origin	Soil type (USDA)	Label	*p*H ($CaCl_2$)	T (°C)	Water content	*DegT50* (d)	*DegT90* (d)	*DegT50* (d) 20 °C, *p*F2	χ^2 err. (%)	Kinetic model	Ref.[(a)]
UK	Sandy loam[(b)]	Ph	6.4[(c)]	22	75 % 33 kPa	289	> 1000	280[(d)]	5.0	HS	1
UK	Clay loam[(b)]	Ph	6.2[(c)]	22	75 % 33 kPa	137	455	148	4.4	SFO	
Speyer 2.2	Loamy sand[(b)]	Ph	6.8[(c)]	22	75 % 33 kPa	233	986	360[(d)]	5.0	HS	2
UK	Loamy sand[(b)]	Ph	6.3[(c)]	22	75 % 33 kPa	290	> 1000	565[(d)]	4.2	HS	3
US	Clay	T	5.7	25	75 % 33 kPa	495	> 1000	376	5.7	SFO	4
Manningtree	Sandy loam	Ph	6.1	25	50 % FC	183[(e)]	702	312[(d)]	3.3	HS	5
						221[(f)]	816	358[(d)]	6.5	HS	
California	Sand	T	8.1[(h)]	20	50 % MHWC	305	> 1000	262	3.1	SFO	6
New Jersey	Loam	Ph & T	6.8[(h)]	20	50 % MHWC	78.8	661	230[(d)]	2.4	DFOP	
Wisconsin	Sandy loam	T	6.0[(h)]	20	50 % MHWC	128	664	199[(d)]	3.2	DFOP	
Li 10	Loamy sand	Ph & T	6.3	20	50 % MWHC	148	633	178[(d)]	1.0	DFOP	7
LUFA 2.2	Loamy sand	-	5.5	20	50 % MWHC	317	> 1000	298	7.3	SFO	8
LUFA 2.3	Sandy loam	-	6.9	20	50 % MWHC	115	381	109	5.9	SFO	
LUFA 5M	Sandy loam	-	7.4	20	50 % MWHC	114	521	161[(d)]	6.3	HS	
					Maximum (n = 13)	**495**	**> 1000**	-	-	SFO	
					Geometric mean (n = 13)[(g)]	-	-	**246**	-	SFO	
					pH-dependency: y/n	**n**	-	**-**	-	-	

(a) Reference:
1: Ayliffe & Austin (1993)
2: Ayliffe & McMillan-Staff (1994)
3: Ayliffe & Godward (1993)
4: Doble et al. (1996)
5: Simmonds et al. (1996)
6: Ta & Strobush (2012)
7: Ta & Strobush (2015)
8: Grella et al. (2014)
(b) Soil texture classification not specified
(c) Matrix not specified
(d) On basis of slow phase *DegT50* (DFOP or HS)
(e) Standard conditions
(f) Reduced application rate
(g) Two experiments in Simmonds et al. (1996) averaged (geometric mean) before averaging different soils
(h) In water

Table B.8.1.1.1-2 Summary on aerobic degradation rates of triticonazole in laboratory soil degradation studies conducted at 10 °C or reduced soil moisture

Soil origin	Soil type (USDA)	Label	*p*H (CaCl₂)	T (°C)	Water content	*DegT50* (d)	*DegT90* (d)	*DegT50* (d) 20 °C, *p*F2	χ^2 err. (%)	Kinetic model	Reference
UK	Sandy loam[a]	Ph	6.3[b]	10	75 % 33 kPa	341	> 1000	nc	3.5	DFOP	Ayliffe & Godward (1993)
UK	Clay loam[a]	Ph	6.1[b]	10	75 % 33 kPa	176	892	nc	5.0	HS	
Speyer 2.2	Loamy sand[a]	Ph	6.3[b]	10	75 % 33 kPa	> 1000	> 1000	nc	2.6	HS	
UK	Loamy sand[a]	Ph	6.2[b]	10	75 % 33 kPa	862	> 1000	nc	3.9	HS	
Manning-tree	Sandy loam	Ph	6.1	10	50 % FC	584	> 1000	nc	4.5	SFO	Simmonds et al. (1996)
				25	20 % FC	259	> 1000	nc	13.1	DFOP	

(a) Soil texture classification not specified
(b) Matrix not specified

Table B.8.1.1.1-3 Summary on aerobic degradation rates of RPA 406341 (Trans-diol) in laboratory soil degradation studies conducted at 20 - 25 °C - trigger & modelling endpoints

Soil origin	Soil type (USDA)	Label	*p*H (CaCl₂)	T (°C)	Water content	*DegT 50* (d)	*DegT 90* (d)	*ff*[i]	*DegT50* (d) 20 °C, *p*F2	χ^2 err. (%)	Kinetic model	Ref.[a]
UK	Sandy loam[b]	Ph	6.4[c]	22	75 % 33 kPa	80.1	266	0.426	56.1	13.2	P_{HS}→M_{SFO}	1
UK	Clay loam[b]	Ph	6.2[c]	22	75 % 33 kPa	68.5	228	0.372	74.0	17.3	P_{SFO}→M_{SFO}	
Speyer 2.2	Loamy sand[b]	Ph	6.8[c]	22	75 % 33 kPa	405	> 1000	0.390	450	7.5	P_{HS}→M_{SFO}	2
UK	Loamy sand[b]	Ph	6.3[c]	22	75 % 33 kPa	105	349	0.473	127	21.3	P_{HS}→M_{SFO}	3
US	Clay	T	5.7	25	75 % 33 kPa	170	566	0.583	139	17.4	P_{SFO}→M_{SFO}	4
Manningtree	Sandy loam	Ph	6.1	25	50 % FC	188[d]	623	0.510	263	7.1	P_{HS}→M_{SFO}	5
						207[e]	686	0.607	290	5.9	P_{HS}→M_{SFO}	
California	Sand	T	8.1[h]	20	50 % MHWC	462	> 1000	0.207	397	10.1	P_{SFO}→M_{SFO}	6
New Jersey	Loam	Ph & T	6.8[h]	20	50 % MHWC	208	692	0.118	185	7.8	P_{DFOP}→M_{SFO}	
Wisconsin	Sandy loam	T	6.0[h]	20	50 % MHWC	176	584	0.160	151	6.3	P_{DFOP}→M_{SFO}	
Li 10	Loamy sand	Ph & T	6.3	20	50 % MWHC	202	670	0.178	172	5.8	P_{DFOP}→M_{SFO}	7
Royston	Clay Loam	Ph	7.0	20	45 % MWHC	165	549	na	102	2.0	SFO	8
Ipswich	Sandy Loam	Ph	5.3	20	45 % MWHC	199	661	na	143	2.3	SFO	
Ongar	Loam	Ph	6.2	20	45 % MWHC	346	> 1000	na	232	3.5	SFO	
					Maximum (n = 13)	**462**	**> 1000**	-	-	-	SFO	
					Geometric mean (n = 13)[f]	-	-	-	**163**	-	SFO	
					Arithmetic mean (n = 13)[g]	-	-	**0.347**	-	-		
					***p*H-dependency: y/n**	**n**	-	-	-	-		

(a) Reference:
1: Ayliffe & Austin (1993)
2: Ayliffe & McMillan-Staff (1994)
3: Ayliffe & Godward (1993)
4: Doble et al. (1996)
5: Simmonds et al. (1996)
6: Ta & Strobush (2012)
7: Ta & Strobush (2015)
8: McGhee (2000)
(b) Soil texture classification not specified
(c) Matrix not specified
(d) Standard conditions
(e) Reduced application rate
(f) Two experiments in Simmonds et al. (1996) averaged (geometric mean) before averaging different soils
(g) Two experiments in Simmonds et al. (1996) averaged (arithmetic mean) before averaging different soils
(h) In water
(i) From parent

Table B.8.1.1.1-4 Summary on aerobic degradation rates of RPA 406341 (Trans-diol) in laboratory soil degradation studies conducted at 10 °C or reduced soil moisture

Soil origin	Soil type (USDA)	Label	*p*H ($CaCl_2$)	T (°C)	Water content	*DegT 50* (d)	*DegT 90* (d)	*ff*[d]	*DegT 50* (d) 20 °C, *p*F2	χ^2 err. (%)	Kinetic model	Ref.[a]
UK	Clay loam[b]	Ph	6.1[c]	10	75 % 33 kPa	309	> 1000	0.370	nc	12.5	P_{HS}→M_{SFO}	1
Manningtree	Sandy loam	Ph	6.1	10	50 % FC	393	> 1000	0.736	nc	18.5	P_{SFO}→M_{SFO}	2

(a) Reference:
1: Ayliffe & Godward (1993)
2: Simmonds et al. (1996)
(b) Soil texture classification not specified
(c) Matrix not specified
(d) From parent

Table B.8.1.1.1-5 Summary on aerobic degradation rates of RPA 404766 (Cis-diol) in laboratory soil degradation studies conducted at 20 - 25 °C - trigger & modelling endpoints

Soil origin	Soil type (USDA)	Label	*p*H ($CaCl_2$)	T (°C)	Water content	*DegT 50* (d)	*DegT 90* (d)	*ff*[i]	*DegT 50* (d) 20 °C, *p*F2	χ^2 err. (%)	Kinetic model	Ref.[a]
UK	Clay loam[b]	Ph	6.2[c]	22	75 % 33 kPa	22.7	75.5	0.628	24.5	19.1	P_{SFO}→M_{SFO}	1
Speyer 2.2	Loamy sand[b]	Ph	6.8[c]	22	75 % 33 kPa	155	516	0.365	172	9.5	P_{HS}→M_{SFO}	2
UK	Loamy sand[b]	Ph	6.3[c]	22	75 % 33 kPa	42.0	141	0.448	50.8	26.2	P_{HS}→M_{SFO}	3
US	Clay	T	5.7	25	75 % 33 kPa	213	707	0.418	175	22.6	P_{SFO}→M_{SFO}	4
Manningtree	Sandy loam	Ph	6.1	25	50 % FC	95.0[d] 98.2[e]	315 326	0.354 0.393	133 137	12.4 6.2	P_{HS}→M_{SFO} P_{HS}→M_{SFO}	5
California	Sand	T	8.1[h]	20	50 % MHWC	170	566	0.305	146	9.9	P_{SFO}→M_{SFO}	6
New Jersey	Loam	Ph & T	6.8[h]	20	50 % MHWC	139	461	0.181	124	4.2	P_{DFOP}→M_{SFO}	
Wisconsin	Sandy loam	T	6.0[h]	20	50 % MHWC	148	493	0.214	127	4.8	P_{DFOP}→M_{SFO}	
Li 10	Loamy sand	Ph & T	6.3	20	50 % MWHC	93.5	311	0.243	79.5	4.5	P_{DFOP}→M_{SFO}	7
Baylham	Sandy loam	Ph	4.5	20	*p*F2.5 - 2	30.9	103	na	30.9	7.2	SFO	
Royston	Silty clay loam	Ph	7.2	20	*p*F2.5 - 2	20.8	69.0	na	20.8	15.8	SFO	8
Ongar	Clay loam	Ph	6.9	20	*p*F2.5 - 2	56.1	187	na	56.1	9.1	SFO	
					Maximum (n = 12)	**213**	**707**	-	-	-	SFO	
					Geometric mean (n = 12)[f]	-	-	**-**	**75.3**	-	SFO	
					Arithmetic mean (n = 12)[g]	-	-	**0.353**	**-**	-		
					***p*H-dependency: y/n**	**n**	**-**	**-**	**-**	**-**		

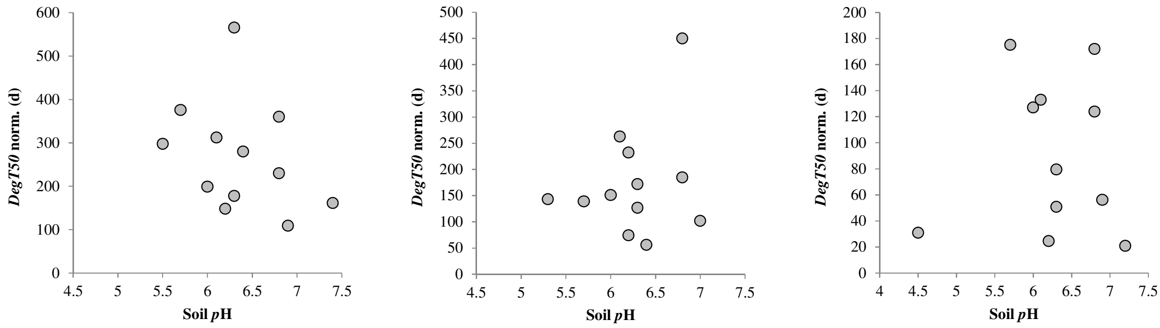
(a) Reference:
1: Ayliffe & Austin (1993)
2: Ayliffe & McMillan-Staff (1994)
3: Ayliffe & Godward (1993)
4: Doble et al. (1996)
5: Simmonds et al. (1996)
6: Ta & Strobush (2012)
7: Ta & Strobush (2015)
8: Crowe (2002)
(b) Soil texture classification not specified
(c) Matrix not specified
(d) Standard conditions
(e) Reduced application rate
(f) Two experiments in Simmonds et al. (1996) averaged (geometric mean)
(g) Two experiments in Simmonds et al. (1996) averaged (arithmetic mean)
(h) In water
(i) From parent

Table B.8.1.1.1-6 Summary on aerobic degradation rates of RPA 404766 (Cis-diol) in laboratory studies conducted at 10 °C or reduced soil moisture

Soil origin	Soil type (USDA)	Label	*p*H (Ca Cl_2)	T (°C)	Water content	*DegT 50* (d)	*DegT 90* (d)	*ff*[(d)]	*DegT 50* (d) 20 °C, *p*F2	χ^2 err. (%)	Kinetic model	Ref.[(a)]
UK	Clay loam[(b)]	Ph	6.1[(c)]	10	75 % 33 kPa	140	464	0.405	nc	21.2	$P_{HS} \rightarrow M_{SFO}$	1
Manningtree	Sandy loam	Ph	6.1	25	20 % FC	296	983	0.209	nc	7.0	$P_{DFOP} \rightarrow M_{SFO}$	2

(a) Reference:
1: Ayliffe & Godward (1993)
2: Simmonds et al. (1996)
(b) Soil texture classification not specified
(c) Matrix not specified
(d) From parent

The RMS AT investigated degradation rates of triticonazole and its metabolites in relation to soil *p*H. No such relationship could be established (see figure below).



Triticonazole **RPA 406341 (Trans-diol)** **RPA 404766 (Cis-diol)**

Figure B.8.1.1.1-1: Normalized *DegT50* of triticonazole, RPA 406341 (Trans-diol) and RPA 404766 (Cis-diol) in relation to soil *p*H

The RMS AT notes that the metabolite fractions **'Met 6 (MWT 333)'** and **'Met 7 (MWT 315)'** have been observed in four legacy soil degradation experiments (conducted at 22 °C) at maximum amounts of 12.8, 4.2, 1.6 and 6.2 % AR ('Met 6 (MWT 333)') and 6.5, 0.9, 3.6 and 5.3 % AR ('Met 7 (MWT 315)') (Ayliffe & Austin, 1993; Ayliffe & McMillan-Staff, 1994; Ayliffe & Godward, 1993). Maximum residues were generally observed at the end of incubation (~ 365 days) or close to the end of incubation. In analogy to averaging substance properties (*DegT50* and formation fraction) of the parent and metabolites in the exposure assessment, the RMS AT considers it defendable to conduct the groundwater assessment for 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)' also on basis of an average (arithmetic mean) occurrence in soil, which is 6.2 and 4.1 % AR for 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)', respectively. Coupling the geometric mean *DegT50* of 78.7 days for the parent (i.e. the modelling endpoint derived from field studies, refer to Chapter B.8.1.2.3, summary on field dissipation/degradation) with a conservative *DegT50* of 1000 days for the two metabolite fractions, a maximum occurrence of 6.2 and 4.1 % for 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)', respectively, in the exposure modelling is archived if the formation fraction is set to **0.077** and **0.051** for 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)', respectively. On overall, the RMS AT considers residues of these two metabolite fractions observed in legacy studies sufficiently covered by this approach.

Under **anaerobic conditions** triticonazole is considered to be stable.

In comparison to dark conditions, the rate of degradation of triticonazole under conditions of **photolysis on soil surface** is relatively fast (*DissT50* of 65.3 days under environmental conditions, 50 °N). However, as triticonazole is intended to be used as a seed treatment the impact of soil photolysis is negligible.

B.8.1.1.2. Field studies

B.8.1.1.2.1. Soil dissipation studies

Refer to section B.8.1.1.2.3, summary on field studies.

B.8.1.1.2.2. Soil accumulation studies

Refer to section B.8.1.1.2.3, summary on field studies.

