

# **FINAL REGISTRATION REPORT**

## **Part B**

### **Section 8**

#### **Environmental Fate**

Detailed summary of the risk assessment

**Product code: FF-075**

**Product name(s): EUSKATEL PRO**

**Chemical active substance:**

**Prothioconazole, 200 g/L**

**Azoxystrobin 150 g/L**

**Central Zone**

**Zonal Rapporteur Member State: Poland**

#### **CORE ASSESSMENT**

**(New Product Authorization)**

Applicant: Rotam Agrochemical Europe Limited

Submission date: May 2021

MS Finalisation date: 02.2022; Updated August 2022

## Version history

When	What
1 May 2021	New product application in accordance with Article 33 of Regulation (EC) No. 1107/2009.
February 2022	Draft assessment by zRMS
August 2022	Updated after commenting

## Table of Contents

<b>8</b>	<b>Fate and behaviour in the environment (KCP 9).....</b>	<b>5</b>
8.1	Critical GAP and overall conclusions.....	6
8.2	Metabolites considered in the assessment.....	11
8.3	Rate of degradation in soil (KCP 9.1.1).....	13
8.3.1	Aerobic degradation in soil (KCP 9.1.1.1) .....	13
8.3.1.1	Prothioconazole and its metabolites.....	13
8.3.1.2	Azoxystrobin and its metabolites .....	14
8.3.2	Anaerobic degradation in soil (KCP 9.1.1.1).....	17
8.4	Field studies (KCP 9.1.1.2).....	17
8.4.1	Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1). .....	17
8.4.1.1	Prothioconazole and its metabolites.....	17
8.4.1.2	Azoxystrobin and its metabolites.....	21
8.4.2	Soil accumulation testing (KCP 9.1.1.2.2) .....	23
8.5	Mobility in soil (KCP 9.1.2) .....	23
8.5.1	Prothioconazole and its metabolites.....	24
8.5.2	Azoxystrobin and its metabolites.....	25
8.5.3	Column leaching (KCP 9.1.2.1).....	28
8.5.4	Lysimeter studies (KCP 9.1.2.2).....	28
8.5.5	Field leaching studies (KCP 9.1.2.3) .....	29
8.6	Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3) .....	29
8.6.1	Prothioconazole and its metabolites.....	29
8.6.2	Azoxystrobin and its metabolites.....	30
8.7	Predicted Environmental Concentrations in soil (PEC <sub>soil</sub> ) (KCP 9.1.3) .....	31
8.7.1	Justification for new endpoints .....	31
8.7.2	Active substance(s) and relevant metabolite(s) .....	31
8.7.2.1	Prothioconazole and its metabolites.....	32
8.7.2.2	Azoxystrobin and its metabolites.....	34
8.7.2.3	PEC <sub>soil</sub> of formulation .....	36
8.8	Predicted Environmental Concentrations in groundwater (PEC <sub>gw</sub> ) (KCP 9.2.4) .....	37
8.8.1	Justification for new endpoints .....	37
8.8.2	Active substances and relevant metabolites (KCP 9.2.4.1) .....	37
8.8.2.1	Prothioconazole and its metabolites.....	39
8.8.2.2	Azoxystrobin and its metabolites.....	45
8.9	Predicted Environmental Concentrations in surface water (PEC <sub>sw</sub> ) (KCP 9.2.5) .....	54
8.9.1	Justification for new endpoints .....	54
8.9.2	Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5) .....	54
8.9.2.1	Prothioconazole and its metabolites.....	56
8.9.2.2	Azoxystrobin and its metabolites.....	78
8.9.2.3	PEC <sub>sw/sed</sub> of formulation .....	91
8.10	Fate and behaviour in air (KCP 9.3, KCP 9.3.1) .....	93
<b>Appendix 1</b>	<b>Lists of data considered in support of the evaluation .....</b>	<b>94</b>

<b>Appendix 2</b>	<b>Detailed evaluation of the new Annex II studies .....</b>	<b>110</b>
<b>Appendix 3</b>	<b>Additional information provided by the applicant (e.g. detailed modelling data).....</b>	<b>111</b>
A 3.1	Thomas, V. (2021) .....	111
A 3.2	Example FOCUS Step 1 and 2 Outputs .....	122
A 3.3	EPAT Graphical Output.....	179

## **8                    Fate and behaviour in the environment (KCP 9)**

### **zRMS comments:**

All comments and conclusions of the zRMS are presented in grey. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information is struck through and shaded for transparency.

## 8.1 Critical GAP and overall conclusions

**Table 8.1-1:** Critical use pattern of the formulated product

[illegible]

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use -No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ synergist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Minor uses according to Article 51 (interzonal uses)														

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

\*\* F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

#### Explanation for column 15 “Conclusion”

A	Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

**Table 8.1-2: Assessed (critical) uses during approval of prothioconazole concerning the Section Environmental Fate**

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. *	Member state(s)	Crop and/or situation (crop destina- tion / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	EU North South	Wheat, rye, triticale	F	Rusts, Eyespot, Fusarium spp., Powd. Mildew, Rhynchospor., Septoria	Overall spray	Start BBCH 26-29 up to BBCH 69	a) 1 b) 3	14	a) 0.8 b) 2.4	a) 200 b) 600	200-400	35	Timing and number of applications depends on national conditions
2	EU North South	Barley, oat	F	Rusts, Eyespot, Pyren. teres, Powd. Mildew, Fusarium spp., Rhynchospor	Overall spray	BBCH 30-61	a) 1 b) 2	14	a) 0.8 b) 1.6	a) 200 b) 400	200-400	35	Timing and number of applications depends on national conditions
3	EU North	Rape	F	Sclerotinia, Botrytis, Alternaria, Leptosphaeria	Overall spray	Start BBCH 53	a) 1 b) 2	14	a) 0.7 b) 1.4	a) 175 b) 350	200-400	56	Timing and number of applications depends on national conditions
4	EU North South	Wheat, rye, triticale, oat. barley	F	Fusarium spp., Bunt, Smut	Seed treat- ment	Pre-sowing	a) 1 b) 1	-	a) 180 kg seed/ha b) 180 kg seed/ha	a) 18 b) 18	200-400	-	5 – 10 g as/dt seed

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

\*\* F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application



**Table 8.1-3: Assessed (critical) uses during approval of azoxystrobin concerning the Section Environmental Fate**

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. *	Member state(s)	Crop and/or situation (crop destina- tion / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	EU	Broccoli	F	<i>Albugo candida</i> , <i>Alternaria brassicae</i> , <i>Mycosphaerella brassicicola</i> , <i>Peronospora parasitica</i>	Foliar spray	BBCH 35-39	a) 1 b) 2	12	a) 1.0 b) 2.0	a) 250 b) 500	200-600	14	
2	EU	Cauliflower	F	<i>Albugo candida</i> , <i>Alternaria brassicae</i> , <i>Mycosphaerella brassicicola</i> , <i>Peronospora parasitica</i>	Foliar spray	BBCH 35-39	a) 1 b) 2	12	a) 1.0 b) 2.0	a) 250 b) 500	200-600	14	
3	EU	Brussels sprouts	F	<i>Albugo candida</i> , <i>Alternaria brassicae</i> , <i>Mycosphaerella brassicicola</i> , <i>Peronospora parasitica</i>	Foliar spray	BBCH 35-39	a) 1 b) 2	12	a) 1.0 b) 2.0	a) 250 b) 500	200-600	14	
4	EU	Kale	F	<i>Albugo candida</i> , <i>Alternaria brassicae</i> , <i>Mycosphaerella brassicicola</i> , <i>Peronospora parasitica</i>	Foliar spray	BBCH 35-39	a) 1 b) 2	12	a) 1.0 b) 2.0	a) 250 b) 500	200-600	14	
5	EU	Barley	F	<i>Pyrenophora teres</i> <i>Puccinia hordei</i> , <i>Rhynchosporium secalis</i> <i>Gaeumannomyces graminis</i> var. <i>tritici</i> Barley spotting	Foliar spray	BBCH 31-59	a) 1 b) 2	14	a) 1.0 b) 2.0	a) 250 b) 500	100-300	35	Timing of applications determined primarily by growth stage; 1 <sup>st</sup> application no later than BBCH 39, 2 <sup>nd</sup> application no later than BBCH 59

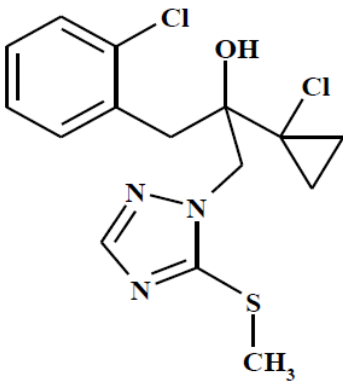
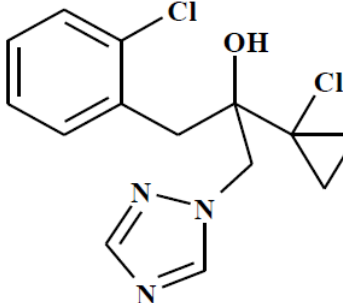
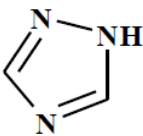
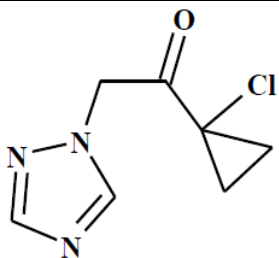
1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. *	Member state(s)	Crop and/or situation (crop destina- tion / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
6	EU	Wheat	F	<i>Septoria tritici</i> , <i>Septoria nodorum</i> , <i>Puccinia Striiformis</i> , <i>Puccinia recondita</i> , <i>Gaeumannomyces</i> <i>graminis var. tritici</i>	Foliar spray	BBCH 31-69	a) 1 b) 2	14	a) 1.0 b) 2.0	a) 250 b) 500	100-300	35	Timing of applications determined primarily by growth stage; 1 <sup>st</sup> application no later than BBCH 39, 2 <sup>nd</sup> application no later than BBCH 69

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

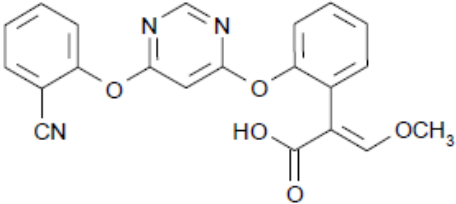
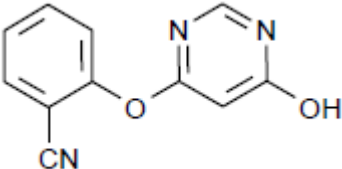
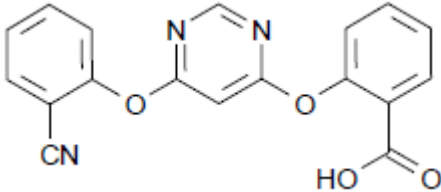
\*\* F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

## 8.2 Metabolites considered in the assessment

**Table 8.2-1: Metabolites of prothioconazole potentially relevant for exposure assessment**

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
Prothioconazole-S-methyl (M01) (JAU 6476-S-methyl)	358.3		Soil:- 14.6% Water/Sediment:- 12.7%	PEC <sub>gw</sub> : >10% of a.s. in soil, leaching assessment required PEC <sub>soil</sub> : >10% of a.s. in soil, assessment required as not covered by EU assessment PEC <sub>sw/sed</sub> : >10% of a.s. in soil and aquatic systems, assessment required as not covered by EU assessment
Prothioconazole-desthio (M04) (JAU 6476-desthio)	312.2		Soil:- 57.1% Water/Sediment:- 54.6%	PEC <sub>gw</sub> : >10% of a.s. in soil, leaching assessment required PEC <sub>soil</sub> : >10% of a.s. in soil, assessment required as not covered by EU assessment PEC <sub>sw/sed</sub> : >10% of a.s. in soil and aquatic systems, assessment required as not covered by EU assessment
1,2,4-triazole (M13)	69.1		Soil:- Not formed Water/Sediment:- 41.8%	PEC <sub>sw/sed</sub> : >10% of a.s. in aquatic systems, assessment required as not covered by EU assessment
Prothioconazole-triazolylketone (M42) (JAU 6476-triazolylketone)	185.7		Soil:- Not formed Water/Sediment:- 9.1%	PEC <sub>sw/sed</sub> : >5% of a.s. in aquatic systems in 2 sequential measurements and increasing in sediment at study end, assessment required as not covered by EU assessment

**Table 8.2-2: Metabolites of azoxystrobin potentially relevant for exposure assessment**

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
R234886	389.4		Soil: 28.8% Water/Sediment:- 18.1%	PEC <sub>gw</sub> : >10% of a.s. in soil, leaching assessment required PEC <sub>soil</sub> : >10% of a.s. in soil, assessment required as not covered by EU assessment PEC <sub>sw/seq</sub> : >10% of a.s. in soil and aquatic systems, assessment required as not covered by EU assessment
R401553	213.2		Soil: 17% Water/Sediment:- 8.9% (aqueous photolysis)	PEC <sub>gw</sub> : >10% of a.s. in soil, leaching assessment required PEC <sub>soil</sub> : >10% of a.s. in soil, assessment required as not covered by EU assessment PEC <sub>sw/seq</sub> : >10% of a.s. in soil, assessment required as not covered by EU assessment
R402173	333.3		Soil: 17% Water/Sediment:- 2.4% (aqueous photolysis)	PEC <sub>gw</sub> : >10% of a.s. in soil, leaching assessment required PEC <sub>soil</sub> : >10% of a.s. in soil, assessment required as not covered by EU assessment PEC <sub>sw/seq</sub> : >10% of a.s. in soil, assessment required as not covered by EU assessment

**zRMS comments:**

Information relating to prothioconazole metabolites are in line with EU agreed endpoints as reported in EFSA Scientific Report (2007) 106, 1-98 and have been considered in the exposure assessment presented in this report. Information relating to azoxystrobin metabolites are in line with EU agreed endpoints as reported in EFSA Journal 2010; 8(4):1542 and have been considered in the exposure assessment presented in this report.

### 8.3 Rate of degradation in soil (KCP 9.1.1)

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

#### 8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

##### 8.3.1.1 Prothioconazole and its metabolites

The aerobic degradation of prothioconazole in soil was evaluated during the EU review and is summarised in the EFSA Conclusion (EFSA Scientific Report (2007) 106, 1-98). No additional studies have been performed.

The aerobic degradation of prothioconazole and its soil metabolites prothioconazole-S-methyl (M01) and prothioconazole-desthio (M04) is summarised in Table 8.3-1 to Table 8.3-3. These data were derived from the Final addendum to the DAR (October, 2005) and the List of Endpoints in the EFSA Conclusion (EFSA Scientific Report (2007) 106, 1-98).

**Table 8.3-1: Summary of aerobic degradation rates for prothioconazole - laboratory studies**

Prothioconazole, Laboratory studies, aerobic conditions									
Soil name	Soil type	pH (H <sub>2</sub> O / CaCl <sub>2</sub> )	t.oC	MWHC %	DT <sub>50</sub> (d)	DT <sub>90</sub> (d)	r <sup>2</sup>	Kinetic model	Evaluated on EU level y/n/ Reference
Laacher Hof	Sandy loam	7.2/6.6	20	34.42	0.07	5.3	1.0	FOMC	Yes (Gilges, 2000, [amended 2001])
Stanley	Silty clay loam	5.9/5.9	20	56.25	0.7	78.2	0.989	FOMC	
Höfchen	Silt	7.1/6.8	20	63.1	0.30	0.99	0.990	SFO	Yes (Hellpointner, (2001b))
Byromville	Loamy sand	6.8/6.1	20	Not determined*	1.27	4.22	0.981	SFO	
Geometric mean (n=4)					0.37				
Median (n=4)					0.50				
pH-dependency:					No				

\* Field moisture capacity at 0.33 bar: 4.8% (75% equivalent to 3.6%)

**Table 8.3-2: Summary of aerobic degradation rates for prothioconazole-S-methyl (M01) - laboratory studies**

Prothioconazole-S-methyl (M01), Laboratory studies, aerobic conditions									
Soil name	Soil type	pH (H <sub>2</sub> O / CaCl <sub>2</sub> )	t.oC	MWHC %	DT <sub>50</sub> (d)	DT <sub>90</sub> (d)	r <sup>2</sup>	Kinetic model	Evaluated on EU level y/n/ Reference
Höfchen	Loamy silt	7.3/6.5	20	63.1	5.9	19.6	0.970	SFO	Yes (Gilges, 2001a)
Laacher Hof AIII	Loamy silt	7.9/6.7	20	36.4	27.2	90.2	0.955	SFO	
Laacher Hof AXXa	Sandy loam	7.2/6.3	20	34.4	8.2	27.2	0.959	SFO	
Stanley	Silty clay	6.3/5.2	20	43.8	46.0	153	0.965	SFO	
Geometric mean (n=4)					15.7				
Median (n=4)					17.7				
pH-dependency:					No				

**Table 8.3-3: Summary of aerobic degradation rates for prothioconazole-desthio (M04) - laboratory studies**

Prothioconazole-desthio (M04), Laboratory studies, aerobic conditions									
Soil name	Soil type	pH (H <sub>2</sub> O / CaCl <sub>2</sub> )	t.oC	MWHC %	DT <sub>50</sub> (d)	DT <sub>90</sub> (d)	r <sup>2</sup>	Kinetic model	Evaluated on EU level y/n/ Reference
Höfchen	Loamy silt	7.3/6.5	20	63.1	34.0	113.0	0.820	SFO	Yes (Gilges, 2001b)
Laacher Hof AIII	Loamy silt	7.9/6.7	20	36.4	29.6	98.3	0.987	SFO	
Laacher Hof AXXa	Sandy loam	7.2/6.3	20	34.4	7.0	23.2	0.985	SFO	
Stanley	Silty clay	6.3/5.2	20	43.8	18.6	61.9	0.979	SFO	
Geometric mean (n=4)					19.0				
Median (n=4)					24.1				
pH-dependency:					No				

### 8.3.1.2 Azoxystrobin and its metabolites

The aerobic degradation of azoxystrobin in soil was evaluated during the EU review and is summarised in the EFSA Conclusion (EFSA Journal 2010; 8(4):1542). No additional studies have been performed.

The aerobic degradation of azoxystrobin and its soil metabolites R234886, R401553 and R402173 is summarised in Table 8.3-4 to Table 8.3-7. These data were derived from the List of Endpoints in the EFSA Conclusion (EFSA Journal, 2010; 8(4):1542).

**Table 8.3-4: Summary of aerobic degradation rates for azoxystrobin - laboratory studies**

Azoxystrobin, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH (H <sub>2</sub> O)	t.oC	MWHC %	DT <sub>50</sub> (d)	DT <sub>90</sub> (d)	DT <sub>50</sub> (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
18 Acres	Sandy clay loam	6.4	20	40% MWHC	56.4	187	35.2	3.70	SFO	Yes (Tummon, 1995)
East Anglia	Sand	7.9	20	40% MWHC	66.9	222	57.2	5.34	SFO	
Wisborough Green	Silty clay loam	5.9	20	40% MWHC	94.1	313	54.1	5.60	SFO	
18 Acres	Sandy clay loam	7.0	20	75% 1/3 bar	87.0	289	65.2	2.06	SFO	Yes (Warinton, Chalofiti and Harvey, 1996)
Hyde Farm	Sandy clay loam	7.0	20	75% 1/3 bar	72.8	242	48.5	7.10	SFO	
Visalia	Sandy loam	8.4	20	75% 1/3 bar	141.6	470	79.9	2.97	SFO	
Derbyshire	Clay loam	7.5	20	Field capacity	118.4	393	118.4	4.84	SFO	Yes (Evans, 2001)
Holland	Sandy loam	8.2	20	Field capacity	153.4	510	153.4	1.92	SFO	
Lincolnshire	Sandy loam	7.4	20	Field capacity	248	824	248	7.5	SFO	
Geometric mean (n=8)							84.5*			
pH-dependency:							No			

\* True geometric mean (geometric mean of 18 Acres soils taken first)

**Table 8.3-5: Summary of aerobic degradation rates for R234886 - laboratory studies**

R234886, Laboratory studies, aerobic conditions											
Soil name	Soil type	pH <sup>(a)</sup>	t.oC	MWHC %	DT <sub>50</sub> (d)	DT <sub>90</sub> (d)	ffm	DT <sub>50</sub> (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Frensham	Sandy loam	6.6	20	40% MWHC	45.2 <sup>(b)</sup>	2136 <sup>(b)</sup>	-	30.4	3.9	DFOP	Yes (Jones and Robertson, 1999)
Wisborough Green	Silty clay loam	6.4	20	40% MWHC	36.7 <sup>(c)</sup>	2124 <sup>(c)</sup>	-	21.2	4.3	DFOP	
East Anglia	Loamy sand	7.9	20	40% MWHC	56.5	188	-	43.4	3.3	SFO	
Hyde Farm	Sandy clay loam	7.0	20	75% 1/3 bar	31.8	105.6	0.9716	21.2	12.3	SFO	Yes (Warinton, Chalofiti and Harvey, 1996)
18 Acres	Sandy clay loam	7.0	20	75% 1/3 bar	23.7	78.8	0.7764	17.8	5.9	SFO	

<b>R234886, Laboratory studies, aerobic conditions</b>											
Soil name	Soil type	pH <sup>(a)</sup>	t.oC	MWHC %	DT <sub>50</sub> (d)	DT <sub>90</sub> (d)	ffm	DT <sub>50</sub> (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Geometric mean (n=5)								<b>25.4*</b>			
pH-dependency:								No			

<sup>(a)</sup> Solution not specified

<sup>(b)</sup> Additional DFOP parameters for the Frensham soil:  $k_1 = 0.0464462 \text{ d}^{-1}$ ,  $k_2 = 0.0007 \text{ d}^{-1}$ ,  $g = 0.554106$

<sup>(c)</sup> Additional DFOP parameters for the Wisborough Green soil:  $k_1 = 0.0570421 \text{ d}^{-1}$ ,  $k_2 = 0.0007 \text{ d}^{-1}$ ,  $g = 0.557696$

- Formation fraction not determined as R234886 applied as parent

\* A default slow phase DFOP DT<sub>50</sub> of 1000 days for the Frensham and Wisborough Green soils was used to calculate a geometric mean normalised DT<sub>50</sub> of 110.4 days for use in the groundwater modelling assessment.

**Table 8.3-6: Summary of aerobic degradation rates for R401553 - laboratory studies**

R401553, Laboratory studies, aerobic conditions											
Soil name	Soil type	pH <sup>(a)</sup>	t.oC	MWHC %	DT <sub>50</sub> (d)	DT <sub>90</sub> (d)	ffm	DT <sub>50</sub> (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Frensham	Sandy loam	6.6	20	40% MWHC	1.36	4.52	-	0.9	9.1	SFO	Yes (Jones and Entwistle, 1998)
Wisborough Green	Silty clay loam	6.4	20	40% MWHC	1.59	5.29	-	0.9	10.9	SFO	
East Anglia	Loamy sand	7.9	20	40% MWHC	2.01	6.68	-	1.5	12.3	SFO	
Geometric mean (n=3)								1.07			
pH-dependency:								No			

<sup>(a)</sup> Solution not specified

- Formation fraction not determined as R401553 applied as parent

**Table 8.3-7: Summary of aerobic degradation rates for R402173 - laboratory studies**

R402173, Laboratory studies, aerobic conditions											
Soil name	Soil type	pH <sup>(a)</sup>	t.oC	MWHC %	DT <sub>50</sub> (d)	DT <sub>90</sub> (d)	ffm	DT <sub>50</sub> (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Frensham	Sandy loam	6.6	20	40% MWHC	8.44	28.0	-	5.7	8.6	SFO	Yes (Jones and Campbell, 1998)
Wisborough Green	Silty clay loam	6.4	20	40% MWHC	4.24	14.1	-	2.4	12.3	SFO	
East Anglia	Loamy sand	7.9	20	40% MWHC	9.80	32.6	-	7.5	12.7	SFO	
Geometric mean (n=3)								4.68			
pH-dependency:								No			

<sup>(a)</sup> Solution not specified

- Formation fraction not determined as R402173 applied as parent



### **8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)**

#### **Prothioconazole**

The anaerobic degradation of prothioconazole in soil was evaluated during the EU review and is summarised in the EFSA Conclusion (EFSA Scientific Report (2007) 106, 1-98). No additional studies have been performed.

Soil degradation under anaerobic conditions was not investigated and a case was presented that due to its proposed use as a foliar applied fungicide, prothioconazole would not, in general, be exposed to anaerobic conditions. However, as a seed treatment formulation was also considered during the EU review, an anaerobic aquatic metabolism study was submitted. The degradation of prothioconazole was relatively rapid under the conditions of this study, resulting in the formation of metabolite prothioconazole-S-methyl (M01), which appeared to accumulate. This might indicate that if prothioconazole was applied to anaerobic soil, there would be significant formation of this metabolite. However, it was concluded that as the only major period of significant anaerobic soil conditions is likely to occur in winter and seed drilling will only take place under aerobic soil conditions, significant formation of metabolite prothioconazole-S-methyl (M01) would not occur under typical agricultural field conditions.

#### **Azoxystrobin**

The anaerobic degradation of azoxystrobin in soil was evaluated during the EU review and is summarised in the EFSA Conclusion (EFSA Journal 2010; 8(4):1542). No additional studies have been performed.

The degradation of azoxystrobin under anaerobic conditions was investigated in two soils. Under anaerobic conditions, azoxystrobin followed a similar degradation pathway to that observed under aerobic conditions, forming no novel metabolites. Calculated DT<sub>50</sub> values ranged from 49.0 to 59.8 days (geometric mean 54.1 days).

### **8.4 Field studies (KCP 9.1.1.2)**

#### **8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)**

##### **8.4.1.1 Prothioconazole and its metabolites**

The field dissipation of prothioconazole was evaluated during the EU review and is summarised in the EFSA Conclusion (EFSA Scientific Report (2007) 106, 1-98). No additional studies have been performed.

The dissipation of prothioconazole was examined in eight trials under field conditions at four sites in northern Europe and two sites in southern Europe. Application of the test substance was directly onto bare soil. Half of the sites were not cropped; the other half were sown with spring barley just prior to application of the test substance and cropped with grass in the second year. The nominal application rate was equivalent to 200 g as/ha. Prothioconazole was dissipated rapidly and was <6 µg/kg (the LOQ) at day 6/7 in six of the trials and <2 µg/kg (the LOD) by day 27/28 in the other two trials. The main metabolite was prothioconazole-desthio (M04), which formed rapidly with the maximum reported value generally either at day 0 or day 7 (the second sampling interval). It dissipated more slowly, but was either <LOQ or <LOD at the end of the study. The metabolite prothioconazole-S-methyl (M01) was observed in five trials, but was not detected above the LOQ in any study.

The field dissipation of prothioconazole and its soil metabolite prothioconazole-desthio (M04) is

summarised in Tables 8.4-1 to 8.4-4. These data were derived from the Final addendum to the DAR (October, 2005) and the List of Endpoints in the EFSA Conclusion (EFSA Scientific Report (2007) 106, 1-98).

### Triggering endpoints

**Table 8.4-1: Summary of aerobic degradation rates for prothioconazole - field studies: Triggering endpoints**

Prothioconazole, Field studies – Triggering endpoints									
Soil type <sup>(a)</sup>	Location	pH <sup>(b)</sup>	Depth (cm) <sup>(c)</sup>	DissT <sub>50</sub> (d) actual	DT <sub>90</sub> (d) actual	Kinetic parameters	r <sup>2</sup>	Method of calculation	Evaluated on EU level y/n/ Reference
Silt loam (bare)	Germany	6.25	(c)	1.9	6.4	-	1.00	SFO	Yes (Schramel, 2001a, Schad, 2001c)
Sandy clay loam (bare)	United Kingdom	7.56	(c)	1.6	5.5	-	1.00	SFO	
Silt (bare)	France (North)	6.42	(c)	1.3	4.4	-	1.00	SFO	
Sandy clay loam (cropped)	United Kingdom	7.56	(c)	2.8	9.3	-	0.99	SFO	
Silt (cropped)	France (North)	6.42	(c)	1.4	4.5	-	1.00	SFO	
Silt loam (cropped)	France (South)	7.61	(c)	1.7	5.6	-	0.99	SFO	
Sandy loam (cropped)	Italy	7.56	(c)	1.6	5.4	-	0.99	SFO	
Sandy loam (bare)	Germany	6.32	(c)	1.5	5.1	-	1.00	SFO	
Maximum (n=8)				<b>2.8</b>					

(a) USDA, (b) Measured in CaCl<sub>2</sub>

(c) Samples were taken to a depth of 50 cm and segmented into 10 cm soil layers prior to homogenisation and analysis. Samples at day 0 were taken to a depth of 10 cm.

**Table 8.4-2: Summary of aerobic degradation rates for prothioconazole-desthio (M04) - field studies: Triggering endpoints**

Prothioconazole-desthio (M04), Field studies – Triggering endpoints										
Soil type <sup>(a)</sup>	Location	pH <sup>(b)</sup>	Depth (cm) <sup>(c)</sup>	DissT <sub>50</sub> (d) actual	DT <sub>90</sub> (d) actual	f.f.	Kinetic parameters	r <sup>2</sup>	Method of calc.	Evaluated on EU level y/n/ Reference
Silt loam (bare)	Germany	6.25	(c)	16.3	54.1	-	-	0.98	SFO	Yes (Schramel, 2001a, Schad, 2001c)
Sandy clay loam (bare)	United Kingdom	7.56	(c)	54.7	182	-	-	0.96	SFO	
Silt (bare)	France (North)	6.42	(c)	47.6	158	-	-	0.94	SFO	

Prothioconazole-desthio (M04), Field studies – Triggering endpoints										
Soil type <sup>(a)</sup>	Location	pH <sup>(b)</sup>	Depth (cm) <sup>(c)</sup>	DissT <sub>50</sub> (d) actual	DT <sub>90</sub> (d) actual	f.f.	Kinetic parameters	r <sup>2</sup>	Method of calc.	Evaluated on EU level y/n/ Reference
Sandy clay loam (cropped)	United Kingdom	7.56	(c)	50.2	167	-	-	0.91	SFO	
Silt (cropped)	France (North)	6.42	(c)	36.8	122	-	-	0.93	SFO	
Silt loam (cropped)	France (South)	7.61	(c)	72.3	240	-	-	0.91	SFO	
Sandy loam (cropped)	Italy	7.56	(c)	30.5	101	-	-	0.98	SFO	
Sandy loam (bare)	Germany	6.32	(c)	27.9	92.6	-	-	0.98	SFO	
Maximum (n=8)				<b>72.3</b>						

(a) USDA, (b) Measured in CaCl<sub>2</sub>

(c) Samples were taken to a depth of 50 cm and segmented into 10 cm soil layers prior to homogenisation and analysis. Samples at day 0 were taken to a depth of 10 cm.

### Modelling endpoints

The field data endpoints were not combined with laboratory values to derive modelling endpoints as EFSA guidance was not in place when the dossier was deemed admissible.