B.8.1.1.2.3. Summary on field studies

The dissipation/degradation of **triticonazole** under realistic outdoor conditions has been assessed in eight field dissipation trials spread all over Europe (IT, DE, UK, FR, ES). Triticonazole was incorporated into bare soils at a nominal application rate of 240 g/ha immediately before planting of winter cereals (in one field trial triticonazole was actually applied as a seed treatment). Notice that all these field trials are clearly overdosed in view of an intended application rate of 12.5 g ai/ha only. In principal, cropping in field trials is not in line with EFSA guidance on *DegT50* (EFSA, 2014)[1] recommending the soil to be kept free from vegetation in order to exclude any possible uptake by plants. However, as the intended use is indeed seed treatment in winter & spring cereals, the RMS AT considers the *DegT50* values obtained in these field trials at least sufficiently robust for the intended use. Notice that plant uptake has to be switched off in exposure models in order to avoid double counting of plant uptake. Using *DegT50* values obtained in these field trials for uses other than winter & spring cereals or at significantly deviating crop stages in winter & spring cereals will be subject to some uncertainties.

Table B.8.1.1.2.3-1 Summary on non-normalized field dissipation rates of triticonazole - trigger endpoints

Field trial	Soil type (USDA)	*p*H ($CaCl_2$)	*DissT50* (d)	*DissT90* (d)	χ^2 err. (%)	Kinetic model	Reference
Bologna (IT)	Loam	8.4[(a)]	169	563	32.5	SFO	Wicks (1996)
Goch (DE)	Sandy loam	6.6[(a)]	183	609	28.5	SFO	
Manningtree (UK) - Spray	Sandy loam	5.3[(a)]	55.0	633	13.5	DFOP	
Manningtree (UK) - Seed treat.	Sandy loam	5.3[(a)]	223	741	38.2	SFO	
Mereville (FR)	Silty clay loam	7.8[(a)]	204	678	17.6	SFO	
Brentwood (UK)	Sandy silt loam	7.3	242	803	27.8	SFO	Duncan et al. (2003)
Saint Trivier sur Moignans (FR)	Sandy silt loam	7.1	118	392	21.1	SFO	
Balaguer (ES)	Clay loam	7.4	99.1	329	31.4	SFO	
Goch (DE)	Sandy silt loam	6.7	36.1	477	8.2	DFOP	
		Maximum (n = 9)	**242**	**803**	**-**	**SFO**	

(a) Measured in water

Table B.8.1.1.2.3-2 Summary on time-step normalized field degradation rates of triticonazole - modelling endpoints

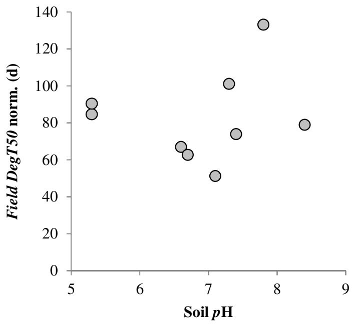
Field trial	Soil type (USDA)	*p*H ($CaCl_2$)	*DegT50* (d)	*DegT90* (d)	χ^2 err. (%)	Kinetic model	Modelling *DegT50* *(d)*	Ref.
Bologna (IT)	Loam	8.4[(a)]	78.9	262	20.7	SFO	78.9	Wicks (1996)
Goch (DE)	Sandy loam	6.6[(a)]	66.9	222	28.7	SFO	66.9	
Manningtree (UK) - Spray	Sandy loam	5.3[(a)]	15.4	281	13.0	DFOP	84.6[(b)]	
Manningtree (UK) - Seed treat.	Sandy loam	5.3[(a)]	90.4	300	33.2	SFO	90.4	
Mereville (FR)	Silty clay loam	7.8[(a)]	35.7	441	13.5	HS	133[(b)]	
Brentwood (UK)	Sandy silt loam	7.3	101	337	30.3	SFO	101	Duncan et al. (2003)
Saint Trivier sur Moignans (FR)	Silty silt loam	7.1	51.2	170	16.9	SFO	51.2	
Balaguer (ES)	Clay loam	7.4	15.2	245	28.5	HS	73.8[(b)]	
Goch (DE)	Sandy silt loam	6.7	12.2	208	9.4	DFOP	62.7[(b)]	
		Geometric mean (n = 8)[(c)]	**-**	**-**	**-**	**SFO**	**78.7**	
		***p*H-dependency: y/n**	**-**	**-**	**-**	**-**	**n[(d)]**	

(a) Measured in water

[1] EFSA (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

(b) Pseudo-SFO *DegT50* based on DFOP or HS overall *DegT90* divided by 3.32 (as residues at study end are clearly below 10 % of initial dose)
(c) Different experiments from Manningtree field site (spray and seed treatment) averaged (geometric mean) before averaging results from different field sites
(d) Refer to text below

The RMS AT investigated field degradation rates of triticonazole in relation to soil *p*H. No such relationship could be established (see figure below).



Triticonazole

Figure B.8.1.1.2.3-1: Time-step normalized field *DegT50* of triticonazole in relation to soil *p*H

The RMS AT notes that in case of the ground water exposure assessment the obtained geometric *DegT50* of 78.7 days, based on a mixture of SFO *DegT50* values and pseudo *DegT50* values from DFOP and HS fits, is of course conservative for the parent triticonazole but not necessarily conservative for its metabolites. In case of biphasic degradation the FOCUS degradation report 2006 (EC, 2014) gives the option to perform the exposure assessment on basis of two separate runs, the first on basis of the slow DFOP/HS degradation rates and the second on basis of the fast phase DFOP/HS degradation rate. The highest concentration of the two sets may then be used in the risk assessment.

In case of this dataset degradation rates from SFO and DFOP/HS models are mixed making the situation more complicated. As already indicated in a draft guidance document, prepared by CRD in view of supporting the current FOCUS degradation kinetics guidance, this situation may be handled assuming the SFO model a special case of the DFOP model with SFO-k = DFOP-k_1 = DFOP-k_2 and g undefined. In analogy, the SFO may also be considered a special case of the HS model with an undefined split point (t_b). If applied to the time-step normalized triticonazole dataset this gives a geometric fast phase *DegT50* of 35.8 days and a geometric slow phase *DegT50* of 98.2 days (see table below). In line with the FOCUS approach mentioned above an additional exposure assessment may therefore be performed on basis of a SFO model with a geometric fast phase *DegT50* of 35.8 days.

Table B.8.1.1.2.3-3 Summary on normalized field degradation rates of <u>triticonazole</u> - <u>alternative approach</u> for deriving modelling endpoints for the fast and slow degradation phase

Field trial	Soil type (USDA)	*p*H ($CaCl_2$)	Fast phase *DegT50* (d)	Slow phase *DegT50* (d)	DFOP-*g*	Kinetic model	Ref.
Bologna (IT)	Loam	8.4[(a)]	78.9[(b)]	78.9[(b)]	na	SFO	Wicks (1996)
Goch (DE)	Sandy loam	6.6[(a)]	66.9[(b)]	66.9[(b)]	na	SFO	
Manningtree (UK) - Spray	Sandy loam	5.3[(a)]	6.9	140	0.60	DFOP	
Manningtree (UK) - Seed treat.	Sandy loam	5.3[(a)]	90.4[(b)]	90.4[(b)]	na	SFO	
Mereville (FR)	Silty clay loam	7.8[(a)]	35.7	191	na	HS	
Brentwood (UK)	Sandy silt loam	7.3	101[(b)]	101[(b)]	na	SFO	Duncan et al. (2003)
Saint Trivier sur Moignans (FR)	Silty silt loam	7.1	51.2[(b)]	51.2[(b)]	na	SFO	
Balaguer (ES)	Clay loam	7.4	15.2	111	na	HS	
Goch (DE)	Sandy silt loam	6.7	7.3	133	0.71	DFOP	
	Geometric mean (n = 8)[(c)]		**35.8**	**98.2**	**-**		
	***p*H-dependency: y/n**		**n**	**-**	**-**		

(a) In water
(b) SFO model considered as a special case of a DFOP or HS model with $k_1 = k_2$ and g and t_b, respectively, undefined
(c) Data from Manningtree soil (spray and seed treatment) averaged (geometric mean) before averaging different soils

The dissipation/degradation of the metabolite **RPA 406341 (Trans-diol)** under realistic outdoor conditions has been assessed in four field dissipation trials spread all over Europe (DE, BE, FR and ES). RPA 406341 (Trans-diol) was sprayed on bare soils at a nominal application rate of 100 g/ha followed by irrigation to satisfy requirements given in EFSA (2014). Obtained dissipation/degradation rates are given in the tables below. It is noted that application of RPA 306341 (Trans-diol) in these field trials was in late August/early September. This application date may not necessarily be considered representative for the intended use in winter cereals. However, as the peak occurrence of metabolite RPA 406431 (Trans-diol) under real field situation is roughly around late summer / early autumn in case of application in spring cereals and somewhere in spring in case of application in winter cereals dissipation rates obtained in this study are considered sufficiently robust for trigger endpoints as well as PEC soil calculation.

Table B.8.1.1.2.3-4 Summary on non-normalized field dissipation rates of RPA 406341 (Trans-diol)

Field trial	Soil type[(a)] (USDA)	*p*H[(a)] ($CaCl_2$)	*DissT50* (d)	*DissT90* (d)	χ^2 error (%)	Kinetic model	Reference
Goch-Nierswalde (DE)	Silt loam	4.7	58.2	193	13.8	SFO	Richter (2009)
Rummen (BE)	Silt loam	5.1	78.9	262	20.7	SFO	
Meauzac (FR)	Loam	5.4	123	407	16.3	SFO	
Alberic/Valencia (ES)	Clay	7.6	25.5	84.7	28.8	SFO	
	Maximum (n = 4)		**123**	**407**	**-**	**SFO**	

(a) Top soil

Table B.8.1.1.2.3-5 Summary on time-step normalized (20 °C and *p*F 2) field degradation rates of RPA 406431 (Trans-diol) - modelling endpoints

Field trial	Soil type[(a)] (USDA)	*p*H[(a)] ($CaCl_2$)	*DegT50* (d)	*DegT90* (d)	χ^2 error (%)	Kinetic model	Reference
Goch-Nierswalde (DE)	Silt loam	4.7	34.8	116	10.9	SFO	Richter (2009)
Rummen (BE)	Silt loam	5.1	32.7	109	23.5	SFO	
Meauzac (FR)	Loam	5.4	55.8	186	12.8	SFO	
Alberic/Valencia (ES)	Clay	7.6	42.6	142	18.4	SFO	
	Geometric mean (n = 4)		**40.6**	**135**	**-**	**SFO**	
	***p*H-dependency: y/n**		**n**	**-**	**-**	**-**	

(a) Top soil

The RMS AT notes, that lab *DegT50* values of **RPA 404766 (Cis-diol)** are partly above 60 days thus triggering field dissipation/degradation studies for this metabolite as well. This is currently not the case and considered a data gap from a formal point of view. However, it may be noted that degradation of RPA 404766 (Cis-diol) in laboratory studies was consistently faster than degradation of RPA 406341 (Trans-diol) in all soils (with the exception of the US clay soil in Doble, 1996). Therefore, from a scientific point of view, the RMS AT considers field degradation data available for RPA 406341 (Trans-diol) sufficiently robust to serve as conservative estimates of RPA 404766 (Cis-diol) field degradation.

A comparison of the laboratory and field modelling endpoints on basis of the EXCEL sheet **EFSA *DegT50* selector** revealed that field studies with triticonazole show significantly shorter modelling *DegT50* values than laboratory studies (lab and field studies considered as different populations). The same is true for RPA 406431 (Trans-diol). Following EFSA guidance (EFSA, 2014), these results indicate that field degradation rates for triticonazole and RPA 406431 (Trans-diol) are appropriate modelling endpoints for the exposure assessment.

For triticonazole, a **field accumulation study** conducted in DE and UK at an elevated application rate of 112.5 g ai/ha (sprayed) revealed that after correction for the application rate the plateau concentration for triticonazole was in the range of 0.001 mg/kg with peak concentrations ranging from 0.0017 to 0.0043 mg/kg. Concentrations of the major soil metabolite RPA 406341 (Trans-diol) were below LOQ (0.002 mg/kg) except for five sampling points in DE (0.002 – 0.004 mg/kg, uncorrected).

B.8.1.2. Mobility in soil

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

B.8.1.2.1. Laboratory studies

Soil adsorption of triticonazole, RPA 406341 (Trans-diol) and RPA 404766 (Cis-diol) in soil has been assessed in OECD guideline 106 batch studies and is summarised in the tables below. The RMS AT notes that the dossier on triticonazole accounts for several studies on sorption of triticonazole and the metabolites which may not be considered fully reliable owing to missing pre-equilibration phases in these experiments. However, as results obtained in studies without pre-equilibration phase are close to results with adequate pre-equilibration phase, results from these studies are considered equally reliable. It is noted that these studies have been repeated some few years later using the same soils (albeit different batches). Unfortunately, there is no guidance on when to assume a soil being 'identical' to another soil. On overall, the soils are considered fairly similar with respect to soil properties. However, in some cases there are quite some differences with respect to soil *p*H or organic matter as well as with respect to the sorption results obtained.

Table B.8.1.2.1-1: Summary on soil adsorption of triticonazole

Soil name	Soil type (USDA)	OC (%)	*p*H ($CaCl_2$)	K_d (mL/g)	K_{oc} (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/*n* (-)	Ref.
Wildacker	Silt loam	1.85	5.7	na	na	11.8	636	0.92	Vasques (2015a)
LUFA 2.3	Sandy loam	0.99	6.7	na	na	3.67	370	0.89	
LUFA 2.1	Sand	0.60	5.6	na	na	5.23	871	0.93	
Li 10	Loamy sand	0.95	6.2	na	na	4.79	504	0.91	
La Gironda	Sandy clay loam	1.22	7.4	na	na	3.97	325	0.94	
Wildacker	Silt loam	2.01	5.8	na	na	13.4	665	0.893	Simmonds (2017a)
LUFA 2.3	Sandy loam	0.66	5.3	na	na	4.52	685	0.898	
LUFA 2.1	Sand	0.72	5.6	na	na	5.60	778	0.889	
Li 10	Loamy sand	0.89	6.1	na	na	5.11	574	0.888	
La Gironda	Silty clay loam	1.92	7.1	na	na	5.56	290	0.848	
	Arithmetic mean (n = 10)			**-**	**-**	**-**	**-**	**0.90**	
	Geometric mean (n = 10)			**-**	**-**	**5.78**	**537**	**-**	
	Minimum[(b)]					**-**	**307**	**-**	
	Maximum[(c)]					**-**	**823**	**-**	
	pH-dependency: y/n			y[(a)]					

(a) Refer to text below
(b) Geometric mean of the two similar La Gironda soils (both sandy clay loam soils, *p*H 7.1 - 7.4).
(c) Geometric mean of the two similar LUFA 2.1 soils (both sand soils, *p*H 5.6)

Table B.8.1.2.1-2: Summary on soil adsorption of RPA 406341 (Trans-diol)

Soil name	Soil type (USDA)	OC (%)	*p*H ($CaCl_2$)	K_d (mL/g)	K_{oc} (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/*n* (-)	Ref.
Wildacker	Clay silt	1.97	5.8	na	na	2.59	132	0.95	Vasques (2015b)
LUFA 2.3	Loamy sand	0.7	7.1	na	na	0.80	114	0.96	
LUFA 2.1	Sand	0.6	6.0	na	na	0.68	114	0.98	
Li 10	Silty sand	0.6	5.5	na	na	1.94	324	1.00	
La Gironda	Sandy clay loam	1.3	7.7	na	na	1.38	106	0.94	
Wildacker	Silt loam	2.01	5.8	na	na	3.72	185	0.919	Kingman (2017)
LUFA 2.3	Sandy loam	0.66	5.3	na	na	1.02	154	0.945	
LUFA 2.1	Sand	0.72	5.6	na	na	1.35	188	0.937	
Li 10	Loamy sand	0.89	6.1	na	na	1.31	148	0.932	
La Gironda[(a)]	Silty clay loam	1.92	7.1	na	na	1.57	81.6	0.839	
	Arithmetic mean (all soil, n = 10)			**-**	**-**	**-**	**-**	**0.94**	
	Geometric mean (all soil, n = 10)			**-**	**-**	**1.45**	**144**	**-**	
	pH-dependency: y/n			n					

(a) Sorption coefficients have been reassessed by the RMS AT excluding NER in the calculation (refer to Kingman, 2017)

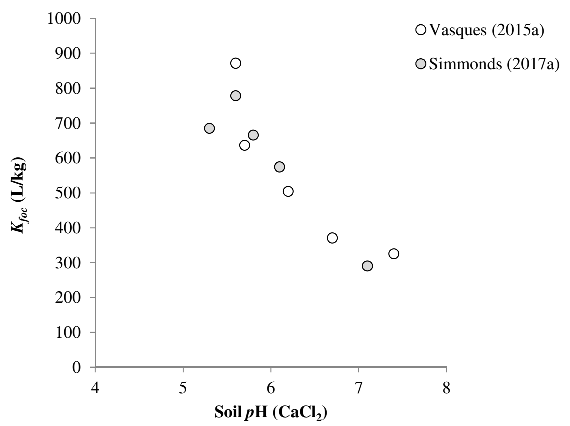
Table B.8.1.2.1-3: Summary on soil adsorption of RPA 404766 (Cis-diol)