**Table 8.4-3: Summary of aerobic degradation rates for prothioconazole - field studies: Modelling endpoints**

Prothioconazole, Field studies – Modelling endpoints						
Soil type <sup>(a)</sup>	Location	pH <sup>(b)</sup>	Depth (cm) <sup>(c)</sup>	DT <sub>50</sub> (d) 20°C	Fit, Kinetic	Evaluated on EU level y/n/ Reference
Silt loam (bare)	Germany	6.25	(c)	1.2	SFO	Yes (Schramel, 2001a, Schad, 2001c)
Sandy clay loam (bare)	United Kingdom	7.56	(c)	0.8	SFO	
Silt (bare)	France (North)	6.42	(c)	1.6	SFO	
Sandy clay loam (cropped)	United Kingdom	7.56	(c)	1.4	SFO	
Silt (cropped)	France (North)	6.42	(c)	1.6	SFO	
Silt loam (cropped)	France (South)	7.61	(c)	1.1	SFO	
Sandy loam (cropped)	Italy	7.56	(c)	1.5	SFO	
Sandy loam (bare)	Germany	6.32	(c)	0.6	SFO	

Prothioconazole, Field studies – Modelling endpoints						
Soil type <sup>(a)</sup>	Location	pH <sup>(b)</sup>	Depth (cm) <sup>(c)</sup>	DT <sub>50</sub> (d) 20°C	Fit, Kinetic	Evaluated on EU level y/n/ Reference
Geometric mean (n=8)				1.2		
pH-dependency:				No		

<sup>(a)</sup> USDA, <sup>(b)</sup> Measured in CaCl<sub>2</sub>

<sup>(c)</sup> Samples were taken to a depth of 50 cm and segmented into 10 cm soil layers prior to homogenisation and analysis. Samples at day 0 were taken to a depth of 10 cm.

**Table 8.4-4: Summary of aerobic degradation rates for prothioconazole-desthio (M04) - field studies: Modelling endpoints**

Prothioconazole-desthio (M04), Field studies – Modelling endpoints							
Soil type <sup>(a)</sup>	Location	pH <sup>(b)</sup>	Depth (cm) <sup>(c)</sup>	DT <sub>50</sub> (d) 20°C	f.f.	Fit, Kinetic	Evaluated on EU level y/n/ Reference
Silt loam (bare)	Germany	6.25	(c)	10.3	-	SFO	Yes (Schramel, 2001a, Schad, 2001c)
Sandy clay loam (bare)	United Kingdom	7.56	(c)	27.0	-	SFO	
Silt (bare)	France (North)	6.42	(c)	27.5	-	SFO	
Sandy clay loam (cropped)	United Kingdom	7.56	(c)	23.4	-	SFO	
Silt (cropped)	France (North)	6.42	(c)	20.1	-	SFO	
Silt loam (cropped)	France (South)	7.61	(c)	61.9	-	SFO	
Sandy loam (cropped)	Italy	7.56	(c)	20.7	-	SFO	
Sandy loam (bare)	Germany	6.32	(c)	15.2	-	SFO	
Geometric mean (n=8)				22.7			
pH-dependency:				No			

<sup>(a)</sup> USDA, <sup>(b)</sup> Measured in CaCl<sub>2</sub>

<sup>(c)</sup> Samples were taken to a depth of 50 cm and segmented into 10 cm soil layers prior to homogenisation and analysis. Samples at day 0 were taken to a depth of 10 cm.

**Table 8.4- 4a: Summary of aerobic degradation rates for relevant metabolite(s) - field studies: Modelling endpoints**

1, 2, 4-triazole (M13), Field studies – Modelling endpoints									
Soil type (bare soil with grass sown immediately after application with exception of Spain site where no grass sown)	Location	pH	Depth (cm)	DT50 slow phase (d) 20°C, pF2	DT50 fast phase (d) 20°C, pF2	“g”	St. (x <sup>2</sup> )	Method of calc.	Evaluated on EU level y/n/ Reference
Silt loam	Germany	6.4	0 – 30	70.7	2.5	0.655	18.8	DFOP	y/ CRD, UK, December 2013, Briefing note for the 13 December 2013 SCFAH, Agenda Item Pt. A 06.01- Amended DT50 values for the 1,2,4-triazole metabolite
Silty clay loam	Italy	7.6	0 – 40	59.8	1.4	0.364	10.6	DFOP	
Sandy loam	UK	7.4	0 – 40	25.1	0.5	0.458	18.1	DFOP	
Loam	Spain	5.8	0 – 30	126.0	4.6	0.489	12.7	DFOP	
Geometric mean (n=4) (arithmetic mean for “g” value)				60.5	1.68	0.489	-	DFOP	
pH-dependency:				No					

#### 8.4.1.2 Azoxystrobin and its metabolites

The field soil dissipation of azoxystrobin was evaluated during the EU review and is summarised in the EFSA Conclusion (EFSA Journal 2010; 8(4):1542). No additional studies have been performed.

The soil dissipation of azoxystrobin was investigated in a number of field trials. The studies were assessed against the relevant FOCUS criteria and kinetic assessments were performed in accordance with current FOCUS guidelines. In the field studies that were submitted for the original EU evaluation, azoxystrobin was applied to the soil surface of ten soils and the calculated DT<sub>50</sub> values from these studies included degradation via photolysis. In these studies, the photolysis metabolites R401553 and R402173 reached a maximum of 17% of applied azoxystrobin and were therefore triggered for inclusion in the exposure assessment. Four additional field studies were submitted for the renewal of approval to supplement those evaluated in the original evaluation. In these new studies, azoxystrobin was incorporated into the soil and a field DT<sub>50</sub> was calculated for the degradation of azoxystrobin by microbial processes. Only metabolite R234886 was formed in significant quantities in these studies, reaching a maximum of 15.4%.

The field dissipation of azoxystrobin is summarised in Table 8.4-5. These data were derived from the List of Endpoints in the EFSA Conclusion (EFSA Journal 2010; 8(4):1542). A geometric mean DT<sub>50field</sub> value of 78 days was selected for use in the environmental exposure assessment. This value is the overall geometric mean DT<sub>50field</sub> of the soil incorporated studies (geomean DT<sub>50</sub> 80.2 days) and the soil non-incorporated studies (slow phase geomean DT<sub>50</sub> 75.9 days).

**Table 8.4-5: Summary of aerobic degradation rates for azoxystrobin - field studies**

<b>Azoxystrobin, Field studies - Azoxystrobin applied to bare soil and incorporated</b>									
<b>Soil type</b>	<b>Location</b>	<b>pH (H<sub>2</sub>O)</b>	<b>Depth (cm)</b>	<b>DissT<sub>50</sub> (d) actual</b>	<b>DT<sub>90</sub> (d) actual</b>	<b>DT<sub>50</sub> (d) 20°C, pF2*</b>	<b>St. (x<sup>2</sup>)</b>	<b>Method of calculation</b>	<b>Evaluated on EU level y/n/ Reference</b>
Sandy clay loam	Spalding, Lincolnshire	7.5	30	261.9	869.9	106.7	10.6	SFO	Yes (Emburey, and Kay, 2002)
Silty clay loam	Nagele, Netherlands	7.9	30	186.4	619.3	86.3	10.2	SFO	Yes (Emburey and Poppezijs, 2002)
Sandy clay loam	Shirebrook, Derbyshire	6.7	30	120.9	401.7	56.1	17.2	SFO	Yes (Emburey, 2002)
Geometric mean (n=3)						<b>80.2</b>			
pH-dependency:						No			

<b>Azoxystrobin, Field studies - Azoxystrobin applied to soil surface and not incorporated</b>								
<b>Soil type</b>	<b>Location</b>	<b>pH (H<sub>2</sub>O)</b>	<b>Depth (cm)</b>	<b>DT<sub>50</sub> (d) 20°C, pF2*</b>		<b>St. (x<sup>2</sup>)</b>	<b>Method of calculation</b>	<b>Evaluated on EU level y/n/ Reference</b>
				<b>Fast phase<sup>#</sup></b>	<b>Slow phase<sup>#</sup></b>			
Clay loam	Volpedo, Italy	8.2	30	2.62	80.6	-	DFOP	Yes (Earl and Bonfanti, 1995)
Sandy loam	Bienenbittel-Varendorf, Germany	6.4	30	2.95	61.3	-	DFOP	Yes (Earl and Chamier, 1995a)
Sandy clay loam	Saxa-Anhalt, Germany	6.6	30	1.64	93.7	-	DFOP	Yes (Earl and Chamier, 1995b)
Clay loam	Isle/Sorgue, France	8.5	30	4.65	121.6	-	DFOP	Yes (Earl, Tummon and Barnaud, 1995a)
Sandy loam	Monteux Vaucluse, France	8.5	30	4.03	68	-	DFOP	Yes (Earl, Tummon and Barnaud, 1995b)
Silt loam	St. Vigor, France	6.1	30	3.02	34.5	-	DFOP	Yes (Earl, Tummon and Barnaud, 1995c)
Silty clay loam	Massalombarda, France	8.3	30	1.39	105	-	DFOP	Yes (Earl, Tummon

Azoxystrobin, Field studies - Azoxystrobin applied to soil surface and not incorporated								
Soil type	Location	pH (H <sub>2</sub> O)	Depth (cm)	DT <sub>50</sub> (d) 20°C, pF2*		St. (x <sup>2</sup> )	Method of calculation	Evaluated on EU level y/n/ Reference
				Fast phase <sup>#</sup>	Slow phase <sup>#</sup>			
								and Bonfanti, 1995)
Clay loam	Grisolles, France	7.7	30	13.3	66	-	DFOP	Yes (Earl, Tummon and Eschenbrenner, 1995)
Clay	Cambridgeshire, UK	8.0	30	2.09	93.7	-	DFOP	Yes (Earl and Hall, 1995)
Clay	Somerset, UK	8.1	30	0.42	73.7	-	DFOP	Yes Earl, Tummon and Myles, 1995)
Geometric mean (n=10)				2.55	75.9			
pH-dependency:				No				

- not reported

\* A DT<sub>50field</sub> value of 78 days was selected for use in the environmental exposure assessment. This value is the overall geometric mean DT<sub>50field</sub> of the soil incorporated studies (80.2 days) and the soil non-incorporated studies (slow phase, 75.9 days).

<sup>#</sup> A Q<sub>10</sub> value of 2.58 was used in the temperature normalisation procedure for the whole biphasic decline

## 8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

### Prothioconazole

Soil accumulation testing is not required for prothioconazole or its metabolite prothioconazole-desthio (M04) since the DT<sub>90field</sub> are considerably less than 365 days. Soil accumulation studies are therefore not required and have not been provided.

### Azoxystrobin

The soil accumulation of azoxystrobin was evaluated during the EU review and is summarised in the EFSA Conclusion (EFSA Journal 2010; 8(4):1542). No additional studies have been performed.

In the absence of experimental data on soil accumulation, long-term plateau and steady-state concentrations for azoxystrobin in soil were predicted based on the worst-case use scenario. Whilst metabolite R234886 showed some evidence of persistence in laboratory studies, the new field studies that were submitted in support of the application for the renewal of approval of azoxystrobin did not show evidence of accumulation in soil, and accumulation PECs were therefore not calculated for this metabolite.

## 8.5 Mobility in soil (KCP 9.1.2)

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate

from data obtained with the active substances.

### 8.5.1 Prothioconazole and its metabolites

The mobility of prothioconazole and its metabolites prothioconazole-S-methyl (M01) and prothioconazole-desthio (M04) in soil was evaluated during the EU review and is summarised in the EFSA Conclusion (EFSA Scientific Report (2007) 106, 1-98). No additional studies have been performed.

$K_d$  and  $K_{oc}$  values for prothioconazole could not be determined in batch equilibrium studies due to the instability of the compound in these systems. Instead, a column leaching test and an aged column leaching study were conducted to obtain information concerning the leaching potential of prothioconazole. Batch equilibrium studies were conducted for the soil metabolites prothioconazole-S-methyl (M01) and prothioconazole-desthio (M04).

**Table 8.5-1: Summary of soil adsorption/desorption for prothioconazole**

Prothioconazole <sup>(a)</sup>							
Soil name	Soil type	OC (%)	pH (H <sub>2</sub> O)	K <sub>d</sub> (mL/g)	K <sub>doc</sub> (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Byromville	Loamy sand	0.86	6.7	15.2	1765	-	Yes (Babczinski, 2001)
Arithmetic mean (n=1)					-	-	
Maximum (n=1)					<b>1765</b>	<b>0.9</b>	
pH-dependency:					-		

<sup>(a)</sup> Determined on the basis of an aged column leaching study



**Table 8.5-2: Summary of soil adsorption/desorption for prothioconazole-S-methyl (M01)**

Prothioconazole-S-methyl (M01)							
Soil Name	Soil Type	OC (%)	pH (H <sub>2</sub> O)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Laacher Höf AXXa	Sandy loam	2.02	7.2	56.0	2772	0.87	Yes (Hein, 1999)
Höfchen	Silt	2.14	7.1	64.1	2995	0.88	
Stanley	Silty clay loam	1.66	5.9	41.2	2484	0.91	
Byromville	Loamy sand	0.79	6.8	15.6	1974	0.85	
Geometric mean (n=4)					<b>2526.0</b>		
Arithmetic mean (n=4)					<b>2556.3</b>	0.88	
pH-dependency:					No		

**Table 8.5-3: Summary of soil adsorption/desorption for prothioconazole-desthio (M04)**

Prothioconazole-desthio (M04)							
Soil Name	Soil Type	OC (%)	pH (H <sub>2</sub> O)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Laacher Höf AXXa	Sandy loam	2.02	7.2	12.46	617	0.79	Yes (Fent, 1998)
Höfchen	Silt	2.14	7.1	13.38	625	0.83	
Stanley	Silty clay loam	1.66	5.9	8.90	536	0.83	
Byromville	Loamy sand	0.79	6.8	4.13	523	0.80	
Geometric mean (n=4)					<b>574</b>		
Arithmetic mean (n=4)					<b>575.4</b>	0.81	
pH-dependency:					No		

**Table 8.5-4: Summary of soil adsorption/desorption for 1,2,4-triazole (M13, from PTZ)**

Soil Name	Soil Type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Data not given in EFSA Scientific Report				not stated	43-202	0.827-1.016	y/ EFSA & DAR
Arithmetic mean (n=4)					89	0.9155	-
Geometric mean (n=4)					83	-	-
pH-dependency y/n					No pH dependence		

## 8.5.2 Azoxystrobin and its metabolites

The mobility of azoxystrobin and its metabolites R234886, R401553 and R402173 in soil was evaluated during the EU review and is summarised in the EFSA Conclusion (EFSA Journal 2010; 8(4):1542). No additional studies have been performed.

**Table 8.5-4: Summary of soil adsorption/desorption for azoxystrobin**

Azoxystrobin							
Soil name	Soil type	OC (%)	pH <sup>(a)</sup>	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Sandy clay loam	Sandy clay loam	1.7	7.5	7.9	465	0.84	Yes (Rowe and Lane, 1994)
Loamy sand A	Loamy sand	1.7	7.8	4.0	235	0.82	
Loamy sand B	Loamy sand	3.0	7.9	6.2	207	0.85	
Sand	Sand	0.3	5.5	1.5	500	0.84	
Silty clay loam	Silty clay loam	1.6	4.9	9.5	594	0.90	
Clay loam	Clay loam	2.8	5.5	15.0	536	0.90	
Geometric mean (n=6)					<b>391.5</b>		
Arithmetic mean (n=6)					<b>423</b>	<b>0.86</b>	
pH-dependency:					No		

<sup>(a)</sup> Solution not specified

**Table 8.5-5: Summary of soil adsorption/desorption for R234886**

R234886							
Soil Name	Soil Type	OC (%)	pH (CaCl <sub>2</sub> )	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Kenny Hill	Loamy sand	2.96	7.5	0.82	28	0.90	Yes (Ferguson, Muller and Lane, 1994)
Pickett Piece	Clay loam	2.78	4.8	10	360	0.89	
East Anglia	Loamy sand	1.68	7.3	0.35	21	0.76	
Lilly Field	Sand	0.29	4.6	1.4	490	0.79	
Nebo	Silty clay loam	1.62	4.2	6.8	420	0.90	
Hyde Farm	Sandy clay loam	1.74	6.8	0.85	49	0.85	
Geometric mean (n=6)					<b>113.5</b>		

<b>R234886</b>							
Soil Name	Soil Type	OC (%)	pH (CaCl <sub>2</sub> )	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Arithmetic mean (n=6)					<b>228</b>	<b>0.85</b>	
pH-dependency:					Yes		

**Table 8.5-6: Summary of soil adsorption/desorption for R401553**

<b>R401553</b>							
Soil Name	Soil Type	OC (%)	pH (H <sub>2</sub> O)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Hyde Farm	Sandy clay loam	1.74	7.5	1.9	110	0.81	Yes Rowe and Lane, 1995a)
ERTC	Loamy sand	0.29	6.8	0.76	260	0.81	
Kenny Hill	Sandy loam	2.96	8.5	2.4	81	0.84	
NRTC	Silty clay loam	2.15	6.2	11	500	0.89	
Wisborough Green	Silty clay loam	2.38	5.6	1.6	66	0.85	
Pickett Piece	Clay loam	2.61	5.4	2.9	110	0.92	
Geometric mean (n=6)					<b>142.6</b>		
Arithmetic mean (n=6)					<b>188</b>	<b>0.85</b>	
pH-dependency:					No		

**Table 8.5-7: Summary of soil adsorption/desorption for R402173**

<b>R402173</b>							
Soil Name	Soil Type	OC (%)	pH (H <sub>2</sub> O)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Hyde Farm	Sandy clay loam	1.74	7.5	0.65	37	0.96	Yes (Rowe and Lane, 1995b)
ERTC	Loamy sand	0.29	6.8	0.27	93	0.95	
Kenny Hill	Sandy loam	2.96	8.5	0.74	25	0.96	
NRTC	Silty clay loam	2.15	6.2	4.2	200	0.92	
Wisborough Green	Silty clay loam	2.38	5.6	2.0	86	0.93	
Pickett Piece	Clay loam	2.61	5.4	2.9	110	0.96	

<b>R402173</b>							
<b>Soil Name</b>	<b>Soil Type</b>	<b>OC (%)</b>	<b>pH (H<sub>2</sub>O)</b>	<b>Kf (mL/g)</b>	<b>Kfoc (mL/g)</b>	<b>1/n (-)</b>	<b>Evaluated on EU level y/n/ Reference</b>
Geometric mean (n=6)					<b>73.9</b>		
Arithmetic mean (n=6)					<b>91.8</b>	<b>0.95</b>	
pH-dependency:					Yes		

### 8.5.3 Column leaching (KCP 9.1.2.1)

#### Prothioconazole

Column leaching studies were evaluated during the EU review and are summarised in the EFSA Conclusion (EFSA Scientific Report (2007) 106, 1-98).

The leaching behaviour of phenyl-UL-<sup>14</sup>C labelled prothioconazole was investigated in a non-aged soil column leaching study on four soils. Radioactivity detected in the leachates was <1% AR in all samples, therefore the leachate fractions were not investigated by analytical methods. The amount of radioactivity detected in the total leachate was 0.13% AR for the Byromville soil and <0.03% for the remaining three soils. Residues of the active substance and the metabolite prothioconazole-S-methyl (M01) were only detected in the 0-6 cm segment (14.6 to 40.7% AR and 5.5 to 11.2% AR, respectively). Residues of the metabolite prothioconazole-desthio (M04) ranged from 15.4 to 28.0% AR in the 0-6 cm segment and were also present in the 6-12 cm segment of one soil (Byromville, 7.5% AR).

An aged column leaching study was conducted in a loamy sand soil using phenyl-UL-<sup>14</sup>C labelled prothioconazole. Following a 30-hour incubation period, prothioconazole had degraded to 22.7% AR and the metabolites prothioconazole-S-methyl (M01) (8.1% AR) and prothioconazole-desthio (M04) (31.8% AR) had formed. Following leaching of the aged soil, total radioactivity in the leachate accounted for only 1.1% AR and was <0.2% AR in individual leachate fractions. The K<sub>oc</sub> of prothioconazole could not be determined using standard equilibrium studies due to the instability of the compound in these systems, therefore the distribution of prothioconazole in the aged column leaching study was used to estimate K<sub>d</sub> and K<sub>oc</sub>. The resulting values for prothioconazole were K<sub>d</sub> = 15.2 mL/g and K<sub>oc</sub> = 1765 mL/g (please refer to Table 8.5-1).

#### Azoxystrobin

Column leaching studies were evaluated during the EU review and are summarised in the EFSA Conclusion (EFSA Journal 2010; 8(4):1542). No additional studies have been performed.

The leaching behaviour of azoxystrobin was investigated in three column leaching studies and an aged column leaching study with three soils aged for 30 days. No leaching was observed.

### 8.5.4 Lysimeter studies (KCP 9.1.2.2)

#### Prothioconazole

Sufficient information to evaluate the mobility and leaching potential of prothioconazole and its soil metabolites prothioconazole-S-methyl (M01) and prothioconazole-desthio (M04) is available from the aged column leaching study for prothioconazole, the adsorption / desorption studies for the metabolites and the FOCUS groundwater modelling assessments (Annex Point 8.8). Lysimeter studies are therefore

not required and further data are not provided.

### **Azoxystrobin**

Sufficient information to evaluate the mobility and leaching potential of azoxystrobin and its soil metabolites R234886, R401553 and R402173 is available from the adsorption / desorption studies and the FOCUS groundwater modelling assessments (Annex Point 8.8). Lysimeter studies are therefore not required and further data are not provided.

## **8.5.5 Field leaching studies (KCP 9.1.2.3)**

### **Prothioconazole**

Sufficient information to evaluate the mobility and leaching potential of prothioconazole and its soil metabolites prothioconazole-S-methyl (M01) and prothioconazole-desthio (M04) is available from the aged column leaching study for prothioconazole, the adsorption / desorption studies for the metabolites and the FOCUS groundwater modelling assessments (Annex Point 8.8). Field leaching studies are therefore not required and further data are not provided.

### **Azoxystrobin**

Sufficient information to evaluate the mobility and leaching potential of azoxystrobin and its soil metabolites R234886, R401553 and R402173 is available from the adsorption / desorption studies and the FOCUS groundwater modelling assessments (Annex Point 8.8). Field leaching studies are therefore not required and further data are not provided.

## **8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)**

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

### **8.6.1 Prothioconazole and its metabolites**

The degradation / dissipation of prothioconazole was investigated in two water-sediment systems. These studies were evaluated during the EU review and are summarised in the EFSA Conclusion (EFSA Scientific Report (2007) 106, 1-98). No additional studies have been performed.

**Table 8.6-1: Summary of degradation in water/sediment of prothioconazole**

<b>Prothioconazole Distribution (max. in water 76.3% (day 0), max. in sediment 23.4 % (day 1))</b>										
<b>Water/sediment system</b>	<b>pH water/sed.</b>	<b>DegT<sub>50</sub> whole syst. (d)</b>	<b>DegT<sub>90</sub> whole syst. (d)</b>	<b>Kinetic, Fit</b>	<b>DissT<sub>50</sub> water (d)</b>	<b>DissT<sub>90</sub> water (d)</b>	<b>Kinetic, Fit</b>	<b>DissT<sub>50</sub> sed. (d)</b>	<b>Kinetic, Fit</b>	<b>Evaluated on EU level y/n/Reference</b>
Hönniger Weiher	7.84 / 5.8 <sup>(a)</sup>	2.8	76.4	Hockey Stick	0.8	2.7	SFO	-	-	Yes (Brumhard, and Oi,
Angler Weiher	7.45 /	1.6	23.6	Hockey	1.0	3.4	SFO	-	-	

Prothioconazole Distribution (max. in water 76.3% (day 0), max. in sediment 23.4 % (day 1))										
Water/sediment system	pH water/sed.	DegT <sub>50</sub> whole syst. (d)	DegT <sub>90</sub> whole syst. (d)	Kinetic, Fit	DissT <sub>50</sub> water (d)	DissT <sub>90</sub> water (d)	Kinetic, Fit	DissT <sub>50</sub> sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
	7.4 <sup>(a)</sup>			Stick						2001 [amended 2002])
Geometric mean (n=2)		2.1	42.5		0.89	3.0		-		

<sup>(a)</sup> Measured in CaCl<sub>2</sub> solution

- Not available

**Table 8.6-2: Summary of observed metabolites**

<b>Prothioconazole-S-methyl (M01)</b> <b>Water/sediment system</b>	Max. in water/sediment 12.7 % after 7 d (Angler Weiher, triazole label) Max. in water 3.1 % after 7 d (Angler Weiher, triazole label) Max. in sediment 9.6 % after 7 d (Angler Weiher, triazole label)	Evaluated on EU level y/n/ Reference Yes (Brumhard and Oi, 2001 [amended 2002])
<b>Prothioconazole-desthio (M04)</b> <b>Water/sediment system</b>	Max. in water/sediment 54.6 % after 7 d (Angler Weiher, phenyl label) Max. in water 32.3 % after 7 d (Angler Weiher, phenyl label) Max. in sediment 26.9 % after 14 d (Angler Weiher, triazole and phenyl labels)	Evaluated on EU level y/n/ Reference Yes (Brumhard and Oi, 2001 [amended 2002])
<b>1,2,4-triazole</b> <b>Water/sediment system</b>	Max. in water/sediment 41.8 % after 121 d (Angler Weiher, triazole label) Max. in water 37.2 % after 121 d (Angler Weiher, triazole label) Max. in sediment 6.1 % after 121 d (Hönniger Weiher, triazole label)	Evaluated on EU level y/n/ Reference Yes (Brumhard and Oi, 2001 [amended 2002])
<b>Prothioconazole-triazolylketone (M42)</b> <b>Water/sediment system</b>	Max. in water/sediment 9.1 % after 59 d (Angler Weiher, triazole label) Max. in water 8.0 % after 59 d (Angler Weiher, triazole label) Max. in sediment 5.8 % after 121 d (Hönniger Weiher, triazole label)	Evaluated on EU level y/n/ Reference Yes (Brumhard and Oi, 2001 [amended 2002])

## 8.6.2 Azoxystrobin and its metabolites

The degradation / dissipation of azoxystrobin was investigated in two water-sediment systems. This study was evaluated during the EU review and is summarised in the EFSA Conclusion (EFSA Journal 2010; 8(4):1542). An outdoor pond study was also submitted in support of the application for the renewal of approval of azoxystrobin. However, the results from this study were not included in the aquatic exposure assessment. No additional studies have been performed.

**Table 8.6-3: Summary of degradation in water/sediment of azoxystrobin**

Azoxystrobin Distribution (max. in water 91.2% after 0 days, max. in /sediment 90.5% after 0 days)										
Water/sediment system	pH water/sed.	DegT <sub>50</sub> whole syst. (d)	DegT <sub>90</sub> whole syst. (d)	Kinetic, Fit	DissT <sub>50</sub> water (d)	DissT <sub>90</sub> water (d)	Kinetic, Fit	DissT <sub>50</sub> sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference

Azoxystrobin Distribution (max. in water 91.2% after 0 days, max. in /sediment 90.5% after 0 days)										
Water/sediment system	pH water/sed.	DegT <sub>50</sub> whole syst. (d)	DegT <sub>90</sub> whole syst. (d)	Kinetic, Fit	DissT <sub>50</sub> water (d)	DissT <sub>90</sub> water (d)	Kinetic, Fit	DissT <sub>50</sub> sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/Reference
Old Basing	7.5/7.8	234	777	SFO	n.c.	n.c.	n.c.	n.c.	n.c.	Yes (Warinton, 1994)
Virginia Water	6.4/6.9	180	598	SFO	n.c.	n.c.	n.c.	n.c.	n.c.	
Outdoor Pond	9.06/7.5	n.c.	n.c.	n.c.	13.1 <sup>#</sup>	43.6 <sup>#</sup>	SFO	n.c.	n.c.	Yes (Jones and Lake, 2000)
Geometric mean (n=2)		205	682		13.1 <sup>#</sup>	43.6 <sup>#</sup>		-		

n.c. not calculated

<sup>#</sup> not used in exposure modelling but provided here for information

**Table 8.6-4: Summary of observed metabolites**

<b>R234886</b> Water/sediment system	Max. in water/sediment 18.1% (overall mean of 3 radiolabels) Max. in water 10.8% after 152 d Max. in sediment 15.6% after 152 d	Evaluated on EU level y/n/Reference Yes (Warinton, 1994)
<b>R401553</b> Water/sediment system	Max. in water/sediment 8.9 % (Photolytic degradation)	EFSA (2010)
<b>R402173</b> Water/sediment system	Max. in water/sediment 2.4 % (Photolytic degradation)	

#### zRMS comments:

Information on degradation of prothioconazole and its metabolites and azoxystrobin and its metabolites in water/sediment systems are in line with EU agreed endpoints.

## 8.7 Predicted Environmental Concentrations in soil (PEC<sub>soil</sub>) (KCP 9.1.3)

### 8.7.1 Justification for new endpoints

There are no deviations from the agreed EU endpoints.

### 8.7.2 Active substance(s) and relevant metabolite(s)

PEC<sub>soil</sub> calculations were performed for the active substances prothioconazole and azoxystrobin and their respective soil metabolites based on a first-tier approach using a Microsoft® Excel spreadsheet. The calculations were based on the critical GAP for the FF-075 formulation in central Europe and assume a soil mixing depth of 5 cm and a soil bulk density of 1.5 g/cm<sup>3</sup>.