Soil name	Soil type (USDA)	OC (%)	*p*H ($CaCl_2$)	K_d (mL/g)	K_{oc} (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/*n* (-)	Ref.
Wildacker	Clay silt	1.97	5.8	na	na	0.68	161	0.95	Vasques (2015b)
LUFA 2.3	Loamy sand	0.7	7.1	na	na	0.83	49.0	0.90	

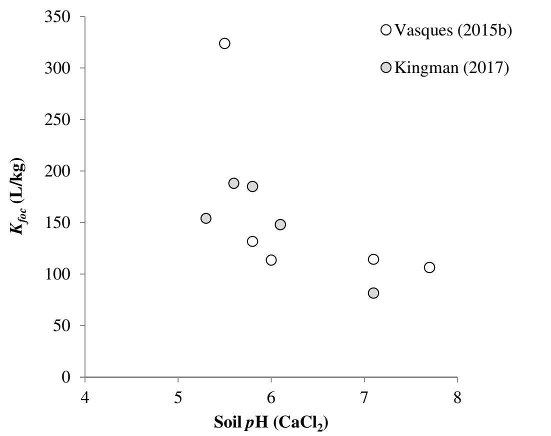
LUFA 2.1	Sand	0.6	6.0	na	na	0.28	46.1	0.97	
Li 10	Silty sand	0.6	5.5	na	na	0.34	139	0.98	
La Gironda	Sandy clay loam	1.3	7.7	na	na	3.17	52.6	0.99	
Wildacker[(a)]	Silt loam	2.01	5.8	na	na	1.71	85.3	0.889	O'Brien (2017)
LUFA 2.3	Sandy loam	0.66	5.3	na	na	0.48	72.6	0.920	
LUFA 2.1	Sand	0.72	5.6	na	na	0.68	94.0	0.946	
Li 10	Loamy sand	0.89	6.1	na	na	0.67	74.8	0.922	
La Gironda[(a)]	Silty clay loam	1.92	7.1	na	na	1.03	53.6	0.868	
	Arithmetic mean (all soil, n = 10)	**-**	**-**	**-**	**-**	**0.93**			
	Geometric mean (all soil, n = 10)	**-**	**-**	**0.76**	**75.7**	**-**			
	pH-dependency: y/n	n							

(a) Sorption coefficients have been reassessed by the RMS AT excluding NER in the calculation (refer to O'Brian, 2017)

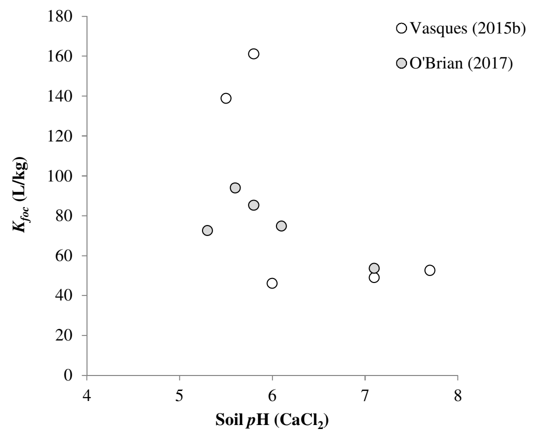
The RMS AT investigated a possible relationship between sorption coefficient (K_{foc}) and soil *p*H for triticonazole, RPA 406341 (Trans-diol) and RPA 404766 (Cis-diol) more in detail (Figure B.8.1.2.1-1). It may be noted that there are neither strong structural reasons nor evidence from phys-chem data to expect a strong *p*H effect (no dissociation, no *p*H effect on Log P_{ow} or solubility). The same is probably true for the metabolites RPA 406341 (Trans-diol) and RPA 404766 (Cis-diol), both structurally similar to the parent. Nevertheless, there appears to be a fairly strong *p*H dependent sorption in case of the parent triticonazole with lower sorption in more alkaline soils with $p = 0.001$ applying Kendall's Tau-b test (two-tailed) on basis of the combined dataset. No such relationship could be found for the $1/n$ value. There is also some indication of *p*H dependent sorption for the two metabolites; however, the relationship is less obvious in these cases (although still significant ($p = 0.01$) in case of RPA 406341 (Trans-diol) applying Kendall's Tau-b test; no significant correlation is given in case of RPA 404766 (Cis-diol)). In order to adequately address these findings in the exposure assessment, the RMS AT recommends accounting for *p*H dependent sorption in case of triticonazole but not necessarily in case of the metabolites as *p*H dependency is much less pronounced for these substances. In case of triticonazole, the RMS AT recommends using the minimum/maximum K_{foc} (307 and 823 mL/g, respectively, both calculated on basis of two similar soils) in combination with the arithmetic mean $1/n$ of 0.90 derived on basis of the entire dataset for the groundwater and surface water exposure assessment.



Triticonazole



RPA 406341 (Trans-diol)



RPA 404766 (Cis-diol)

Figure B.8.1.2.1-1: Soil sorption (K_{foc}) of triticonazole and its metabolites *vs.* soil *p*H (in $CaCl_2$)

On basis of their relative HPLC retention time (rRT) observed in Ayliffe & Austin (1993), set into context with measured mean adsorption properties and retention times of triticonazole, RPA 406341 (Trans-diol) and RPA 404766 (Cis-diol) observed in this study, K_{foc} values of the two metabolite fractions **'Met 6 (MWT 333)'** (rRT = 0.63) and **'Met 7 (MWT 315)'** (rRT = 0.70) are estimated to be approx. 278 mL/g and 327 mL/g, respectively (on basis of the regression K_{foc} (mL/g) = 697 × rRT - 161, r^2 = 0.999).

Results of a **non-aged and aged column study** show that the mobility of triticonazole was dependent on the soil type, having a medium to low mobility in all but a sand soil where up to 71 % AR (non-aged experiment) was found in the leachate. In the experiment on aged residues (with still 95 % of triticonazole present after 30 days) amounts of triticonazole in the leachate of the sand soil have been reduced to 27.1 % AR indicating that triticonazole is prone to aged sorption in soil. This is also evident from the OECD guideline 106 batch experiments with sorption coefficients consistently increasing with the number of desorption cycles. In view of the RMS AT aged sorption of triticonazole in soil is also most probably responsible for the bi-phasic decline behaviour observed in many laboratory degradation experiments.

B.8.1.2.2. Lysimeter studies

Two **lysimeter studies** have been conducted on a silty sand (1.32 % OC) with either [phenyl-U-^{14}C] or [triazole-3(5)-^{14}C] labelled triticonazole. Triticonazole was applied as a seed treatment in winter cereals with an intended application rate of 12.5 g ai/ha. Application took place in the first year only or in the first and second year with study durations of two years in case of the phenyl label and three years in case of the triazole label. Annual amounts of leachates collected were in the range from 295 - 590 L/m^2. Neither triticonazole nor RPA 406341 (Trans-diol) or RPA 404766 (Cis-diol) have been detected in the leachate samples (LOD = 0.008 - 0.01 µg/L). Unknown radioactivity did not exceed annual mean concentrations of 0.026 µg/L a.i. equivalents for the phenyl label. In case of the triazole label unidentified radioactivity at annual mean concentrations of 0.180 µg/L a.i. equivalents has been detected. The vast majority (0.150 µg/L mean annual concentration) was very polar material considered not to exceed 0.1 µg/L on individual basis. However, as the peak concentration was observed in the last year, the study does not allow concluding on residues in the leachates in subsequent years.

B.8.1.2.3. Field leaching studies

No studies provided.

B.8.1.3. Estimation of concentrations in soil

No separate report was written for the calculation of the predicted environmental concentration of triticonazole, RPA 406341 (Trans-diol) and RPA 404766 (Cis-diol) in soil (PEC_s). The calculations were directly presented within this dossier. A statement (Szegedi, 2018) was provided for estimating PEC_S for the two metabolite fractions 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)', observed above 5 % AR at two consecutive sampling points in a legacy soil degradation studies (Ayliffe & Austin, 1993).

Material and methods:

Calculations were conducted using Microsoft® EXCEL spreadsheets. All calculations and all assumptions were made according to the Guidance Documents on Persistence in soil (EU Commission, 2000 [*EU Commission (2000): Guidance Document on Persistence in Soil (Working Document) 9188/VI/97 rev. 8. July 12th, 2000*] and *FOCUS, 1997* (*FOCUS (1997): Soil persistence models and EU Registration. The final report of the work of the Soil Modelling Work group of FOCUS, February 1997*).

The input parameters used for modelling are summarised in the table below.

RPA 406203 (the Z-isomer of triticonazole), was not considered in the assessment as it is only formed in the presence of light. As triticonazole is applied as seed treatment and the seeds are incorporated into the soil, RPA 406203 (Z-isomer) is not expected to be formed. This is in line with the EFSA conclusions on triticonazole (*EFSA Scientific Report (2005) 33, 1-69*) stating that it is “not relevant for the representative use proposed (seed treatment)” and thus “no assessment required”.

For both, triticonazole and RPA 406341 (Trans-diol), *DissT90* vales were greater than one year in more than one soil. Therefore, the accumulation behaviour of these substances was addressed as well.

Table B.8.1.3-1: Input parameters of triticonazole and its metabolites used for modelling

Compound	*DegT50* (days)	Max. occurrence in soil (f_{met}) (-)	Molar mass (g/mol)	Molar mass correction factor (f_{mol}) (-)
Triticonazole	250[a]	-	317.8	-
RPA 404766 (Cis-diol)	30.9[b]	0.139	333.8	1.050
RPA 406341 (Trans-diol)	78.2[a]	0.202	333.8	1.050
RPA 407922	1.1[b]	0.128	333.8	1.050

a) Worst-case field, persistence endpoint, non-normalised
b) Worst-case laboratory, persistence endpoint, non-normalised

Application and GAP
Based on the GAP, an appropriate application scenario was defined using worst-case assumptions regarding application rate and timing. Assuming a maximum seeding rate of 250 kg/ha and 5 g a.s. (0.2 L product) per 100 kg seeds, a maximum application rate of 12.5 g a.s./ha can be derived. Thus, seed treatments in cereals corresponding to a maximum application rate of 12.5 g a.s./ha was simulated. Crop interception was assumed to be 0 % yielding a total annual soil load of 12.5 g a.s./ha.

Calculation methods
Maximum, actual and time-weighted average concentrations of triticonazole and its metabolites in soil ($PEC_{s, max}$, $PEC_{s, actual}$, $PEC_{s, twa}$) were calculated. An even distribution of the substances within the top soil layer with a depth of 5 cm and a bulk density of 1.5 g/cm³ were assumed in PEC_s calculations.

Initial, maximum, and time-weighted average concentrations
The maximum PEC_s values for the substances were calculated according to equation 2.1 in the *FOCUS 1997* guidance. The actual concentrations in soil (PEC_s) and the time-weighted average concentrations in soil ($PEC_{s, twa}$) were calculated using equation 2.2 and equation 2.3 in the same guidance, respectively. The maximum time-weighted average value for each time period is reported in the results.

Accumulation potential after long-term use
Potential accumulation after long term use is also assessed, based on the $PEC_{s, max}$ concentration of the respective compound, obtained as described before. The concentration in soil immediately before the application in the last year ($PEC_{soil,plateau}$) was calculated according to equation *2.6* in the *FOCUS 1997* guidance. The total

$PEC_{soil,accu,overall}$ taking the effect of accumulation into account is then the sum of $PEC_{soil,plateau}$ and the maximum PEC_s.

Equation 2.6

$$PEC_{soil,accu,overall} = PEC_{soil,plateau} + PEC_{soil,max}$$

Results and discussion:

Maximum PEC in soil

The maximum PEC_s values of triticonazole and its metabolites are summarised in the table below.

Table B.8.1.3-2: Maximum PEC_s of triticonazole and its metabolites following an application of 12.5 g a.s./ha as seed treatment

Triticonazole $PEC_{s,max}$ (µg/kg)	RPA 404766 (Cis-diol) $PEC_{s,max}$ (µg/kg)	RPA 406341 (Trans-diol) $PEC_{s,max}$ (µg/kg)	RPA 407922 $PEC_{s,max}$ (µg/kg)
16.667	2.433	3.536	2.241

Actual and time-weighted average PEC_s

Actual and time weighted PEC_s of triticonazole and its metabolites RPA 404766 (Cis-diol), RPA 406341 (Trans-diol), and RPA 407922 are presented in the tables below.

Table B.8.1.3-3: Actual and time weighted PEC_s of <u>triticonazole</u> for single-year application (5 cm soil depth)

Time (d)	$PEC_{s,act}$ (µg/kg)	$PEC_{s,twa}$ (µg/kg)
0	16.667	-
1	16.621	16.644
2	16.575	16.621
4	16.483	16.575
7	16.346	16.506
14	16.032	16.347
21	15.724	16.191
28	15.422	16.036
50	14.509	15.563
100	12.631	14.556

Table B.8.1.3-4: Actual and time weighted PEC_s of <u>RPA 404766 (Cis-diol)</u> for single-year application (5 cm soil depth)

Time (d)	$PEC_{s,act}$ (µg/kg)	$PEC_{s,twa}$ (µg/kg)
0	2.433	-
1	2.379	2.406
2	2.327	2.380
4	2.224	2.327
7	2.080	2.252
14	1.777	2.088
21	1.519	1.940
28	1.298	1.807
50	0.793	1.463
100	0.258	0.970

Table B.8.1.3-5: Actual and time weighted PEC_s of <u>RPA 406341 (Trans-diol)</u> for single-year application (5 cm soil depth)

Time (d)	$PEC_{s,act}$ (µg/kg)	$PEC_{s,twa}$ (µg/kg)
0	3.536	-

1	3.505	3.521
2	3.474	3.505
4	3.413	3.474
7	3.323	3.429
14	3.123	3.326
21	2.936	3.227
28	2.759	3.132
50	2.270	2.857
100	1.457	2.345

Table B.8.1.3-6: Actual and time weighted PEC$_s$ of RPA 407922 for single-year application (5 cm soil depth)

Time (d)	PEC$_{s,act}$ (µg/kg)	PEC$_{s,twa}$ (µg/kg)
0	2.241	-
1	1.193	1.662
2	0.635	1.274
4	0.180	0.818
7	0.027	0.502
14	0.000	0.254
21	0.000	0.169
28	0.000	0.127
50	0.000	0.071
100	0.000	0.036

Accumulation potential in soil

The accumulation potential of triticonazole and its metabolite RPA 406341 (Trans-diol) after long-term use was also assessed. Results are presented in the table below.

Table B.8.1.3-7: Results of PEC$_{soil,accu}$ calculation of triticonazole and RPA 406341 following seed treatment in cereals for a period of 30 years (accumulation depth of 20 cm)

Compound	PEC$_{s,ini}$ (5 cm) (µg/kg)	PEC$_{soil, plateau}$ (20 cm) (µg/kg)	PEC$_{soil, accu,overall}$ (µg/kg)
Triticonazole	16.667	2.386	19.046
RPA 406341 (Trans-diol)	3.536	0.036	3.572

Conclusion:

Predicted environmental concentrations in soil (PEC$_s$) were calculated for triticonazole and its metabolites RPA 404766 (Cis-diol), RPA 406341 (Trans-diol) and RPA 407922 for the use in cereals as seed treatment in accordance with recommendations of FOCUS (1997) and EU Commission (2000).

The results of PEC$_s$ values for the active substance and its metabolites were used for the eco-toxicological risk assessment.

Comments (RMS AT):

- On overall, the modelling approach on PEC$_{soil}$ calculations provided by the applicant is considered acceptable. However, as there are some changes with respect to *DegT50/DissD50* values of triticonazole and its metabolites proposed by the RMS AT, PEC$_{soil}$ values for triticonazole and its metabolites were re-calculated accordingly.

- No soil exposure assessment is triggered for RPA 407922 as this metabolite could not be identified in soil degradation experiments. Notice that the applicant originally claimed metabolite fraction 'Met 6 (MWT 333)' observed in Ayliffe & Austin (1993) at max. 12.8 % AR being identified as RPA 407922. As discussed in Vol. 3CA this finding is not supported anymore.

- The soil exposure assessment for the metabolite fractions 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)' observed in Ayliffe & Austin (1993) above 5 % AR at two consecutive sampling points is addressed in a separate statement (Szegedi, 2018), see next study.