**Table 8.7-1: Input parameters related to application for PEC<sub>soil</sub> calculations**

Use No.	1	2
---------	---	---

Crop	Winter oilseed rape	Winter and spring cereals
Application rate (g as/ha)	Prothioconazole: 160 Azoxystrobin: 120	Prothioconazole: 200 Azoxystrobin: 150
Number of applications/interval	2 (14 day interval)	2 (14 day interval)
Crop interception (%)	80 (flowering)	80 (stem elongation)
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm (no tillage) (worst-case assumption)	5 cm (no tillage) (worst-case assumption)

**Table 8.7-2: Input parameter for active substances and relevant metabolites for  $PEC_{soil}$  calculations**

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT <sub>50</sub> (days)	Value in accordance to EU end-point y/n/ Reference
Prothioconazole	344.3	-	2.8 d (worst-case non-normalised DT <sub>50field</sub> , SFO)	Yes EFSA Conclusion (EFSA Scientific Report (2007) 106, 1-98)
Prothioconazole-S-methyl (M01)	358.3	14.6	46 d (worst-case DT <sub>50lab</sub> , SFO)	
Prothioconazole-desthio (M04)	312.2	57.1 (field soil)	72.3 d (worst-case non-normalised DT <sub>50field</sub> , SFO)	
Azoxystrobin	403.4	-	262 (worst-case non-normalised DT <sub>50field</sub> (incorporated), SFO)	Yes EFSA Conclusion (EFSA Journal 2010; 8(4):1542)
R234886	389.4	28.8	Not required	
R401553	213.2	17	Not required	
R402173	333.3	17	Not required	

### 8.7.2.1 Prothioconazole and its metabolites

**Table 8.7-3:  $PEC_{soil}$  for prothioconazole on winter oilseed rape**

$PEC_{soil}$ (mg/kg)		Winter oilseed rape			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0427	-	0.0440	-
Short term	24h	0.0333	0.0378	0.0344	0.0390
	2d	0.0260	0.0337	0.0268	0.0347
	4d	0.0159	0.0271	0.0163	0.0279
Long term	7d	0.0075	0.0203	0.0078	0.0209
	14d	0.0013	0.0119	0.0014	0.0123
	21d	0.0002	0.0082	0.0002	0.0084



	28d	<0.0001	0.0061	<0.0001	0.0063
	42d	<0.0001	0.0041	<0.0001	0.0042
	50d	<0.0001	0.0034	<0.0001	0.0036
	100d	<0.0001	0.0017	<0.0001	0.0018
Plateau concentration		Not required	-	Not required	-
PEC <sub>accumulation</sub> (PEC <sub>act</sub> + PEC <sub>soil plateau</sub> )		Not required	-	Not required	-

**Table 8.7-4: PEC<sub>soil</sub> for prothioconazole on cereals**

PEC <sub>soil</sub> (mg/kg)		Winter and spring cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0533	-	0.0550	-
Short term	24h	0.0416	0.0472	0.0429	0.0487
	2d	0.0325	0.0421	0.0335	0.0434
	4d	0.0198	0.0339	0.0204	0.0349
Long term	7d	0.0094	0.0253	0.0097	0.0261
	14d	0.0017	0.0149	0.0017	0.0154
	21d	0.0003	0.0102	0.0003	0.0105
	28d	0.0001	0.0077	0.0001	0.0079
	42d	<0.0001	0.0051	<0.0001	0.0053
	50d	<0.0001	0.0043	<0.0001	0.0044
	100d	<0.0001	0.0022	<0.0001	0.0022
Plateau concentration		Not required	-	Not required	-
PEC <sub>accumulation</sub> (PEC <sub>act</sub> + PEC <sub>soil plateau</sub> )		Not required	-	Not required	-

#### PEC<sub>soil</sub> of metabolites

As a worst-case, the calculations for the metabolites were based on a single application of the total applied dose of parent active substance (320 g as/ha for winter oilseed rape and 400 g as/ha for cereals) adjusted to account for the maximum observed percentage in soil and the molar correction factor. This simplified approach ignores the timing of peak occurrence and the application interval for the multiple application pattern and calculates the maximum theoretical peak occurrence for each metabolite.

**Table 8.7-5: PEC<sub>soil</sub> for prothioconazole-S-methyl (M01)**

PEC <sub>soil</sub> (mg/kg)		Winter oilseed rape		Winter and spring cereals	
		Actual	TWA	Actual	TWA
Initial		0.0130	-	0.0162	-
Short term	24h	0.0128	0.0129	0.0160	0.0161
	2d	0.0126	0.0128	0.0157	0.0160
	4d	0.0122	0.0126	0.0153	0.0157
Long term	7d	0.0117	0.0123	0.0146	0.0154

PEC <sub>soil</sub> (mg/kg)		Winter oilseed rape		Winter and spring cereals	
		Actual	TWA	Actual	TWA
	14d	0.0105	0.0117	0.0131	0.0146
	21d	0.0094	0.0111	0.0118	0.0139
	28d	0.0085	0.0106	0.0106	0.0132
	42d	0.0069	0.0096	0.0086	0.0120
	50d	0.0061	0.0091	0.0076	0.0114
	100d	0.0029	0.0067	0.0036	0.0084
Plateau concentration (5 cm) after year 2		0.0001	-	0.0001	-
PEC <sub>accumulation</sub> (PEC <sub>act</sub> + PEC <sub>soil plateau</sub> )		0.0130	-	0.0163	-

**Table 8.7-6: PEC<sub>soil</sub> for prothioconazole-desthio (M04)**

PEC <sub>soil</sub> (mg/kg)		Winter oilseed rape		Winter and spring cereals	
		Actual	TWA	Actual	TWA
Initial		0.0442	-	0.0552	-
Short term	24h	0.0438	0.0440	0.0547	0.0550
	2d	0.0433	0.0438	0.0542	0.0547
	4d	0.0425	0.0433	0.0532	0.0542
Long term	7d	0.0413	0.0427	0.0516	0.0534
	14d	0.0386	0.0413	0.0483	0.0517
	21d	0.0361	0.0400	0.0452	0.0500
	28d	0.0338	0.0387	0.0422	0.0484
	42d	0.0295	0.0364	0.0369	0.0455
	50d	0.0274	0.0351	0.0342	0.0439
	100d	0.0169	0.0284	0.0212	0.0355
Plateau concentration (5 cm) after year 2		0.0014	-	0.0017	-
PEC <sub>accumulation</sub> (PEC <sub>act</sub> + PEC <sub>soil plateau</sub> )		0.0456	-	0.0569	-

### 8.7.2.2 Azoxystrobin and its metabolites

**Table 8.7-7: PEC<sub>soil</sub> for azoxystrobin on winter oilseed rape**

PEC <sub>soil</sub> (mg/kg)		Winter oilseed rape			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0320	-	0.0628	-
Short term	24h	0.0319	0.0320	0.0627	0.0628
	2d	0.0318	0.0319	0.0625	0.0627

PEC <sub>soil</sub> (mg/kg)		Winter oilseed rape			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Long term	4d	0.0317	0.0318	0.0622	0.0625
	7d	0.0314	0.0317	0.0617	0.0623
	14d	0.0308	0.0314	0.0606	0.0617
	21d	0.0303	0.0311	0.0594	0.0611
	28d	0.0297	0.0308	0.0583	0.0606
	42d	0.0286	0.0303	0.0562	0.0595
	50d	0.0280	0.0300	0.0551	0.0589
	100d	0.0246	0.0281	0.0482	0.0552
Plateau concentration (5 cm) after year 7		0.0197	-	0.0393*	-
PEC <sub>accumulation</sub> (PEC <sub>act</sub> + PEC <sub>soil plateau</sub> )		0.0517		0.1033*	

\* As a worst-case and in line with the approach presented in the EFSA Conclusion for azoxystrobin, the PEC<sub>accumulation</sub> calculation for the multiple application pattern was based on a single application of the total applied dose (240 g as./ha for winter oilseed rape), thus ignoring any dissipation between applications.

**Table 8.7-8: PEC<sub>soil</sub> for azoxystrobin on cereals**

PEC <sub>soil</sub> (mg/kg)		Winter and spring cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0400	-	0.0785	-
Short term	24h	0.0399	0.0399	0.0783	0.0784
	2d	0.0398	0.0399	0.0781	0.0783
	4d	0.0396	0.0398	0.0777	0.0781
Long term	7d	0.0393	0.0396	0.0771	0.0778
	14d	0.0385	0.0393	0.0757	0.0771
	21d	0.0378	0.0389	0.0743	0.0764
	28d	0.0371	0.0386	0.0729	0.0757
	42d	0.0358	0.0379	0.0703	0.0743
	50d	0.0350	0.0375	0.0688	0.0736
	100d	0.0307	0.0351	0.0603	0.0690
Plateau concentration (5 cm) after year 7		0.0246	-	0.0492*	-
PEC <sub>accumulation</sub> (PEC <sub>act</sub> + PEC <sub>soil plateau</sub> )		0.0646		0.1292*	

\* As a worst-case and in line with the approach presented in the EFSA Conclusion for azoxystrobin, the PEC<sub>accumulation</sub> calculation for the multiple application pattern was based on a single application of the total applied dose (300 g as./ha for cereals), thus ignoring any dissipation between applications.

### PEC<sub>soil</sub> of metabolites

As a worst-case, the calculations for the metabolites were based on a single application of the total

applied dose of parent active substance (240 g as/ha for winter oilseed rape and 300 g as/ha for cereals) adjusted to account for the maximum observed percentage in soil and the molar correction factor. This simplified approach ignores the timing of peak occurrence and the application interval for the multiple application pattern and calculates the maximum theoretical peak occurrence for each metabolite. In line with the approach presented in the EFSA Conclusion for azoxystrobin, only the maximum initial values are presented for each metabolite.

**Table 8.7-9: PEC<sub>soil</sub> for R234886**

PEC <sub>soil</sub> (mg/kg)	Winter oilseed rape		Winter and spring cereals	
	Actual	TWA	Actual	TWA
Initial	0.0178	-	0.0222	-

**Table 8.7-10: PEC<sub>soil</sub> for R401553**

PEC <sub>soil</sub> (mg/kg)	Winter oilseed rape		Winter and spring cereals	
	Actual	TWA	Actual	TWA
Initial	0.0058	-	0.0072	-

**Table 8.7-11: PEC<sub>soil</sub> for R402173**

PEC <sub>soil</sub> (mg/kg)	Winter oilseed rape		Winter and spring cereals	
	Actual	TWA	Actual	TWA
Initial	0.0090	-	0.0112	-

### 8.7.2.3 PEC<sub>soil</sub> of formulation

**Table 8.7-12: PEC<sub>soil</sub> for FF-075**

Preparation	Crop	Application rate (g/ha)*	Interception (%)	PEC <sub>act</sub> (mg/kg)
FF-075	Winter oilseed rape	1 x 880**	80 (flowering)	0.2347
	Cereals	1 x 1100**	80 (stem elongation)	0.2933
	Winter oilseed rape	1 x 1760	80 (flowering)	0.469
	Cereals	1 x 2200	80 (stem elongation)	0.587

\* Formulation components other than the active substances are assumed to dissipate rapidly in the environment, therefore only one application is considered

\*\* The maximum proposed use rates for FF-075 are 0.8 L/ha for winter oilseed rape and 1.0 L/ha for cereals. The formulated product has a relative density of 1.100 g/mL, which corresponds to a formulation application rate of 880 g/ha for winter oilseed rape and 1100 g/ha for cereals.

#### zRMS comments:

##### Prothioconazole

PEC<sub>soil</sub> calculations has been accepted for the active substance prothioconazole and its metabolites. The input parameters used in calculations were taken from the endpoints available in the EFSA conclusion on Scientific Report EFSA Scientific Report (2007) 106, 1-98. Interception is appropriate to the proposed BBCH of crops (guidance 2014).

Agreed PEC<sub>soil</sub> for has been presented for prothioconazole in Tables 8.7.3 -8.7.6 above.

##### Azoxystrobin

PEC<sub>soil</sub> calculations has been accepted for the active substance azoxystrobin and its metabolites.

The input parameters used in calculations were taken from the endpoints available in the EFSA conclusion on Scientific Report EFSA 2010; 8(4):1542). Interception is appropriate to the proposed BBCH of crops (guidance 2014).

Agreed PEC<sub>soil</sub> for has been presented for azoxystrobin in Tables 8.7.7 -8.7.11 above.

#### Formulation FF-075

PEC<sub>soil</sub>

Winter oilseed rape 0.2347 0.469 mg/kg

Cereals -0.2933 0.587 mg/kg

The acceptable predicted environmental concentrations active substances and their metabolites in soil are appropriate to be used for the subsequent risk assessment.

## 8.8 Predicted Environmental Concentrations in groundwater (PEC<sub>gw</sub>) (KCP 9.2.4)

### 8.8.1 Justification for new endpoints

There are no significant deviations from the agreed EU endpoints.

Minor deviations relating to the selection of some modelling input parameters (i.e. the selection of geometric mean K<sub>loc</sub> values, where appropriate, in accordance with current FOCUS recommendations) are discussed in further detail in Sections 8.8.2.1 and 8.8.2.2 below.

### 8.8.2 Active substances and relevant metabolites (KCP 9.2.4.1)

The critical GAP and application parameters used for the groundwater modelling assessment are summarised in Tables 8.8-1 and 8.8-2.

**Table 8.8-1: Input parameters related to application for PEC<sub>gw</sub> calculations**

Use No.	1	2
Crop	Winter oilseed rape	Winter and spring cereals
Application rate (g as/ha)	Prothioconazole: 160 Azoxystrobin: 120	Prothioconazole: 200 Azoxystrobin: 150
Number of applications/interval (d)	2 (14 day interval)	2 (14 day interval)
Relative application date	Not applicable	Not applicable
Crop interception (%)	80 (flowering)	80 (stem elongation) 90 (flowering)
Frequency of application	Annual	Annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v5.5.4	

**Table 8.8-2: Application dates used for groundwater risk assessment**

Crop	Scenario	Application dates (absolute)*
------	----------	-------------------------------

Crop	Scenario	Application dates (absolute)*	
		Early application	Late application
Winter oilseed rape	Châteaudun	10 April, 24 April	30 April, 14 May
	Hamburg	01 May, 15 May	16 May, 30 May
	Kremsmünster	30 April, 14 May	16 May, 30 May
	Okehampton	25 April, 09 May	11 May, 25 May
	Piacenza	05 April, 19 April	21 April, 05 May
	Porto	23 March, 06 April	30 April, 14 May
Winter cereals	Châteaudun	15 April, 29 April	31 May, 14 June
	Hamburg	04 May, 18 May	08 June, 22 June
	Jokioinen	14 May, 28 May	26 June, 10 July
	Kremsmünster	24 April, 08 May	11 June, 25 June
	Okehampton	21 April, 05 May	24 May, 07 June
	Piacenza	19 March, 02 April	12 May, 26 May
	Porto	30 January, 13 February	04 May, 18 May
	Sevilla	06 January, 20 January	14 March, 28 March
	Thiva	18 January, 01 February	13 April, 27 April

Crop	Scenario	Application dates (absolute)*	
Spring cereals	Châteaudun	16 April, 30 April	08 June, 22 June
	Hamburg	28 April, 12 May	14 June, 28 June
	Jokioinen	05 June, 19 June	03 July, 17 July
	Kremsmünster	27 April, 11 May	14 June, 28 June
	Okehampton	22 April, 06 May	04 June, 18 June
	Porto	16 April, 30 April	08 June, 22 June

\* Application timings derived from AppDate v3.06 (June 2019). To cover the proposed application windows, two application timings (early and late) were simulated. For early application, the first application date was set to coincide with the earliest BBCH growth stage. For late application, the final application date was set to coincide with the latest BBCH growth stage.

### 8.8.2.1 Prothioconazole and its metabolites

The following groundwater modelling on prothioconazole and its soil metabolites prothioconazole-S-methyl (M01) and prothioconazole-desthio (M04) has not previously been reviewed and is provided in support of this assessment.

Groundwater modelling of prothioconazole and its metabolites, prothioconazole-S-methyl (M01) and prothioconazole-desthio (M04) has been performed using the relevant FOCUS groundwater scenarios and the FOCUS groundwater models, PEARL (version 4.4.4), PELMO (version 5.5.3) and MACRO (version 5.5.4). The modelling was based on applications to winter oilseed rape and winter and spring cereals in accordance with the critical GAP for the FF-075 formulation in Europe. The FOCUS crops ‘winter oilseed rape’, ‘winter cereals’ and ‘spring cereals’ and their associated scenarios were selected for the simulations. For winter oilseed rape, two applications of 160 g as/ha were simulated at an interval of 14 days, with application dates selected to coincide with BBCH GS 55-69. For winter and spring cereals, two applications of 200 g as/ha were simulated at an interval of 14 days, with application dates selected to coincide with BBCH growth stage 30-69. Absolute application dates were selected for each crop group using the AppDate tool (v3.06). In order to cover the relatively wide application windows for each crop, two application timings (early and late) were simulated. For early application, the first application date was set to coincide with the date of the earliest recommended growth stage and for late application, the final application date was set to coincide with the date of the latest recommended growth stage. The simulated application dates for each crop scenario are shown in Table 8.8-2 above. As the formulation is foliar applied, crop interception was accounted for in the simulations in accordance with FOCUS guidance. For winter oilseed rape, a value of 80%, which corresponds to flowering at BBCH GS 40-89 was assumed in the simulations. For winter and spring cereals, a value of 80%, corresponding to stem elongation at BBCH GS 30-39 was assumed in the early application simulations and a value of 90%, corresponding to flowering at BBCH GS 40-69 was assumed in the applications for late application.

The key chemical input parameters for prothioconazole and its metabolites selected for use in the modelling are summarised in Table 8.8-3. Unless otherwise stated, these values were derived from Volume 3, Annex B.8 of the Draft Assessment Report (DAR, July, 2005), the Addendum to the DAR (October, 2005) and the list of endpoints in the EFSA Conclusion (EFSA Scientific Report (2007) 106, 1-98).

**Table 8.8-3: Input parameters related to active substance prothioconazole and its metabolites for PEC<sub>gw</sub> calculations**

Compound	Prothioconazole	Prothioconazole-S-methyl (M01)	Prothioconazole-desthio (M04)	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	344.3	358.3	312.2	Yes EFSA Conclusion (EFSA Scientific Report (2007) 106, 1-98)
Water solubility (mg/L)	300 (20°C, pH 8)	1000 (20°C) (conservative default)	1000 (20°C) (conservative default)	
Saturated vapour pressure (Pa)	0 (worst-case assumption)	0 (worst-case assumption)	0 (worst-case assumption)	
DT <sub>50</sub> in soil (d)	1.2 (geometric mean DegT <sub>50field</sub> , normalised to 20°C, n =8)	15.7 (geometric mean DegT <sub>50lab</sub> at 20°C and pF2, n=4)	22.7 (geometric mean DegT <sub>50field</sub> , normalised to 20°C, n=8)	
K <sub>foc</sub> (mL/g)/K <sub>fom</sub>	1765/1024* (derived from aged column leaching study)	2556/1465* (geometric mean, n=4)	575/333* (geometric mean, n=4)	
1/n	1.0 (FOCUS default)	0.88 (arithmetic mean, n=4)	0.81 (arithmetic mean, n=4)	
Plant uptake factor	0 (worst-case assumption)	0 (worst-case assumption)	0 (worst-case assumption)	
Formation fraction <sup>#</sup>	-	0.14 (from parent)	0.57 (from parent) 1.0 (from prothioconazole-S-methyl (M01))	
FCONVERT**	-	0.146	0.517 (accounts for formation from parent and prothioconazole-S-methyl (M01))	

\* K<sub>fom</sub> calculated from K<sub>foc</sub>/1.724

<sup>#</sup> The metabolite formation fractions reported in the agreed EU list of endpoints were not kinetically determined in accordance with current FOCUS guidance on degradation kinetics. However, at the time of writing, it is noted that these values are equivalent to or more conservative than the kinetically derived values proposed in the Draft Renewal Assessment Report for prothioconazole (0.09 for prothioconazole-S-methyl (M01) from parent and 0.57 for prothioconazole-desthio (M04) from parent) (RAR, 2018). The use of these values in the modelling is therefore considered to be acceptable and sufficiently protective in this case.

\*\* Specific MACRO parameter. The molar based formation fractions were adjusted to account for molar mass differences between metabolite and parent to obtain conversion fractions for input into the MACRO model.

The DT<sub>50</sub> values for prothioconazole and metabolite prothioconazole-desthio (M04) were derived from field data that were temperature normalised using a Q<sub>10</sub> correction factor of 2.2 as described in Volume 3, Annex B.8 of the Draft Assessment Report (DAR) for prothioconazole. Therefore, in accordance with FOCUS guidance, the Q<sub>10</sub> value was set to 2.2 for these substances in PELMO, the Arrhenius activation energy was set to 54 kJ mol<sup>-1</sup> for these substances in PEARL and the exponent for temperature response was set to 0.079 K<sup>-1</sup> for these substances in MACRO. In addition, as the DegT<sub>50field</sub> values for prothioconazole and prothioconazole-desthio (M04) were not normalised for soil moisture, the moisture exponent was set to zero for these substances in the simulations. As a worst-case and in order to avoid double accounting associated with the use of field dissipation data, volatilisation was disabled in the simulations by setting vapour pressure to zero.



Since the soil degradation scheme of prothioconazole cannot be implemented in the GUI of the MACRO model, all metabolites were assumed to form directly from parent. For this purpose and in order to account for residues of metabolite prothioconazole-desthio (M04) formed from prothioconazole-S-methyl (M01), the individual formation fractions (prothioconazole to prothioconazole-desthio (M04) and the overall fraction from prothioconazole to prothioconazole-S-methyl (M01) to prothioconazole-desthio (M04)) can be combined to produce an overall fraction for modelling. However, in this case, as the formation fraction for prothioconazole-desthio (M04) is derived from field studies in which metabolite prothioconazole-S-methyl (M01) was always <LOQ and mostly <LOD, it was assumed that the field formation fraction for prothioconazole-desthio (M04) will already include any formation from prothioconazole-S-methyl (M01). Therefore, the field formation fraction (0.57) for prothioconazole-desthio (M04) was used in the MACRO simulations without further adjustment. The molar based formation fractions were adjusted to account for molar mass differences between metabolite and parent to obtain conversion fractions for MACRO.

Predicted 80<sup>th</sup> percentile annual average concentrations in groundwater (PEC<sub>gw</sub>) at 1 m depth for prothioconazole and its metabolites prothioconazole-S-methyl (M01) and prothioconazole-desthio (M04) are shown in Tables 8.8-4 to 8.8-6. An electronic copy of all modelling files is available on request.

**Table 8.8-4: PEC<sub>gw</sub> for prothioconazole and its metabolites calculated using FOCUS PEARL (version 4.4.4)**

Crop	Scenario	80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)		
		Prothioconazole	Prothioconazole-S-methyl (M01)	Prothioconazole-desthio (M04)
Winter oilseed rape (2 x 160 g as/ha, 14-day appln interval, BBCH GS 55-69)	<b>Early application timing</b>			
	Châteaudun	<0.001	<0.001	<0.001
	Hamburg	<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
	<b>Late application timing</b>			
	Châteaudun	<0.001	<0.001	<0.001
	Hamburg	<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

Crop	Scenario	80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)		
		Prothioconazole	Prothioconazole-S-methyl (M01)	Prothioconazole-desthio (M04)
Winter cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69)	<b>Early application timing</b>			
	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
	<b>Late application timing</b>			
	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
Spring cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69)	<b>Early application timing</b>			
	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
	<b>Late application timing</b>			
	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 8.8-5: PEC<sub>gw</sub> for prothioconazole and its metabolites calculated using FOCUS PELMO (version 5.5.3)**

Crop	Scenario	80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)		
		Prothioconazole	Prothioconazole-S-methyl (M01)	Prothioconazole-desthio (M04)
Winter oilseed rape (2 x 160 g as/ha, 14-day appln interval, BBCH GS 55-69)	<b>Early application timing</b>			
	Châteaudun	<0.001	<0.001	<0.001
	Hamburg	<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
	<b>Late application timing</b>			
	Châteaudun	<0.001	<0.001	<0.001
	Hamburg	<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
Winter cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69)	<b>Early application timing</b>			
	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
	<b>Late application timing</b>			
	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

Crop	Scenario	80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)		
		Prothioconazole	Prothioconazole-S-methyl (M01)	Prothioconazole-desthio (M04)
Spring cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69)	<b>Early application timing</b>			
	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
	<b>Late application timing</b>			
	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 8.8-6: PEC<sub>gw</sub> for prothioconazole and its metabolites calculated using FOCUS MACRO (version 5.5.4)**

Crop	Scenario	80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)		
		Prothioconazole	Prothioconazole-S-methyl (M01)	Prothioconazole-desthio (M04)
Winter oilseed rape (2 x 160 g as/ha, 14-day appln interval, BBCH GS 55-69)	<b>Early application timing</b>			
	Châteaudun	<0.001	<0.001	<0.001
	<b>Late application timing</b>			
	Châteaudun	<0.001	<0.001	<0.001
Winter cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69)	<b>Early application timing</b>			
	Châteaudun	<0.001	<0.001	<0.001
	<b>Late application timing</b>			
	Châteaudun	<0.001	<0.001	<0.001
Spring cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69)	<b>Early application timing</b>			
	Châteaudun	<0.001	<0.001	<0.001
	<b>Late application timing</b>			
	Châteaudun	<0.001	<0.001	<0.001

In all cases, PEC<sub>gw</sub> for prothioconazole and its metabolites prothioconazole-S-methyl (M01) and prothioconazole-desthio (M04) were <0.001 µg/L. These results clearly demonstrate that the FF-075 formulation can be used as proposed throughout central Europe, without risk of prothioconazole or its soil metabolites exceeding acceptable levels in groundwater.

### **8.8.2.2            Azoxystrobin and its metabolites**

The following groundwater modelling on azoxystrobin and its soil metabolites R234886, R401553 and R402173 has not previously been reviewed and is provided in support of this assessment. A full summary of the modelling report is provided in Appendix 3.1 (Report KCP 9.2.4.1/01) and an electronic copy of all modelling files is available on request.

The critical GAP and application parameters for azoxystrobin are summarised in Tables 8.8-1 and 8.8-2 above.

The key chemical input parameters for azoxystrobin and its metabolites selected for use in the modelling are summarised in Table 8.8-7. Unless otherwise stated, these values were derived from the list of endpoints in the EFSA Conclusion (EFSA Journal 2010; 8(4):1542).

**Table 8.8-7: Input parameters related to active substance azoxystrobin and its metabolites for PEC<sub>gw</sub> calculations**

Compound	Azoxystrobin	R234886	R401553	R402173	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	403.4	389.4	213.2	333.3	Yes EFSA Conclusion (EFSA Journal 2010; 8(4):1542)
Water solubility (g/mol)	6.0 (20°C)	57 (20°C)	560 (20°C)	61 (20°C)	
Saturated vapour pressure (Pa)	1.1 x 10 <sup>-10</sup> (20°C)	0 (worst-case assumption)	0 (worst-case assumption)	0 (worst-case assumption)	
DT <sub>50</sub> in soil (d) (normalised to pF2, 20°C, with Q <sub>10</sub> of 2.58)	Microbial: <sup>#</sup> 78 (overall geometric mean DegT <sub>50field</sub> of the soil incorporated studies (80.2 days, n=3) and the soil non- incorporated studies (slow phase, 75.9 days, n=10))  Photolysis: <sup>#</sup> 3 (geometric mean DegT <sub>50field</sub> of the soil non- incorporated studies (fast phase, n=10))	110.4 (geometric mean DegT <sub>50lab</sub> , n=5) (correct DT50 soil used for conserva- tive 1st tier modelling)	1.1 (geometric mean DegT <sub>50lab</sub> , n=3)	4.7 (geometric mean DegT <sub>50lab</sub> , n=3)	
K <sub>foc</sub> (mL/g)/K <sub>fom</sub>	391.5/227.1* (geometric mean, n=6)	Tier 1: 21/12.18* (worst-case, n=6)**  Tier 2: Scenario specific K <sub>foc</sub> / K <sub>fom</sub> values:** Châteaudun = 24/14* Hamburg = 133/77* Jokioinen = 159/92* Kremsmünster = 38/22* Okehampton = 242/140* Piacenza = 68/40* Porto = 624/362*	142.6/82.71* (geometric mean, n=6)	25/14.5* (worst-case, n=6)**	

Compound	Azoxystrobin	R234886	R401553	R402173	Value in accordance with EU endpoint y/n/ Reference
		Sevilla = 50/29* Thiva = 38/22*			
1/n	0.86 (arithmetic mean, n=6)	Tier 1: 0.76 (corresponds to worst-case $K_{foc}$ )**  Tier 2: 0.85 (arithmetic mean, n=6)	0.85 (arithmetic mean, n=6)	0.96 (corresponds to worst-case $K_{foc}$ )**	
Plant uptake factor	0 (worst-case assumption)	0 (worst-case assumption)	0 (worst-case assumption)	0 (worst-case assumption)	
Formation fraction	-	0.874 (from parent)	0.392 (from parent) 0.468 (from R402173)	0.385 (from parent)	
FCONVERT***	-	0.844	1.0 (worst-case assumption, accounts for combined formation from parent and R402173)	0.318	No MACRO specific parameter

# In order to account for the microbial and photolytic degradation of azoxystrobin in soil, two sets of modelling simulations were conducted. The first simulation set assumes that azoxystrobin undergoes microbial degradation with a  $DegT_{50}$  of 78 days to form metabolite R234886 and the second simulation set assumes that azoxystrobin undergoes photolytic degradation with a  $DegT_{50}$  of 3 days to form metabolites R401553 and R402173 (with R402173 subsequently degrading to R401553).

\*  $K_{fom}$  calculated from  $K_{foc}/1.724$

\*\* As the sorption of metabolites R234886 and R402173 is pH dependent, the lowest  $K_{foc}$  and associated 1/n values from the sorption datasets were selected for input as a worst-case at Tier 1. Tier 2 calculations were performed for metabolite R234883, using scenario specific  $K_{foc}$  values derived using regression analysis.

\*\*\* Specific MACRO parameter. The molar based formation fractions for metabolites R234886 and R402173 were adjusted to account for molar mass differences between metabolite and parent to obtain conversion fractions for input into the MACRO model.

The degradation mechanism of azoxystrobin in soil is complex and depends on the relative importance of microbial and photolytic processes. Modelling the three metabolites, which form via the different mechanisms (microbial action and photolytic action) is not possible in a single simulation, therefore, as a worst-case and in line with the approach presented in the EFSA Conclusion (EFSA Journal 2010; 8(4):1542), two sets of simulations were performed. The first set assumed that azoxystrobin degraded via microbial degradation to metabolite R234886 and the second set assumed that azoxystrobin degraded due to photolysis to form metabolites R401553 and R402173, with metabolite R402173 subsequently degrading to form metabolite R401553.

As the sorption of metabolites R234886 and R402173 is pH dependent (increasing sorption with decreasing soil pH), the lowest  $K_{\text{foc}}$  and associated  $1/n$  values from the sorption datasets for each metabolite were selected for input as a worst-case at Tier 1. Further simulations were performed for metabolite R234886 at Tier 2 using scenario specific  $K_{\text{foc}}$  values, which were derived using regression analysis.

Since the soil degradation schemes of azoxystrobin cannot be implemented in the GUI of the MACRO model, each metabolite was assumed to form directly from parent. For this purpose and in order to account for residues of metabolite R401553 formed from R402173, the individual formation fractions (azoxystrobin to R401553 and the overall fraction from azoxystrobin to R402173 to R401553) can be combined to produce an overall fraction for modelling. However, in this case, as a simplified and conservative approach, a worst-case formation fraction of 1.0 from parent to R401553 was assumed in the MACRO simulations, without further adjustment. The molar based formation fractions for metabolites R234886 and R402173 were adjusted to account for molar mass differences between metabolite and parent to obtain conversion fractions for MACRO.

Predicted 80<sup>th</sup> percentile annual average concentrations in groundwater ( $\text{PEC}_{\text{gw}}$ ) at 1 m depth for azoxystrobin and its metabolites R234886, R401553 and R402173, based on worst-case sorption endpoints for metabolites R234886 and R402173 (Tier 1), are shown in Tables 8.8-8 to 8.8-10.

**Table 8.8-8:  $\text{PEC}_{\text{gw}}$  for azoxystrobin and its metabolites calculated using FOCUS PEARL (version 4.4.4)**

Crop	Scenario	80 <sup>th</sup> Percentile $\text{PEC}_{\text{gw}}$ at 1 m Soil Depth ( $\mu\text{g/L}$ )			
		Azoxystrobin	R234886	R401553	R402173
Winter oilseed rape (2 x 120 g as/ha, 14-day appln interval, BBCH 55-69)	<b>Early application timing</b>				
	Châteaudun	<0.001	3.019	<0.001	<0.001
	Hamburg	<0.001	4.229	<0.001	<0.001
	Kremsmünster	<0.001	2.711	<0.001	<0.001
	Okehampton	<0.001	2.717	<0.001	<0.001
	Piacenza	<0.001	1.746	<0.001	<0.001
	Porto	<0.001	2.017	<0.001	<0.001
	<b>Late application timing</b>				
	Châteaudun	<0.001	3.053	<0.001	<0.001
	Hamburg	<0.001	4.264	<0.001	<0.001
	Kremsmünster	<0.001	2.721	<0.001	<0.001
	Okehampton	<0.001	2.744	<0.001	<0.001
	Piacenza	<0.001	1.758	<0.001	<0.001
	Porto	<0.001	2.072	<0.001	<0.001



Crop	Scenario	80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)			
		Azoxystrobin	R234886	R401553	R402173
Winter cereals (2 x 150 g as/ha, 14-day appln interval, BBCH 30-69)	<b>Early application timing</b>				
	Châteaudun	<0.001	3.323	<0.001	<0.001
	Hamburg	<0.001	5.575	<0.001	<0.001
	Jokioinen	<0.001	4.492	<0.001	<0.001
	Kremsmünster	<0.001	3.625	<0.001	<0.001
	Okehampton	<0.001	3.781	<0.001	<0.001
	Piacenza	<0.001	2.811	<0.001	<0.001
	Porto	<0.001	2.325	<0.001	<0.001
	Sevilla	<0.001	0.182	<0.001	<0.001
	Thiva	<0.001	3.577	<0.001	<0.001
	<b>Late application timing</b>				
	Châteaudun	<0.001	1.286	<0.001	<0.001
	Hamburg	<0.001	2.306	<0.001	<0.001
	Jokioinen	<0.001	1.764	<0.001	<0.001
	Kremsmünster	<0.001	1.504	<0.001	<0.001
	Okehampton	<0.001	1.594	<0.001	<0.001
	Piacenza	<0.001	1.146	<0.001	<0.001
	Porto	<0.001	0.970	<0.001	<0.001
	Sevilla	<0.001	0.041	<0.001	<0.001
	Thiva	<0.001	1.533	<0.001	<0.001
Spring cereals (2 x 150 g as/ha, 14-day appln interval, BBCH 30-69)	<b>Early application timing</b>				
	Châteaudun	<0.001	3.048	<0.001	<0.001
	Hamburg	<0.001	6.938	<0.001	<0.001
	Jokioinen	<0.001	4.242	<0.001	<0.001
	Kremsmünster	<0.001	3.987	<0.001	<0.001
	Okehampton	<0.001	3.993	<0.001	<0.001
	Porto	<0.001	2.475	<0.001	<0.001
	<b>Late application timing</b>				
	Châteaudun	<0.001	1.177	<0.001	<0.001
	Hamburg	<0.001	2.867	<0.001	<0.001
	Jokioinen	<0.001	1.641	<0.001	<0.001
	Kremsmünster	<0.001	1.611	<0.001	<0.001
	Okehampton	<0.001	1.668	<0.001	<0.001
	Porto	<0.001	1.054	<0.001	<0.001

**Table 8.8-9: PEC<sub>gw</sub> for azoxystrobin and its metabolites calculated using FOCUS PELMO (version 5.5.3)**

Crop	Scenario	80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)			
		Azoxystrobin	R234886	R401553	R402173
Winter oilseed rape (2 x 120 g as/ha, 14-day appln interval, BBCH 55-69)	<b>Early application timing</b>				
	Châteaudun	<0.001	2.971	<0.001	<0.001
	Hamburg	<0.001	4.519	<0.001	<0.001
	Kremsmünster	<0.001	3.144	<0.001	<0.001
	Okehampton	<0.001	3.033	<0.001	<0.001
	Piacenza	<0.001	2.451	<0.001	<0.001
	Porto	<0.001	2.345	<0.001	<0.001
	<b>Late application timing</b>				
	Châteaudun	<0.001	2.999	<0.001	<0.001
	Hamburg	<0.001	4.568	<0.001	<0.001
	Kremsmünster	<0.001	3.155	<0.001	<0.001
	Okehampton	<0.001	3.066	<0.001	<0.001
	Piacenza	<0.001	2.466	<0.001	<0.001
	Porto	<0.001	2.423	<0.001	<0.001
Winter cereals (2 x 150 g as/ha, 14-day appln interval, BBCH 30-69)	<b>Early application timing</b>				
	Châteaudun	<0.001	3.270	<0.001	<0.001
	Hamburg	<0.001	6.011	<0.001	<0.001
	Jokioinen	<0.001	4.837	<0.001	<0.001
	Kremsmünster	<0.001	4.259	<0.001	<0.001
	Okehampton	<0.001	3.927	<0.001	<0.001
	Piacenza	<0.001	3.527	<0.001	<0.001
	Porto	<0.001	2.822	<0.001	<0.001
	Sevilla	<0.001	0.903	<0.001	<0.001
	Thiva	<0.001	2.250	<0.001	<0.001
	<b>Late application timing</b>				
	Châteaudun	<0.001	1.280	<0.001	<0.001
	Hamburg	<0.001	2.478	<0.001	<0.001
	Jokioinen	<0.001	1.936	<0.001	<0.001
	Kremsmünster	<0.001	1.779	<0.001	<0.001
	Okehampton	<0.001	1.688	<0.001	<0.001
	Piacenza	<0.001	1.562	<0.001	<0.001
	Porto	<0.001	1.215	<0.001	<0.001
	Sevilla	<0.001	0.237	<0.001	<0.001
	Thiva	<0.001	0.922	<0.001	<0.001

Crop	Scenario	80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)			
		Azoxystrobin	R234886	R401553	R402173
Spring cereals (2 x 150 g as/ha, 14-day appln interval, BBCH 30-69)	<b>Early application timing</b>				
	Châteaudun	<0.001	2.659	<0.001	<0.001
	Hamburg	<0.001	5.665	<0.001	<0.001
	Jokioinen	<0.001	4.156	<0.001	<0.001
	Kremsmünster	<0.001	4.013	<0.001	<0.001
	Okehampton	<0.001	3.816	<0.001	<0.001
	Porto	<0.001	2.613	<0.001	<0.001
	<b>Late application timing</b>				
	Châteaudun	<0.001	1.028	<0.001	<0.001
	Hamburg	<0.001	2.332	<0.001	<0.001
	Jokioinen	<0.001	1.608	<0.001	<0.001
	Kremsmünster	<0.001	1.613	<0.001	<0.001
	Okehampton	<0.001	1.627	<0.001	<0.001
	Porto	<0.001	1.163	<0.001	<0.001

**Table 8.8-10: PEC<sub>gw</sub> for azoxystrobin and its metabolites calculated using FOCUS MACRO (version 5.5.4)**

Crop	Scenario	80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)			
		Azoxystrobin	R234886	R401553	R402173
Winter oilseed rape (2 x 120 g as/ha, 14-day appln interval, BBCH 55-69)	<b>Early application timing</b>				
	Châteaudun	<0.001	2.350	<0.001	<0.001
	<b>Late application timing</b>				
	Châteaudun	<0.001	2.310	<0.001	<0.001
Winter cereals (2 x 150 g as/ha, 14-day appln interval, BBCH 30-69)	<b>Early application timing</b>				
	Châteaudun	<0.001	2.960	<0.001	<0.001
	<b>Late application timing</b>				
	Châteaudun	<0.001	1.170	<0.001	<0.001
Spring cereals (2 x 150 g as/ha, 14-day appln interval, BBCH 30-69)	<b>Early application timing</b>				
	Châteaudun	<0.001	2.600	<0.001	<0.001
	<b>Late application timing</b>				
	Châteaudun	<0.001	1.060	<0.001	<0.001

In all cases, PEC<sub>gw</sub> for azoxystrobin and its metabolites R401553 and R402173 were considerably below the 0.1 µg/L regulatory threshold (max. PEC<sub>gw</sub> <0.001 µg/L), clearly demonstrating that the FF-075 formulation can be used as proposed in central Europe, without risk of azoxystrobin or its metabolites R401553 and R402173 exceeding acceptable levels in groundwater. PEC<sub>gw</sub> for metabolite R234886 were >0.1 µg/L in the majority of scenarios (max. PEC<sub>gw</sub> 6.938 µg/L). Therefore, in line with the approach presented in the EFSA Conclusion, since the sorption of this metabolite is pH dependent (increasing

sorption with decreasing soil pH), further simulations were conducted at Tier 2 using scenario specific  $K_{\text{foc}}$  values derived using linear regression analysis. The predicted 80<sup>th</sup> percentile annual average concentrations in groundwater ( $\text{PEC}_{\text{gw}}$ ) at 1 m depth for metabolite R234886 at Tier 2 are shown in Table 8.8-11.

**Table 8.8-11:  $\text{PEC}_{\text{gw}}$  for metabolite R234886 calculated using scenario specific  $K_{\text{foc}}$  values with FOCUS PEARL (version 4.4.4), FOCUS PELMO (version 5.5.3) and FOCUS MACRO (version 5.5.4)**

Crop	Scenario	80 <sup>th</sup> Percentile $\text{PEC}_{\text{gw}}$ at 1 m Soil Depth ( $\mu\text{g/L}$ )		
		FOCUS PEARL	FOCUS PELMO	FOCUS MACRO
Winter oilseed rape (2 x 120 g as/ha, 14-day appln interval, BBCH 55-69)	<b>Early application timing</b>			
	Châteaudun	4.678	4.682	3.770
	Hamburg	0.268	0.249	-
	Kremsmünster	2.478	2.848	-
	Okehampton	0.013	0.019	-
	Piacenza	0.639	0.819	-
	Porto	<0.001	<0.001	-
	<b>Late application timing</b>			
	Châteaudun	4.709	4.742	3.740
	Hamburg	0.271	0.253	-
	Kremsmünster	2.486	2.859	-
	Okehampton	0.013	0.019	-
	Piacenza	0.647	0.828	-
	Porto	<0.001	<0.001	-

Crop	Scenario	80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)		
		FOCUS PEARL	FOCUS PELMO	FOCUS MACRO
Winter cereals (2 x 150 g as/ha, 14-day appln interval, BBCH 30-69)	<b>Early application timing</b>			
	Châteaudun	4.901	4.731	4.400
	Hamburg	0.362	0.378	-
	Jokioinen	0.013	0.015	-
	Kremsmünster	3.229	3.781	-
	Okehampton	0.022	0.024	-
	Piacenza	1.041	1.301	-
	Porto	<0.001	<0.001	-
	Sevilla	0.049	0.166	-
	Thiva	3.046	1.893	-
	<b>Late application timing</b>			
	Châteaudun	2.259	2.193	1.990
	Hamburg	0.125	0.122	-
	Jokioinen	0.002	0.002	-
	Kremsmünster	1.462	1.646	-
	Okehampton	0.005	0.006	-
	Piacenza	0.430	0.549	-
	Porto	<0.001	<0.001	-
	Sevilla	0.016	0.041	-
	Thiva	1.365	0.844	-
Spring cereals (2 x 150 g as/ha, 14-day appln interval, BBCH 30-69)	<b>Early application timing</b>			
	Châteaudun	4.515	3.979	3.870
	Hamburg	0.418	0.321	-
	Jokioinen	0.010	0.008	-
	Kremsmünster	3.492	3.459	-
	Okehampton	0.019	0.016	-
	Porto	<0.001	<0.001	-
	<b>Late application timing</b>			
	Châteaudun	2.078	1.841	1.790
	Hamburg	0.146	0.106	-
	Jokioinen	0.001	0.001	-
	Kremsmünster	1.554	1.507	-
	Okehampton	0.004	0.004	-
	Porto	<0.001	<0.001	-

- Scenario not defined in FOCUS MACRO

PEC<sub>gw</sub> for R234886 based on scenario specific K<sub>foc</sub> values at Tier 2 remained above the 0.1 µg/L regulatory threshold in several scenarios (max. PEC<sub>gw</sub> 4.901 µg/L), thus triggering a groundwater

relevance assessment for this metabolite. A full relevance assessment for R234886 in groundwater is provided in document Part B Section 10.

#### **zRMS comments:**

##### Prothioconazole

The PEC<sub>gw</sub> calculations have been accepted for the active substance prothioconazole and its metabolites prothioconazole-S-methyl (M01) and prothioconazole-desthio (M04). Substance input parameters correspond with the EFSA Conclusions (EFSA Conclusion 2010) and/or are in line with the current guidance document(s) (geomean K<sub>loc</sub>, geomean DT<sub>50</sub>).

Appropriate application dates (according to AppDate) and all relevant scenarios were considered in the assessment. Latest versions of the FOCUS tools (PELMO 5.5.3, PEARL 4.4.4 and MACRO 5.5.4) were used.

In all cases, PEC<sub>gw</sub> for prothioconazole and its metabolites prothioconazole-S-methyl (M01) and prothioconazole-desthio (M04) were <0.001 µg/L.

Nevertheless, additional simulations may be required by the SMS that do not accept calculations performed using FOCUS models.

##### Azoxystrobin

The PEC<sub>gw</sub> calculations have been accepted for the active substance azoxystrobin and its metabolites R234886, R401553, R402173

Substance input parameters correspond with the EFSA Conclusions (EFSA Journal 2010; 8(4):1542) and/or are in line with the current guidance document(s) (geomean K<sub>loc</sub>, geomean DT<sub>50</sub>).

Appropriate application dates (according to AppDate) and all relevant scenarios were considered in the assessment. Latest versions of the FOCUS tools (PELMO 5.5.3, PEARL 4.4.4 and MACRO 5.5.4) were used.

In all cases, PEC<sub>gw</sub> for azoxystrobin and its metabolites R401553 and R402173 were <0.001 µg/L. The PEC<sub>gw</sub> values for metabolite R234886 for application in all crops are above the trigger 0.1 µg/L in most scenarios.

The assessment relevance of the metabolite R234886 in ground water according to SANCO/221/2000 – rev.10 document will be done and reported in the dRR Part B10.

## **8.9 Predicted Environmental Concentrations in surface water (PEC<sub>sw</sub>) (KCP 9.2.5)**

### **8.9.1 Justification for new endpoints**

There are no significant deviations from the agreed EU endpoints.

Minor deviations relating to the selection of some modelling input parameters (i.e. the selection of geometric mean K<sub>loc</sub> values, where appropriate, in accordance with current FOCUS recommendations) are discussed in further detail in Sections 8.9.2.1 and 8.9.2.2 below.

### **8.9.2 Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5)**

**Table 8.9-1: Input parameters related to application for PEC<sub>SW/SED</sub> calculations**

Plant protection product	FF-075	
Use No.	1	2

Crop	Winter oilseed rape	Winter and spring cereals
Application rate (g as/ha)	Prothioconazole: 160 Azoxystrobin: 120	Prothioconazole: 200 Azoxystrobin: 150
Number of applications/interval (d)	2 (14 day interval)	2 (14 day interval)
Application window	March-May	March-May
Application method	Ground spray	Ground spray
CAM (Chemical application method)	2	2
Soil depth (cm)	4	4
Models used for calculation	STEPS 1-2 in FOCUS calculator (version 3.2) FOCUS SWASH (version 5.3) SPIN (version 3.3) FOCUS MACRO (version 5.5.4) FOCUS PRZM (version 4.3.1) FOCUS TOXSWA (version 5.5.3) SWAN (version 5.0.1)	

**Table 8.9-2: FOCUS Step 3 Scenario related input parameters for PEC<sub>sw/sed</sub> calculations for the application of FF-075**

Crop	Scenario	Application window used in modelling	
		Early application	Late application
Winter oilseed rape	D2	22 May – 05 July	-
	D3	02 May – 15 June	-
	D4	12 May – 25 June	-
	D5	23 April – 06 June	-
	R1	15 May – 28 June	-
	R3	09 April – 23 May	-
Winter cereals	D1	25 March – 08 May	08 June – 22 July
	D2	04 April – 18 May	20 May – 03 July
	D3	16 April – 30 May	28 May – 11 July
	D4	18 March – 01 May	03 June – 17 July
	D5	15 March – 28 April	27 April – 10 June
	D6	16 February – 01 April	12 April – 26 May
	R1	24 April – 07 June	13 May – 26 June
	R3	19 March – 02 May	13 April – 27 May
	R4	24 January – 09 March	27 April – 10 June
Spring cereals	D1	27 May – 10 July	17 June – 31 July
	D3	28 April – 11 June	02 June – 16 July
	D4	18 May – 01 July	08 June – 22 July
	D5	09 April – 23 May	02 May – 15 June
	R4	09 April – 23 May	02 May – 15 June

- Late application timing was not simulated for winter oilseed rape

### **8.9.2.1 Prothioconazole and its metabolites**

The following surface water modelling on prothioconazole and its metabolites has not previously been reviewed and is provided in support of this assessment.

#### **FOCUS Steps 1 and 2**

Predicted environmental concentrations of prothioconazole and its soil and/or aquatic metabolites prothioconazole-S-methyl (M01), prothioconazole-desthio (M04), 1,2,4-triazole (M13) and prothioconazole-triazolylketone (M42), in surface water and sediment were calculated at FOCUS Steps 1 and 2 using the STEPS 1-2 in FOCUS calculator (version 3.2).

The key chemical input parameters for prothioconazole and its metabolites selected for use in the modelling are summarised in Table 8.9-3. Unless otherwise stated, these values were derived from data reported in Volume 3, Annex B.8 of the Draft Assessment Report (DAR, July, 2005), the Addendum to the DAR (October, 2005) and the list of endpoints in the EFSA Conclusion (EFSA Scientific Report (2007) 106, 1-98).



**Table 8.9-3: Input parameters for PEC<sub>sw/sed</sub> calculations for active substance prothioconazole and its metabolites (FOCUS Steps 1-2)**

Compound	Prothioconazole	Prothioconazole-S-methyl (M01)	Prothioconazole-desthio (M04)	1,2,4-triazole (M13)	Prothioconazole-triazolylketone (M42)	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	344.3	358.3	312.2	69.1*	185.7	Yes EFSA Scientific Report (2007) 106, 1-98
Water solubility (mg/L)	300	1000 (conservative default)	1000 (conservative default)	730,000*	1000 (conservative default)	
K <sub>foc</sub> (mL/g)	1765 (derived from aged column leaching study)	2526 (geometric mean, n=4)	574 (geometric mean, n=4)	83 (geometric mean, n=4)*	1.0 (conservative assumption)	
DT <sub>50,soil</sub> (d)	1.2 (geometric mean DegT <sub>50field</sub> , normalised to 20°C, n=8)	15.7 (geometric mean DegT <sub>50lab</sub> at 20°C and pF2, n=4)	22.7 (geometric mean DegT <sub>50field</sub> , normalised to 20°C, n=8)	1000 (conservative default)	1000 (conservative default)	
DT <sub>50,water</sub> (d)	39.5 (geometric mean DegT <sub>50,whole system</sub> (slow-phase), n=2)**	1000 (conservative default)	1000 (conservative default)	1000 (conservative default)	1000 (conservative default)	
DT <sub>50,sed</sub> (d)	39.5 (geometric mean DegT <sub>50,whole system</sub> (slow-phase), n=2)**	1000 (conservative default)	1000 (conservative default)	1000 (conservative default)	1000 (conservative default)	
DT <sub>50,whole system</sub> (d)	39.5 (geometric mean DegT <sub>50,whole system</sub> (slow-phase), n=2)**	1000 (conservative default)	1000 (conservative default)	1000 (conservative default)	1000 (conservative default)	
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 14.6 Water / Sediment: 12.7	Soil: 57.1 Water / Sediment: 54.6	Soil: 0 Water / Sediment: 41.8	Soil: 0 Water / Sediment: 9.1	

\* Endpoints for 1,2,4-triazole (M13) taken from the EFSA Conclusion for tebuconazole (EFSA Journal 2014; 12(1): 3485)

\*\* Whole system DegT<sub>50/90</sub> values for prothioconazole were determined using Hockey Stick (HS) kinetics (refer to page 471 of the DAR). The geometric mean slow phase DegT<sub>50</sub> value (39.5 days, n=2) was therefore selected for modelling purposes

Separate simulations were run for prothioconazole and each of its metabolites at FOCUS Steps 1 and 2. Application rates for the metabolites were set internally within the STEPS 1-2 in FOCUS calculator. The rates are based on the application rate for the active substance adjusted to account for the maximum percentage of each metabolite formed in soil and aquatic systems, the difference in molecular weight between parent and metabolite and crop interception. At Step 2, the calculations were conducted with the region of application set to both North and South Europe and the season of application was selected in line with the GAP. As the formulation is intended for application post crop emergence, crop interception was accounted for at FOCUS Step 2. Full canopy was selected for winter oilseed rape (BBCH GS 55-69) and average crop cover was selected for cereals (BBCH GS 30-69).

Maximum  $PEC_{sw}$  and  $PEC_{sed}$  values for prothioconazole and its metabolites prothioconazole-S-methyl (M01), prothioconazole-desthio (M04), 1,2,4-triazole (M13) and prothioconazole-triazolylketone (M42) at FOCUS Steps 1 and 2 for each crop group are shown in Table 8.9-4 to Table 8.9-8. Example output files from the STEPS 1-2 in FOCUS calculator are provided for illustrative purposes in Appendix 3.2 and an electronic copy of all modelling files is available on request.

**Table 8.9-4: FOCUS Step 1 and 2  $PEC_{sw}$  and  $PEC_{sed}$  for prothioconazole following applications of FF-075 to winter oilseed rape and cereals**

Crop and application pattern	FOCUS Step	Application window	Crop interception	Multiple applications		Single application	
				Max PEC <sub>sw</sub> (µg/L)	Max PEC <sub>sed</sub> (µg/kg)	Max PEC <sub>sw</sub> (µg/L)	Max PEC <sub>sed</sub> (µg/kg)
Winter oilseed rape							
Winter oilseed rape (2 x 160 g as/ha, 14-day appln interval, BBCH GS 55-69)	Step 1	-	-	34.7521	566.8858	-	-
	Step 2 - NEU	March-May	Full canopy	1.6962	12.5411	1.4715	8.4627
	Step 2 - SEU			1.6962	13.9098	1.4715	9.8310
Cereals							
Winter cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69)	Step 1	-	-	43.4401	708.6072	-	-
	Step 2 - NEU	March-May	Average crop cover	2.1202	19.4404	1.8393	14.3412
	Step 2 - SEU			2.1202	24.9153	1.8393	19.8144
Spring cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69)	Step 1	-	-	43.4401	708.6072	-	-
	Step 2 - NEU	March-May	Average crop cover	2.1202	19.4404	1.8393	14.3412
	Step 2 - SEU			2.1202	24.9153	1.8393	19.8144

NEU = northern Europe, SEU = southern Europe

**Table 8.9-5: FOCUS Step 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for prothioconazole-S-methyl (M01) following applications of FF-075 to winter oilseed rape and cereals**

Crop and application pattern	FOCUS Step	Application window	Crop interception	Multiple applications		Single application	
				Max PEC <sub>sw</sub> (µg/L)	Max PEC <sub>sed</sub> (µg/kg)	Max PEC <sub>sw</sub> (µg/L)	Max PEC <sub>sed</sub> (µg/kg)
Winter oilseed rape							
Winter oilseed rape (2 x 160 g as/ha, 14-day appln interval, BBCH GS 55-69)	Step 1	-	-	7.3267	177.3738	-	-
	Step 2 - NEU	March-May	Full canopy	0.2333	5.1933	0.1945	3.2852
	Step 2 - SEU			0.3609	8.4155	0.2318	5.4497
Cereals							
Winter cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69)	Step 1	-	-	9.1584	221.7173	-	-
	Step 2 - NEU	March-May	Average crop cover	0.6426	15.3527	0.4184	10.0588
	Step 2 - SEU			1.1532	28.2415	0.7614	18.7166
Spring cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69)	Step 1	-	-	9.1584	221.7173	-	-
	Step 2 - NEU	March-May	Average crop cover	0.6426	15.3527	0.4184	10.0588
	Step 2 - SEU			1.1532	28.2415	0.7614	18.7166

NEU = northern Europe, SEU = southern Europe

**Table 8.9-6: FOCUS Step 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for prothioconazole-desthio (M04) following applications of FF-075 to winter oilseed rape and cereals**

Crop and application pattern	FOCUS Step	Application window	Crop interception	Multiple applications		Single application	
				Max PEC <sub>sw</sub> (µg/L)	Max PEC <sub>sed</sub> (µg/kg)	Max PEC <sub>sw</sub> (µg/L)	Max PEC <sub>sed</sub> (µg/kg)
Winter oilseed rape							
Winter oilseed rape (2 x 160 g as/ha, 14-day appln interval, BBCH GS 55-69)	Step 1	-	-	62.6570	355.7786	-	-
	Step 2 - NEU	March-May	Full canopy	2.0640	11.1372	1.2476	6.7566
	Step 2 - SEU			3.2818	18.1227	2.0140	11.1527
Cereals							
Winter cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69)	Step 1	-	-	78.3212	444.7232	-	-
	Step 2 - NEU	March-May	Average crop cover	5.9290	33.1316	3.6670	20.5350
	Step 2 - SEU			10.8003	61.0736	6.7326	38.1192
Spring cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69)	Step 1	-	-	78.3212	444.7232	-	-
	Step 2 - NEU	March-May	Average crop cover	5.9290	33.1316	3.6670	20.5350
	Step 2 - SEU			10.8003	61.0736	6.7326	38.1192

NEU = northern Europe, SEU = southern Europe

**Table 8.9-7: FOCUS Step 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for 1,2,4-triazole (M13) following applications of FF-075 to winter oilseed rape and cereals**

Crop and application pattern	FOCUS Step	Application window	Crop interception	Multiple applications		Single application	
				Max PEC <sub>sw</sub> (µg/L)	Max PEC <sub>sed</sub> (µg/kg)	Max PEC <sub>sw</sub> (µg/L)	Max PEC <sub>sed</sub> (µg/kg)
Winter oilseed rape							
Winter oilseed rape (2 x 160 g as/ha, 14-day appln interval, BBCH GS 55-69)	Step 1	-	-	8.3037	6.8669	-	-
	Step 2 - NEU	March-May	Full canopy	0.2216	0.1783	0.1346	0.1085
	Step 2 - SEU			0.2416	0.1948	0.1546	0.1251
Cereals							
Winter cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69)	Step 1	-	-	10.3796	8.5836	-	-
	Step 2 - NEU	March-May	Average crop cover	0.3320	0.2684	0.2232	0.1812
	Step 2 - SEU			0.4120	0.3347	0.3032	0.2475
Spring cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69)	Step 1	-	-	10.3796	8.5836	-	-
	Step 2 - NEU	March-May	Average crop cover	0.3320	0.2684	0.2232	0.1812
	Step 2 - SEU			0.4120	0.3347	0.3032	0.2475

NEU = northern Europe, SEU = southern Europe

**Table 8.9-8: FOCUS Step 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for prothioconazole-triazolyketone (M42) following applications of FF-075 to winter oilseed rape and cereals**

Crop and application pattern	FOCUS Step	Application window	Crop interception	Multiple applications		Single application	
				Max PEC <sub>sw</sub> (µg/L)	Max PEC <sub>sed</sub> (µg/kg)	Max PEC <sub>sw</sub> (µg/L)	Max PEC <sub>sed</sub> (µg/kg)
Winter oilseed rape							
Winter oilseed rape (2 x 160 g as/ha, 14-day appln interval, BBCH GS 55-69)	Step 1	-	-	5.3728	0.0537	-	-
	Step 2 - NEU	March-May	Full canopy	0.1395	0.0014	0.0849	0.0008
	Step 2 - SEU			0.1525	0.0015	0.0979	0.0010
Cereals							
Winter cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69)	Step 1	-	-	6.7160	0.0671	-	-
	Step 2 - NEU	March-May	Average crop cover	0.2101	0.0021	0.1418	0.0014
	Step 2 - SEU			0.2620	0.0026	0.1937	0.0019
Spring cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69)	Step 1	-	-	6.7160	0.0671	-	-
	Step 2 - NEU	March-May	Average crop cover	0.2101	0.0021	0.1418	0.0014
	Step 2 - SEU			0.2620	0.0026	0.1937	0.0019

NEU = northern Europe, SEU = southern Europe

### FOCUS Steps 3 and 4

Surface water modelling of prothioconazole and its soil and aquatic metabolite prothioconazole-desthio (M04), was conducted using the FOCUS surface water models and scenarios. The modelling was based on applications to winter oilseed rape and winter and spring cereals in accordance with the critical GAP for the FF-075 formulation in Europe. The FOCUS crop scenarios ‘winter oilseed rape’, ‘winter cereals’ and ‘spring cereals’ were selected for the simulations.

Predicted environmental concentrations of prothioconazole and its metabolite prothioconazole-desthio (M04) in surface water and sediment were calculated at FOCUS Step 3. FOCUS Step 4 calculations were also conducted for prothioconazole-desthio (M04). At Step 3, via SWASH (version 5.3) and SPIN (version 3.3), the FOCUS MACRO (version 5.5.4) or PRZM (version 4.3.1) models were used to simulate potential surface water exposure via drainage or runoff and the FOCUS TOXSWA model (version 5.5.3) was used to simulate the fate and behaviour of the compounds in the water body, with spray drift added as an additional loading. FOCUS Step 4 calculations were performed by reducing spray drift deposition and runoff inputs to simulate the use of 10 and 20 metre spray drift and runoff reduction buffer zones (vegetated filter strips). The Step 4 calculations were performed using the SWAN tool (version 5.0.1). In accordance with FOCUS guidance, the simulations were performed based on both multiple and respective single applications, and the highest  $PEC_{sw}$  and  $PEC_{sed}$  values were selected for input into the environmental risk assessment.

The key chemical input parameters for prothioconazole and prothioconazole-desthio (M04) selected for use in the modelling are summarised in Table 8.9-9. Unless otherwise stated, these values were derived from data reported in Volume 3, Annex B.8 of the Draft Assessment Report (DAR, July, 2005), the Addendum to the DAR (October, 2005) and the list of endpoints in the EFSA Conclusion (EFSA Scientific Report (2007) 106, 1-98).