Table B.8.1.3-8: Revised substance properties of triticonazole and its metabolites for PEC_{soil} calculation - RMS AT assessment

Compound	*DT50* (days)	Max. occurrence in soil (f_{met}) (-)	Molar mass (g/mol)	Molar mass correction factor (f_{mol}) (-)
Triticonazole	242[(a)]	-	317.8	-
RPA 406341 (Trans-diol)	123[(a)]	0.202	333.8	1.050
RPA 404766 (Cis-diol)	213[(b)]	0.139	333.8	1.050

(a) Worst-case field, persistence endpoint, non-normalised
(b) Worst-case laboratory, persistence endpoint, non-normalised

Table B.8.1.3-9: PEC_{soil} and $TWAC_{soil}$ of triticonazole and its metabolites - RMS AT assessment

Days after maximum	Triticonazole		RPA 406341 (Trans-diol)	
	PEC soil (mg/kg)[(a)]	TWAC soil (mg/kg)[(a)]	PEC soil (mg/kg)[(a)]	TWAC soil (mg/kg)[(a)]
0	**0.0189**	-	**0.0037**	-
1	0.0189	0.0189	0.0036	0.0037
2	0.0188	0.0189	0.0036	0.0036
4	0.0187	0.0188	0.0036	0.0036
7	0.0186	0.0188	0.0035	0.0036
14	0.0183	0.0186	0.0034	0.0035
21	0.0180	0.0184	0.0033	0.0035
28	0.0176	0.0183	0.0031	0.0034
50	0.0167	0.0178	0.0028	0.0032
100	0.0148	0.0168	0.0021	0.0028
Plateau concentration	0.0023	-	0.0001	-

Days after maximum	RPA 404766 (Cis-diol)	
	PEC soil (mg/kg)[(a)]	TWAC soil (mg/kg)[(a)]
0	**0.0027**	-
1	0.0027	0.0027
2	0.0027	0.0027
4	0.0027	0.0027
7	0.0026	0.0027
14	0.0026	0.0026
21	0.0025	0.0026
28	0.0025	0.0026
50	0.0023	0.0025
100	0.0020	0.0023
Plateau concentration	0.0003	-

(a) Including plateau concentration

Reference:	**Statement - Exposure assessment for "Met 6" and "Met 7", potential degradation products of BAS 595F triticonazole**
Author(s), year:	Szegedi, K., 2018
Report/Doc. Number:	2018/1091281
Guideline(s):	None
GLP:	Not applicable (statement)
Validity:	Yes
Status:	**New submission**

Material and methods:

Predicted environmental concentrations in soil (PEC_s) were calculated for 'Met 6 (MWT 333)' and for 'Met 7 (MWT 315)'. Calculations were performed according to FOCUS (1997) guidance. The accumulation potential of both compounds was assessed. A soil depth of 5 cm was considered for calculating maximum concentrations in the first year of application and a mixing depth of 20 cm was considered for application over several years. Immediate formation of the metabolites at their maximum occurrence after application of the parent substance was considered. Applied procedures are described in the guidance. Substance specific input parameters are described in the table below.

Table B.8.1.3-10: Parameters of triticonazole and its metabolites used for PEC_{soil} calculations

Compound	*$DegT_{50}$* (days)	Max. occurrence in soil (f_{met}) (-)	Molar mass (g/mol)	Molar mass correction factor (f_{mol}) (-)
Triticonazole	Not relevant	-	317.8	-
'Met 6 (MWT 333)'	1000[a]	0.128	333.8	1.050
'Met 7 (MWT 315)'	1000[a]	0.065	315.8	0.946

[(a)] Conservative worst-case default value, real value is expected to be substantially lower

Results:

The summary of predicted environmental concentrations in soil of 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)' are presented in the table below. Due to long half-lives in the calculations time weighted average values do not differ from maximum values and are, thus, not reported.

Table B.8.1.3-11: Results of PEC_{soil} calculation of 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)' following seed treatment with triticonazole in cereals for a period of multiple years

Compound	$PEC_{s, max}$ (5 cm) (mg/kg)	$PEC_{soil, plateau}$ (20 cm) (mg/kg)	$PEC_{soil, acc., overall}$ (mg/kg)
'Met 6 (MWT 333)'	0.0022	0.0019	0.0042
'Met 7 (MWT 315)'	0.0010	0.0009	0.0019

Comments (RMS AT):

- The RMS AT notes that there is some uncertainty about the molecular structure of metabolite fraction 'Met 6 (MWT 333)'. However, this has no impact on the mol weight of the metabolite fraction (i.e. 333.8 g/mol). On overall, the RMS AT considers the soil exposure assessment for these two metabolite fractions as presented by the applicant sufficiently addressed.

B.8.2. FATE AND BEHAVIOUR IN WATER AND SEDIMENT

B.8.2.1. Aerobic mineralisation in surface water

Studies on degradation in aerobic water with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

Triticonazole is considered stable under conditions of aerobic mineralisation studies in surface water (studied at low and high dose level).

B.8.2.2. Water/sediment studies

Studies on degradation in water/sediment with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

The rate of degradation/dissipation of triticonazole in water/sediment systems is summarized below.

Table B.8.2.2-1: Summary on degradation and dissipation of triticonazole in the total water/sediment system as well as in the water and sediment phase (20 °C) - trigger & modelling endpoints

Water / sediment system	*p*H water / sed.[(a)]	Label	*DegT50* system (d)	*DegT90* system (d)	Kinetic model	*DissT50* water (d)	Kinetic model	*DissT50* sed. (d)	Kinetic model	Reference
Rhine River	7.7 / 6.9	Ph	399	1325	SFO	5.3	FOMC	-	-	Wyss-Benz, 1995
Anwil Pond	8.0 / 6.9	Ph	225	748	SFO	9.5	FOMC	-	-	
Geometric mean (n = 2)			**300**	**996**		**-**		**-**		

(a) Measured in KCl (sediment phase)

B.8.2.3. Irradiation studies

Studies on degradation in irradiated water/sediment systems with the formulation were not performed. Water/sediment studies under influence of a light/dark regime may additionally be submitted as a higher tier option, however, the studies submitted are considered sufficient to meet the current data requirements.

B.8.2.4. Estimation of concentrations in groundwater

B.8.2.4.1. Calculation of concentrations in groundwater

Reference:	**Predicted environmental concentrations of triticonazole and its metabolites in groundwater (PEC_{gw}) following seed treatment in cereals**
Author(s), year:	Kreschnak, C., 2015
Report/Doc. Number:	2015/1183788
Guideline(s):	FOCUS Groundwater (2000) SANCO/321/2000, FOCUS Groundwater (2014) Generic Guidance for Tier 1 FOCUS Ground Water Assessments v 2.2.
GLP:	Not applicable (modelling study)
Deviations:	Not applicable
Validity:	Not fully reliable (Refer to comment section)
Status:	**New submission**

Material and methods:

Calculations were conducted using the models FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3. All calculations were run and all assumptions were made according to FOCUS guidance documents.

Summary of input parameters used for modelling
A summary of the relevant substance related model input data is given in the tables below for triticonazole and its metabolites, respectively. FOCUS default values were selected for parameters which are not explicitly listed below.

RPA 406203 (the Z-isomer of triticonazole), was not considered in the assessment as it is only formed under the presence of light. As triticonazole is applied as seed treatment and the seeds are incorporated into the soil, RPA 406203 (Z-isomer) is not expected to be formed. This is in line with the EFSA conclusions on triticonazole (*EFSA Scientific Report (2005) 33, 1-69*) stating that it is “not relevant for the representative use proposed (seed treatment)” and thus “no assessment required”.

Table B.8.2.4.1-1: Input parameters of triticonazole used for groundwater modelling

Parameter	Triticonazole	Remarks
Molecular mass (g/mol)	317.8	
Aqueous solubility (mg/L)	9.3	At 20 °C, *p*H 7.3 - 8.7
Vapour pressure (Pa)	9.0E-08	At 25 °C
DegT50 soil (days)	82.2	Geomean, field, normalised, n = 9
K_{foc} (mL/g)	494	Geometric mean, n = 13
K_{fom} (mL/g)	287	K_{foc} / 1.724
1/*n*	0.89	Arithmetic mean, n = 13
Plant uptake factor	0	Default

Table B.8.2.4.1-2: Input parameters of metabolites used for groundwater modelling

Parameter	Metabolite	Value	Remarks
	RPA 404766 (Cis-diol)	333.8	
Molecular mass (g/mol)	RPA 406341 (Trans-diol)	333.8	
	RPA 407922	333.8	
Aqueous solubility (mg/L)	All metabolites	9.3	Parent data
Vapour pressure (Pa)	All metabolites	0	No data available, worst-case assumption
	RPA 404766 (Cis-diol)	38.6	Geometric mean, laboratory, n = 4, normalised
DegT50 soil (days)	RPA 406341 (Trans-diol)	42.1	Geometric mean, field, normalised, n = 4
	RPA 407922	1.0	Geometric mean, lab, normalised, n = 3
	RPA 404766 (Cis-diol)	76	Geometric mean, n = 9
K_{foc} (mL/g)	RPA 406341 (Trans-diol)	130	Geometric mean, n = 9
	RPA 407922	486	Geometric mean, n = 9
	RPA 404766 (Cis-diol)	44	
K_{fom} (mL/g)	RPA 406341 (Trans-diol)	75	K_{foc} / 1.724
	RPA 407922	282	
1/*n* (-)	RPA 404766 (Cis-diol)	0.91	Arithmetic mean, n = 9

	RPA 406341 (Trans-diol)	0.92	Arithmetic mean, n = 9
	RPA 407922	0.86	Arithmetic mean, n = 9
Formation fraction (-)	RPA 404766 (Cis-diol) RPA 406341 (Trans-diol) RPA 407922	0.425[(a)] 0.549[(b)] 1	Arithmetic mean, lab, n = 13, from parent Arithmetic mean, lab, n = 13, from parent Worst-case assumption (only two values available)
Plant uptake factor	All metabolites	0	Default

(a) Based on preliminary data, correct value would be 0.413, no significant impact on modelling results, used value is more conservative then final value
(b) Based on preliminary data, correct value would be 0.526, no significant impact on modelling results, used value is more conservative then final value

Application scenario
A single application of 12.5 g a.s./ha was considered in the simulations. As triticonazole is applied as seed treatment, none of the applied product was assumed to be intercepted by the plant foliage, i.e. 100 % of the intended application rate was assumed to reach the soil surface and become available for leaching. Winter and spring cereals were chosen as FOCUS crops.

The application scenarios considered for the simulations are presented in the table below.

Table B.8.2.4.1-3: Application scenarios considered in simulations

Crop	Application rate (g a.s./ha)	No. of appl.	Growth stage (BBCH)	Crop interception (%)	Total yearly soil load (g a.s./ha)
Winter and spring cereals	12.5	1	Pre-emergence (seed treatment)	0	12.5

Appropriate application dates were chosen based on the recommended usage of triticonazole as seed treatment in cereals and based on plant and scenario specific dates for emergence as specified by the FOCUS Groundwater Scenarios Workgroup (FOCUS 2000 [*FOCUS (2000): FOCUS groundwater scenarios in the EU review of active substances. Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference SANCO/321/2000 rev.2, 202 pp*] & 2014 [*FOCUS (2014): Generic Guidance for Tier 1 FOCUS Ground Water Assessments, ver. 2.2 May 2014, 66 pp*]; European Commission, 2014 [*European Commission (2014) Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU. Report of the FOCUS Ground Water Work Group. EC Document Reference Sanco/13144/2010, ver. 3, 613 pp*]).

Application was considered to take place 14 days before crop emergence. The detailed application dates are summarised in the table below.

Table B.8.2.4.1-4: Application dates used for modelling

Crop	Scenario	Date
Winter cereals	Châteaudun	12-Oct
	Hamburg	18-Oct
	Jokioinen	06-Sep
	Kremsmünster	22-Oct
	Okehampton	03-Oct
	Piacenza	17-Nov
	Porto	16-Nov
	Sevilla	16-Nov
	Thiva	16-Nov
Spring cereals	Châteaudun	24-Feb
	Hamburg	18-Mar
	Jokioinen	04-May
	Kremsmünster	18-Mar
	Okehampton	18-Mar
	Porto	24-Feb

Simulation tools and scenarios
The groundwater leaching models FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3, and FOCUS MACRO 5.5.4 were used for the simulations. All runs were simulated with annual applications over a total period of 26 years. The first six years are a warming-up period, results are extracted from the following 20 years.

Results and discussion:

Predicted environmental concentrations (PEC_{gw}) for triticonazole and its metabolites following seed treatment in cereals obtained with FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3 and MACRO 5.5.4 are presented in the tables below.

Table B.8.2.4.1-5: FOCUS PEARL 80th percentile leachate concentrations of triticonazole and its metabolites in groundwater at 1 m soil depth following seed treatment in cereals

Crop	Scenario	80th percentile PEC_{gw} (µg/L)			
		Triticonazole	RPA 404766 (Cis-diol)	RPA 406341 (Trans-diol)	RPA 407922
Winter cereals	Châteaudun	< 0.001	0.001	< 0.001	< 0.001
	Hamburg	< 0.001	0.013	0.004	< 0.001
	Jokioinen	< 0.001	0.002	< 0.001	< 0.001
	Kremsmünster	< 0.001	0.007	0.002	< 0.001
	Okehampton	< 0.001	0.013	0.005	< 0.001
	Piacenza	< 0.001	0.005	0.002	< 0.001
	Porto	< 0.001	0.006	0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001	< 0.001
Spring cereals	Châteaudun	< 0.001	0.001	< 0.001	< 0.001
	Hamburg	< 0.001	0.014	0.004	< 0.001
	Jokioinen	< 0.001	0.002	< 0.001	< 0.001
	Kremsmünster	< 0.001	0.007	0.002	< 0.001
	Okehampton	< 0.001	0.010	0.004	< 0.001
	Porto	< 0.001	0.006	0.001	< 0.001

Table B.8.2.4.1-6: FOCUS PELMO 80th percentile leachate concentrations of triticonazole and its metabolites in groundwater at 1 m soil depth following seed treatment in cereals

Crop	Scenario	80th percentile PEC_{gw} (µg/L)			
		Triticonazole	RPA 404766 (Cis-diol)	RPA 406341 (Trans-diol)	RPA 407922
Winter cereals	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	0.002	0.001	< 0.001
	Jokioinen	< 0.001	0.001	< 0.001	< 0.001
	Kremsmünster	< 0.001	0.001	< 0.001	< 0.001
	Okehampton	< 0.001	0.002	0.001	< 0.001
	Piacenza	< 0.001	0.001	< 0.001	< 0.001
	Porto	< 0.001	0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001	< 0.001
Spring cereals	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	0.001	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001
	Kremsmünster	< 0.001	0.001	< 0.001	< 0.001
	Okehampton	< 0.001	0.001	< 0.001	< 0.001
	Porto	< 0.001	0.001	< 0.001	< 0.001

Table B.8.2.4.1-7: FOCUS MACRO 80th percentile leachate concentrations of triticonazole and its metabolites in groundwater at 1 m soil depth following seed treatment in cereals

Crop	Scenario	80th percentile PEC_{gw} (µg/L)			
		Triticonazole	RPA 404766 (Cis-diol)	RPA 406341 (Trans-diol)	RPA 407922
Winter cereals	Châteaudun	< 0.001	0.002	< 0.001	< 0.001
Spring cereals	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001

The predicted environmental concentrations in groundwater (PEC_{gw}) of the active substance triticonazole and its metabolites RPA 404766 (Cis-diol), RPA 406341 (Trans-diol) and RPA 407922 were calculated to be < 0.1 µg/L in all scenarios. Therefore, it can be concluded that the use of triticonazole is not likely to pose an unacceptable risk to shallow groundwater if the active substance is used in compliance with label recommendations.

Conclusion:

The PEC_{gw} for triticonazole and its metabolites 404766 (Cis-diol), RPA 406341 (Trans-diol) and RPA 407922 were calculated for the use in winter and spring cereals in Europe in accordance with recommendations of FOCUS (2000 & 2014) and European Commission (2014).

The maximum 80th percentile PEC_{gw} values of the active substance triticonazole and its metabolites RPA 404766 (Cis-diol), RPA 406341 (Trans-diol) and RPA 407922 in the leachate at 1 m soil depth were calculated to be < 0.1 µg/L in all scenarios for both crops.

Thus, it can be concluded that the use of triticonazole is not likely to pose an unacceptable risk to shallow groundwater if the active substance is used in compliance with label recommendations.

Comments (RMS AT):

- The RMS AT proposes deviating substance properties for triticonazole and its metabolites to be used in the leaching assessment:
    - Triticonazole is likely to show *p*H dependent sorption in soil with lower sorption under more alkaline soil conditions. In line with pertinent guidance the RMS AT recommends using a worst case K_{foc} of 307 mL/g in the leaching assessment (also refer to Vol. 3CA).
    - Following re-evaluation proposed modelling degradation rates, formation fractions and sorption values of triticonazole and its metabolites by the RMS AT are different from the applicant approach (refer to table below)

  The RMS AT re-calculated PEC_{gw} values on basis of the application scheme provided by the applicant with PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4.

- On overall, triticonazole is considered to partly show biphasic degradation patterns in the field studies (similar to the lab). As already noted in Vol. 3CA, the *DegT50* of 78.7 days for triticonazole obtained on basis of a mixture of SFO *DegT50* values and pseudo *DegT50* values from DFOP and HS fits is considered worst case for the parent but not necessarily for the metabolites. As outlined more in detail in Vol. 3CA, additional runs may therefore be performed on basis of the fast decline phase of triticonazole combining SFO *DegT50* and fast phase DFOP *DegT50* values, which finally gives a geometric *DegT50* of 35.8 days. However, as can be deduced from results obtained from additional runs applying a *DegT50* of 35.8 days (only performed with PEARL 4.4.4, refer to results given in the tables below) the *DegT50* of 78.7 days for triticonazole is actually worst-case for parent and metabolites as well. Thus no additional/alternative modelling approach is considered necessary in this case.