**Table 8.9-9: Input parameters for  $PEC_{sw/sed}$  calculations for active substance prothioconazole and metabolite prothioconazole-desthio (M04) (FOCUS Steps 3-4)**

Compound	Prothioconazole	Prothioconazole-desthio (M04)	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	344.3	312.2	Yes
Saturated vapour pressure (Pa)	0 (worst-case assumption)	0 (worst-case assumption)	EFSA Scientific Report (2007) 106, 1-98
Water solubility (mg/L)	300 (20°C, pH 8)	1000 (conservative default)	
Diffusion coefficient in water (m <sup>2</sup> /d)	4.3 x 10 <sup>-5</sup>	4.3 x 10 <sup>-5</sup>	FOCUS default
Diffusion coefficient in air (m <sup>2</sup> /d)	0.43	0.43	FOCUS default
K <sub>foc</sub> (mL/g)	1765 (derived from aged column leaching study)	574 (geometric mean, n=4)	Yes
Freundlich Exponent 1/n	1.0 (FOCUS default)	0.81 (arithmetic mean, n=4)	EFSA Scientific Report (2007) 106, 1-98
Plant Uptake	0	0	
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	0.05 (MACRO) 0.50 (PRZM)	FOCUS default

Compound	Prothioconazole	Prothioconazole-desthio (M04)	Value in accordance to EU endpoint y/n/ Reference
DT <sub>50,soil</sub> (d)	1.2 (geometric mean DegT <sub>50field</sub> , normalised to 20°C, n=8)	22.7 (geometric mean DegT <sub>50field</sub> , normalised to 20°C, n=8)	Yes EFSA Scientific Report (2007) 106, 1-98
DT <sub>50,water</sub> (d)	1000 (conservative default) Parent only simulations	-	
	1.2 (geometric mean DegT <sub>50,whole system</sub> (fast-phase), n=2) Parent and metabolite simulations	1000 (conservative default)	
DT <sub>50,sed</sub> (d)	39.5 (geometric mean DegT <sub>50,whole system</sub> (slow-phase), n=2) Parent only simulations	-	
	1000 (conservative default) Parent and metabolite simulations	1000 (conservative default)	
Formation fraction in soil*	-	0.57	
Formation fraction in water and sediment*	-	0.546	

\* In the absence of kinetically determined formation fractions for prothioconazole-desthio (M04), values were selected based on the maximum amounts formed in soil and water/sediment systems. At the time of writing, it is noted that these values are equivalent to or more conservative than the kinetically derived values proposed in the Draft Renewal Assessment Report for prothioconazole (RAR, 2018) (0.57 for soil and 0.50 for water and sediment, respectively). When combined with the use of a conservative default DegT<sub>50</sub> value of 1000 days for prothioconazole-desthio (M04) in the water and sediment compartments, the use of these values in the modelling is therefore considered to be acceptable and sufficiently protective in this case.

The aquatic whole system DegT<sub>50/90</sub> values for prothioconazole that are reported in Volume 3, Annex B.8 of the Draft Assessment Report (DAR, 2005, page 471) and the EU agreed list of endpoints in the EFSA Conclusion (EFSA Scientific Report (2007) 106, 1-98), were derived using Hockey Stick (HS) kinetics. Current FOCUS guidance on degradation kinetics recommends that the whole system DegT<sub>50</sub> value is applied to the water phase for compounds with a K<sub>OC</sub> of less than *ca.* 100 mL/g and applied to the sediment phase for compounds with a K<sub>OC</sub> of greater than *ca.* 2000 mL/g, with a default value of 1000 days used for the other compartment. Since the K<sub>OC</sub> values of prothioconazole and prothioconazole-desthio (M04) are between 100 and 2000 mL/g, the guidance recommends that both combinations of aquatic DT<sub>50</sub> values are simulated at FOCUS Steps 3 and 4. However, this would necessitate running the simulations with at least four combinations of aquatic DT<sub>50</sub> values. Therefore, as the aquatic exposure assessment is driven by the risk to surface water for both prothioconazole and prothioconazole-desthio (M04), the DT<sub>50</sub> combination resulting in the highest predicted concentrations in surface water (PEC<sub>sw</sub>) was used for all modelling. Accordingly, for the parent only simulations, degradation in water was set to the default value of 1000 days and the slow-phase whole system DegT<sub>50</sub> value (39.5 days, geometric mean, n=2) was assigned to the sediment compartment. For the parent and metabolite simulations, the fast-phase whole system DegT<sub>50</sub> value (1.2 days, geometric mean, n=2) was used for parent in the water phase, with the default value of 1000 days assigned to the sediment compartment. In the absence of a kinetic assessment for the metabolite, the default value of 1000 days was assigned to both the water and sediment compartments.

The soil DT<sub>50</sub> values for prothioconazole and metabolite prothioconazole-desthio (M04) were derived from field data that were temperature normalised using a Q<sub>10</sub> correction factor of 2.2 as described in Volume 3, Annex B.8 of the Draft Assessment Report (DAR) for prothioconazole. Accordingly, the Q<sub>10</sub> value was therefore set to 2.2 in the simulations and the exponent for temperature response was set to 0.079 K<sup>-1</sup>. In addition, as the DT<sub>50field</sub> values for prothioconazole and prothioconazole-desthio (M04) were not normalised for soil moisture, the moisture exponent was set to zero in the simulations. As a worst-case and in order to avoid double accounting associated with the use of field dissipation data, volatilisation was also disabled in the simulations by setting vapour pressure to zero.

Application windows starting from the earliest proposed BBCH growth stage were defined for each crop scenario using the AppDate tool (v 3.06). In order to cover the relatively wide application window for cereals, two application timings (early and late) were simulated for these crop scenarios. For early application, the start of the application window was set to coincide with the date of the earliest recommended growth stage and for late application, the end of the application window was set to coincide with the latest possible application date based on the proposed PHI (35 days). The application windows used in the modelling are shown in Table 8.9-2 above. Actual application dates for each scenario were determined automatically in PRZM and MACRO using the Pesticide Application Timing calculator (PAT). Crop interception was calculated internally in the MACRO and PRZM models as a function of the application method, the maximum interception reached at the maximum leaf area of the simulated crop and the leaf area index at the time of application.

### FOCUS Step 3

Maximum PEC<sub>sw</sub> and PEC<sub>sed</sub> values for prothioconazole at FOCUS Step 3 for each crop group are shown in Table 8.9-10 to Table 8.9-14. Maximum PEC<sub>sw</sub> and PEC<sub>sed</sub> values for metabolite prothioconazole-desthio (M04) at Step 3 for each crop group are shown in Table 8.9-15 to Table 8.9-19. In accordance with FOCUS guidance, both multiple and single applications were simulated for each crop group and the highest resulting PEC<sub>sw</sub> and PEC<sub>sed</sub> values are selected for input into the risk assessment. An electronic copy of all modelling files which includes the full range of actual and time-weighted average PEC<sub>sw</sub> and PEC<sub>sed</sub> values for prothioconazole and prothioconazole-desthio (M04) at Step 3 is available on request.

**Table 8.9-10: FOCUS Step 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for prothioconazole following application of FF-075 to winter oilseed rape (2 x 160 g as/ha, 14-day appln interval, BBCH GS 55-69)**

Scenario	Waterbody	Multiple applications			Single application		
		Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)	Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)
Step 3							
D2	Ditch	1.4310	Spray drift	4.6820	1.0240	Spray drift	2.6140
D2	stream	0.8002	Spray drift	2.1080	0.8869	Spray drift	0.4150
D3	ditch	0.8877	Spray drift	0.6759	1.0140	Spray drift	0.6045
D4	pond	0.0515	Spray drift	0.2187	0.0350	Spray drift	0.1352
D4	stream	0.7575	Spray drift	0.1567	0.8535	Spray drift	0.0897
D5	pond	0.0518	Spray drift	0.2345	0.0350	Spray drift	0.1451
D5	stream	0.8172	Spray drift	0.2087	0.9029	Spray drift	0.0760
R1	pond	0.0849	Spray drift	0.3764	0.0753	Runoff	0.2943
R1	stream	0.5726	Spray drift	0.6807	0.6688	Spray drift	1.3100
R3	stream	0.8152	Spray drift	0.8295	0.9415	Spray drift	0.8360

**Table 8.9-11: FOCUS Step 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for prothioconazole following application of FF-075 to winter cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69 – early application timing)**

Scenario	Waterbody	Multiple applications			Single application		
		Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)	Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)
Step 3							
D1	ditch	1.1190	Spray drift	2.4660	1.2700	Spray drift	0.9196
D1	stream	0.9437	Spray drift	0.1678	0.9869	Spray drift	0.0404
D2	ditch	1.1240	Spray drift	2.2600	1.2780	Spray drift	1.2820
D2	stream	0.9793	Spray drift	1.7970	1.0850	Spray drift	0.1676
D3	ditch	1.1080	Spray drift	0.7367	1.2650	Spray drift	0.6498
D4	pond	0.0588	Spray drift	0.2817	0.0437	Spray drift	0.1733
D4	stream	0.8366	Spray drift	0.0320	0.9347	Spray drift	0.0270
D5	pond	0.0648	Spray drift	0.2938	0.0437	Spray drift	0.1806
D5	stream	0.9651	Spray drift	0.0723	1.0100	Spray drift	0.0287
D6	ditch	1.1120	Spray drift	1.0300	1.2510	Spray drift	0.3396
R1	pond	0.0645	Runoff	0.2996	0.0437	Spray drift	0.1653
R1	stream	0.7210	Spray drift	0.2770	0.8338	Spray drift	0.1085
R3	stream	1.0190	Spray drift	0.8333	1.1710	Spray drift	0.2181
R4	stream	0.7242	Spray drift	0.2076	0.8374	Spray drift	0.1223



**Table 8.9-12: FOCUS Step 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for prothioconazole following application of FF-075 to winter cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69 – late application timing)**

Scenario  FOCUS	Waterbody	Multiple applications			Single application		
		Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)	Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)
Step 3							
D1	ditch	1.8030	Spray drift	5.3690	1.2810	Spray drift	3.2090
D1	stream	0.9692	Spray drift	0.5661	1.1200	Spray drift	0.5461
D2	ditch	1.2760	Spray drift	2.6150	1.2770	Spray drift	1.9170
D2	stream	0.9872	Spray drift	1.2530	1.0740	Spray drift	0.1330
D3	ditch	1.1090	Spray drift	0.7699	1.2680	Spray drift	0.7443
D4	pond	0.0612	Spray drift	0.2699	0.0437	Spray drift	0.1680
D4	stream	0.9469	Spray drift	0.1903	1.0650	Spray drift	0.1074
D5	pond	0.0652	Spray drift	0.2839	0.0437	Spray drift	0.1777
D5	stream	1.0220	Spray drift	0.2904	1.1810	Spray drift	0.2888
D6	ditch	1.2230	Spray drift	2.6880	1.2770	Spray drift	2.0740
R1	pond	0.1040	Spray drift	0.4573	0.0753	Runoff	0.3353
R1	stream	0.7188	Spray drift	0.8327	0.8306	Spray drift	0.8368
R3	stream	1.0190	Spray drift	1.1410	1.1780	Spray drift	1.1510
R4	stream	0.7600	Runoff	1.1580	0.8374	Spray drift	1.1600

**Table 8.9-13: FOCUS Step 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for prothioconazole following application of FF-075 to spring cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69 – early application timing)**

Scenario  FOCUS	Waterbody	Multiple applications			Single application		
		Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)	Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)
Step 3							
D1	ditch	1.8030	Spray drift	5.3690	1.2810	Spray drift	3.2100
D1	stream	0.9692	Spray drift	0.5662	1.1200	Spray drift	0.5461
D3	ditch	1.1080	Spray drift	0.7661	1.2670	Spray drift	0.7015
D4	pond	0.0640	Spray drift	0.2710	0.0437	Spray drift	0.1669
D4	stream	0.9247	Spray drift	0.1090	1.0360	Spray drift	0.0690
D5	pond	0.0621	Spray drift	0.2857	0.0437	Spray drift	0.1771
D5	stream	0.9555	Spray drift	0.0630	1.0640	Spray drift	0.0443
R4	stream	0.8775	Runoff	1.0310	0.8374	Spray drift	0.6277

**Table 8.9-14: FOCUS Step 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for prothioconazole following application of FF-075 to spring cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69 – late application timing)**

Scenario	Waterbody	Multiple applications			Single application		
		Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)	Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)
Step 3							
D1	ditch	1.8030	Spray drift	5.3690	1.2810	Spray drift	3.2090
D1	stream	0.9692	Spray drift	0.5661	1.1200	Spray drift	0.5461
D3	ditch	1.1110	Spray drift	0.9190	1.2690	Spray drift	0.8246
D4	pond	0.0651	Spray drift	0.2770	0.0437	Spray drift	0.1681
D4	stream	0.9469	Spray drift	0.2090	1.0910	Spray drift	0.1919
D5	pond	0.0648	Spray drift	0.2821	0.0437	Spray drift	0.1754
D5	stream	1.0200	Spray drift	0.2489	1.1050	Spray drift	0.0684
R4	stream	0.7508	Runoff	1.1120	0.8374	Spray drift	1.1150

**Table 8.9-15: FOCUS Step 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for prothioconazole-desthio (M04) following application of FF-075 to winter oilseed rape (2 x 160 g as/ha, 14-day appln interval, BBCH GS 55-69)**

Scenario	Waterbody	Multiple applications			Single application		
		Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)	Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)
Step 3							
D2	Ditch	0.4992	Spray drift	3.4010	0.2779	Spray drift	1.8960
D2	stream	0.2939	Spray drift	1.6120	0.0945	Spray drift	0.1585
D3	ditch	0.0942	Spray drift	0.1333	0.0985	Spray drift	0.0957
D4	pond	0.0207	Spray drift	0.2476	0.0134	Spray drift	0.1556
D4	stream	0.0593	Spray drift	0.0166	0.0552	Spray drift	0.0067
D5	pond	0.0210	Spray drift	0.2700	0.0131	Spray drift	0.1688
D5	stream	0.0789	Spray drift	0.0268	0.0704	Spray drift	0.0065
R1	pond	0.1330	Spray drift	1.2820	0.0402	Spray drift	0.5146
R1	stream	0.7872	Spray drift	1.2550	0.2928	Spray drift	0.4396
R3	stream	0.7569	Spray drift	0.6068	0.3330	Spray drift	0.3503

**Table 8.9-16: FOCUS Step 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for prothioconazole-desthio (M04) following application of FF-075 to winter cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69- early application timing)**

Scenario	Waterbody	Multiple applications			Single application		
		Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)	Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)
Step 3							
D1	ditch	0.2539	Drainflow	0.8401	0.0567	Drainflow	0.0804
D1	stream	0.0810	Drainflow	0.0246	0.0799	Spray drift	0.0044
D2	ditch	0.3065	Drainflow	0.7788	0.1194	Drainflow	0.1420
D2	stream	0.3069	Drainflow	0.7989	0.0938	Spray drift	0.0181
D3	ditch	0.0977	Drainflow	0.1045	0.0577	Drainflow	0.0485
D4	pond	0.0209	Drainflow	0.2694	0.0131	Drainflow	0.1620
D4	stream	0.0503	Drainflow	0.0027	0.0562	Spray drift	0.0017
D5	pond	0.0252	Drainflow	0.3247	0.0153	Drainflow	0.2013
D5	stream	0.0741	Drainflow	0.0068	0.0755	Spray drift	0.0023
D6	ditch	0.1287	Drainflow	0.1859	0.0310	Spray drift	0.0130
R1	pond	0.1177	Runoff	1.1260	0.0423	Runoff	0.4494
R1	stream	1.0220	Runoff	0.9812	0.3335	Runoff	0.3403
R3	stream	0.9933	Runoff	1.1190	0.4267	Runoff	0.5304
R4	stream	1.4750	Runoff	0.8711	0.5359	Runoff	0.3372

**Table 8.9-17: FOCUS Step 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for prothioconazole-desthio (M04) following application of FF-075 to winter cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69 – late application timing)**

Scenario  FOCUS	Waterbody	Multiple applications			Single application		
		Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)	Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)
Step 3							
D1	ditch	0.6428	Drainflow	3.4450	0.3736	Spray drift	2.0260
D1	stream	0.1518	Drainflow	0.1746	0.1423	Spray drift	0.1258
D2	ditch	0.3574	Drainflow	1.4550	0.2847	Spray drift	0.6041
D2	stream	0.3157	Drainflow	0.4807	0.0940	Spray drift	0.0348
D3	ditch	0.1226	Drainflow	0.1541	0.1210	Spray drift	0.1151
D4	pond	0.0251	Drainflow	0.3080	0.0169	Spray drift	0.1910
D4	stream	0.0791	Drainflow	0.0213	0.0710	Spray drift	0.0084
D5	pond	0.0267	Drainflow	0.3350	0.0170	Spray drift	0.2103
D5	stream	0.0986	Spray drift	0.0423	0.1140	Spray drift	0.0352
D6	ditch	0.3773	Drainflow	1.3550	0.3376	Spray drift	0.8718
R1	pond	0.1651	Runoff	1.6490	0.0965	Spray drift	0.9865
R1	stream	1.0270	Spray drift	1.5010	0.5483	Spray drift	0.7325
R3	stream	0.8068	Runoff	0.8234	0.4990	Spray drift	0.5574
R4	stream	0.5252	Runoff	0.7713	0.5242	Spray drift	0.7707

**Table 8.9-18: FOCUS Step 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for prothioconazole-desthio (M04) following application of FF-075 to spring cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69 – early application timing)**

Scenario  FOCUS	Waterbody	Multiple applications			Single application		
		Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)	Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)
Step 3							
D1	ditch	0.6415	Drainflow	3.4010	0.3725	Drainflow	1.9920
D1	stream	0.1517	Drainflow	0.1520	0.1423	Spray drift	0.1067
D3	ditch	0.1017	Drainflow	0.1298	0.1131	Drainflow	0.1005
D4	pond	0.0258	Drainflow	0.2880	0.0167	Drainflow	0.1818
D4	stream	0.0628	Drainflow	0.0099	0.0653	Spray drift	0.0048
D5	pond	0.0248	Drainflow	0.3243	0.0154	Drainflow	0.2003
D5	stream	0.0736	Drainflow	0.0063	0.0795	Spray drift	0.0036
R4	stream	1.2080	Runoff	1.3850	0.6271	Runoff	0.9398

**Table 8.9-19: FOCUS Step 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for prothioconazole-desthio (M04) following application of FF-075 to spring cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69 – late application timing)**

Scenario	Waterbody	Multiple applications			Single application		
		Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)	Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)
Step 3							
D1	ditch	0.6421	Drainflow	3.4130	0.3732	Drainflow	2.0090
D1	stream	0.1518	Drainflow	0.2512	0.1423	Drainflow	0.1188
D3	ditch	0.1382	Drainflow	0.2114	0.1517	Drainflow	0.1592
D4	pond	0.0269	Drainflow	0.3195	0.0174	Drainflow	0.1843
D4	stream	0.0791	Spray drift	0.0429	0.0892	Drainflow	0.0192
D5	pond	0.0265	Drainflow	0.3327	0.0168	Spray drift	0.2077
D5	stream	0.0977	Spray drift	0.0312	0.0851	Spray drift	0.0059
R4	stream	0.5815	Runoff	0.8514	0.5798	Runoff	0.8500

#### FOCUS Step 4

FOCUS step 4 calculations were triggered for metabolite prothioconazole-desthio (M04). In accordance with the permissible mitigation measures for field crops in the Central Zone Member States, the calculations were performed by reducing spray drift deposition and runoff inputs to simulate the use of 10 and 20 metre spray drift and runoff reduction buffer zones (vegetated filter strips). The Step 4 calculations were performed using the SWAN tool (version 5.0.1).

Maximum PEC<sub>sw</sub> values for prothioconazole at FOCUS Step 4 for each crop group are shown in Table 8.9-20 to Table 8.9-24. Maximum PEC<sub>sw</sub> values for metabolite prothioconazole-desthio (M04) at FOCUS Step 4 for each crop group are shown in Table 8.9-25 to Table 8.9-29. In accordance with FOCUS guidance, both multiple and single applications were simulated for each crop group and the highest resulting PEC<sub>sw</sub> values are selected for input into the risk assessment. An electronic copy of all modelling files which includes the full range of actual and time-weighted average PEC<sub>sw</sub> and PEC<sub>sed</sub> values for prothioconazole and prothioconazole-desthio (M04) at Step 4 is available on request.

**Table 8.9-20: Global maximum PEC<sub>sw</sub> values for prothioconazole at FOCUS Step 4 following application of FF-075 to winter oilseed rape (2 x 160 g as/ha, 14-day appln interval, BBCH GS 55-69)**

PEC <sub>sw</sub> (µg/L)	Scenario	STEP 4 – prothioconazole			
		Multiple applications		Single application	
Nozzle reduction	Vegetative strip (m)	10	20	10	20
	No spray buffer (m)	10	20	10	20
None	D2 ditch	0.1238	0.0630	0.1472	0.0765
None	D2 stream	0.1452	0.0739	0.1718	0.0893
None	D3 ditch	0.1196	0.0608	0.1458	0.0758
None	D4 pond	0.0176	0.0116	0.0217	0.0145
None	D4 stream	0.1390	0.0707	0.1654	0.0859
None	D5 pond	0.0176	0.0116	0.0217	0.0145
None	D5 stream	0.1500	0.0763	0.1749	0.0909
None	R1 pond	0.0215	0.0136	0.0217	0.0145
None	R1 stream	0.2418	0.1267	0.1972	0.1033
None	R3 stream	0.2323	0.1219	0.2323	0.1219

**Table 8.9-21: Global maximum PEC<sub>sw</sub> values for prothioconazole at FOCUS Step 4 following application of FF-075 to winter cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69 – early application timing)**

PEC <sub>sw</sub> (µg/L)	Scenario	STEP 4 – prothioconazole			
		Multiple applications		Single application	
Nozzle reduction	Vegetative strip (m)	10	20	10	20
	No spray buffer (m)	10	20	10	20
None	D1 ditch	0.1507	0.0767	0.1826	0.0949
None	D1 stream	0.1732	0.0880	0.1912	0.0994
None	D2 ditch	0.1512	0.0769	0.1838	0.0955
None	D2 stream	0.1797	0.0914	0.2103	0.1093
None	D3 ditch	0.1492	0.0759	0.1820	0.0945
None	D4 pond	0.0223	0.0146	0.0272	0.0181
None	D4 stream	0.1535	0.0781	0.1811	0.0941
None	D5 pond	0.0232	0.0152	0.0272	0.0181
None	D5 stream	0.1771	0.0900	0.1958	0.1017
None	D6 ditch	0.1499	0.0762	0.1799	0.0935
None	R1 pond	0.0226	0.0149	0.0272	0.0181
None	R1 stream	0.1323	0.0673	0.1616	0.0839
None	R3 stream	0.2093	0.1098	0.2269	0.1179
None	R4 stream	0.1329	0.0676	0.1623	0.0843

**Table 8.9-22: Global maximum PEC<sub>sw</sub> values for prothioconazole at FOCUS Step 4 following application of FF-075 to winter cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69 – late application timing)**

PEC <sub>sw</sub> (µg/L)	Scenario	STEP 4 – prothioconazole			
		Multiple applications		Single application	
Nozzle reduction	Vegetative strip (m)	10	20	10	20
	No spray buffer (m)	10	20	10	20
None	D1 ditch	0.1540	0.0783	0.1842	0.0957
None	D1 stream	0.1778	0.0904	0.2171	0.1128
None	D2 ditch	0.1528	0.0777	0.1836	0.0954
None	D2 stream	0.1811	0.0921	0.2080	0.1081
None	D3 ditch	0.1494	0.0760	0.1823	0.0947
None	D4 pond	0.0218	0.0144	0.0272	0.0182
None	D4 stream	0.1737	0.0883	0.2063	0.1072
None	D5 pond	0.0220	0.0145	0.0272	0.0182
None	D5 stream	0.1875	0.0953	0.2289	0.1189
None	D6 ditch	0.1512	0.0769	0.1836	0.0954
None	R1 pond	0.0266	0.0168	0.0272	0.0181
None	R1 stream	0.2956	0.1548	0.2956	0.1548
None	R3 stream	0.3020	0.1585	0.3020	0.1585
None	R4 stream	0.3401	0.1776	0.3401	0.1776



**Table 8.9-23:** Global maximum PEC<sub>sw</sub> values for prothioconazole at FOCUS Step 4 following application of FF-075 to spring cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69 – early application timing)

PEC <sub>sw</sub> (µg/L)	Scenario	STEP 4 – prothioconazole			
		Multiple applications		Single application	
Nozzle reduction	Vegetative strip (m)	10	20	10	20
	No spray buffer (m)	10	20	10	20
None	D1 ditch	0.1540	0.0783	0.1842	0.0957
None	D1 stream	0.1778	0.0904	0.2171	0.1128
None	D3 ditch	0.1493	0.0759	0.1822	0.0946
None	D4 pond	0.0219	0.0144	0.0272	0.0182
None	D4 stream	0.1697	0.0863	0.2007	0.1043
None	D5 pond	0.0219	0.0144	0.0272	0.0182
None	D5 stream	0.1753	0.0892	0.2061	0.1071
None	R4 stream	0.3938	0.2057	0.2313	0.1207

**Table 8.9-24:** Global maximum PEC<sub>sw</sub> values for prothioconazole at FOCUS Step 4 following application of FF-075 to spring cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69 – late application timing)

PEC <sub>sw</sub> (µg/L)	Scenario	STEP 4 – prothioconazole			
		Multiple applications		Single application	
Nozzle reduction	Vegetative strip (m)	10	20	10	20
	No spray buffer (m)	10	20	10	20
None	D1 ditch	0.1540	-	0.1842	-
None	D1 stream	0.1778	-	0.2171	-
None	D3 ditch	0.1496	-	0.1825	-
None	D4 pond	0.0219	-	0.0272	-
None	D4 stream	0.1737	-	0.2115	-
None	D5 pond	0.0220	-	0.0272	-
None	D5 stream	0.1872	-	0.2141	-
None	R4 stream	0.3362	-	0.3292	-

- Simulation not performed

**Table 8.9-25: Global maximum PEC<sub>sw</sub> values for prothioconazole-desthio (M04) at FOCUS Step 4 following application of FF-075 to winter oilseed rape (2 x 160 g as/ha, 14-day appln interval, BBCH GS 55-69)**

PEC <sub>sw</sub> (µg/L)	Scenario	STEP 4 – prothioconazole-desthio (M04)			
		Multiple applications		Single application	
Nozzle reduction	Vegetative strip (m)	10	20	10	20
	No spray buffer (m)	10	20	10	20
None	D2 ditch	0.0652	0.0520	0.0383	0.0198
None	D2 stream	0.0528	0.0327	0.0185	0.0098
None	D3 ditch	0.0127	0.0064	0.0141	0.0073
None	D4 pond	0.0125	0.0082	0.0083	0.0055
None	D4 stream	0.0109	0.0055	0.0107	0.0055
None	D5 pond	0.0127	0.0083	0.0081	0.0054
None	D5 stream	0.0145	0.0073	0.0136	0.0071
None	R1 pond	0.0571	0.0302	0.0183	0.0105
None	R1 stream	0.3582	0.1876	0.1323	0.0691
None	R3 stream	0.3388	0.1764	0.1519	0.0797

**Table 8.9-26: Global maximum PEC<sub>sw</sub> values for prothioconazole-desthio (M04) at FOCUS Step 4 following application of FF-075 to winter cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69 – early application timing)**

PEC <sub>sw</sub> (µg/L)	Scenario	STEP 4 – prothioconazole-desthio (M04)			
		Multiple applications		Single application	
Nozzle reduction	Vegetative strip (m)	10	20	10	20
	No spray buffer (m)	10	20	10	20
None	D1 ditch	0.0328	0.0166	0.0082	0.0043
None	D1 stream	0.0150	0.0078	0.0155	0.0081
None	D2 ditch	0.0403	0.0245	0.0172	0.0089
None	D2 stream	0.0545	0.0274	0.0182	0.0095
None	D3 ditch	0.0132	0.0067	0.0083	0.0043
None	D4 pond	0.0126	0.0082	0.0081	0.0053
None	D4 stream	0.0092	0.0047	0.0109	0.0057
None	D5 pond	0.0153	0.0100	0.0095	0.0063
None	D5 stream	0.0136	0.0069	0.0146	0.0076
None	D6 ditch	0.0173	0.0088	0.0044	0.0023
None	R1 pond	0.0519	0.0280	0.0197	0.0111
None	R1 stream	0.4643	0.2431	0.1515	0.0793
None	R3 stream	0.4532	0.2378	0.1947	0.1021
None	R4 stream	0.6706	0.3513	0.2437	0.1276

**Table 8.9-27: Global maximum PEC<sub>sw</sub> values for prothioconazole-desthio (M04) at FOCUS Step 4 following application of FF-075 to winter cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69 – late application timing)**

PEC <sub>sw</sub> (µg/L)	Scenario	STEP 4 – prothioconazole-desthio (M04)			
		Multiple applications		Single application	
Nozzle reduction	Vegetative strip (m)	10	20	10	20
	No spray buffer (m)	10	20	10	20
None	D1 ditch	0.0839	0.0429	0.0525	0.0276
None	D1 stream	0.0278	0.0142	0.0276	0.0143
None	D2 ditch	0.1087	0.1087	0.0410	0.0335
None	D2 stream	0.0688	0.0688	0.0212	0.0212
None	D3 ditch	0.0165	0.0084	0.0174	0.0090
None	D4 pond	0.0152	0.0099	0.0104	0.0069
None	D4 stream	0.0145	0.0144	0.0137	0.0071
None	D5 pond	0.0162	0.0106	0.0105	0.0070
None	D5 stream	0.0181	0.0092	0.0221	0.0115
None	D6 ditch	0.0502	0.0254	0.0477	0.0246
None	R1 pond	0.0710	0.0375	0.0414	0.0219
None	R1 stream	0.4671	0.2447	0.2490	0.1304
None	R3 stream	0.3669	0.1921	0.2277	0.1194
None	R4 stream	0.2389	0.1251	0.2385	0.1249

**Table 8.9-28:** Global maximum PEC<sub>sw</sub> values for prothioconazole-desthio (M04) at FOCUS Step 4 following application of FF-075 to spring cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69 – early application timing)

PEC <sub>sw</sub> (µg/L)	Scenario	STEP 4 – prothioconazole-desthio (M04)			
		Multiple applications		Single application	
Nozzle reduction	Vegetative strip (m)	10	20	10	20
	No spray buffer (m)	10	20	10	20
None	D1 ditch	0.0828	0.0419	0.0515	0.0267
None	D1 stream	0.0278	0.0142	0.0276	0.0143
None	D3 ditch	0.0137	0.0070	0.0162	0.0084
None	D4 pond	0.0156	0.0102	0.0103	0.0069
None	D4 stream	0.0115	0.0059	0.0126	0.0066
None	D5 pond	0.0150	0.0098	0.0095	0.0063
None	D5 stream	0.0135	0.0069	0.0154	0.0080
None	R4 stream	0.5439	0.2837	0.2852	0.1495

**Table 8.9-29:** Global maximum PEC<sub>sw</sub> values for prothioconazole-desthio (M04) at FOCUS Step 4 following application of FF-075 to spring cereals (2 x 200 g as/ha, 14-day appln interval, BBCH GS 30-69 – late application timing)

PEC <sub>sw</sub> (µg/L)	Scenario	STEP 4 – prothioconazole-desthio (M04)			
		Multiple applications		Single application	
Nozzle reduction	Vegetative strip (m)	10	20	10	20
	No spray buffer (m)	10	20	10	20
None	D1 ditch	0.0834	-	0.0521	-
None	D1 stream	0.0278	-	0.0276	-
None	D3 ditch	0.0186	-	0.0218	-
None	D4 pond	0.0163	-	0.0108	-
None	D4 stream	0.0381	-	0.0173	-
None	D5 pond	0.0161	-	0.0104	-
None	D5 stream	0.0179	-	0.0165	-
None	R4 stream	0.2645	-	0.2578	-

- Simulation not performed

## EPAT Analysis

In all cases the highest maximum initial  $PEC_{sw}$  values for metabolite prothioconazole-desthio (M04) at FOCUS Step 4 were observed in the Runoff (R) scenarios, where run-off was shown to be the predominant route of surface water exposure. Based on the critical GAP for FF-075 in central Europe and the maximum permissible level of runoff mitigation (20 metre vegetated filter strip), a slight exceedance of the threshold concentration for this metabolite ( $0.334 \mu\text{g/L}$ ) is predicted in the R4 stream scenario for winter cereals (early application timing) (maximum  $PEC_{sw}$   $0.3513 \mu\text{g/L}$ ). The corresponding TOXSWA exposure profile for this scenario was therefore analysed using the ECPA EPAT software (Exposure Pattern Analysis Tool; version 1.2.0). A single threshold concentration of  $0.334 \mu\text{g/L}$  was entered into the EPAT interface and each reported exceedance therefore represents an exceedance of this concentration. The results of this analysis are shown in Table 8.9-30 and the graphical output from the EPAT interface is provided in Appendix 3.3.

**Table 8.9-30: Exceedance events for prothioconazole-desthio (M04) at FOCUS Step 4 calculated using EPAT against a threshold concentration of  $0.334 \mu\text{g/L}$**

Step / mitigation	Scenario	Event no.	Start date	Interval (days)	Max. $PEC_{sw}$ ( $\mu\text{g/L}$ )	Duration (days)	Area under curve ( $\text{h}\cdot\mu\text{g/L}$ )
<b>Winter cereals (2 x 200 g a.s./ha, 14-day application interval, BBCH GS 30-69 – early application timing)</b>							
Step 4 20 m no-spray buffer with VFS	R4 stream	1	19/03/1980	-	0.3513	0.583	4.902E+00

VFS = vegetated filter strip

### 8.9.2.2 Azoxystrobin and its metabolites

The following surface water modelling on azoxystrobin and its metabolites has not previously been reviewed and is provided in support of this assessment.

## FOCUS Steps 1 and 2

Predicted environmental concentrations of azoxystrobin and its soil and aquatic metabolites R234886, R401553 and R402173, in surface water and sediment were calculated at FOCUS Steps 1 and 2 using the STEPS 1-2 in FOCUS calculator (version 3.2).

The key chemical input parameters for azoxystrobin and its metabolites selected for use in the modelling are summarised in Table 8.9-31. Unless otherwise stated, these values were derived from the list of endpoints in the EFSA Conclusion (EFSA Journal 2010; 8(4):1542).

**Table 8.9-31: Input parameters for PEC<sub>sw/sed</sub> calculations for active substance azoxystrobin and its metabolites (FOCUS Steps 1-2)**

Compound	Azoxystrobin	R234886	R401553	R402173	Value in accordance to EU end-point y/n/ Reference
Molecular weight (g/mol)	403.4	389.4	213.2	333.3	Yes EFSA Conclusion (EFSA Journal 2010; 8(4):1542)
Water solubility (mg/L)	6.0	57	560	61	
K <sub>foc</sub> (mL/g)	391.5 (geometric mean, n=6)	21 (used for PEC <sub>sw</sub> , lowest value, n=6)*  490 (used for PEC <sub>sed</sub> , highest value, n=6)*	142.6 (geometric mean, n=6)	25 (used for PEC <sub>sw</sub> , lowest value, n=6)*  200 (used for PEC <sub>sed</sub> , highest value, n=6)*	
DT <sub>50,soil</sub> (d)	78 (overall geometric mean DegT <sub>50field</sub> of the soil incorporated studies (80.2 days, n=3) and the soil non-incorporated studies (slow phase, 75.9 days, n=10))	110.4 (geometric mean DegT <sub>50lab</sub> , n=5)	1.1 (geometric mean DegT <sub>50lab</sub> , n=3)	4.7 (geometric mean, DegT <sub>50lab</sub> , n=3)	
DT <sub>50,water</sub> (d)	1000 (conservative default)	1000 (conservative default)	1000 (conservative default)	1000 (conservative default)	
DT <sub>50,sed</sub> (d)	205 (geometric mean DegT <sub>50,whole system</sub> , n=2)	1000 (conservative default)	1000 (conservative default)	1000 (conservative default)	
DT <sub>50,whole system</sub> (d)	205 (geometric mean DegT <sub>50,whole system</sub> , n=2)	1000 (conservative default)	1000 (conservative default)	1000 (conservative default)	
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 28.8 Water / Sediment: 18.1	Soil: 17 Water / Sediment: 8.9	Soil: 17 Water / Sediment: 2.4	

\* The sorption of metabolites R234886 and R402173 is pH dependent. Therefore as a worst-case, the lowest K<sub>foc</sub> value from each sorption dataset was used for the PEC<sub>sw</sub> calculations and the highest value was used for the PEC<sub>sed</sub> calculations.

Separate simulations were run for azoxystrobin and each of its metabolites at FOCUS Steps 1 and 2. Application rates for the metabolites were set internally within the STEPS 1-2 in FOCUS calculator. The rates are based on the application rate for the active substance adjusted to account for the maximum percentage of each metabolite formed in soil and aquatic systems, the difference in molecular weight between parent and metabolite and crop interception. At Step 2, the calculations were conducted with the

region of application set to both North and South Europe and the season of application was selected in line with the GAP. As the formulation is intended for application post crop emergence, crop interception was accounted for at FOCUS Step 2. Full canopy was selected for winter oilseed rape (BBCH GS 55-69) and average crop cover was selected for cereals (BBCH GS 30-69).

Maximum  $PEC_{sw}$  and  $PEC_{sed}$  values for azoxystrobin and its metabolites R234886, R401553 and R402173 at FOCUS Steps 1 and 2 for each crop group are shown in Table 8.9-32 to Table 8.9-35. Example output files from the STEPS 1-2 in FOCUS calculator are provided for illustrative purposes in Appendix 3.2 and an electronic copy of all modelling files is available on request.

**Table 8.9-32: FOCUS Step 1 and 2  $PEC_{sw}$  and  $PEC_{sed}$  for azoxystrobin following applications of FF-075 to winter oilseed rape and cereals**

Crop and application pattern	FOCUS Step	Application window	Crop interception	Multiple applications		Single application	
				Max PEC <sub>sw</sub> (µg/L)	Max PEC <sub>sed</sub> (µg/kg)	Max PEC <sub>sw</sub> (µg/L)	Max PEC <sub>sed</sub> (µg/kg)
Winter oilseed rape							
Winter oilseed rape (2 x 120 g as/ha, 14-day appln interval, BBCH GS 55-69)	Step 1	-	-	54.7696	210.7456	-	-
	Step 2 - NEU	March-May	Full canopy	3.8143	14.2424	2.0831	7.7619
	Step 2 - SEU			6.2023	23.5599	3.3513	12.7100
Cereals							
Winter cereals (2 x 150 g as/ha, 14-day appln interval, BBCH GS 30-69)	Step 1	-	-	68.4620	263.4320	-	-
	Step 2 - NEU	March-May	Average crop cover	11.3349	43.4260	6.0913	23.3098
	Step 2 - SEU			20.8868	80.6956	11.1640	43.1023
Spring cereals (2 x 150 g as/ha, 14-day appln interval, BBCH GS 30-69)	Step 1	-	-	68.4620	263.4320	-	-
	Step 2 - NEU	March-May	Average crop cover	11.3349	43.4260	6.0913	23.3098
	Step 2 - SEU			20.8868	80.6956	11.1640	43.1023

NEU = northern Europe, SEU = southern Europe



**Table 8.9-33: FOCUS Step 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for R234886 following applications of FF-075 to winter oilseed rape and cereals**

Crop and application pattern	FOCUS Step	Application window	Crop interception	Multiple applications		Single application	
				Max PEC <sub>sw</sub> (µg/L)*	Max PEC <sub>sed</sub> (µg/kg)*	Max PEC <sub>sw</sub> (µg/L)*	Max PEC <sub>sed</sub> (µg/kg)*
Winter oilseed rape							
Winter oilseed rape (2 x 120 g as/ha, 14-day appln interval, BBCH GS 55-69)	Step 1	-	-	35.6170	108.4070	-	-
	Step 2 - NEU	March-May	Full canopy	1.9602	5.9589	1.0443	3.1741
	Step 2 - SEU			3.5885	10.9162	1.8998	5.7788
Cereals							
Winter cereals (2 x 150 g as/ha, 14-day appln interval, BBCH GS 30-69)	Step 1	-	-	44.5213	135.5087	-	-
	Step 2 - NEU	March-May	Average crop cover	6.9279	21.0812	3.6580	11.1304
	Step 2 - SEU			13.4409	40.9105	7.0800	21.5490
Spring cereals (2 x 150 g as/ha, 14-day appln interval, BBCH GS 30-69)	Step 1	-	-	44.5213	135.5087	-	-
	Step 2 - NEU	March-May	Average crop cover	6.9279	21.0812	3.6580	11.1304
	Step 2 - SEU			13.4409	40.9105	7.0800	21.5490

NEU = northern Europe, SEU = southern Europe

\* As the sorption of metabolite R234886 is pH dependent, the lowest K<sub>foc</sub> value (21 mL/g) was used as a worst-case for the PEC<sub>sw</sub> calculations and the highest K<sub>foc</sub> value (490 mL/g) was used as a worst-case for the PEC<sub>sed</sub> calculations

**Table 8.9-34: FOCUS Step 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for R401553 following applications of FF-075 to winter oilseed rape and cereals**

Crop and application pattern	FOCUS Step	Application window	Crop interception	Multiple applications		Single application	
				Max PEC <sub>sw</sub> (µg/L)	Max PEC <sub>sed</sub> (µg/kg)	Max PEC <sub>sw</sub> (µg/L)	Max PEC <sub>sed</sub> (µg/kg)
Winter oilseed rape							
Winter oilseed rape (2 x 120 g as/ha, 14-day appln interval, BBCH GS 55-69)	Step 1	-	-	9.3050	13.2362	-	-
	Step 2 - NEU	March-May	Full canopy	0.2366	0.3310	0.1344	0.1880
	Step 2 - SEU			0.3924	0.5530	0.2228	0.3140
Cereals							
Winter cereals (2 x 150 g as/ha, 14-day appln interval, BBCH GS 30-69)	Step 1	-	-	11.6313	16.5452	-	-
	Step 2 - NEU	March-May	Average crop cover	0.7242	1.0243	0.4111	0.5815
	Step 2 - SEU			1.3473	1.9123	0.7648	1.0855
Spring cereals (2 x 150 g as/ha, 14-day appln interval, BBCH GS 30-69)	Step 1	-	-	11.6313	16.5452	-	-
	Step 2 - NEU	March-May	Average crop cover	0.7242	1.0243	0.4111	0.5815
	Step 2 - SEU			1.3473	1.9123	0.7648	1.0855

NEU = northern Europe, SEU = southern Europe

**Table 8.9-35: FOCUS Step 1 and 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for R402173 following applications of FF-075 to winter oilseed rape and cereals**

Crop and application pattern	FOCUS Step	Application window	Crop interception	Multiple applications		Single application	
				Max PEC <sub>sw</sub> (µg/L)*	Max PEC <sub>sed</sub> (µg/kg)*	Max PEC <sub>sw</sub> (µg/L)*	Max PEC <sub>sed</sub> (µg/kg)*
Winter oilseed rape							
Winter oilseed rape (2 x 120 g as/ha, 14-day appln interval, BBCH GS 55-69)	Step 1	-	-	12.4532	20.3019	-	-
	Step 2 - NEU	March-May	Full canopy	0.2771	0.4512	0.2091	0.3405
	Step 2 - SEU			0.5167	0.8418	0.3968	0.6467
Cereals							
Winter cereals (2 x 150 g as/ha, 14-day appln interval, BBCH GS 30-69)	Step 1	-	-	15.5665	25.3774	-	-
	Step 2 - NEU	March-May	Average crop cover	1.0052	1.6382	0.7777	1.2675
	Step 2 - SEU			1.9635	3.2006	1.5287	2.4920
Spring cereals (2 x 150 g as/ha, 14-day appln interval, BBCH GS 30-69)	Step 1	-	-	15.5665	25.3774	-	-
	Step 2 - NEU	March-May	Average crop cover	1.0052	1.6382	0.7777	1.2675
	Step 2 - SEU			1.9635	3.2006	1.5287	2.4920

NEU = northern Europe, SEU = southern Europe

\* As the sorption of metabolite R402173 is pH dependent, the lowest K<sub>foc</sub> value (25 mL/g) was used as a worst-case for the PEC<sub>sw</sub> calculations and the highest K<sub>foc</sub> value (200 mL/g) was used as a worst-case for the PEC<sub>sed</sub> calculations

### FOCUS Steps 3 and 4

Surface water modelling of azoxystrobin was conducted using the FOCUS surface water models and scenarios. The modelling was based on applications to winter oilseed rape and winter and spring cereals in accordance with the critical GAP for the FF-075 formulation in Europe. The FOCUS crop scenarios 'winter oilseed rape', 'winter cereals' and 'spring cereals' were selected for the simulations. At Step 3, via SWASH (version 5.3) and SPIN (version 3.3), the FOCUS MACRO (version 5.5.4) or PRZM (version 4.3.1) models were used to simulate potential surface water exposure via drainage or runoff and the FOCUS TOXSWA model (version 5.5.3) was used to simulate the fate and behaviour of the compound in the water body, with spray drift added as an additional loading. FOCUS Step 4 calculations were performed by reducing spray drift deposition and runoff inputs to simulate the use of 10 and 20 metre spray drift and runoff reduction buffer zones (vegetated filter strips). The Step 4 calculations were performed using the SWAN tool (version 5.0.1). In accordance with FOCUS guidance, the simulations were performed based on both multiple and respective single applications, and the highest PEC<sub>sw</sub> and PEC<sub>sed</sub> values were selected for input into the environmental risk assessment.

The key chemical input parameters for azoxystrobin selected for use in the modelling are summarised in Table 8.9-36. Unless otherwise stated, these values were derived from the list of endpoints in the EFSA Conclusion (EFSA Journal 2010; 8(4):1542).

**Table 8.9-36: Input parameters for  $PEC_{sw/sed}$  calculations for active substance azoxystrobin (FOCUS Steps 3-4)**

Compound	Azoxystrobin	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	403.4	Yes EFSA Conclusion (EFSA Journal 2010; 8(4):1542)
Saturated vapour pressure (Pa)	$1.1 \times 10^{-10}$ (20°C)	
Water solubility (mg/L)	6.0 (20°C)	
Diffusion coefficient in water (m <sup>2</sup> /d)	$4.3 \times 10^{-5}$	FOCUS default
Diffusion coefficient in air (m <sup>2</sup> /d)	0.43	FOCUS default
$K_{foc}$ (mL/g)	391.5 (geometric mean, n=6)	Yes EFSA Conclusion (EFSA Journal 2010; 8(4):1542)
Freundlich Exponent 1/n	0.86 (arithmetic mean, n=6)	
Plant Uptake	0 (worst-case assumption)	
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	FOCUS default
DT <sub>50,soil</sub> (d)	78 (overall geometric mean DegT <sub>50field</sub> of the soil incorporated studies (80.2 days, n=3) and the soil non-incorporated studies (slow phase, 75.9 days, n=10))	Yes EFSA Conclusion (EFSA Journal 2010; 8(4):1542)
DT <sub>50,water</sub> (d)	1000 (conservative default)	
DT <sub>50,sed</sub> (d)	205 (geometric mean DegT <sub>50,whole system</sub> , n=2)	

Application windows starting from the earliest proposed BBCH growth stage were defined for each crop scenario using the AppDate tool (v 3.06). In order to cover the relatively wide application window for cereals, two application timings (early and late) were simulated for these crop scenarios. For early application, the start of the application window was set to coincide with the date of the earliest recommended growth stage and for late application, the end of the application window was set to coincide with the latest possible application date based on the proposed PHI (35 days). The application windows used in the modelling are shown in Table 8.9-2 above. Actual application dates for each scenario were determined automatically in PRZM and MACRO using the Pesticide Application Timing calculator (PAT). Crop interception was calculated internally in the MACRO and PRZM models as a function of the application method, the maximum interception reached at the maximum leaf area of the simulated crop and the leaf area index at the time of application.

### FOCUS Step 3

Maximum  $PEC_{sw}$  and  $PEC_{sed}$  values for azoxystrobin at FOCUS Step 3 for each crop group are shown in Table 8.9-37 to Table 8.9-41. In accordance with FOCUS guidance, both multiple and single applications were simulated for each crop group and the highest resulting  $PEC_{sw}$  and  $PEC_{sed}$  values are selected for input into the risk assessment. An electronic copy of all modelling files which includes the full range of actual and time-weighted average  $PEC_{sw}$  and  $PEC_{sed}$  values for azoxystrobin at Step 3 is available on request.

**Table 8.9-37: FOCUS Step 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for azoxystrobin following application of FF-075 to winter oilseed rape (2 x 120 g as/ha, 14-day appln interval, BBCH GS 55-69)**

Scenario	Waterbody	Multiple applications			Single application		
		Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)	Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)
Step 3							
D2	Ditch	2.5380	Drainflow	9.0800	1.1480	Drainflow	4.9210
D2	stream	1.5870	Drainflow	5.2810	0.7946	Spray drift	2.6810
D3	ditch	0.6661	Spray drift	0.4856	0.7612	Spray drift	0.4158
D4	pond	0.2223	Drainflow	1.5450	0.0941	Drainflow	0.7320
D4	stream	0.5684	Spray drift	0.5670	0.6404	Spray drift	0.2472
D5	pond	0.1228	Drainflow	1.0320	0.0622	Spray drift	0.5219
D5	stream	0.6133	Spray drift	0.2651	0.6779	Spray drift	0.1259
R1	pond	0.3225	Runoff	1.7350	0.1164	Runoff	0.7572
R1	stream	1.8250	Runoff	1.6470	0.8888	Runoff	1.1640
R3	stream	1.9730	Runoff	1.0650	1.0770	Runoff	0.9171

**Table 8.9-38: FOCUS Step 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for azoxystrobin following application of FF-075 to winter cereals (2 x 150 g as/ha, 14-day appln interval, BBCH GS 30-69 – early application timing)**

Scenario	Waterbody	Multiple applications			Single application		
		Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)	Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)
Step 3							
D1	ditch	5.0820	Drainflow	23.5600	2.7880	Drainflow	12.6900
D1	stream	3.1790	Drainflow	13.8300	1.7440	Drainflow	7.4900
D2	ditch	7.3640	Drainflow	17.7300	3.4890	Drainflow	8.7690
D2	stream	4.6670	Drainflow	9.5640	2.1840	Drainflow	4.6660
D3	ditch	0.8311	Spray drift	0.5228	0.9496	Spray drift	0.4467
D4	pond	0.5513	Drainflow	3.3940	0.2306	Drainflow	1.5560
D4	stream	0.6285	Spray drift	1.2940	0.7028	Spray drift	0.5817
D5	pond	0.1784	Drainflow	1.5740	0.0893	Spray drift	0.7491
D5	stream	0.7284	Spray drift	0.3542	0.7613	Spray drift	0.1710
D6	ditch	0.8387	Spray drift	0.8818	0.9506	Spray drift	0.4282
R1	pond	0.3034	Runoff	1.6780	0.1134	Runoff	0.6868
R1	stream	2.9400	Runoff	1.3420	1.0090	Runoff	0.4720
R3	stream	3.2190	Runoff	2.2330	1.4250	Runoff	0.9487
R4	stream	4.1960	Runoff	1.8950	1.8120	Runoff	0.8302

**Table 8.9-39: FOCUS Step 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for azoxystrobin following application of FF-075 to winter cereals (2 x 150 g as/ha, 14-day appln interval, BBCH GS 30-69 – late application timing)**

Scenario  FOCUS	Waterbody	Multiple applications			Single application		
		Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)	Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)
Step 3							
D1	ditch	3.2780	Drainflow	15.2500	1.6170	Drainflow	8.7610
D1	stream	2.0570	Drainflow	9.4570	1.0190	Drainflow	4.9530
D2	ditch	4.4720	Drainflow	13.6500	2.0040	Drainflow	7.2710
D2	stream	2.7980	Drainflow	8.0870	1.2520	Drainflow	4.3120
D3	ditch	0.8319	Spray drift	0.5564	0.9513	Spray drift	0.5072
D4	pond	0.4951	Drainflow	3.0930	0.1946	Drainflow	1.3670
D4	stream	0.7105	Spray drift	1.1760	0.7989	Spray drift	0.4904
D5	pond	0.1803	Drainflow	1.3830	0.0895	Drainflow	0.7302
D5	stream	0.7667	Spray drift	0.3593	0.8865	Spray drift	0.2864
D6	ditch	0.9146	Spray drift	1.8700	0.9585	Spray drift	1.3620
R1	pond	0.3926	Runoff	2.1520	0.2226	Runoff	1.2550
R1	stream	2.3100	Runoff	1.9750	1.7850	Runoff	1.1090
R3	stream	2.3660	Runoff	1.5230	1.6600	Runoff	1.3630
R4	stream	1.6260	Runoff	1.3980	1.6260	Runoff	1.4000

**Table 8.9-40: FOCUS Step 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for azoxystrobin following application of FF-075 to spring cereals (2 x 150 g as/ha, 14-day appln interval, BBCH GS 30-69 – early application timing)**

Scenario  FOCUS	Waterbody	Multiple applications			Single application		
		Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)	Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)
Step 3							
D1	ditch	3.8850	Drainflow	20.6000	2.2160	Drainflow	12.8000
D1	stream	2.4300	Drainflow	11.6800	1.3880	Drainflow	7.0890
D3	ditch	0.8315	Spray drift	0.5471	0.9506	Spray drift	0.4805
D4	pond	0.5289	Drainflow	3.3420	0.2681	Drainflow	1.8040
D4	stream	0.6944	Spray drift	1.2510	0.7777	Spray drift	0.6662
D5	pond	0.1777	Drainflow	1.5150	0.0919	Spray drift	0.8016
D5	stream	0.7200	Spray drift	0.3505	0.8003	Spray drift	0.1861
R4	stream	3.0690	Runoff	2.4000	1.7960	Runoff	1.4590

**Table 8.9-41: FOCUS Step 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for azoxystrobin following application of FF-075 to spring cereals (2 x 150 g as/ha, 14-day appln interval, BBCH GS 30-69 – late application timing)**

Scenario	Waterbody	Multiple applications			Single application		
		Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)	Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	Max PEC <sub>sed</sub> (µg/kg)
Step 3							
D1	ditch	3.1150	Drainflow	18.1900	1.5820	Drainflow	10.7700
D1	stream	1.9530	Drainflow	9.9490	0.9937	Drainflow	5.9490
D3	ditch	0.8335	Spray drift	0.6504	0.9525	Spray drift	0.5573
D4	pond	0.7920	Drainflow	4.6820	0.2559	Drainflow	1.7190
D4	stream	0.7818	Drainflow	1.8190	0.8192	Spray drift	0.6420
D5	pond	0.1845	Drainflow	1.4030	0.0913	Drainflow	0.7369
D5	stream	0.7657	Spray drift	0.3647	0.8300	Spray drift	0.1885
R4	stream	1.7970	Runoff	1.4570	1.7960	Runoff	1.4590

#### FOCUS Step 4

FOCUS Step 4 calculations were conducted for azoxystrobin. In accordance with the permissible mitigation measures for field crops in the Central Zone Member States, the calculations were performed by reducing spray drift deposition and runoff inputs to simulate the use of 10 and 20 metre spray drift and runoff reduction buffer zones (vegetated filter strips). The Step 4 calculations were performed using the SWAN tool (version 5.0.1).

Maximum PEC<sub>sw</sub> values for azoxystrobin at FOCUS Step 4 are shown in Table 8.9-42 to Table 8.9-46. In accordance with FOCUS guidance, both multiple and single applications were simulated for each crop group and the highest resulting PEC<sub>sw</sub> values are selected for input into the risk assessment. An electronic copy of all modelling files which includes the full range of actual and time-weighted average PEC<sub>sw</sub> and PEC<sub>sed</sub> values for azoxystrobin at Step 4 is available on request.

**Table 8.9-42: Global maximum PEC<sub>sw</sub> values for azoxystrobin at FOCUS Step 4 following application of FF-075 to winter oilseed rape (2 x 120 g as/ha, 14-day appln interval, BBCH GS 55-69)**

PEC <sub>sw</sub> (µg/L)	Scenario	STEP 4 – azoxystrobin			
		Multiple applications		Single application	
Nozzle reduction	Vegetative strip (m)	10	20	10	20
	No spray buffer (m)	10	20	10	20
None	D2 ditch	2.5380	-	1.1480	-
None	D2 stream	1.5870	-	0.7170	-
None	D3 ditch	0.0898	-	0.1094	-
None	D4 pond	0.2189	-	0.0922	-
None	D4 stream	0.2584	-	0.1290	-
None	D5 pond	0.1228	-	0.0571	-
None	D5 stream	0.1849	-	0.1316	-
None	R1 pond	0.1363	-	0.0518	-
None	R1 stream	0.8307	-	0.4045	-
None	R3 stream	0.8834	-	0.4915	-

- Simulation not performed

**Table 8.9-43: Global maximum PEC<sub>sw</sub> values for azoxystrobin at FOCUS Step 4 following application of FF-075 to winter cereals (2 x 150 g as/ha, 14-day appln interval, BBCH GS 30-69 – early application timing)**

PEC <sub>sw</sub> (µg/L)	Scenario	STEP 4 – azoxystrobin			
		Multiple applications		Single application	
Nozzle reduction	Vegetative strip (m)	10	20	10	20
	No spray buffer (m)	10	20	10	20
None	D1 ditch	5.0820	5.0820	2.7880	-
None	D1 stream	3.1790	3.1790	1.7440	-
None	D2 ditch	7.3640	7.3640	3.4890	-
None	D2 stream	4.6670	4.6670	2.1840	-
None	D3 ditch	0.1120	0.0569	0.1365	-
None	D4 pond	0.5484	0.5469	0.2291	-
None	D4 stream	0.5819	0.5819	0.2615	-
None	D5 pond	0.1784	0.1784	0.0819	-
None	D5 stream	0.2763	0.2763	0.1501	-
None	D6 ditch	0.4351	0.4351	0.2442	-
None	R1 pond	0.1291	0.0675	0.0497	-
None	R1 stream	1.3350	0.6994	0.4581	-
None	R3 stream	1.4690	0.7704	0.6504	-
None	R4 stream	1.9090	1.0000	0.8243	-

- Simulation not performed



**Table 8.9-44: Global maximum PEC<sub>sw</sub> values for azoxystrobin at FOCUS Step 4 following application of FF-075 to winter cereals (2 x 150 g as/ha, 14-day appln interval, BBCH GS 30-69 – late application timing)**

PEC <sub>sw</sub> (µg/L)	Scenario	STEP 4 – azoxystrobin			
		Multiple applications		Single application	
Nozzle reduction	Vegetative strip (m)	10	20	10	20
	No spray buffer (m)	10	20	10	20
None	D1 ditch	3.2780	-	1.6170	-
None	D1 stream	2.0570	-	1.0190	-
None	D2 ditch	4.4720	-	2.0040	-
None	D2 stream	2.7980	-	1.2520	-
None	D3 ditch	0.1121	-	0.1367	-
None	D4 pond	0.4906	-	0.1922	-
None	D4 stream	0.5247	-	0.2378	-
None	D5 pond	0.1803	-	0.0895	-
None	D5 stream	0.2594	-	0.1717	-
None	D6 ditch	0.3074	-	0.1379	-
None	R1 pond	0.1661	-	0.0945	-
None	R1 stream	1.0510	-	0.8107	-
None	R3 stream	1.0760	-	0.7575	-
None	R4 stream	0.7398	-	0.7398	-

- Simulation not performed

**Table 8.9-45:** Global maximum PEC<sub>sw</sub> values for azoxystrobin at FOCUS Step 4 following application of FF-075 to spring cereals (2 x 150 g as/ha, 14-day appln interval, BBCH GS 30-69 – early application timing)

PEC <sub>sw</sub> (µg/L)	Scenario	STEP 4 – azoxystrobin			
		Multiple applications		Single application	
Nozzle reduction	Vegetative strip (m)	10	20	10	20
	No spray buffer (m)	10	20	10	20
None	D1 ditch	3.8850	-	2.2160	-
None	D1 stream	2.4300	-	1.3880	-
None	D3 ditch	0.1120	-	0.1367	-
None	D4 pond	0.5251	-	0.2659	-
None	D4 stream	0.5564	-	0.3046	-
None	D5 pond	0.1777	-	0.0897	-
None	D5 stream	0.2733	-	0.1568	-
None	R4 stream	1.3790	-	0.8106	-

- Simulation not performed

**Table 8.9-46:** Global maximum PEC<sub>sw</sub> values for azoxystrobin at FOCUS Step 4 following application of FF-075 to spring cereals (2 x 150 g as/ha, 14-day appln interval, BBCH GS 30-69 – late application timing)

PEC <sub>sw</sub> (µg/L)	Scenario	STEP 4 – azoxystrobin			
		Multiple applications		Single application	
Nozzle reduction	Vegetative strip (m)	10	20	10	20
	No spray buffer (m)	10	20	10	20
None	D1 ditch	3.1150	-	1.5820	-
None	D1 stream	1.9530	-	0.9937	-
None	D3 ditch	0.1123	-	0.1369	-
None	D4 pond	0.7875	-	0.2534	-
None	D4 stream	0.7818	-	0.2791	-
None	D5 pond	0.1845	-	0.0913	-
None	D5 stream	0.2696	-	0.1614	-
None	R4 stream	0.8109	-	0.8109	-

- Simulation not performed

Comparison of the FOCUS Step 4  $PEC_{sw}$  values for azoxystrobin with the appropriate ecotoxicology endpoints indicated an acceptable risk to aquatic life in all cases, with the exception of the D1 (ditch) and D2 (ditch and stream) scenarios for winter cereals (early application timing), the D2 (ditch) scenario for winter cereals (late application timing) and the D1 (ditch) scenario for spring cereals (early application timing). Since drainflow is the predominant route of surface water exposure for azoxystrobin in the D1 and D2 scenarios, the spray drift mitigation measures applied to these scenarios at FOCUS Step 4 had no impact and the maximum  $PEC_{sw}$  values for these scenarios at Step 4 are equivalent to those obtained at FOCUS Step 3. As specific refinement options for drainflow at FOCUS Step 4 are not available, further calculations were therefore not conducted for these scenarios. However, in accordance with guidance in the Central Zone Working Document<sup>1</sup>, the D1 and D2 scenarios are not considered relevant for national assessment in the Central Zone Member States. Therefore, further assessment is not required.