- No field degradation rates are available for RPA 404766 (Cis-diol), therefore lab degradation are used for the leaching assessment at a first step. However, the RMS notes that in lab degradation studies RPA 404766 (Cis-diol) was shown to consistently degrade faster than its isomeric sibling RPA 406341 (Trans-diol) with the only exception of the US clay soil (Doble, 1996) where RPA 404766 (Cis-diol) appeared to degrade slower than RPA 406341 (Trans-diol). In all other cases degradation of RPA 404766 (Cis-diol) was 1.2 - 3.0 times faster than degradation of RPA 406341 (Trans-diol). Thus, from a scientific point of view is appears defendable to also use the geometric mean field degradation rate of RPA 406341 (Trans-diol) of 40.6 days as a conservative estimate of the (unknown) field degradation rate of RPA 404766 (Cis-diol) in a modelling refinement step. Data on this refinement step are shown in the result tables below.

- It may also be noted that triticonazole and its metabolites appear to be prone to aged sorption as indicated in desorption experiments and in an aged column leaching study conducted with triticonazole. In this light, the leaching assessment for triticonazole and its metabolites assuming equilibrium sorption is considered conservative.

- As already announced no leaching assessment is triggered for RPA 407922 as this metabolite could not be identified in soil degradation experiments. Notice that the applicant originally claimed metabolite fraction 'Met 6 (MWT 333)' observed in Ayliffe & Austin (1993) at max. 12.8 % AR being identified as RPA 407922. As discussed in Vol. 3CA this finding is not supported anymore.

- The leaching assessment for the metabolite fractions 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)' observed in Ayliffe & Austin (1993) above 5 % AR at two consecutive sampling points is addressed in a separate statement (Szegedi, 2018), see next study.

Table B.8.2.4.1-8: Revised substance properties of triticonazole and its metabolites for PEC_{GW} calculation - RMS AT assessment

Parameter	Triticonazole	RPA 406341 (Trans-diol)	RPA 404766 (Cis-diol)
Mol weight (g/mol)	317.8	333.8	333.8
Vapour pressure (Pa)	9.0E-08 (25 °C)	0.0[(a)]	0.0[(a)]
Water solubility (mg/L)	9.3 (20 °C)	9.3 (20 °C)[(b)]	9.3 (20 °C)[(b)]
K_{foc}/K_{fom} (mL/g)	307 / 178[(c)]	144 / 84.0	75.7 / 43.9
1/n (-)	0.90	0.94	0.93
DegT50 (d)	78.7 (field)	40.6 (field)	No refinement: 75.3 (lab) Refinement: 40.6 (field)[(d)]
Plant uptake	0.0	0.0	0.0
Formation fraction	na	0.347 (from parent)	0.356 (from parent)
Q_{10}	2.58	2.58	2.58

na denotes not applicable
(a) No data, default value of 0 used
(b) No data, parent data used
(c) Worst case K_{foc}/K_{fom} (*p*H dependent sorption)
(d) Field degradation rate of RPA 406341 (Trans-diol) used in a refinement step (also refer to comment above)

Table B.8.2.4.1-9: Predicted 80th percentile concentrations of triticonazole and its metabolites in shallow groundwater (PEC_{GW}) following application of triticonazole as seed treatment in winter and spring cereals (PEARL 4.4.4) - RMS AT assessment

Use	Scenario	Triticonazole	RPA 406341 (Trans-diol)	RPA 404766 (Cis-diol) *DegT50* = 75.3 days (lab)	RPA 404766 (Cis-diol) *DegT50* = 40.6 days (field)[(a)]
Winter cereals	Châteaudun	< 0.001	< 0.001	0.047	0.004
	Hamburg	< 0.001	0.005	0.134	0.029
	Jokioinen	< 0.001	0.001	0.070	0.009
	Kremsmünster	< 0.001	0.003	0.093	0.019
	Okehampton	< 0.001	0.006	0.120	0.029
	Piacenza	< 0.001	0.002	0.071	0.013
	Porto	< 0.001	0.002	0.070	0.016
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	0.036	0.002
Spring cereals	Châteaudun	< 0.001	< 0.001	0.036	0.002
	Hamburg	< 0.001	0.005	0.147	0.030
	Jokioinen	< 0.001	< 0.001	0.065	0.008
	Kremsmünster	< 0.001	0.003	0.093	0.018
	Okehampton	< 0.001	0.004	0.109	0.023
	Porto	< 0.001	0.001	0.063	0.013

(a) Refinement step: Field degradation rate of RPA 406341 (Trans-diol) used as a conservative estimate of the (unknown) field degradation rate of its isomeric sibling RPA 404766 (Cis-diol)

Table B.8.2.4.1-10: Predicted 80th percentile concentrations of triticonazole and its metabolites in shallow groundwater (PEC_{GW}) following application of triticonazole as seed treatment in winter and spring cereals (PELMO 5.5.3) - RMS AT assessment

Use	Scenario	Triticonazole	RPA 406341	RPA 404766 (Cis-diol)

			(Trans-diol)	*DegT50* = 75.3 days (lab)	*DegT50* = 40.6 days (field)[(a)]
Winter cereals	Châteaudun	< 0.001	< 0.001	0.033	0.002
	Hamburg	< 0.001	0.004	0.124	0.026
	Jokioinen	< 0.001	0.001	0.071	0.010
	Kremsmünster	< 0.001	0.002	0.085	0.016
	Okehampton	< 0.001	0.005	0.110	0.025
	Piacenza	< 0.001	0.002	0.077	0.014
	Porto	< 0.001	0.003	0.087	0.024
	Sevilla	< 0.001	< 0.001	0.002	< 0.001
	Thiva	< 0.001	< 0.001	0.018	0.001
Spring cereals	Châteaudun	< 0.001	< 0.001	0.021	0.001
	Hamburg	< 0.001	0.003	0.107	0.021
	Jokioinen	< 0.001	< 0.001	0.050	0.006
	Kremsmünster	< 0.001	0.002	0.078	0.014
	Okehampton	< 0.001	0.003	0.090	0.018
	Porto	< 0.001	0.002	0.062	0.014

(a) Refinement step: Field degradation rate of RPA 406341 (Trans-diol) used as a conservative estimate of the (unknown) field degradation rate of its isomeric sibling RPA 404766 (Cis-diol)

Table B.8.2.4.1-11: Predicted 80th percentile concentrations of triticonazole and its metabolites in shallow groundwater (PEC_{GW}) following application of triticonazole as seed treatment in winter and spring cereals (MACRO 5.5.4) - RMS AT assessment

Use	Scenario	Triticonazole	RPA 406341 (Trans-diol)	RPA 404766 (Cis-diol) *DegT50* = 75.3 days (lab)
Winter cereals	Châteaudun	< 0.001	< 0.001	0.048
Spring cereals	Châteaudun	< 0.001	< 0.001	0.035

Table B.8.2.4.1-12: Predicted 80th percentile concentrations of triticonazole and its metabolites in shallow groundwater (PEC_{GW}) following application of triticonazole as seed treatment in winter and spring cereals (PEARL 4.4.4) - RMS AT assessment applying an alternative triticonazole *DegT50* of 35.8 days representing the fast decline phase of triticonazole

Use	Scenario	Triticonazole	RPA 406341 (Trans-diol)	RPA 404766 (Cis-diol) *DegT50* = 75.3 days (lab)
Winter cereals	Châteaudun	< 0.001	< 0.001	0.040
	Hamburg	< 0.001	0.003	0.119
	Jokioinen	< 0.001	< 0.001	0.061
	Kremsmünster	< 0.001	0.001	0.081
	Okehampton	< 0.001	0.003	0.107
	Piacenza	< 0.001	0.001	0.060
	Porto	< 0.001	0.001	0.063
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	0.029
Spring cereals	Châteaudun	< 0.001	< 0.001	0.029
	Hamburg	< 0.001	0.002	0.129
	Jokioinen	< 0.001	< 0.001	0.057
	Kremsmünster	< 0.001	0.001	0.081
	Okehampton	< 0.001	0.002	0.093
	Porto	< 0.001	0.001	0.047

Reference:	**Statement - Exposure assessment for "Met 6" and "Met 7", potential degradation products of BAS 595F triticonazole**
Author(s), year:	Szegedi, K., 2018
Report/Doc. Number:	2018/1091281
Guideline(s):	None
GLP:	Not applicable (statement)
Validity:	None reliable with respect to groundwater leaching assessment

Status: **New submission**

Material and methods:

Predicted environmental concentrations in groundwater were calculated for the active substance triticonazole and its metabolites 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)' with FOCUS PELMO 5.5.3 according to FOCUS. Scenarios and general procedures are the same as reported in the draft RAR. Technical details are described in the respective guidance documents. The following environmental fate parameters of triticonazole and its metabolites were used for the simulations:

Table B.8.2.4.1-13: Parameters of triticonazole and 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)' used for the simulations

Compound	Triticonazole	'Met 6 (MWT 333)'	'Met 7 (MWT 315)'	Remarks
Molecular mass (g/mol)	317.8	333.8	315.8	
Aqueous solubility (mg/L)	9.3			Parent data
Vapour pressure (Pa)	$9 \cdot 10^{-8}$ (at 25 °C)	0	0	Conservative worst case for metabolites
DegT50 soil (days)	78.7	1000	1000	Parent: Draft RAR Metabolites: Conservative worst case for metabolites
Formation fraction from parent	na	0.132	0.137	Refer to Vol. 3CA
PELMO degradation rates	To 'Met 6 (MWT 333)': 0.00116258 To 'Met 7 (MWT 315)': 0.00120662 To Sink: 0.00643825	To Sink: 0.00069	To Sink: 0.00069	
K_{foc} (mL/g)	168	577.1	547.3	Parent: Worst case (Draft RAR) Metabolites: Estimated on basis of KocWIN 2.00 (EPISuite)
1/*n*	0.883	1	1	Parent: Draft RAR Metabolites: Default
Plant uptake factor	0			FOCUS default

Results:

Results of the PEC_{gw} calculations for triticonazole and its metabolites are presented below.

Table B.8.2.4.1-14: PEC_{gw} of triticonazole and its metabolites 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)' following seed treatment with triticonazole in spring cereals

Scenario	PEC_{gw} (µg/L) Triticonazole	'Met 6 (MWT 333)'	'Met 7 (MWT 315)'
Châteaudun	< 0.001	< 0.001	< 0.001
Hamburg	< 0.001	< 0.001	< 0.001
Jokioinen	< 0.001	< 0.001	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001
Okehampton	< 0.001	< 0.001	< 0.001
Porto	< 0.001	< 0.001	< 0.001

Table B.8.2.4.1-15: PEC_{gw} of triticonazole and its metabolites 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)' following seed treatment with triticonazole in winter cereals

Scenario	PEC_{gw} (µg/L) Triticonazole	'Met 6 (MWT 333)'	'Met 7 (MWT 315)'
Châteaudun	< 0.001	< 0.001	< 0.001
Hamburg	< 0.001	< 0.001	< 0.001
Jokioinen	< 0.001	< 0.001	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001

Okehampton	< 0.001	0.001	< 0.001
Piacenza	< 0.001	< 0.001	< 0.001
Porto	< 0.001	< 0.001	< 0.001
Sevilla	< 0.001	< 0.001	< 0.001
Thiva	< 0.001	< 0.001	< 0.001

Based on the results obtained by simulations with FOCUS PELMO 5.5.3 it can be concluded that the formation of metabolites 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)' after the use of triticonazole is not likely to pose an unacceptable risk to shallow groundwater. The 80th percentile predicted environmental concentrations in groundwater (PEC_{gw}) of the active substance triticonazole and its metabolites were calculated to be < 0.001 µg/L in all scenarios. Due to the extremely low estimated concentrations and the harmonization between FOCUS models calculations with an additional model are not necessary.

Comments (RMS AT):

- The RMS AT notes that, although indicated to be based on the conservative *DegT50* value of 1000 days, *DegT50* values for 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)' actually used in the applicant's calculations (PELMO 5.5.3) were 38.6 and 42.1 days, respectively, for unknown reasons (PELMO input file).
- Formation fractions of 'Met 6 (WMT 333)' and 'Met 7 (MWT 315)' have been re-assessed by the RMS AT (refer to Vol. 3, CA).
- As already indicated in Vol. 3CA, the RMS AT considers the estimated K_{foc} values on basis of KocWIN 2.00 (EPISuite) unrealistic in view of the relative retention times (rRT) of the two metabolite fractions observed in the HPLC chromatograms in Ayliffe & Austin (1993). As discussed more in detail in Vol. 3CA, the RMS AT considers K_{foc} values estimated on basis of the rRT more reliable. Consequently, the RMS AT re-calculated PEC_{gw} values for these two metabolites fractions on basis of the following substance properties (see table below).
- The RMS AT notes that no Freundlich exponent is available for 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)'. In view of their structural similarity to the parent and the metabolites RPA 406341 (Trans-diol) and RPA 404766 (Cis-diol), the RMS AT considers it scientifically defendable to use the worst case 1/*n* value of these three compounds (i.e. 0.94) in the leaching assessment.

Table B.8.2.4.1-16: Revised substance properties of triticonazole and its metabolites for PEC_{GW} calculation - RMS AT assessment

Parameter	Triticonazole	'Met 6 (MWT 333)'	'Met 7 (MWT 315)'
Mol weight (g/mol)	317.8	333.8	315.8
Vapour pressure (Pa)	9.0E-08 (25 °C)	0.0[(a)]	0.0[(a)]
Water solubility (mg/L)	9.3 (20 °C)	9.3 (20 °C)[(b)]	9.3 (20 °C)[(b)]
K_{foc}/K_{fom} (mL/g)	307 / 178[(c)]	278 / 161[(d)]	327 / 190[(d)]
1/n (-)	0.90	0.94	0.94
DegT50 (d)	78.7 (field)	1000 (default)	1000 (default)
Plant uptake	0.0	0.0	0.0
Formation fraction	na	0.077 (from parent)	0.051 (from parent)
Q_{10}	2.58	2.58	2.58

na denotes not applicable
(a) No data, default value of 0 used
(b) No data, parent data used
(c) Worst case K_{foc}/K_{fom} (*p*H dependent sorption)
(d) Estimated on basis of the relative retention times observed in Ayliffe & Austin (1993) (for details refer to Vol. 3CA)

Table B.8.2.4.1-17: Predicted 80th percentile concentrations of metabolite fractions 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)' in shallow groundwater (PEC_{GW}) following application of triticonazole as seed treatment in winter and spring cereals (PEARL 4.4.4 & PELMO 5.5.3) - RMS AT assessment

	PEARL 4.4.4	PELMO 5.5.3

Use	Scenario	'Met 6 (MWT 333)	'Met 7' (MWT 315)'	'Met 6 (MWT 333)	'Met 7 (MWT 315)'
Winter cereals	Châteaudun	0.141	0.058	0.113	0.037
	Hamburg	0.161	0.083	0.173	0.087
	Jokioinen	0.047	0.011	0.031	0.006
	Kremsmünster	0.118	0.062	0.138	0.071
	Okehampton	0.123	0.067	0.128	0.070
	Piacenza	0.130	0.066	0.149	0.076
	Porto	0.089	0.048	0.091	0.050
	Sevilla	0.005	0.001	0.008	0.001
	Thiva	0.131	0.037	0.095	0.024
Spring cereals	Châteaudun	0.112	0.045	0.097	0.034
	Hamburg	0.187	0.094	0.157	0.080
	Jokioinen	0.034	0.007	0.028	0.006
	Kremsmünster	0.129	0.067	0.126	0.065
	Okehampton	0.125	0.068	0.117	0.064
	Porto	0.083	0.045	0.083	0.044

- The RMS AT notes that modelling results obtained indicate a leaching risk for metabolite fractions 'Met 6 (MWT 333)' and 'Met 7 (MWT 315), the latter close to the regulatory threshold of 0.1 µg/L. However, it should be kept in mind that these two metabolite fractions have only been overserved in legacy studies (Ayliffe & Austin, 1993; Ayliffe & McMillan-Staff, 1994; and Ayliffe & Godward, 1993) applying chromatographic methods which may not have been fully capable to adequately separate all metabolites of triticonazole. In all later studies, applying more sophisticated HPLC separation methods, no metabolites other than RPA 406341 (Trans-diol) and RPA 404766 (Cis-diol) were observed above 5 % AR at two consecutive sampling points.

B.8.2.4.2. Additional field tests

None

B.8.2.5. Estimation of concentrations in surface water and sediment

Reference:	**Predicted environmental concentrations of Triticonazole and its metabolites in surface water and sediment (PECsw and PECsed) following seed treatment in cereals using the FOCUS surface water scenarios**
Author(s), year:	Lamers, M., 2015
Report/Doc. Number:	2015/1183789
Guideline(s):	SANCO/4802/2001 rev. 2 (FOCUS surface water scenarios), SANCO/10058/2005 rev. 2 (FOCUS kinetics report), FOCUS (2007): Landscape And Mitigation Factors Volume 2 SANCO/10422/2005 v2.0., FOCUS (2015): Generic guidance for FOCUS surface water scenarios v 1.4
GLP:	Not applicable
Validity:	Not fully reliable (refer to comment section)
Status:	**Submitted for renewal**

Material and methods:

Calculations were carried out according to FOCUS (FOCUS, 2001 [*FOCUS (2001): Focus Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios. EC Document Reference SANCO/4802/2012 rev. 0*], 2015 [*FOCUS (2015):Generic guidance for FOCUS surface water Scenarios, ver. 1.4, 367 pp.*]). At Step1 and 2, calculations were carried out for the active substance triticonazole and all metabolites using FOCUS STEPS 1-2 (version 3.2). At Step 3, calculations were conducted for the active substance only using FOCUS SWASH (version 5.3). The FOCUS crops 'winter cereals' and 'spring cereals' were chosen for the simulations. All scenarios which are parameterised for spring and winter cereals were considered. In addition to FOCUS SW, exposure to surface water via dust drift deposition was calculated for the parent and its photo-metabolite RPA 406203 (Z-isomer of triticonazole).