### 8.9.2.3 $PEC_{sw/sed}$ of formulation

The specific application details of the formulated product FF-075 are summarised in Table 8.9-47.

**Table 8.9-47: Specific application data for FF-075**

Crop group	Application rate
Winter oilseed rape	0.8 L/ha or 880 g/ha <sup>1</sup> (FF-075)
Cereals	1.0 L/ha or 1100 g/ha <sup>1</sup> (FF-075)

1: Based on a formulation relative density of 1.100 g/mL.

Initial predicted environmental concentrations in surface water due to spray drift of the formulated product FF-075 are presented in Table 8.9-48. The calculations were conducted using the FOCUS spray drift calculator in SWASH. Since the formulation components other than the active substances are assumed to dissipate rapidly in the environment, it is only necessary to consider the initial concentration for FF-075 and only one application is considered. Calculations are presented considering the default FOCUS buffer and 5, 10 and 20 m no-spray buffer zones.

**Table 8.9-48: Drift  $PEC_{sw}$  for FF-075**

FOCUS water body	Distance (m)	FF-075 $PEC_{sw}$ (µg/L)	
		Winter oilseed rape 1 x 880 g/ha	Winter and spring cereals 1 x 1100 g/ha
Ditch	Default	5.6537	7.0671
	5	1.5325	1.9156
	10	0.8128	1.0159
	20	0.4223	0.5279
Pond	Default	0.1928	0.2410
	5	0.1668	0.2085
	10	0.1199	0.1499
	20	0.0801	0.1001
Stream*	Default	5.0348	6.2936
	5	1.8390	2.2987
	10	0.9754	1.2191
	20	0.5068	0.6335

\*  $PEC_{sw}$  for the stream scenario were manually adjusted by a factor of 1.2 to account for the additional 20% mass contribution from the upstream catchment in the FOCUS stream scenario

<sup>1</sup> Working Document of the Central Zone in the authorisation of plant protection products – Part B Section 8 – Environmental fate and behaviour. Version 1 rev. 1 – June 2018

The maximum predicted environmental concentration of FF-075 in surface water is 7.0671 µg/L considering a FOCUS default buffer, 2.2987 µg/L considering a 5 m no-spray buffer zone, 1.2191 µg/L considering a 10 m no-spray buffer zone and 0.6335 µg/L considering a 20 m no-spray buffer zone.

#### **zRMS comments:**

##### Prothioconazole

The PEC<sub>sw</sub> calculations have been accepted for the active substance prothioconazole and its metabolites prothioconazole-S-methyl (M01) and prothioconazole-desthio (M04), (M13) and (M42).

Substance input parameters correspond with the EFSA Conclusions (EFSA Conclusion 2010) and/or are in line with the current guidance document(s) (geomean K<sub>foc</sub>, geomean DT<sub>50</sub>).

Predicted environmental concentrations of prothioconazole and its soil and /or aquatic metabolites prothioconazole-S-methyl (M01), prothioconazole-desthio (M04), 1,2,4-triazole (M13) and prothioconazole-triazolylketone (M42), in surface water and sediment were calculated at FOCUS Steps 1 and 2. FOCUS Step 3 calculations were also conducted for prothioconazole and its metabolite prothioconazole-desthio (M04). Step 4 calculations were triggered for prothioconazole-desthio (M04) and additional calculations were therefore performed at FOCUS Step 4 by reducing spray drift and runoff inputs to simulate the use of 10 and 20 metre spray drift and runoff reduction buffer zones (vegetated filter strips).

##### Azoxystrobin

The PEC<sub>sw</sub> calculations have been accepted for the active substance azoxystrobin and its metabolites R234886, R401553, R402173.

Substance input parameters correspond with the EFSA Conclusions (EFSA Journal 2010; 8(4):1542) and/or are in line with the current guidance document(s) (geomean K<sub>foc</sub>, geomean DT<sub>50</sub>).

Predicted environmental concentrations of azoxystrobin and its soil and aquatic metabolites R234886, R401553 and R402173, in surface water and sediment were calculated at FOCUS Steps 1 and 2. FOCUS Steps 3 and 4 calculations were also conducted for azoxystrobin. Step 4 calculations were performed by reducing spray drift and runoff inputs to simulate the use of 10 and 20 metre spray drift and runoff reduction buffer zones (vegetated filter strips).

##### Formulation

The PEC<sub>sw</sub> calculations have been accepted for the formulation FF-775.

Predicted environmental concentrations of the formulated product FF-775 in surface water due to spray drift were calculated using the FOCUS spray drift calculator. The PEC<sub>sw</sub> calculations for formulation FF-0775 are presented in Table 8.9-48 considering the default FOCUS buffer and 5, 10 and 20 m no-spray buffer zones.

Nevertheless, additional simulations may be required by the SMS that do not accept calculations performed using FOCUS models.

## 8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

### Prothioconazole

**Table 8.10-1 Summary of atmospheric degradation and behaviour**

Compound	Prothioconazole
Direct photolysis in air	Not available, not required
Quantum yield of direct phototransformation	Not available, not required
Photochemical oxidative degradation in air	Half-life: 1.1 hours Chemical lifetime: 1.6 hours Calculated according to Atkinson (AOPWIN v1.87, 12 hour day, $1.5 \times 10^6$ OH radicals/cm <sup>3</sup> )
Volatilisation	Vapour pressure (Pa): $<4 \times 10^{-7}$ (20°C) Henry's Law Constant (Pa.m <sup>3</sup> /mol): $<3 \times 10^{-5}$ (20°C)
Metabolites	Prothioconazole-desthio (M04): Half-life: 14.2 hours Chemical lifetime: 20.5 hours Calculated according to Atkinson (AOPWIN v1.87, 12 hour day, $1.5 \times 10^6$ OH radicals/cm <sup>3</sup> )

The vapour pressure at 20°C of the active substance prothioconazole is  $< 10^{-5}$  Pa. Hence the active substance prothioconazole is regarded as non-volatile. In addition, the laboratory soil metabolism and degradation studies indicated that significant volatilisation of prothioconazole and its metabolite prothioconazole-desthio (M04) is unlikely to occur as no volatiles were detected at levels above 0.1% AR. Therefore, consideration of exposure of adjacent surface waters and terrestrial ecosystems by the active substance prothioconazole due to volatilisation with subsequent deposition is not required.

### Azoxystrobin

**Table 8.10-2 Summary of atmospheric degradation and behaviour**

Compound	Azoxystrobin
Direct photolysis in air	Not available, not required
Quantum yield of direct phototransformation	Not available, not required
Photochemical oxidative degradation in air	DT <sub>50</sub> : 2.7 hours derived by the Atkinson model (AOPWIN version 1.8) OH (12h) concentration assumed = $1.5 \times 10^6$ cm <sup>3</sup>
Volatilisation	Vapour pressure (Pa): $1.1 \times 10^{-10}$ at 20°C Henry's Law Constant (Pa.m <sup>3</sup> /mol): $7.4 \times 10^{-9}$ at 20°C No significant tendency for volatilisation was observed from soil and bean leaf surfaces up to 24 hours after the application of radiolabelled azoxystrobin (dose rates: 264 or 291 g as/ha)
Metabolites	None

The vapour pressure at 20°C of the active substance azoxystrobin is  $< 10^{-5}$  Pa. Hence the active substance azoxystrobin is regarded as non-volatile. Therefore consideration of exposure of adjacent surface waters and terrestrial ecosystems by the active substance azoxystrobin due to volatilisation with subsequent deposition is not required.

## Appendix 1 Lists of data considered in support of the evaluation

### List of data submitted by the applicant and relied on

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study</b> <b>Y/N</b>	<b>Owner</b>
KCP 9.2.4.1/01	Thomas, V.	2021	Predicted environmental concentrations of azoxystrobin and its metabolites in groundwater using the FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3 and FOCUS MACRO 5.5.4 groundwater models and scenarios Company Report No. 18-015-26-001 TSG Consulting Non GLP Unpublished	N	Rotam

**List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review**

**Prothioconazole**

Data evaluated as part of the EU review of prothioconazole under Directive 91/414/EEC

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
IIA 7/01	Borchers, H., Klein, O.	2002	JAU 6476: List of metabolites Bayer AG, Report No.: REG02-0014 Date: 2002-02-28 Non GLP Unpublished	N	BAY
IIA 7.1.1.1.1/01 IIA 7.1.1.2.1/01	Gilges, M.	2000	Aerobic degradation of JAU 6476 in two soils Bayer AG, Report No. MR-549/99 Date: 2000-01-27, amended: 2000-09-06 and 2001-12-05 GLP Unpublished	N	BAY
IIA 7.1.1.1.1/02 IIA 7.1.1.2.1/02	Hellpointner, E.	2001b	Degradation and metabolism of JAU6476 in aerobic soils Bayer AG, Report No. MR-104/01 Date: 2001-07-25 GLP Unpublished	N	BAY
IIA 7.1.1.1.1/03 IIA 7.1.1.2.1/03	Gilges, M.	2001a	Degradation of JAU6476-S-methyl (WAK7861) in four soils under aerobic conditions Bayer AG, Report No. MR-340/00 Date: 2001-06-29, amended: 2001-07-31 GLP Unpublished	N	BAY

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	Owner
IIA 7.1.1.1.1/04 IIA 7.1.1.2.1/04	Gilges, M.	2001b	Degradation of JAU6476-desthio (SXX0665) in four soils under aerobic conditions Bayer AG, Report No. MR-327/00 Date: 2001-06-29, amended: 2001-07-31 GLP Unpublished	N	BAY
IIA 7.1.1.1.2/01 IIA 7.1.1.2.1/02	Gilges, M.	2001d	Photolysis of JAU6476 on soil surface Bayer AG, Report No. MR-242/00 Date: 2001-07-25, amended: 2002-01-23 GLP Unpublished	N	BAY
IIA 7.1.1.2.2/01	Schramel, O.	2001a	Dissipation of JAU6476 (250 EC) in soil under field conditions (France, Germany, Great Britain, Italy) Bayer AG, Report No. RA-2152/98 Date: 2001-03-30 Report includes study nos.: R812587, R812595, R812609, R812617, R812625, R812633, R815667, R815675 GLP Unpublished	N	BAY
IIA 7.1.1.2.3/01	Schramel, O.	2001b	Determination of the storage stability of JAU6476 and the metabolites JAU6476-desthio and JAU6476-S-methyl in soil Bayer AG, Report No. MR-644/99 Date: 2001-03-30 GLP Unpublished	N	BAY
IIA 7.1.2/01	Hein, W.	1999	Adsorption/desorption of S-methyl-JAU 6476 on four different soils Generated by SLFA Neustadt, Bayer AG, Report No. FM774 Date: 1999-12-21 GLP Unpublished	N	BAY



<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
IIA 7.1.2/02	Briggs, G.G.	1973	A simple relationship between soil adsorption of organic chemicals and their octanol /water partition coefficients 7th British Insecticide and Fungicide Conference Proc., Nottingham/UK, 83-86, 1973 Report No. M9976 = MO-00-00125 Date: 1973 Non GLP Published	N	BAY
IIA 7.1.2/03	Fent, G.	1998	Adsorption/desorption of [phenyl- UL-14C]SXX 0665 on four different soils Generated by SLFA Neustadt, Bayer AG, Report No. FM768 Date: 1998-08-11 GLP Unpublished	N	BAY
IIA 7.1.3.1/01	Riegner, K.	1999	Leaching behaviour of JAU 6476 formulated as 250 EC in soil (parent leaching) Bayer AG, Report No.: MR-098/99 Date: 1999-04-20 GLP Unpublished	N	BAY
IIA 7.1.3.2/01	Babczinski, P.	2001	Aged soil column leaching of JAU6476 Bayer AG, Report No.: MR-364/00 Date: 2001-06-01, amended: 2001-07-04 GLP Unpublished	N	BAY
IIA 7.1.3.4/01	Schad, T.	2001b	Calculation of degradation rates of JAU6476 based on aerobic soil degradation studies Bayer AG, Report No.: MR-383/01 Date: 2001-10-04 Non GLP (calculation) Unpublished	N	BAY

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
IIA 7.1.3.4/02	Schad, T.	2001c	Calculation of temperature referenced first order DT <sub>50</sub> of JAU6476 and its metabolite JAU6476-desthio based on field dissipation studies conducted in Europe Bayer AG, Report No.: MR-468/01 Date: 2001-10-04 Non GLP (calculation) Unpublished	N	BAY
IIA 7.2.1/01	Schneider, J.	2001	Physical and chemical properties of JAU 6476 Bayer AG, Report No. 14 0120 0950 Date: 2001-08-08 GLP Unpublished	N	BAY
IIA 7.2.1.1/01	Riegner, K.	1998	Hydrolysis of [phenyl-UL-14C]JAU 6476 in sterile aqueous buffer solutions Bayer AG, Report No. MR-623/98 Date: 1998-11-16 GLP Unpublished	N	BAY
IIA 7.2.1.2/01	Hellpointner, E.	2001a	Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation in water of JAU 6476 Bayer AG, Report No. MR-101/01 Date: 2001-04-10 GLP Unpublished	N	BAY
IIA 7.2.1.2/02	Gilges, M.; Bornatsch, W.	2001	Photolysis of JAU 6476 in sterile aqueous buffer Bayer AG, Report No. MR-213/01 Date: 2001-07-20 GLP Unpublished	N	BAY

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
IIA 7.2.1.2/03	Hellpointner, E.	1993a	Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation of SXX 0665 in water Bayer AG, Report No. PF3852 Date: 1993-03-25 GLP Unpublished	N	BAY
IIA 7.2.1.2/04	Schaefer, H.	2001h	Calculation of DT <sub>50</sub> values of JAU6476 metabolite thiazocine generated by photolysis in aqueous solution Bayer AG, Report No. MR-591/01 Date: 2001-12-04 Non GLP (calculation) Unpublished	N	BAY
IIA 7.2.1.2/05	Schaefer, H.	2001i	Prediction of maximum amounts of JAU6476-thiazocine in surface water under natural conditions Bayer AG, Report No. MR-597/01 Date: 2001-12-07 Non GLP (calculation) Unpublished	N	BAY
IIA 7.2.1.2/06	Oggenfuss, P.	2000	Spectra of CGA 71019 Source: Novartis Crop Protection, Report No. 83573 Date: 2000-04-13 GLP Unpublished	N	Triazole Alanine Group (TAG)
IIA 7.2.1.3.2/01	Brumhard, B., Oi, M.	2001	Aerobic degradation and metabolism of the active ingredient JAU6476 in the water/sediment system Bayer AG, Report No. MR-395/01 Date: 2001-12-22, amended: 2002-02-27 GLP Unpublished	N	BAY

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
IIA 7.2.1.3.2/02	Scholz, K.	2001	Anaerobic aquatic metabolism of JAU6476 Bayer AG, Report No.: MR-275/01 Date: 2001-07-31 Non GLP Unpublished	N	BAY
IIA 7.2.2.2/01	Hellpointner, E.	1999	Calculation of the chemical lifetime of JAU 6476 in the troposphere Bayer AG, Report No. MR-093/99 Date: 1999-03-09 Non GLP Unpublished	N	BAY
IIA 7.2.2.2/02	Hellpointner, E.	2000	Calculation of the chemical lifetime of JAU 6476-DESTHIO in the troposphere Bayer AG, Report No. MR-323/00 Date: 2000-07-13 Non GLP Unpublished	N	BAY

## Azoxystrobin

Data evaluated as part of the original EU review of azoxystrobin under Directive 91/414/EEC

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	Owner
IIA 7.1.1.1.1 IIA 7.1.1.1.2 IIA 7.1.1.2.1	Mason, R. Butters, C.A.	1994	Degradation in soil under aerobic and anaerobic conditions Company Report No.: RJ 1754B GLP Unpublished	N	ZNC
IIA 7.1.1.2.1	Tummon, O.J.	1995	Laboratory degradation in three selected soil types Company Report No.: RJ 1819B GLP Unpublished	N	ZNC
IIA 7.1.1.2.1	Warinton, J.S., Chalofti, I., Harvey, B.R.	1995	Degradation of 14C-labelled compound in soil under laboratory conditions Company Report No.: RJ 1801B GLP Unpublished	N	ZNC
IIA 7.1.1.1.2	Winter, L., Joseph, R.S.	1995	Soil surface photolysis Company Report No.: RJ 1716B GLP Unpublished	N	ZNC
IIA 7.1.1.2.2	Earl, M., Chamier, O.D.	1995a	Field soil dissipation in a trial carried out in Germany during 1993/1994: Final report Company Report No.: RJ 1935B GLP Unpublished	N	ZNC

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
IIA 7.1.1.2.2	Earl, M., Chamier, O.D.	1995b	Field soil dissipation in a trial carried out in Germany during 1994/95 Company Report No.: RJ 1946B GLP Unpublished	N	ZNC
IIA 7.1.1.2.2	Earl, M., Hall, G.	1995	Field soil dissipation in a trial carried out in the United Kingdom during 1993/1994: Final report Company Report No.: RJ 1940B GLP Unpublished	N	ZNC
IIA 7.1.1.2.2	Earl, M., Bonfanti, F.	1995	Field soil dissipation in a trial carried out in Italy during 1993/1994 Company Report No.: RJ 1942B GLP Unpublished	N	ZNC
IIA 7.1.1.2.2	Earl, M., Tummon, O.J., Barnaud, C.	1995a	Field soil dissipation in a trial carried out in France during 1993/1994 Company Report No.: RJ 1938B GLP Unpublished	N	ZNC
IIA 7.1.1.2.2	Earl, M., Tummon, O.J., Barnaud, C.	1995b	Field soil dissipation in a trial carried out in France during 1993/1994 Company Report No.: RJ 1928B GLP Unpublished	N	ZNC
IIA 7.1.1.2.2	Earl, M., Tummon, O.J., Barnaud, C.	1995c	Field soil dissipation in a trial carried out in France during 1994/1995 Company Report No.: RJ 1943B GLP Unpublished	N	ZNC
IIA 7.1.1.2.2	Earl, M., Tummon, O.J., Bonfanti, F.	1995	Field soil dissipation in a trial carried out in Italy during 1994/95 Company Report No.: RJ 1944B GLP Unpublished	N	ZNC

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
IIA 7.1.1.2.2	Earl, M., Tummon, O.J., Eschenbrenner, P.	1995	Field soil dissipation in a trial carried out in France during 1993/1994 Company Report No.: RJ 1941B GLP Unpublished	N	ZNC
IIA 7.1.1.2.2	Earl, M., Tummon, O.J., Myles, P.	1995	Field soil dissipation in a trial carried out in the United Kingdom during 1994/95 Company Report No.: RJ 1945B GLP Unpublished	N	ZNC
IIA 7.1.2	Rowe, D., Lane, M.C.G.	1994	Adsorption and desorption in soil Company Report No.: RJ 1541B GLP Unpublished	N	ZNC
IIA 7.1.3.1 IIA 7.1.3.2	Butters, C.A., Mason, R.	1994	Mobility of ICIA5504 and its degradation products in prepared soil columns Company Report No.: RJ 1694B GLP Unpublished	N	ZNC
IIA 7.1.3.1	Hurt, A.D.	1994	Leaching of formulated material in soil columns Company Report No.: RJ 1777B GLP Unpublished	N	ZNC
IIA 7.1.3.1	Hurt, A.D.	1995	Leaching of formulated material in soil columns Company Report No.: RJ 1852B GLP Unpublished	N	ZNC
IIA 7.1.3.1	Hurt, A.D.	1995	Leaching of formulated material in soil columns Company Report No.: RJ 1874B GLP Unpublished	N	ZNC

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
IIA 7.2.1.1	Tummon, O.J.	1995	Aqueous hydrolysis at pH 4, 7 and 9 at 50°C Company Report No.: RJ 1971B GLP Unpublished	N	ZNC
IIA 7.2.1.3.2	Warinton, J.S.	1994	Degradation in water-sediment systems under laboratory conditions Company Report No.: RJ 1679B GLP Unpublished	N	ZNC
IIA 7.2.2	Kuet, S.F.	1995	Volatilization from soil and leaf surfaces following application as a SC formulation Company Report No.: RJ 1885B GLP Unpublished	N	ZNC

Data evaluated as part of the renewal of approval of azoxystrobin under Directive 91/414/EEC

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
IIA 7.2.1/01	Evans, P.G.	2001	Azoxystrobin: Laboratory degradation study in three soil types Syngenta Report No.: ICI5504/1154 Syngenta Crop Protection AG, Switzerland Non GLP Unpublished	N	SYN



<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
IIA 7.2.1/02	Warinton, J.S., Chalofti, I., Harvey, B.R.	1996	ICIA5504: Degradation in soil under aerobic and anaerobic laboratory conditions: Final report Syngenta Report No.: ICI5504/0782 Zeneca Agrochemicals, UK GLP Unpublished	N	SYN
IIA 7.2.1/03	Harvey, B.	2008	Azoxystrobin: Rate of degradation of azoxystrobin in laboratory soils according to FOCUS kinetics (2006) guidance Syngenta Report No.: ICI5504_10293 Syngenta, UK Non GLP Unpublished	N	SYN
IIA 7.2.3/01	Jones, R.N., Entwistle, K.	1998	R401553: Laboratory degradation in three soil types Syngenta Report No.: ICI5504/0841 Zeneca Agrochemicals, UK GLP Unpublished	N	SYN
IIA 7.2.3/02	Jones, R.N., Campbell, A.	1998	R402173: Laboratory degradation in three soil types Syngenta Report No.: ICI5504/0840 Zeneca Agrochemicals, UK GLP Unpublished	N	SYN
IIA 7.2.3/03	Jones, R.N., Robertson, T.	1999	R234886: Laboratory degradation in three soil types Syngenta Report No.: ICI5504/0842 Zeneca Agrochemicals, UK GLP Unpublished	N	SYN

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
IIA 7.2.3/04	Harvey, B.	2008a	Rate of degradation of azoxystrobin soil degradates according to FOCUS kinetics (2006) guidance Syngenta Report No.: R234886/0006 Syngenta, UK Non GLP Unpublished	N	SYN
IIA 7.3.1/01	Hardy, I., Patel, M.	2008	Azoxystrobin – kinetic modelling evaluation of data from field soil residue studies conducted in Europe normalised to 20°C (Q10 2.58) and pF2 Syngenta Report No.: ICI5504_10854 Battelle UK Ltd., UK Non GLP Unpublished	N	SYN
IIA 7.3.1/02	Emburey, S.N., Kay, J.	2002	Residue levels in soil following in-furrow treatment from a trial carried out in the United Kingdom during 2000/2001 Syngenta Report No.: ICI5504/1522 Syngenta Crop Protection AG, Switzerland GLP Unpublished	N	SYN
IIA 7.3.1/03	Emburey, S.N., Poppezijs, W.F.B.	2002	Residue levels in soil following in-furrow treatment from a trial carried out in the Netherlands during 2000/2001 Syngenta Report No.: ICI5504/1593 Syngenta Crop Protection AG, Switzerland GLP Unpublished	N	SYN
IIA 7.3.1/04	Emburey, S.N.	2002	Residue levels in soil following in-furrow treatment from a trial carried out in the United Kingdom during 2000/2001 Syngenta Report No.: ICI5504/1560 Syngenta Crop Protection AG, Switzerland GLP Unpublished	N	SYN

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
IIA 7.3.1/05	Jones, R.N., Bouwmann, J.J.	2001	Residue levels in soil following in-furrow treatment from trials carried out in the Netherlands during 1999-2000 Syngenta Report No.: ICI5504/1297 Syngenta Crop Protection AG, Switzerland GLP Unpublished	N	SYN
IIA 7.3.1/06	Hardy, I., Patel, M.	2008a	Azoxystrobin – kinetic modelling analysis of azoxystrobin from in-furrow field soil residue studies conducted in Europe normalised to 20°C (Q10 2.58) and pF2 Syngenta Report No.: ICI5504_10853 Battelle UK Ltd., UK Non GLP Unpublished	N	SYN
IIA 7.4.2/01	Rowe, D., Lane, M.C.G.	1995a	ICIA5504: Adsorption and desorption properties in soil of R401553 Syngenta Report No.: ICI5504/0792 Zeneca Agrochemicals, UK GLP Unpublished	N	SYN
IIA 7.4.2/02	Rowe, D., Lane, M.C.G.	1995b	ICIA5504: Adsorption and desorption properties in soil of R402173 Syngenta Report No.: ICI5504/0789 Zeneca Agrochemicals, UK GLP Unpublished	N	SYN
IIA 7.4.2/03	Ferguson, R.E., Muller, K., Lane, M.C.G.	1994	ICIA5504: Adsorption and desorption properties in soil of R234886 Syngenta Report No.: ICI5504/0783 Zeneca Agrochemicals, UK GLP Unpublished	N	SYN

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	Owner
IIA 7.8.3/01	Harvey, B.	2008b	Azoxystrobin: Rate of degradation in laboratory water/sediment systems according to FOCUS kinetics (2006) guidance Syngenta Report No.: ICI5504_10132 Syngenta, UK Non GLP Unpublished	N	SYN
IIA 7.8.3/02	Jones, R.N., Lake, A.	2000	Azoxystrobin: Dissipation in an outdoor experimental pond Syngenta Report No.: ICI5504/0831 Zeneca Agrochemicals, UK GLP Unpublished	N	SYN
IIA 7.10/01	Hayes, S.E.	1996	Azoxystrobin – calculation of half-life by reaction with atmospheric hydroxyl radicals Syngenta Report No.: ICI5504/1559 Zeneca Agrochemicals, UK Non GLP Unpublished	N	SYN

**List of data submitted by the applicant and not 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	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP	Y/N	Owner

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	Owner
			Published/Unpublished		

**List of data relied on not submitted by the applicant but necessary for evaluation**

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	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

## **Appendix 2 Detailed evaluation of the new Annex II studies**

No new Annex II data are submitted.

## Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)

### A 3.1 Thomas, V. (2021)

The following groundwater modelling on azoxystrobin and its metabolites has not previously been reviewed and is provided in support of this assessment.

Comments of zRMS:	Accepted.
-------------------	-----------

Reference:	KCP 9.2.4.1/01
Report	Predicted Environmental Concentrations of Azoxystrobin and its Metabolites in Groundwater using the FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3 and FOCUS MACRO 5.5.4 Groundwater Models and Scenarios
	Thomas, V. (2021)
	TSG Consulting, Report No. 18-015-26-001
Guideline(s):	FOCUS (2000, 2002, 2011, 2012, 2014)
Deviations:	No
GLP:	No (not applicable)
Acceptability:	Yes/No/Supplementary

### Methodology

Groundwater modelling of azoxystrobin and its metabolites R234886, R401553 and R402173 has been performed using the relevant FOCUS groundwater scenarios and the FOCUS groundwater models, PEARL (version 4.4.4), PELMO (version 5.5.3) and MACRO (version 5.5.4). The modelling was based on applications to winter oilseed rape and winter and spring cereals in accordance with the critical GAP for the FF-075 formulation in Europe. The FOCUS crops 'winter oilseed rape', 'winter cereals' and 'spring cereals' and their associated scenarios were selected for the simulations. For winter oilseed rape, two applications of 120 g as/ha were simulated at an interval of 14 days, with application dates selected to coincide with BBCH growth stage 55-69. For winter and spring cereals, two applications of 150 g as/ha were simulated at an interval of 14 days, with application dates selected to coincide with BBCH growth stage 30-69. Absolute application dates were selected for each crop group using the AppDate tool (v3.06). In order to cover the relatively wide application windows for each crop, two application timings (early and late) were simulated. For early application, the first application date was set to coincide with the date of the earliest recommended growth stage and for late application, the final application date was set to coincide with the date of the latest recommended growth stage. The simulated application dates for each crop scenario are shown in Table A 3-1. As the formulation is foliar applied, crop interception was accounted for in the simulations in accordance with FOCUS guidance. For winter oilseed rape, a value of 80%, which corresponds to flowering at BBCH GS 40-89 was assumed in the simulations. For winter and spring cereals, a value of 80%, corresponding to stem elongation at BBCH GS 30-39 was assumed in the early application simulations and a value of 90%, corresponding to flowering at BBCH GS 40-69 was assumed in the simulations for late application.

**Table A 3-1: Application dates used for groundwater risk assessment**

Crop	Scenario	Application dates (absolute)	
		Early application	Late application
Winter oilseed rape	Châteaudun	10 April, 24 April	30 April, 14 May
	Hamburg	01 May, 15 May	16 May, 30 May
	Kremsmünster	30 April, 14 May	16 May, 30 May
	Okehampton	25 April, 09 May	11 May, 25 May
	Piacenza	05 April, 19 April	21 April, 05 May
	Porto	23 March, 06 April	30 April, 14 May
Winter cereals	Châteaudun	15 April, 29 April	31 May, 14 June
	Hamburg	04 May, 18 May	08 June, 22 June
	Jokioinen	14 May, 28 May	26 June, 10 July
	Kremsmünster	24 April, 08 May	11 June, 25 June
	Okehampton	21 April, 05 May	24 May, 07 June
	Piacenza	19 March, 02 April	12 May, 26 May
	Porto	30 January, 13 February	04 May, 18 May
	Sevilla	06 January, 20 January	14 March, 28 March
	Thiva	18 January, 01 February	13 April, 27 April
Spring cereals	Châteaudun	16 April, 30 April	08 June, 22 June
	Hamburg	28 April, 12 May	14 June, 28 June
	Jokioinen	05 June, 19 June	03 July, 17 July
	Kremsmünster	27 April, 11 May	14 June, 28 June
	Okehampton	22 April, 06 May	04 June, 18 June
	Porto	16 April, 30 April	08 June, 22 June

The key chemical input parameters for azoxystrobin and its metabolites selected for use in the modelling are summarised in Table A 3-2. Unless otherwise stated, these values were derived from the agreed EU list of endpoints in the EFSA Conclusion (EFSA Journal 2010; 8(4):1542) and the Assessment Report for azoxystrobin (May 2009). All the other pesticide related inputs were used as per the default values provided by FOCUS.