Summary of input parameters used for modelling

The substance related parameters used for triticonazole and its metabolites in the calculations are summarised in the tables below. FOCUS default values were selected for parameters which are not explicitly listed below.

Table B.8.2.5-1: Input parameters of triticonazole used for modelling

Parameter	Triticonazole	Remarks
Molecular mass (g/mol)	317.8	-
Aqueous solubility (mg/L)	9.3	At 20 °C, pH 7.3-8.7
Vapour pressure (Pa)	9.0E-08	At 25°C
DT50 soil (days)	82.2	Geomean, field, normalised, n = 9
DT50 total system (days), Steps 1-2	300	Geometric mean, n = 2, total system
DT50 water (days)	Steps 1-2: 300 Step 3: 300 / 1000 Dust drift: 7.1	Geometric mean, n = 2, total system K_{oc} > 100 and < 2000 mL/g, therefore two runs to be conducted: Geometric mean, n = 2, total system / default Geometric mean, dissipation in water, n = 2
DT50 sediment (days)	Steps 1-2: 300 Step 3: 1000 / 300 Dust drift: 1000	geometric mean, n = 2, total system K_{oc} > 100 and < 2000 mL/g, therefore two runs to be conducted: default / geometric mean, n = 2, total system Default
K_{foc} (mL/g)	494	Geometric mean, n = 13
1/*n*	0.89	Arithmetic mean, n =13
Maximum occurrence in soil (%)	100	Parent
Maximum occ. in wat/sed. (%)	100	Parent
Plant uptake factor	0	Default

Table B.8.2.5-2: Input parameters of metabolites used for modelling

Parameter	Metabolite	Value	Remarks
Molecular mass (g/mol)	RPA 404766 (Cis-diol) RPA 406341 (Trans-diol) RPA 407922 RPA 406203 (Z-isomer)	333.8 333.8 333.8 317.8	-
Aqueous solubility (mg/L)	All metabolites	9.3	Parent data
DT50 soil (days)	RPA 404766 (Cis-diol) RPA 406341 (Trans-diol) RPA 407922 RPA 406203 (Z-isomer)	38.6 42.1 1.0 1000	Geometric mean, laboratory, n = 4, normalised Geometric mean, field, normalised, n = 4 Geometric mean, lab, normalised, n = 3 Default
DT50 total system (days) *DT50* water (days) *DT50* sediment (days)	all metabolites all metabolites all metabolites	1000 1000 1000	Default Default Default
K_{foc} (mL/g)	RPA 404766 (Cis-diol) RPA 406341 (Trans-diol) RPA 407922 RPA 406203 (Z-isomer)	76 130 486 1E-10	Geometric mean, n = 9 Geometric mean, n = 9 Geometric mean, n = 9 Default
Maximum occurrence in soil (%)	RPA 404766 (Cis-diol) RPA 406341 (Trans-diol) RPA 407922 RPA 406203 (Z-isomer)	13.9 20.2 12.8 11.0	- - - From soil photolysis
Maximum occ. in wat/sed. (%)	RPA 404766 (Cis-diol) RPA 406341 (Trans-diol) RPA 407922 RPA 406203 (Z-isomer)	1.0E-05 1.0E-05 1.0E-05 51.3	Default, not detected in w/s studies Default, not detected in w/s studies Default, not detected in w/s studies From aqueous photolysis

Application and GAP:

Use pattern
The use of triticonazole as seed treatment in cereals was assessed according to ‘Good Agricultural Practice’ (GAP). Assuming a maximum seeding rate of 250 kg/ha and 5 g a.s. (0.2 L product) per 100 kg seeds, a maximum application rate of 12.5 g a.s./ha can be derived.

Application scenario
A single application of 12.5 g a.s./ha was considered in the simulations. As triticonazole is applied as seed treatment, the interception rate was set to 0 %. The application methods ‘no drift (incorporation or seed treatment)’ and ‘granular application’ were selected for Step 1-2 and Step 3 calculations, respectively.

The application scenarios considered for the simulations are presented in the table below.

Table B.8.2.5-3: Application scenarios of triticonazole considered for the application

Crop	Application method	Application rate (g a.s./ha)	Max. number of applications	Interception rate (%)
Winter cereals	Seed treatment	12.5	1	0
Spring cereals	Seed treatment	12.5	1	0

Applied modelling strategy and application timing
Calculations for triticonazole were carried out at Step 1 to Step 3 while calculations for the metabolites were conducted at Steps 1-2 only.

At Step 2, the regions ‘North Europe’ and ‘South Europe’ and the application periods ‘March – May’ and ‘October – February’ were taken into account for modelling.

Step 3 calculations for triticonazole were carried out using FOCUS SWASH (version 5.3) with the Chemical Application Method (CAM) 6 (incorporation soil linear decrease) including a standard incorporation depth of 4 cm. The ‘granular’ application method was chosen to simulate seed treatment. Appropriate application windows for winter and spring cereals were chosen based on recommended application of triticonazole as seed treatment and on emergence dates specified in FOCUS (2001, 2015).

A summary of application dates used for modelling at Step 3 is presented in the table below.

Table B.8.2.5-4: Step 3: Application dates used for modelling

Crop	FOCUS Scenario	Application window 1st date of application window	Application window Last date of application window	Actual application date(a)
Winter cereals	D1	11-Sep (254)	11-Oct (284)	11-Sep (254)
	D2	11-Oct (284)	10-Nov (314)	11-Oct (284)
	D3	07-Nov (311)	07-Dez (341)	06-Nov (310)
	D4	08-Sep (251)	08-Oct (281)	10-Sep (253)
	D5	27-Oct (300)	26-Nov (330)	26-Nov (330)
	D6	16-Nov (320)	16-Dez (350)	06-Dez (340)
	R1	29-Oct (302)	28-Nov (332)	14-Nov (318)
	R3	17-Nov (321)	17-Dez (351)	17-Nov (321)
	R4	27-Oct (300)	26-Nov (330)	03-Nov (307)
Spring cereals	D1	21-Apr (111)	21-May (141)	25-Apr (115)
	D3	18-Mar (77)	17-Apr (107)	17-Mar (76)
	D4	12-Apr (102)	12-May (132)	18-Apr (108)
	D5	01-Mar (60)	31-Mar (90)	07-Mar (66)
	R4	01-Mar (60)	31-Mar (90)	05-Mar (64)

(a) Determined by PAT
Numbers in brackets indicate 'Julian Days'

Preliminary ground dust drift percentages have been determined for cereals at 1 m distance from field edge. They can be used for a first tier assessment of PEC_{sw} and PEC_{sed} for the entry pathway dust drift. The values were normalised for maximum Heubach values, drill width and a.s. % in dust (EU Commission, 2012 [*EU Commission (2012): Guidance document on the authorisation of plant protection products for seed treatment. SANCO/10553/2012 rev. 0*]). The 2-D dust drift values can also be used for the calculation of the off-field risk assessment for non-target arthropods (if no 3D-exposure values are available). The dust drift rates are summarised in the following table:

Table B.8.2.5-5: Predicted exposures in 2- and 3-dimensional structures

Crop	Type of seeder	Experimental ground dust deposition (uncorrected value) (% a.s. field rate/ha)	Normalised exposure 2-D / 3-D (% a.s. field rate/ha)
Cereals	Pneumatic	0.266	0.33 / 4.1

Simulation tools and scenarios
Calculations were carried out according to FOCUS (FOCUS, 2001, 2015) at Step 1-2 and Step 3 using the current version of FOCUS STEPS 1-2 (version 3.2), and FOCUS SWASH (version 5.3) including the operational models FOCUS MACRO (version 5.5.4), FOCUS PRZM (version 4.3.1) and FOCUS TOXSWA (version 4.4.3). Calculations for dust drift exposure were conducted by excel-spreadsheet following guidance as given by EU Commission (2012).

<u>Results and discussion:</u>

Results of Steps 1 and 2

Maximum PEC_{sw} and PEC_{sed}
Global maximum PEC_{sw} and PEC_{sed} of triticonazole and its metabolites RPA 404766 (Cis-diol), RPA 406341 (Trans-diol), RPA 407922 and RPA 406203 (Z-isomer) at Step 1 and 2 following a single application of 12.5 g a.s./ha as seed treatment to cereals are presented in the tables below.

Table B.8.2.5-6: Step 1-2: Maximum PEC_{sw} of triticonazole and its metabolites following application of 12.5 g a.s./ha as seed treatment to cereals

FOCUS STEP	PEC_{sw} (µg/L)

	Triticonazole	RPA404766 (Cis-diol)	RPA406341 (Trans-diol)	RPA407922	RPA406203 (Z-isomer)
Step 1	2.512	0.552	0.753	0.340	2.598
Step 2, North Europe, March – May	0.486	0.103	0.141	0.004	0.505
Step 2, North Europe, October – February	1.214	0.257	0.353	0.011	1.263
Step 2, South Europe, March – May	0.972	0.206	0.282	0.009	1.010
Step 2, South Europe, October – February	0.972	0.206	0.282	0.009	1.010

Table B.8.2.5-7: Step 1-2: Maximum PEC_{sed} of triticonazole and its metabolites following application of 12.5 g a.s./ha as seed treatment to cereals

FOCUS STEP	PEC_{sed} (µg/kg)				
	Triticonazole	RPA404766 (Cis-diol)	RPA406341 (Trans-diol)	RPA407922	RPA406203 (Z-isomer)
Step 1	12.410	0.420	0.980	1.652	< 0.001
Step 2, North Europe, March – May	2.400	0.078	0.183	0.021	< 0.001
Step 2, North Europe, October – February	5.999	0.195	0.459	0.052	< 0.001
Step 2, South Europe, March – May	4.799	0.156	0.367	0.041	< 0.001
Step 2, South Europe, October – February	4.799	0.156	0.367	0.041	< 0.001

Actual and time-weighted average PEC_{sw} and PEC_{sed}

Actual and time-weighted average concentrations of triticonazole in surface water and sediment at Step 2 for the application of 12.5 g a.s./ha as seed treatment in cereals are presented in the tables below.

Table B.8.2.5-8: Steps 1-2: Actual and time-weighted average concentrations in surface water ($PEC_{sw,act}$, $PEC_{sw,twa}$) of triticonazole following seed treatment in cereals (Mar – May)

Time (d)	Step 1		Step 2 – North Europe		Step 2 – South Europe	
	$PEC_{sw,act}$ (µg/L)	$PEC_{sw,twa}$ (µg/L)	$PEC_{sw,act}$ (µg/L)	$PEC_{sw,twa}$ (µg/L)	$PEC_{sw,act}$ (µg/L)	$PEC_{sw,twa}$ (µg/L)
0	2.512	-	0.486	-	0.972	-
1	2.506	2.509	0.485	0.485	0.969	0.970
2	2.501	2.506	0.484	0.485	0.967	0.969
4	2.489	2.501	0.481	0.484	0.963	0.967
7	2.472	2.492	0.478	0.482	0.956	0.964
14	2.432	2.472	0.470	0.478	0.941	0.956
21	2.393	2.452	0.463	0.474	0.926	0.948
28	2.355	2.433	0.455	0.470	0.911	0.941
42	2.280	2.394	0.441	0.463	0.882	0.926
50	2.238	2.372	0.433	0.459	0.866	0.918
100	1.994	2.243	0.386	0.434	0.771	0.867

Table B.8.2.5-9: Steps 1-2: Actual and time-weighted average concentrations in surface water ($PEC_{sw,act}$, $PEC_{sw,twa}$) of triticonazole following seed treatment in cereals (Oct – Feb)

Time (d)	Step 1		Step 2 – North Europe		Step 2 – South Europe	
	$PEC_{sw,act}$ (µg/L)	$PEC_{sw,twa}$ (µg/L)	$PEC_{sw,act}$ (µg/L)	$PEC_{sw,twa}$ (µg/L)	$PEC_{sw,act}$ (µg/L)	$PEC_{sw,twa}$ (µg/L)
0	2.512	-	1.214	-	0.972	-
1	2.506	2.509	1.212	1.213	0.969	0.970
2	2.501	2.506	1.209	1.212	0.967	0.969
4	2.489	2.501	1.203	1.209	0.963	0.967
7	2.472	2.492	1.195	1.205	0.956	0.964
14	2.432	2.472	1.176	1.195	0.941	0.956
21	2.393	2.452	1.157	1.185	0.926	0.948
28	2.355	2.433	1.138	1.176	0.911	0.941
42	2.280	2.394	1.102	1.157	0.882	0.926
50	2.238	2.372	1.082	1.147	0.866	0.918
100	1.994	2.243	0.964	1.084	0.771	0.867

Results of Step 3

Maximum PEC_{sw} and PEC_{sed}

Calculations at Step 3 were only carried out for the active substance triticonazole. Maximum PEC_{sw} and PEC_{sed} of triticonazole following a single application of 12.5 g a.s./ha as seed treatment in winter and spring cereals are presented in Table 9.2.5-15 and in Table 9.2.5-16, respectively.

Table B.8.2.5-10: Step 3: Maximum PEC_{sw} of triticonazole following seed treatment in winter and spring cereals

Scenario	Water body		Winter cereals		Spring cereals	
			Option 1[a]	Option 2[a]	Option 1[a]	Option 2[a]
D1	ditch	$PEC_{sw,max}$ (µg/L)	0.011	0.011	0.004	0.004
		main entry route:	Drainage	Drainage	Drainage	Drainage
D1	stream	$PEC_{sw,max}$ (µg/L)	0.007	0.007	0.003	0.003
		main entry route:	Drainage	Drainage	Drainage	Drainage
D2	ditch	$PEC_{sw,max}$ (µg/L)	0.022	0.022	-[b]	-[b]
		main entry route:	Drainage	Drainage	-[b]	-[b]
D2	stream	$PEC_{sw,max}$ (µg/L)	0.014	0.014	-[b]	-[b]
		main entry route:	Drainage	Drainage	-[b]	-[b]
D3	ditch	$PEC_{sw,max}$ (µg/L)	< 0.001	< 0.001	< 0.001	< 0.001
		main entry route:	Drainage	Drainage	Drainage	Drainage
D4	pond	$PEC_{sw,max}$ (µg/L)	< 0.001	< 0.001	< 0.001	< 0.001
		main entry route:	Drainage	Drainage	Drainage	Drainage
D4	stream	$PEC_{sw,max}$ (µg/L)	0.001	0.001	0.001	0.001
		main entry route:	Drainage	Drainage	Drainage	Drainage
D5	pond	$PEC_{sw,max}$ (µg/L)	< 0.001	< 0.001	< 0.001	< 0.001
		main entry route:	Drainage	Drainage	Drainage	Drainage
D5	stream	$PEC_{sw,max}$ (µg/L)	0.001	0.001	< 0.001	< 0.001
		main entry route:	Drainage	Drainage	Drainage	Drainage
D6	ditch	$PEC_{sw,max}$ (µg/L)	0.006	0.006	-[b]	-[b]
		main entry route:	Drainage	Drainage	-[b]	-[b]
R1	pond	$PEC_{sw,max}$ (µg/L)	0.010	0.011	-[b]	-[b]
		main entry route:	Runoff	Runoff	-[b]	-[b]
R1	stream	$PEC_{sw,max}$ (µg/L)	0.129	0.129	-[b]	-[b]
		main entry route:	Runoff	Runoff	-[b]	-[b]
R3	stream	$PEC_{sw,max}$ (µg/L)	0.168	0.168	-[b]	-[b]
		main entry route:	Runoff	Runoff	-[b]	-[b]
R4	stream	$PEC_{sw,max}$ (µg/L)	0.153	0.153	0.082	0.082
		main entry route:	Runoff	Runoff	Runoff	Runoff

(a) Option 1: DT_{50} in water = 300 d and DT_{50} in sediment = 1000 d, option 2: DT_{50} in water = 1000 d and DT_{50} in sediment = 300 d
(b) Scenario not defined for spring cereals

Table B.8.2.5-11: Step 3: Maximum PEC_{sed} of triticonazole following seed treatment in winter and spring cereals

Scenario	Water body	PEC_{sed} (µg/kg)			
		Winter cereals		Spring cereals	
		Option 1[a]	Option 2[a]	Option 1[a]	Option 2[a]
D1	ditch	0.086	0.081	0.046	0.043
D1	stream	0.049	0.047	0.027	0.025
D2	ditch	0.093	0.087	-[b]	-[b]
D2	stream	0.051	0.048	-[b]	-[b]
D3	ditch	< 0.001	< 0.001	< 0.001	< 0.001
D4	pond	0.002	0.002	0.002	0.002
D4	stream	0.001	0.001	0.001	0.001
D5	pond	0.004	0.004	0.002	0.002
D5	stream	0.001	0.001	< 0.001	< 0.001
D6	ditch	0.003	0.003	-[b]	-[b]
R1	pond	0.067	0.066	-[b]	-[b]
R1	stream	0.051	0.051	-[b]	-[b]
R3	stream	1.478	1.478	-[b]	-[b]
R4	stream	0.075	0.075	0.058	0.058

(a) Option 1: DT_{50} in water = 300 d and DT_{50} in sediment = 1000 d, option 2: DT_{50} in water = 1000 d and DT_{50} in sediment = 300 d

(b) Scenario not defined for spring cereals

Actual and time-weighted average PEC_{sw}

Actual and time-weighted average concentrations of triticonazole in surface water at Step 3 are presented in Table 9.2.5-17. Regarding PEC in surface water, only the results for option 2 (DT_{50} in water = 1000 d and DT_{50} in sediment = 300 d) are presented for each scenario, since these values represent the worst-case.

Table B.8.2.5-12: Step 3: Actual and time-weighted average concentrations in surface water ($PEC_{sw,act}$, $PEC_{sw,twa}$) of triticonazole following seed treatment in cereals

Scenario	Water body	Time (d)	Winter cereals[a] $PEC_{sw,act}$ (µg/L)	Winter cereals[a] $PEC_{sw,twa}$ (µg/L)	Spring cereals[a] $PEC_{sw,act}$ (µg/L)	Spring cereals[a] $PEC_{sw,twa}$ (µg/L)
D1	ditch	**0**	0.011	-	0.004	-
		1	0.010	0.010	0.004	0.004
		2	0.010	0.010	0.004	0.004
		4	0.010	0.010	0.004	0.004
		7	0.010	0.010	0.004	0.004
		14	0.010	0.010	0.004	0.004
		21	0.009	0.010	0.004	0.004
		28	0.008	0.009	0.003	0.004
		42	0.008	0.009	0.003	0.004
		50	0.007	0.009	0.003	0.004
		100	0.004	0.007	0.002	0.003
D1	stream	**0**	0.007	-	0.003	-
		1	0.006	0.007	0.003	0.003
		2	0.006	0.006	0.003	0.003
		4	0.006	0.006	0.003	0.003
		7	0.006	0.006	0.003	0.003
		14	0.006	0.006	0.002	0.003
		21	0.006	0.006	0.002	0.002
		28	0.005	0.006	0.002	0.002
		42	0.005	0.006	0.002	0.002
		50	0.004	0.005	0.002	0.002
		100	< 0.001	0.004	< 0.001	0.002
D2	ditch	**0**	0.022	-	-[b]	-[b]
		1	0.005	0.014	-[b]	-[b]
		2	0.008	0.010	-[b]	-[b]
		4	0.006	0.009	-[b]	-[b]
		7	0.004	0.009	-[b]	-[b]
		14	0.003	0.008	-[b]	-[b]
		21	0.003	0.007	-[b]	-[b]
		28	< 0.001	0.007	-[b]	-[b]
		42	-[c]	0.007	-[b]	-[b]
		50	-[c]	0.007	-[b]	-[b]
		100	-[c]	0.007	-[b]	-[b]
D2	stream	**0**	0.014	-	-[b]	-[b]
		1	0.002	0.008	-[b]	-[b]
		2	0.003	0.005	-[b]	-[b]
		4	0.003	0.005	-[b]	-[b]
		7	0.002	0.004	-[b]	-[b]
		14	0.002	0.004	-[b]	-[b]
		21	0.002	0.004	-[b]	-[b]
		28	< 0.001	0.004	-[b]	-[b]
		42	-[c]	0.004	-[b]	-[b]
		50	-[c]	0.004	-[b]	-[b]
		100	-[c]	0.003	-[b]	-[b]
D3	ditch	**0**	< 0.001	-	< 0.001	-
		1	< 0.001	< 0.001	< 0.001	< 0.001
		2	< 0.001	< 0.001	< 0.001	< 0.001
		4	< 0.001	< 0.001	< 0.001	< 0.001
		7	< 0.001	< 0.001	< 0.001	< 0.001
		14	< 0.001	< 0.001	< 0.001	< 0.001
		21	< 0.001	< 0.001	< 0.001	< 0.001

Scenario	Water body	Time (d)	Winter cereals[(a)] PEC$_{sw,act}$ (µg/L)	Winter cereals[(a)] PEC$_{sw,twa}$ (µg/L)	Spring cereals[(a)] PEC$_{sw,act}$ (µg/L)	Spring cereals[(a)] PEC$_{sw,twa}$ (µg/L)
		28	< 0.001	< 0.001	< 0.001	< 0.001
		42	< 0.001	< 0.001	< 0.001	< 0.001
		50	< 0.001	< 0.001	< 0.001	< 0.001
		100	< 0.001	< 0.001	< 0.001	< 0.001
D4	pond	**0**	< 0.001	-	< 0.001	-
		1	< 0.001	< 0.001	< 0.001	< 0.001
		2	< 0.001	< 0.001	< 0.001	< 0.001
		4	< 0.001	< 0.001	< 0.001	< 0.001
		7	< 0.001	< 0.001	< 0.001	< 0.001
		14	< 0.001	< 0.001	< 0.001	< 0.001
		21	< 0.001	< 0.001	< 0.001	< 0.001
		28	< 0.001	< 0.001	< 0.001	< 0.001
		42	< 0.001	< 0.001	< 0.001	< 0.001
		50	< 0.001	< 0.001	< 0.001	< 0.001
		100	< 0.001	< 0.001	< 0.001	< 0.001
D4	stream	**0**	0.001	-	0.001	-
		1	< 0.001	0.001	< 0.001	< 0.001
		2	0.001	0.001	0.001	< 0.001
		4	< 0.001	< 0.001	< 0.001	< 0.001
		7	< 0.001	< 0.001	< 0.001	< 0.001
		14	< 0.001	< 0.001	< 0.001	< 0.001
		21	< 0.001	< 0.001	< 0.001	< 0.001
		28	< 0.001	< 0.001	< 0.001	< 0.001
		42	< 0.001	< 0.001	< 0.001	< 0.001
		50	< 0.001	< 0.001	< 0.001	< 0.001
		100	< 0.001	< 0.001	< 0.001	< 0.001
D5	pond	**0**	< 0.001	-	< 0.001	-
		1	< 0.001	< 0.001	< 0.001	< 0.001
		2	< 0.001	< 0.001	< 0.001	< 0.001
		4	< 0.001	< 0.001	< 0.001	< 0.001
		7	< 0.001	< 0.001	< 0.001	< 0.001
		14	< 0.001	< 0.001	< 0.001	< 0.001
		21	< 0.001	< 0.001	< 0.001	< 0.001
		28	< 0.001	< 0.001	< 0.001	< 0.001
		42	< 0.001	< 0.001	< 0.001	< 0.001
		50	< 0.001	< 0.001	< 0.001	< 0.001
		100	< 0.001	< 0.001	< 0.001	< 0.001
D5	stream	**0**	0.001	-	< 0.001	-
		1	< 0.001	< 0.001	< 0.001	< 0.001
		2	< 0.001	< 0.001	< 0.001	< 0.001
		4	< 0.001	< 0.001	< 0.001	< 0.001
		7	< 0.001	< 0.001	< 0.001	< 0.001
		14	< 0.001	< 0.001	< 0.001	< 0.001
		21	< 0.001	< 0.001	< 0.001	< 0.001
		28	< 0.001	< 0.001	< 0.001	< 0.001
		42	< 0.001	< 0.001	< 0.001	< 0.001
		50	< 0.001	< 0.001	< 0.001	< 0.001
		100	< 0.001	< 0.001	< 0.001	< 0.001
D6	ditch	**0**	0.006	-	-[(b)]	-[(b)]
		1	< 0.001	0.003	-[(b)]	-[(b)]
		2	< 0.001	0.002	-[(b)]	-[(b)]
		4	< 0.001	0.001	-[(b)]	-[(b)]
		7	< 0.001	0.001	-[(b)]	-[(b)]
		14	< 0.001	< 0.001	-[(b)]	-[(b)]
		21	< 0.001	< 0.001	-[(b)]	-[(b)]
		28	< 0.001	< 0.001	-[(b)]	-[(b)]
		42	< 0.001	< 0.001	-[(b)]	-[(b)]
		50	< 0.001	< 0.001	-[(b)]	-[(b)]
		100	< 0.001	< 0.001	-[(b)]	-[(b)]
R1	pond	**0**	0.011	-	-[(b)]	-[(b)]
		1	0.010	0.010	-[(b)]	-[(b)]
		2	0.010	0.010	-[(b)]	-[(b)]

Scenario	Water body	Time (d)	Winter cereals[(a)] $PEC_{sw,act}$ (µg/L)	Winter cereals[(a)] $PEC_{sw,twa}$ (µg/L)	Spring cereals[(a)] $PEC_{sw,act}$ (µg/L)	Spring cereals[(a)] $PEC_{sw,twa}$ (µg/L)
		4	0.010	0.010	-[(b)]	-[(b)]
		7	0.009	0.010	-[(b)]	-[(b)]
		14	0.009	0.009	-[(b)]	-[(b)]
		21	0.008	0.009	-[(b)]	-[(b)]
		28	0.007	0.009	-[(b)]	-[(b)]
		42	0.008	0.008	-[(b)]	-[(b)]
		50	0.008	0.008	-[(b)]	-[(b)]
		100	0.005	0.007	-[(b)]	-[(b)]
R1	stream	**0**	0.129	-	-[(b)]	-[(b)]
		1	< 0.001	0.055	-[(b)]	-[(b)]
		2	< 0.001	0.028	-[(b)]	-[(b)]
		4	< 0.001	0.020	-[(b)]	-[(b)]
		7	< 0.001	0.012	-[(b)]	-[(b)]
		14	0.007	0.006	-[(b)]	-[(b)]
		21	0.001	0.004	-[(b)]	-[(b)]
		28	< 0.001	0.003	-[(b)]	-[(b)]
		42	< 0.001	0.003	-[(b)]	-[(b)]
		50	< 0.001	0.003	-[(b)]	-[(b)]
		100	< 0.001	0.002	-[(b)]	-[(b)]
R3	**stream**	**0**	0.168	-	-[(b)]	-[(b)]
		1	0.138	0.129	-[(b)]	-[(b)]
		2	0.018	0.109	-[(b)]	-[(b)]
		4	0.001	0.075	-[(b)]	-[(b)]
		7	0.001	0.043	-[(b)]	-[(b)]
		14	< 0.001	0.022	-[(b)]	-[(b)]
		21	0.001	0.017	-[(b)]	-[(b)]
		28	< 0.001	0.013	-[(b)]	-[(b)]
		42	< 0.001	0.010	-[(b)]	-[(b)]
		50	< 0.001	0.008	-[(b)]	-[(b)]
		100	< 0.001	0.004	-[(b)]	-[(b)]
R4	**stream**	**0**	0.153	-	0.082	-
		1	0.119	0.081	< 0.001	0.054
		2	< 0.001	0.066	< 0.001	0.042
		4	< 0.001	0.033	0.041	0.025
		7	< 0.001	0.019	< 0.001	0.020
		14	< 0.001	0.010	< 0.001	0.012
		21	< 0.001	0.006	< 0.001	0.008
		28	< 0.001	0.005	< 0.001	0.006
		42	< 0.001	0.003	< 0.001	0.004
		50	< 0.001	0.003	< 0.001	0.003
		100	< 0.001	0.002	0.003	0.002

(a) Only actual and time-weighted average concentrations for option 2 (DT_{50} in water = 1000 d and DT_{50} in sediment = 300 d) are presented since they represent the worst-case for PEC in surface water
(b) Scenario not defined for spring cereals
(c) Date of PEC_{sw} is later than end of simulated period

Results of dust drift assessment

Global maximum PEC_{sw} and PEC_{sed} (dust drift)

Global maximum PEC_{sw} and PEC_{sed} of triticonazole and its metabolite RPA 406203 (Z-isomer) following dust drift deposition after application of 12.5 g a.s./ha as seed treatment to cereals are presented in the table below. Metabolites RPA 404766 (Cis-diol), RPA 406341 (Trans-diol) and RPA 407922 were not considered in the dust drift assessment as they are only formed in soil and, thus, are not relevant for drift entries into surface water bodies.

Table B.8.2.5-13: Global maximum PEC_{sw} and PEC_{sed} of triticonazole and its metabolite RPA 406203 due to dust drift after seed treatment in cereals

	Triticonazole PEC_{sw} (µg/L)	Triticonazole PEC_{sed} (µg/kg)	RPA 406203 (Z-isomer) PEC_{sw} (µg/L)	RPA 406203 (Z-isomer) PEC_{sed} (µg/kg)
0 % drift reduction				

2-D dust drift (0.33 %)	0.014	0.103	0.007	nr
3-D dust drift (4.10 %)	0.171	1.281	0.088	nr
		50 % drift reduction		
2-D dust drift (0.33 %)	0.007	0.052	0.004	nr
3-D dust drift (4.10 %)	0.085	0.641	0.044	nr
		75 % drift reduction		
2-D dust drift (0.33 %)	0.003	0.026	0.002	nr
3-D dust drift (4.10 %)	0.043	0.320	0.022	nr
		90 % drift reduction		
2-D dust drift (0.33 %)	0.001	0.010	0.001	nr
3-D dust drift (4.10 %)	0.017	0.128	0.009	nr

nr = not relevant as RPA 406203 (Z-isomer) is only formed under the presence of light

Actual and time-weighted average PEC_{sw} (dust drift)

Actual and time-weighted average concentrations of triticonazole and its metabolite RPA 406203 (Z-isomer) following seed treatment in cereals are presented in the tables below.

Table B.8.2.5-14: Actual and time weighted PEC_{sw} of triticonazole due to dust drift following seed treatment in cereals (no drift reduction)

Time (d)	2-D dust drift (0.33 %)		3-D dust drift (4.10 %)	
	$PEC_{sw,act}$ (µg/L)	$PEC_{sw,twa}$ (µg/L)	$PEC_{sw,act}$ (µg/L)	$PEC_{sw,twa}$ (µg/L)
0	0.014	-	0.171	-
1	0.013	0.013	0.155	0.163
2	0.012	0.013	0.141	0.155
4	0.009	0.012	0.116	0.142
7	0.007	0.010	0.086	0.124
14	0.004	0.008	0.044	0.093
21	0.002	0.006	0.022	0.073
28	< 0.001	0.005	0.011	0.058
50	< 0.001	0.003	0.003	0.041
100	< 0.001	0.001	< 0.001	0.018

Table B.8.2.5-15: Actual and time weighted PEC_{sw} of RPA 406203 (Z-isomer) due to dust drift following seed treatment in cereals (no drift reduction)

Time (d)	2-D dust drift (0.33%)		3-D dust drift (4.10%)	
	$PEC_{sw,act}$ (µg/L)	$PEC_{sw,twa}$ (µg/L)	$PEC_{sw,act}$ (µg/L)	$PEC_{sw,twa}$ (µg/L)
0	0.007	-	0.088	-
1	0.007	0.007	0.088	0.088
2	0.007	0.007	0.088	0.088
4	0.007	0.007	0.088	0.088
7	0.007	0.007	0.088	0.088
14	0.007	0.007	0.087	0.088
21	0.007	0.007	0.087	0.087
28	0.007	0.007	0.086	0.087
50	0.007	0.007	0.085	0.087
100	0.007	0.007	0.082	0.085

Conclusion:

Predicted environmental concentrations in surface water and sediment were calculated for triticonazole and its metabolites RPA 404766 (Cis-diol), RPA 406341 (Trans-diol), RPA 407922 and RPA 406203 (Z-isomer) using the simulation models FOCUS STEPS 1-2 (version 3.2). For triticonazole, additional calculations at Step 3 were performed with FOCUS SWASH (version 5.3). Single application to cereals at a maximum application rate of 12.5 g a.s./ha as seed treatment was considered. Additionally, the entry path dust drift was considered relevant for triticonazole and its photolytic isomer RPA 406203 (Z-isomer).

The overall maximum PEC_{sw} values of triticonazole and its metabolites RPA 404766 (Cis-diol), RPA 406341 (Trans-diol), RPA 407922 and RPA 406203 (Z-isomer) at **Step 2** were 1.214, 0.257, 0.353, 0.011 and 1.263 µg/L, respectively. The overall maximum PEC_{sed} values of triticonazole and its metabolites RPA 404766 (Cis-diol), RPA 406341 (Trans-diol), RPA 407922 and RPA 406203 (Z-isomer) at Step 2 were 5.999, 0.195, 0.459, 0.052 and >0.001 µg/kg, respectively.

At **Step 3**, the overall maximum PEC_{sw} values of triticonazole for application on winter cereals and spring cereals were 0.168 (R3, stream) and 0.082 µg/L (R4, stream), respectively. The overall maximum PEC_{sed} values of triticonazole for application on winter cereals and spring cereals were 1.478 (R3, stream) and 0.058 µg/kg (R4, stream), respectively.

The maximum PEC_{sw} of triticonazole following **dust drift** without considering any drift reduction were 0.014 (2-D dust drift) and 0.171 µg/L (3-D dust drift). The maximum PEC_{sed} of triticonazole following dust drift without considering any drift reduction were 0.103 (2-D dust drift) and 1.281 µg/L (3-D dust drift). The maximum PEC_{sw} of RPA 406203 (Z-isomer) were 0.007 (2-D dust drift) and 0.088 µg/L (3-D dust drift). RPA 406203 is not relevant in sediment.

The results of the PEC calculations in surface water and sediment were used for the eco-toxicological risk assessment.

Comments RMS AT:

- The RMS AT proposes deviating substance properties for triticonazole and its metabolites to be used in the leaching assessment:
  - Triticonazole is likely to show *p*H dependent sorption in soil with lower sorption under more alkaline soil conditions (also refer to Vol. 3CA). As *p*H dependent sorption is not covered by the FOCUS sw scenarios, the RMS AT recommends using the minimum K_{foc} of 307 mL/g in case of the drainage scenarios (FOCUS sw Step 3). As the impact of sorption is less clear in case of runoff & erosion, two separate runs were considered for the runoff scenarios (FOCUS sw Step 3), one with the minimum and one with the maximum K_{foc} (see table below). At FOCUS sw Step 1 & 2 the minimum K_{foc} is used for the PEC_{sw}, the maximum K_{foc} for the PEC_{sed}.
  - Following re-evaluation proposed modelling degradation rates and sorption values of triticonazole and its metabolites by the RMS AT are different from the applicant approach (see table below).

  Finally, the RMS AT re-calculated $PEC_{sw/sed}$ values on basis of the application scheme provided by the applicant with Steps in FOCUS 3.2 and FOCUS SWASH 5.3. In case of dust drift calculations the RMS AT does not consider surface areas of water bodies representing a 3-D structure. Therefore, dust drift calculation is based on 2-D drift rates (0.33 %) only. The RMS AT notes that the SANCO guidance document on seed treatment is still in a draft version and not noted yet.

- No aquatic risk assessment is triggered for RPA 407922 as this metabolite could neither be identified in soil degradation nor in water/sediment studies. Notice that the applicant originally claims metabolite fraction 'Met 6 (MWT 333)' observed in Ayliffe & Austin (1993) at max. 12.8 % AR being identified as RPA 407922. As discussed in Vol. 3CA this finding is not supported anymore.

- The aquatic risk assessment for the metabolite fractions 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)' observed in Ayliffe & Austin (1993) above 5 % AR at two consecutive sampling points is addressed in a separate statement (Szegedi, 2018), see next study.

Table B.8.2.5-16: Revised substance properties of triticonazole and its metabolites for FOCUS surface water Step 1 & 2 calculation - <u>RMS AT assessment</u>

Substance property	Triticonazole	RPA 406341 (Trans-diol)	RPA 404766 (Cis-diol)	RPA 406203 (Z-isomer)
Molecular weight (g/mol)	317.8	333.8	333.8	317.8

Water solubility (mg/L) (20 °C)	9.3	9.3[(a)]	9.3[(a)]	9.3[(a)]
Vapour pressure (Pa) (20 °C)	9.0E-08 (25 °C)	na	na	na
K_{foc} (mL/g)	307 / 823[(b)]	144	75.7	0 / 1000[(c)]
1/*n* (-)	0.90	na	na	na
DegT50 soil (days)	78.7	40.6	75.3	1000[(d)]
DegT50 water (days)	1000	1000[(d)]	1000[(d)]	1000[(d)]
DegT50 sediment (days)	300	1000[(d)]	1000[(d)]	1000[(d)]
DegT50 water/sediment (days)	300	1000[(d)]	1000[(d)]	1000[(d)]
DT50 crop (days)	10	na	na	na
Wash off (m^{-1})	50	na	na	na
Plant uptake (-)	0	na	na	na
Max. in water/sediment (%)	na	0	0	42.3[(e)]
Max. in soil (%)	na	20.2	13.9	4.4

na denotes not applicable
(a) Set to default value (field degradation used)
(b) *p*H dependent sorption:
Step 1& 2: Minimum value of 307 mL/g used for PEC_{sw}, maximum value of 823 used for PEC_{sed};
Step 3: Minimum value of 307 mL/g used in drainage scenarios, minimum (307 mL/g) or maximum (823 mL/g) value used in run-off scenarios (two runs)
(c) No data: 0 mL/g used for PEC_{sw}, 1000 mL/g used for PEC_{sed}
(d) No data: default value
(e) Aquatic photolysis (without sensitizer)

Table B.8.2.5-17: <u>FOCUS surface water Step 1 & 2:</u> Global maximum $PEC_{sw/sed}$ values for triticonazole and its metabolites following seed treatment in winter and spring cereals - <u>RMS AT assessment</u>

Scenario	Substance	STEP 1		STEP 2	
		PEC_{sw} (µg/l)	**PEC_{sed} (µg/kg)**	**PEC_{sw} (µg/l)**	**PEC_{sed} (µg/kg)**
Winter cereals, North-EU, Oct.-Feb.	Triticonazole	3.07	16.76	1.52	8.32
	RPA406341 (Trans-diol)	0.74	1.07	0.35	0.50
	RPA404766 (Cis-diol)	0.55	0.42	0.27	0.20
	RPA406203 (Z-isomer)	1.99	8.54	0.99	4.24
Winter cereals, South-EU, Oct.-Feb.	Triticonazole	3.07	16.76	1.23	6.75
	RPA406341 (Trans-diol)	0.74	1.07	0.28	0.40
	RPA404766 (Cis-diol)	0.55	0.42	0.21	0.16
	RPA406203 (Z-isomer)	1.99	8.54	0.80	3.44
Spring cereals, North-EU, March-May	Triticonazole	3.07	16.76	0.66	3.60
	RPA406341 (Trans-diol)	0.74	1.07	0.14	0.20
	RPA404766 (Cis-diol)	0.55	0.42	0.11	0.08
	RPA406203 (Z-isomer)	1.99	8.54	0.43	1.82
Spring cereals, South-EU, March-May	Triticonazole	3.07	16.76	1.23	6.75
	RPA406341 (Trans-diol)	0.74	1.07	0.28	0.40
	RPA404766 (Cis-diol)	0.55	0.42	0.21	0.16
	RPA406203 (Z-isomer)	1.99	8.54	0.80	3.44

Table B.8.2.5-18: <u>FOCUS surface water Step 3:</u> Global maximum $PEC_{sw/sed}$ values of triticonazole following seed treatment in <u>winter cereals</u> - <u>RMS AT assessment</u>

FOCUS scenario	Water body	Minimum K_{foc} (307 mL/g)		Maximum K_{foc} (823 mL/g)	
		PEC_{sw} (µg/l)	**PEC_{sed} (µg/kg)**	**PEC_{sw} (µg/l)**	**PEC_{sed} (µg/kg)**
D1	Ditch	0.600	2.793	nc	nc
	Stream	0.375	1.566	nc	nc
D2	Ditch	0.915	2.325	nc	nc
	Stream	0.571	1.381	nc	nc
D3	Ditch	< 0.001	< 0.001	nc	nc
D4	Pond	0.098	0.471	nc	nc
	Stream	0.100	0.185	nc	nc
D5	Pond	0.082	0.392	nc	nc
	Stream	0.101	0.113	nc	nc
D6	Ditch	0.326	0.262	nc	nc
R1	Pond	0.009	0.042	0.009	0.073
	Stream	0.208	0.056	0.084	0.055
R3	Stream	0.272	0.901	0.108	2.108

R4	Stream	0.188	0.060	0.113	0.068

Table B.8.2.5-19: FOCUS surface water Step 3: Global maximum $PEC_{sw/sed}$ values of triticonazole following seed treatment in spring cereals - RMS AT assessment

FOCUS scenario	Water body	Minimum K_{foc} (307 mL/g)		Maximum K_{foc} (823 mL/g)	
		PEC_{sw} (µg/l)	PEC_{sed} (µg/kg)	PEC_{sw} (µg/l)	PEC_{sed} (µg/kg)
D1	Ditch	0.235	1.212	nc	nc
	Stream	0.147	0.715	nc	nc
D3	Ditch	< 0.001	< 0.001	nc	nc
D4	Pond	0.037	0.192	nc	nc
	Stream	0.037	0.074	nc	nc
D5	Pond	0.012	0.093	nc	nc
	Stream	0.014	0.020	nc	nc
R4	Stream	0.066	0.025	0.073	0.074

Table B.8.2.5-20: Dust drift: Global maximum $PEC_{sw/sed}$ values of triticonazole and its photolysis metabolite RPA 406203 (Z-isomer) in a FOCUS standard water body due to dust drift (2-D dust drift, 0.33 %) following seed treatment in winter and spring cereals - RMS AT assessment

Dust drift reduction (%)	Triticonazole		RPA 406203 (Z-isomer)	
	PEC_{sw} (µg/l)	PEC_{sed} (µg/kg)	PEC_{sw} (µg/l)	PEC_{sed} (µg/kg)
0	0.014	0.103	0.007	nr
50	0.007	0.052	0.004	nr
75	0.003	0.026	0.002	nr
90	0.001	0.010	0.001	nr

nr denotes not relevant as RPA 406203 (Z-isomer) is only formed under the presence of light

Reference:	**Statement - Exposure assessment for “Met 6” and “Met 7”, potential degradation products of BAS 595F triticonazole**
Author(s), year:	Szegedi, K., 2018
Report/Doc. Number:	2018/1091281
Guideline(s):	None
GLP:	Not applicable (statement)
Validity:	Study not considered reliable (with respect to aquatic exposure assessment)
Status:	**New submission**

Material and methods:

Predicted environmental concentrations in surface water (PEC_{sw}) and sediment (PEC_{sed}) were calculated for the metabolites 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)' following FOCUS guidance. FOCUS sw Step1-2, calculations were carried out for both compounds using FOCUS STEPS 1-2 (version 3.2).

Applied procedures are the same as described in the draft RAR, details of the scenarios and applied tools are presented in the respective guidance documents and manuals.

The following environmental fate parameters for the metabolites 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)' were used for the simulations.

Table B.8.2.5-21: Parameters of 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)' used for the simulations

Compound	'Met 6 (MWT 333)'	'Met 7 (MWT 315)'	Remarks
Molecular mass (g/mol)	333.8	315.8	None
Aqueous solubility (mg/L)	9.3	9.3	Parent data
DegT50 soil (days)	1000	1000	Default worst case
DegT50 water (days)	1000	1000	Default worst case
DegT50 sediment (days)	1000	1000	Default worst case

DegT50 total system (days)	1000	1000	Default worst case
Maximum occurrence in soil / water / sediment (%)	12.8 / 0 / 0	6.5 / 0 / 0	Soil metabolites
K_{foc} (mL/g)	577.1	547.3	KocWin (refer to Vol. 3CA)

Results:

Predicted environmental concentrations in surface water (PEC_{sw}) and sediment (PEC_{sed}) for the metabolites 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)' are listed below.

Table B.8.2.5-22: STEPS 1-2: Maximum PEC_{sw} (µg/L) of 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)' following seed treatment with triticonazole in winter cereals

Scenario	PEC_{sw} (µg/L)	
	'Met 6 (MWT 333)'	'Met 7 (MWT 315)'
Step 1	0.3166	0.1556
Step 2, North Europe, March – May	0.0631	0.0310
Step 2, North Europe, October – February	0.1579	0.0776
Step 2, South Europe, March – May	0.1263	0.0621
Step 2, South Europe, October – February	0.1263	0.0621

Table B.8.2.5-23: STEPS 1-2: Maximum PEC_{sed} (µg/kg) of 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)' following seed treatment with triticonazole in winter cereals

Scenario	PEC_{sed} (µg/kg)	
	'Met 6 (MWT 333)'	'Met 7 (MWT 315)'
Step 1	1.8270	0.8515
Step 2, North Europe, March – May	0.3644	0.1698
Step 2, North Europe, October – February	0.9110	0.4246
Step 2, South Europe, March – May	0.7288	0.3397
Step 2, South Europe, October – February	0.7288	0.3397

Comments (RMS AT):

- As already indicated in Vol. 3CA, the RMS AT considers the estimated K_{foc} values on basis of KocWIN 2.00 (EPISuite) unrealistic in view of relative retention times (rRT) of the two metabolite fractions observed in the HPLC chromatograms in Ayliffe & Austin (1993). As discussed more in detail in Vol. 3CA, the RMS AT considers K_{foc} values estimated on basis of the rRT more reliable. Consequently, the RMS AT re-calculated PEC_{sw} and PEC_{sed} values for these two metabolites fractions on basis of the following substance properties (see table below).

Table B.0-24: Revised substance properties of the metabolite fractions 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)' for $PEC_{sw/sed}$ calculation (FOCUS sw STEP 1 & 2) - RMS AT assessment

Parameter	'Met 6 (MWT 333)'	'Met 7 (MWT 315)'
Mol weight (g/mol)	333.8	315.8
Water solubility (mg/L)	9.3 (20 °C)[(a)]	9.3 (20 °C)[(a)]
K_{foc}/K_{fom} (mL/g)	278 / 161[(b)]	327 / 190[(b)]
DegT50 soil (d)	1000 (default)	1000 (default)
DegT50 water (d)	1000 (default)	1000 (default)
DegT50 sediment (d)	1000 (default)	1000 (default)
DegT50 total system (d)	1000 (default)	1000 (default)
Max. in water/sediment (%)	0	0
Max. in soil (%)	12.8	6.5

na denotes not applicable
(a) No data, parent data used
(b) Estimated on basis of the relative retention times observed in HPLC chromatograms in Ayliffe & Austin (1993) (for details refer to Vol. 3CA)

Table B.8.2.5-25: FOCUS surface water Step 1 & 2: Global maximum $PEC_{sw/sed}$ values for the

metabolite fractions 'Met 6 (MWT 333)' and 'Met 7 (MWT 315)' following seed treatment in winter and spring cereals - RMS AT assessment

Scenario	Substance	STEP 1 PEC$_{sw}$ (µg/l)	STEP 1 PEC$_{sed}$ (µg/kg)	STEP 2 PEC$_{sw}$ (µg/l)	STEP 2 PEC$_{sed}$ (µg/kg)
Winter cereals, North-EU, Oct.-Feb.	'Met 6 (MWT 333)'	0.41	1.14	0.20	0.57
	'Met 7 (MWT 315)'	0.19	0.61	0.09	0.31
Winter cereals, South-EU, Oct.-Feb.	'Met 6 (MWT 333)'	0.41	1.14	0.16	0.45
	'Met 7 (MWT 315)'	0.19	0.61	0.07	0.24
Spring cereals, North-EU, March-May	'Met 6 (MWT 333)'	0.41	1.14	0.08	0.23
	'Met 7 (MWT 315)'	0.19	0.61	0.04	0.12
Spring cereals, South-EU, March-May	'Met 6 (MWT 333)'	0.41	1.14	0.16	0.45
	'Met 7 (MWT 315)'	0.19	0.61	0.07	0.24

B.8.3. FATE AND BEHAVIOUR IN AIR

B.8.3.1. Route and rate of degradation in air and transport via air

The vapour pressure of triticonazole was determined as 9×10^{-8} Pa at 25 °C. Therefore, concentrations in air are considered to be negligible. Furthermore, the atmospheric half-life was re-calculated according to Atkinson using the current version of AOPWIN in EPI Suite v4.11. A value of 1.4 hrs (corresponding to 0.114 days) was determined (for a 12 hrs day). Thus, long range transport of triticonazole can be disclosed.

Due to the low vapour pressure and the *DT50* in air being below 2 days, no exposure and long-range transport of triticonazole in air is expected. Furthermore, as triticonazole is applied as seed treatment no relevant atmospheric input is expected. Thus, no calculation of PEC from airborne transport was conducted as this is not a relevant entry pathway.

B.8.4. PREDICTED ENVIRONMENTAL CONCENTRATIONS FROM OTHER ROUTES OF EXPOSURE

Apart from the exposure routes already discussed in the chapters above, no further routes of exposure are expected to be of any relevance for triticonazole.

B.8.5. 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 Reason for submission and justification for vertebrate studies art 62 1107/2009 (if applicable)	Owner	Previous evaluation Y/N
KCP 9.1.3 KCP 9.2.4.1 KCP 9.2.5	Szegedi, K.	2018	Statement. Exposure assessment for “Met 6” and “Met 7”, potential degradation products of BAS 595F triticonazole 2018/1091281 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	Yes	New data for AIR3 renewal	BASF	No
KCP 9.2.4.1	Kreschnak C.	2015	Predicted environmental concentrations of Triticonazole and its metabolites in groundwater (PECgw) following seed treatment in cereals 2015/1183788 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	Yes	New data for AIR3 renewal	BASF	No
KCP 9.2.5	Lamers M.	2015	Predicted environmental concentrations of Triticonazole and its metabolites in surface water and sediment (PECsw and PECsed) following seed treatment in cereals using the FOCUS surface water scenarios 2015/1183789 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	Yes	New data for AIR3 renewal	BASF	No