**Table A 3-2: Chemical input parameters used for azoxystrobin and its metabolites in the groundwater simulations**

Compound	Azoxystrobin	R234886	R401553	R402173	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	403.4	389.4	213.2	333.3	Yes (EFSA Journal 2010; 8(4):1542)
Water solubility (g/mol)	6.0 (20°C)	57 (20°C)	560 (20°C)	61 (20°C)	
Saturated vapour pressure (Pa)	1.1 x 10 <sup>-10</sup> (20°C)	0 (worst-case assumption)	0 (worst-case assumption)	0 (worst-case assumption)	
DT <sub>50</sub> in soil (d) (normalised to pF2, 20°C, with Q <sub>10</sub> of 2.58)	Microbial: <sup>#</sup> 78 (overall geometric mean DegT <sub>50field</sub> of the soil incorporated studies (80.2 days, n=3) and the soil non- incorporated studies (slow phase, 75.9 days, n=10))  Photolysis: <sup>#</sup> 3 (geometric mean DegT <sub>50field</sub> of the soil non- incorporated studies (fast phase, n=10))	110.4 (geometric mean DegT <sub>50lab</sub> , n=5)	1.1 (geometric mean DegT <sub>50lab</sub> , n=3)	4.7 (geometric mean DegT <sub>50lab</sub> , n=3)	
K <sub>foc</sub> (mL/g)/K <sub>fom</sub>	391.5/227.1* (geometric mean, n=6)	Tier 1: 21/12.18* (worst-case, n=6)**  Tier 2: Scenario specific K <sub>foc</sub> / K <sub>fom</sub> values:** Châteaudun = 24/14* Hamburg = 133/77* Jokioinen = 159/92* Kremsmünster = 38/22* Okehampton = 242/140* Piacenza = 68/40*	142.6/82.71* (geometric mean, n=6)	25/14.5* (worst-case, n=6)**	

Compound	Azoxystrobin	R234886	R401553	R402173	Value in accordance with EU endpoint y/n/ Reference
		Porto = 624/362* Sevilla = 50/29* Thiva = 38/22*			
1/n	0.86 (arithmetic mean, n=6)	Tier 1: 0.76 (corresponds to worst-case $K_{foc}$ )**  Tier 2: 0.85 (arithmetic mean, n=6)	0.85 (arithmetic mean, n=6)	0.96 (corresponds to worst-case $K_{foc}$ )**	
Plant uptake factor	0 (worst-case assumption)	0 (worst-case assumption)	0 (worst-case assumption)	0 (worst-case assumption)	
Formation fraction	-	0.874 (from parent)	0.392 (from parent) 0.468 (from R402173)	0.385 (from parent)	
FCONVERT***	-	0.844	1.0 (worst-case assumption, accounts for combined formation from parent and R402173)	0.318	No MACRO specific parameter

# In order to account for the microbial and photolytic degradation of azoxystrobin in soil, two sets of modelling simulations were conducted. The first simulation set assumes that azoxystrobin undergoes microbial degradation with a DegT<sub>50</sub> of 78 days to form metabolite R234886 and the second simulation set assumes that azoxystrobin undergoes photolytic degradation with a DegT<sub>50</sub> of 3 days to form metabolites R401553 and R402173 (with R402173 subsequently degrading to R401553).

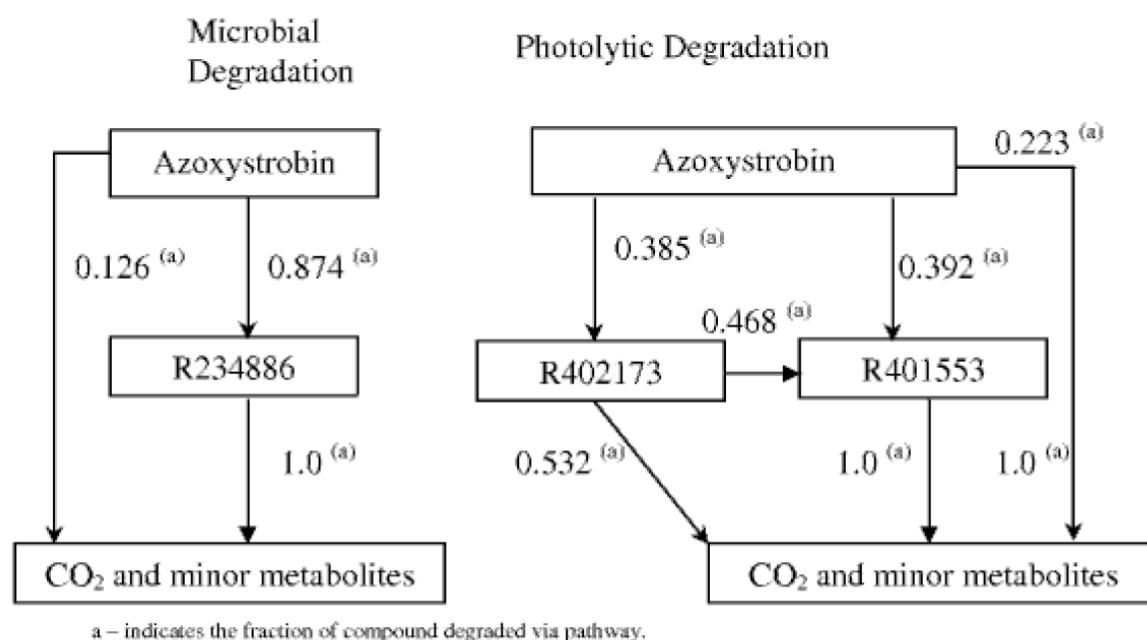
\*  $K_{fom}$  calculated from  $K_{foc}/1.724$

\*\* As the sorption of metabolites R234886 and R402173 is pH dependent, the lowest  $K_{foc}$  and associated 1/n values from the sorption datasets were selected for input as a worst-case at Tier 1. Tier 2 calculations were performed for metabolite R234883, using scenario specific  $K_{foc}$  values derived using regression analysis.

\*\*\* Specific MACRO parameter. The molar based formation fractions for metabolites R234886 and R402173 were adjusted to account for molar mass differences between metabolite and parent to obtain conversion fractions for input into the MACRO model.

The degradation mechanism of azoxystrobin in soil is complex and depends on the relative importance of microbial and photolytic processes. Modelling the three metabolites R234886, R401553 and R402173, which form via the different mechanisms (microbial action and photolytic action) is not possible in a single simulation, therefore, as a worst-case and in line with the approach presented in the EFSA Conclusion (EFSA Journal 2010; 8(4):1542), two sets of simulations were performed. The first set assumed that azoxystrobin degraded via microbial degradation to metabolite R234886 and the second set assumed that azoxystrobin degraded due to photolysis to form metabolites R401553 and R402173, with metabolite R402173 subsequently degrading to form metabolite R401553. The simulated degradation schemes are illustrated in Figure A 3-1 below.

**Figure A 3-1: Schematic of the simulated degradation pathways for azoxystrobin and its metabolites R234886, R401553 and R402173**



As the sorption of metabolites R234886 and R402173 is pH dependent (increasing sorption with decreasing soil pH), the lowest  $K_{\text{foc}}$  and associated  $1/n$  values from the sorption datasets for each metabolite were initially selected for input as a worst-case at Tier 1. In line with the approach presented in the EFSA Conclusion (EFSA Journal 2010; 8(4):1542) and detailed in the Assessment Report for azoxystrobin (May 2009), further simulations were then performed for metabolite R234886 at Tier 2 using scenario specific  $K_{\text{foc}}$  values, which were derived using regression analysis (see Table A 3-2).

Since the soil degradation schemes of azoxystrobin cannot be implemented in the GUI of the MACRO model, each metabolite was assumed to form directly from parent. For this purpose and in order to account for residues of metabolite R401553 formed from R402173, the individual formation fractions (azoxystrobin to R401553 and the overall fraction from azoxystrobin to R402173 to R401553) can be combined to produce an overall fraction for modelling. However, in this case, as a simplified and conservative approach, a worst-case formation fraction of 1.0 from parent to R401553 was assumed in the MACRO simulations, without further adjustment. The molar based formation fractions for metabolites R234886 and R402173 were adjusted to account for molar mass differences between metabolite and parent to obtain conversion fractions for MACRO.

## Results and discussion

Predicted 80<sup>th</sup> percentile annual average concentrations in groundwater ( $\text{PEC}_{\text{gw}}$ ) at 1 m depth for azoxystrobin and its metabolites R234886, R401553 and R402173, based on worst-case sorption endpoints for metabolites R234886 and R402173 (Tier 1), are shown in Tables A 3-3 to A 3-5. In all

cases, PEC<sub>gw</sub> for azoxystrobin and its metabolites R401553 and R402173 were <0.001 µg/L. PEC<sub>gw</sub> for metabolite R234886 were >0.1 µg/L in the majority scenarios, ranging from 0.041 to 6.938 µg/L.

**Table A 3-3: PEC<sub>gw</sub> for azoxystrobin and its metabolites calculated using FOCUS PEARL (version 4.4.4)**

Crop	Scenario	80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)			
		Azoxystrobin	R234886	R401553	R402173
Winter oilseed rape (2 x 120 g as/ha, 14-day appln interval, BBCH 55-69)	<b>Early application timing</b>				
	Châteaudun	<0.001	3.019	<0.001	<0.001
	Hamburg	<0.001	4.229	<0.001	<0.001
	Kremsmünster	<0.001	2.711	<0.001	<0.001
	Okehampton	<0.001	2.717	<0.001	<0.001
	Piacenza	<0.001	1.746	<0.001	<0.001
	Porto	<0.001	2.017	<0.001	<0.001
	<b>Late application timing</b>				
	Châteaudun	<0.001	3.053	<0.001	<0.001
	Hamburg	<0.001	4.264	<0.001	<0.001
	Kremsmünster	<0.001	2.721	<0.001	<0.001
	Okehampton	<0.001	2.744	<0.001	<0.001
	Piacenza	<0.001	1.758	<0.001	<0.001
	Porto	<0.001	2.072	<0.001	<0.001
Winter cereals (2 x 150 g as/ha, 14-day appln interval, BBCH 30-69)	<b>Early application timing</b>				
	Châteaudun	<0.001	3.323	<0.001	<0.001
	Hamburg	<0.001	5.575	<0.001	<0.001
	Jokioinen	<0.001	4.492	<0.001	<0.001
	Kremsmünster	<0.001	3.625	<0.001	<0.001
	Okehampton	<0.001	3.781	<0.001	<0.001
	Piacenza	<0.001	2.811	<0.001	<0.001
	Porto	<0.001	2.325	<0.001	<0.001
	Sevilla	<0.001	0.182	<0.001	<0.001
	Thiva	<0.001	3.577	<0.001	<0.001
	<b>Late application timing</b>				
	Châteaudun	<0.001	1.286	<0.001	<0.001
	Hamburg	<0.001	2.306	<0.001	<0.001
	Jokioinen	<0.001	1.764	<0.001	<0.001
	Kremsmünster	<0.001	1.504	<0.001	<0.001
	Okehampton	<0.001	1.594	<0.001	<0.001
	Piacenza	<0.001	1.146	<0.001	<0.001
	Porto	<0.001	0.970	<0.001	<0.001

Crop	Scenario	80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)			
		Azoxystrobin	R234886	R401553	R402173
	Sevilla	<0.001	0.041	<0.001	<0.001
	Thiva	<0.001	1.533	<0.001	<0.001
Spring cereals (2 x 150 g as/ha, 14-day appln interval, BBCH 30-69)	<b>Early application timing</b>				
	Châteaudun	<0.001	3.048	<0.001	<0.001
	Hamburg	<0.001	6.938	<0.001	<0.001
	Jokioinen	<0.001	4.242	<0.001	<0.001
	Kremsmünster	<0.001	3.987	<0.001	<0.001
	Okehampton	<0.001	3.993	<0.001	<0.001
	Porto	<0.001	2.475	<0.001	<0.001
	<b>Late application timing</b>				
	Châteaudun	<0.001	1.177	<0.001	<0.001
	Hamburg	<0.001	2.867	<0.001	<0.001
	Jokioinen	<0.001	1.641	<0.001	<0.001
	Kremsmünster	<0.001	1.611	<0.001	<0.001
	Okehampton	<0.001	1.668	<0.001	<0.001
	Porto	<0.001	1.054	<0.001	<0.001

**Table A 3-4: PEC<sub>gw</sub> for azoxystrobin and its metabolites calculated using FOCUS PELMO (version 5.5.3)**

Crop	Scenario	80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)			
		Azoxystrobin	R234886	R401553	R402173
Winter oilseed rape (2 x 120 g as/ha, 14-day appln interval, BBCH 55-69)	<b>Early application timing</b>				
	Châteaudun	<0.001	2.971	<0.001	<0.001
	Hamburg	<0.001	4.519	<0.001	<0.001
	Kremsmünster	<0.001	3.144	<0.001	<0.001
	Okehampton	<0.001	3.033	<0.001	<0.001
	Piacenza	<0.001	2.451	<0.001	<0.001
	Porto	<0.001	2.345	<0.001	<0.001
	<b>Late application timing</b>				
	Châteaudun	<0.001	2.999	<0.001	<0.001
	Hamburg	<0.001	4.568	<0.001	<0.001
	Kremsmünster	<0.001	3.155	<0.001	<0.001
	Okehampton	<0.001	3.066	<0.001	<0.001
	Piacenza	<0.001	2.466	<0.001	<0.001
	Porto	<0.001	2.423	<0.001	<0.001

Crop	Scenario	80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)			
		Azoxystrobin	R234886	R401553	R402173
Winter cereals (2 x 150 g as/ha, 14-day appln interval, BBCH 30-69)	<b>Early application timing</b>				
	Châteaudun	<0.001	3.270	<0.001	<0.001
	Hamburg	<0.001	6.011	<0.001	<0.001
	Jokioinen	<0.001	4.837	<0.001	<0.001
	Kremsmünster	<0.001	4.259	<0.001	<0.001
	Okehampton	<0.001	3.927	<0.001	<0.001
	Piacenza	<0.001	3.527	<0.001	<0.001
	Porto	<0.001	2.822	<0.001	<0.001
	Sevilla	<0.001	0.903	<0.001	<0.001
	Thiva	<0.001	2.250	<0.001	<0.001
	<b>Late application timing</b>				
	Châteaudun	<0.001	1.280	<0.001	<0.001
	Hamburg	<0.001	2.478	<0.001	<0.001
	Jokioinen	<0.001	1.936	<0.001	<0.001
	Kremsmünster	<0.001	1.779	<0.001	<0.001
	Okehampton	<0.001	1.688	<0.001	<0.001
	Piacenza	<0.001	1.562	<0.001	<0.001
	Porto	<0.001	1.215	<0.001	<0.001
	Sevilla	<0.001	0.237	<0.001	<0.001
	Thiva	<0.001	0.922	<0.001	<0.001
Spring cereals (2 x 150 g as/ha, 14-day appln interval, BBCH 30-69)	<b>Early application timing</b>				
	Châteaudun	<0.001	2.659	<0.001	<0.001
	Hamburg	<0.001	5.665	<0.001	<0.001
	Jokioinen	<0.001	4.156	<0.001	<0.001
	Kremsmünster	<0.001	4.013	<0.001	<0.001
	Okehampton	<0.001	3.816	<0.001	<0.001
	Porto	<0.001	2.613	<0.001	<0.001
	<b>Late application timing</b>				
	Châteaudun	<0.001	1.028	<0.001	<0.001
	Hamburg	<0.001	2.332	<0.001	<0.001
	Jokioinen	<0.001	1.608	<0.001	<0.001
	Kremsmünster	<0.001	1.613	<0.001	<0.001
	Okehampton	<0.001	1.627	<0.001	<0.001
	Porto	<0.001	1.163	<0.001	<0.001

**Table A 3-5: PEC<sub>gw</sub> for azoxystrobin and its metabolites calculated using FOCUS MACRO (version 5.5.4)**

Crop	Scenario	80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)			
		Azoxystrobin	R234886	R401553	R402173
Winter oilseed rape (2 x 120 g as/ha, 14-day appln interval, BBCH 55-69)	<b>Early application timing</b>				
	Châteaudun	<0.001	2.350	<0.001	<0.001
	<b>Late application timing</b>				
	Châteaudun	<0.001	2.310	<0.001	<0.001
Winter cereals (2 x 150 g as/ha, 14-day appln interval, BBCH 30-69)	<b>Early application timing</b>				
	Châteaudun	<0.001	2.960	<0.001	<0.001
	<b>Late application timing</b>				
	Châteaudun	<0.001	1.170	<0.001	<0.001
Spring cereals (2 x 150 g as/ha, 14-day appln interval, BBCH 30-69)	<b>Early application timing</b>				
	Châteaudun	<0.001	2.600	<0.001	<0.001
	<b>Late application timing</b>				
	Châteaudun	<0.001	1.060	<0.001	<0.001

Further simulations were conducted for metabolite R234886 at Tier 2 using scenario specific K<sub>loc</sub> values derived using linear regression analysis. The predicted 80<sup>th</sup> percentile annual average concentrations in groundwater (PEC<sub>gw</sub>) at 1 m depth for metabolite R234886 at Tier 2 are shown in Table A 3-6.

**Table A 3-6: PEC<sub>gw</sub> for metabolite R234886 calculated using scenario specific K<sub>loc</sub> values with FOCUS PEARL (version 4.4.4), FOCUS PELMO (version 5.5.3) and FOCUS MACRO (version 5.5.4)**

Crop	Scenario	80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)		
		FOCUS PEARL	FOCUS PELMO	FOCUS MACRO
Winter oilseed rape (2 x 120 g as/ha, 14-day appln interval, BBCH 55-69)	<b>Early application timing</b>			
	Châteaudun	4.678	4.682	3.770
	Hamburg	0.268	0.249	-
	Kremsmünster	2.478	2.848	-
	Okehampton	0.013	0.019	-
	Piacenza	0.639	0.819	-
	Porto	<0.001	<0.001	-
	<b>Late application timing</b>			
	Châteaudun	4.709	4.742	3.740
	Hamburg	0.271	0.253	-
	Kremsmünster	2.486	2.859	-
	Okehampton	0.013	0.019	-
	Piacenza	0.647	0.828	-

Crop	Scenario	80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)		
		FOCUS PEARL	FOCUS PELMO	FOCUS MACRO
	Porto	<0.001	<0.001	-
Winter cereals (2 x 150 g as/ha, 14-day appln interval, BBCH 30-69)	<b>Early application timing</b>			
	Châteaudun	4.901	4.731	4.400
	Hamburg	0.362	0.378	-
	Jokioinen	0.013	0.015	-
	Kremsmünster	3.229	3.781	-
	Okehampton	0.022	0.024	-
	Piacenza	1.041	1.301	-
	Porto	<0.001	<0.001	-
	Sevilla	0.049	0.166	-
	Thiva	3.046	1.893	-
	<b>Late application timing</b>			
	Châteaudun	2.259	2.193	1.990
	Hamburg	0.125	0.122	-
	Jokioinen	0.002	0.002	-
	Kremsmünster	1.462	1.646	-
	Okehampton	0.005	0.006	-
	Piacenza	0.430	0.549	-
	Porto	<0.001	<0.001	-
	Sevilla	0.016	0.041	-
	Thiva	1.365	0.844	-
Spring cereals (2 x 150 g as/ha, 14-day appln interval, BBCH 30-69)	<b>Early application timing</b>			
	Châteaudun	4.515	3.979	3.870
	Hamburg	0.418	0.321	-
	Jokioinen	0.010	0.008	-
	Kremsmünster	3.492	3.459	-
	Okehampton	0.019	0.016	-
	Porto	<0.001	<0.001	-
	<b>Late application timing</b>			
	Châteaudun	2.078	1.841	1.790
	Hamburg	0.146	0.106	-
	Jokioinen	0.001	0.001	-
	Kremsmünster	1.554	1.507	-
	Okehampton	0.004	0.004	-
	Porto	<0.001	<0.001	-

- Scenario not defined in FOCUS MACRO



PEC<sub>gw</sub> for metabolite R234886 based on scenario specific K<sub>foc</sub> values at Tier 2 were >0.1 µg/L in four of the six scenarios for winter oilseed rape ranging from <0.001 to 4.742 µg/L. For cereals, PEC<sub>gw</sub> were >0.1 µg/L in six of the nine scenarios for winter cereals, ranging from <0.001 µg/L to 4.901 µg/L, and in three of the six scenarios for spring cereals, ranging from <0.001 to 4.515 µg/L.

## Conclusion

The risk to groundwater from azoxystrobin and its metabolites R234886, R401553 and R402173 was assessed following applications to winter oilseed rape at the maximum recommended application rate of 2 x 120 g as/ha, with a minimum application interval of 14 days and applications to winter and spring cereals at the maximum recommended application rate of 2 x 150 g as/ha, with a minimum application interval of 14 days. In all cases, PEC<sub>gw</sub> for azoxystrobin and its metabolites R401553 and R402173 were considerably below the 0.1 µg/L regulatory threshold (max. PEC<sub>gw</sub> <0.001 µg/L), clearly demonstrating that the FF-075 formulation can be used as proposed in Europe, without risk of azoxystrobin or its metabolites R401553 and R402173 exceeding acceptable levels in groundwater. For metabolite R234886, PEC<sub>gw</sub> were >0.1 µg/L in four of the six scenarios for winter oilseed rape (max. PEC<sub>gw</sub> 4.742 µg/L), in six of the nine scenarios for winter cereals (max. PEC<sub>gw</sub> 4.901 µg/L) and in three of the six scenarios for spring cereals (max. PEC<sub>gw</sub> 4.515 µg/L), thus triggering a groundwater relevance assessment for this metabolite. A full relevance assessment for R234886 in groundwater is provided in document Part B Section 10.

## **A 3.2                    Example FOCUS Step 1 and 2 Outputs**

### **Prothioconazole and its metabolites**

**Prothioconazole (winter oilseed rape, 2 x 160 g as/ha – winter oilseed rape, Step 1)**

**STEPS 1-2 in FOCUS**

**FOCUS Surface water Tool for Exposure Predictions Step 1**

*developed by Michael Klein*

Program version: Version 3.2  
Date of this simulation: 18/01/2021, 16:53:10

**OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION**

*Comments: OSR, winter*

Active substance:	Prothio 1
Application rate (g/ha) of a.i.:	160.00
Application/crop type:	oil seed rape, winter
Number of applications per season:	2.00
Application interval (d):	14.00
Water solubility (mg/L):	300.00
KOC compound(L/kg):	1765.00
DT50 water/sediment (d):	39.50

**SCENARIO DATA USED IN THE CALCULATION**

Distance to the water body (m):	1.00
Spraydrift (% of application):	2.7590
Runoff + drainage(% of application):	10.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

**RESULTS OF THE CALCULATION**

Equivalent app. rate for drift (g/ha):	160.00
Equivalent app. rate for runoff/drainage(g/ha):	160.00
Equivalent app. rate for runoff/drainage(g/ha) of parent:	0.00E+00
Loading to water body via drift (mg/m <sup>2</sup> ):	0.8829
Loading to water body via runoff/drainage(mg/m <sup>2</sup> ):	32.0000
fraction of substance entering water body in water phase:	0.2982
fraction of substance entering water body in sediment phase:	0.7018

Table: Calculated Concentrations in the water body

Time (d)	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	34.7521		561.4314	
1	32.1182	33.4351	566.8858	564.1586
2	31.5595	32.6366	557.0248	563.0497

---

4	30.4711	31.8243	537.8145	555.2066
7	28.9084	30.9066	510.2341	541.7909
14	25.5669	29.0550	451.2554	510.9660
21	22.6116	27.3897	399.0941	482.1910
28	19.9979	25.8617	352.9622	455.5323
42	15.6419	23.1514	276.0794	408.0043
50	13.5932	21.7822	239.9197	383.9359
100	5.6529	15.4160	99.7735	271.8323

Maximum PEC<sub>sw</sub> values in water and sediment are calculated from sum of individual applications.

**Compare with ecotox endpoints. If TER values are less than regulatory triggers, then go to Step 2**

**Prothioconazole (winter oilseed rape, 2 x 160 g as/ha – winter oilseed rape, NEU, Step 2)**

## **STEPS 1-2 in FOCUS**

### **FOCUS Surface water Tool for Exposure Predictions Step 2**

*developed by Michael Klein*

Program version: Version 3.2  
Date of this simulation: 18/01/2021, 15:32:20

#### OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

*Comments: OSR, winter*

Active substance:	Prothio 1
Application rate (g/ha) of a.i.:	160.00
Crop Interception:	full canopy (75 %)
Application/crop type:	oil seed rape, winter
Number of applications per season:	2
Application interval (d):	14.00
Region and season of application:	North Europe, Mar. - May
Water solubility (mg/L):	300.00
KOC assessed compound(L/kg):	1765.00
KOC parent compound(L/kg):	0.00E+00
DT50 water(d):	39.50
DT50 sediment (d):	39.50
DT50 soil (d):	1.20

#### SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m):	1.00
Spraydrift for multiple applications (% of application):	2.4380
Spraydrift for single application (% of application):	2.7590
Runoff + drainage(% of application):	2.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

#### RESULTS OF THE CALCULATION

Number of application per season considered for this run:	2
Equivalent application rate for drift (g/ha):	160.00
Equivalent application rate for runoff/drainage(g/ha):	40.00
Loading to water body per drift event(mg/m <sup>2</sup> ):	0.3901
Loading to water body via runoff/drainage (mg/m <sup>2</sup> ):	0.0794
fraction of substance entering water body in water phase:	0.2982

fraction of substance entering water body in sediment:	0.7018
Total Loading to water body via drift (mg/m <sup>2</sup> ):	0.7802 ( 90.7633%)
Total Loading to water body via water phase(mg/m <sup>2</sup> ):	0.0237 ( 2.7545%)
Total Loading to water body via sediment phase (mg/m <sup>2</sup> ):	0.0557 ( 6.4822%)
Maximum PEC <sub>SW</sub> (µg/L):	1.6962
Maximum PEC <sub>SW</sub> occurring on day:	14
Maximum PEC <sub>sed</sub> (µg/kg dry sediment):	12.5411
Maximum PEC <sub>sed</sub> occurring on day:	19

Table: Calculated Concentrations in the water body (multiple application)

Time after max. peak(d)	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	1.6962	---	12.5411	---
1	1.0689	1.3825	12.3230	12.4320
2	0.9129	1.1867	12.1086	12.3239
4	0.9221	1.0391	11.6910	12.1114
7	0.6860	0.9099	11.0915	11.8018
14	0.6067	0.7777	9.8094	11.1197
21	0.5366	0.7088	8.6755	10.4901
28	0.4746	0.6579	7.6727	9.9086
42	0.3712	0.5788	6.0014	8.8734
50	0.3226	0.5416	5.2154	8.3496
100	0.1342	0.3782	2.1689	5.9109

#### RESULTS OF THE CALCULATION FOR THE RESPECTIVE SINGLE APPLICATION PATTERN

Number of application per season considered for this run:	1
Equivalent application rate for drift (g/ha):	160.00
Equivalent application rate for runoff/drainage(g/ha):	40.00
Loading to water body per drift event(mg/m <sup>2</sup> ):	0.4414
Loading to water body via runoff(mg/m <sup>2</sup> ):	0.0794
fraction of substance entering water body in water phase:	0.2982
fraction of substance entering water body in sediment phase:	0.7018
Total Loading to water body via drift (mg/m <sup>2</sup> ):	0.4414 ( 84.7603%)
Total Loading to water body via water phase(mg/m <sup>2</sup> ):	0.0237 ( 4.5447%)
Total Loading to water body via sediment phase (mg/m <sup>2</sup> ):	0.0557 ( 10.6951%)
Maximum PEC <sub>SW</sub> (µg/L):	1.4715
Maximum PEC <sub>SW</sub> occurring on day:	0
Maximum PEC <sub>sed</sub> (µg/kg dry sediment):	8.4627
Maximum PEC <sub>sed</sub> occurring on day:	5

Table: Calculated Concentrations in the water body (respective single application pattern)

Time after max. peak(d)	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	1.4715	---	8.4627	---
1	0.7694	1.1204	8.3155	8.3891
2	0.6005	0.9027	8.1708	8.3161
4	0.6154	0.7419	7.8890	8.1727
7	0.4629	0.6368	7.4845	7.9638

---

14	0.4094	0.5362	6.6193	7.5035
21	0.3621	0.4859	5.8542	7.0787
28	0.3202	0.4496	5.1775	6.6863
42	0.2505	0.3944	4.0497	5.9877
50	0.2177	0.3687	3.5193	5.6342
100	0.0905	0.2568	1.4635	3.9887

**Prothioconazole-S-methyl (M01) (winter cereals, 2 x 200 g as/ha – winter cereals, Step 1)**

**STEPS 1-2 in FOCUS**

**FOCUS Surface water Tool for Exposure Predictions Step 1**

*developed by Michael Klein*

Program version: Version 3.2  
Date of this simulation: 18/01/2021, 17:04:23

**OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION**

*Comments: metabolite*

Active substance:	M01_4
Compound for PEC calculation:	SEU_cereals winter
Application rate (g/ha) of a.i.:	200.00
Application/crop type:	cereals, winter
Number of applications per season:	2.00
Application interval (d):	14.00
Molecular mass of active ingredient (g/mole):	344.30
Molecular mass of calc. compound (g/mole):	358.30
Maximum observed in water/sediment studies (%)	12.70
Maximum observed in soil studies (%)	14.60
KOC of parent compound(L/kg):	1765.00
Water solubility (mg/L):	1000.00
KOC compound(L/kg):	2526.00
DT50 water/sediment (d):	1000.00

**SCENARIO DATA USED IN THE CALCULATION**

Distance to the water body (m):	1.00
Spraydrift (% of application):	2.7590
Runoff + drainage(% of application):	10.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

**RESULTS OF THE CALCULATION**

Equivalent app. rate for drift (g/ha):	26.43
Equivalent app. rate for runoff/drainage(g/ha):	30.39
Equivalent app. rate for runoff/drainage(g/ha) of parent:	26.43
Loading to water body via drift (mg/m <sup>2</sup> ):	0.1459
Loading to water body via runoff/drainage(mg/m <sup>2</sup> ):	11.3640
fraction of substance entering water body in water phase:	0.2289
fraction of substance entering water body in sediment phase:	0.7711



Table: Calculated Concentrations in the water body

Time (d)	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	9.1584		219.0594	
1	8.7774	8.9679	221.7173	220.3883
2	8.7713	8.8711	221.5636	221.0144
4	8.7592	8.8182	221.2567	221.2123
7	8.7410	8.7890	220.7971	221.1328
14	8.6987	8.7544	219.7284	220.6975
21	8.6566	8.7288	218.6648	220.1971
28	8.6147	8.7055	217.6064	219.6816
42	8.5315	8.6613	215.5050	218.6391
50	8.4843	8.6368	214.3133	218.0422
100	8.1953	8.4879	207.0130	214.3421

Maximum PEC<sub>sw</sub> values in water and sediment are calculated from sum of individual applications.

**Compare with ecotox endpoints. If TER values are less than regulatory triggers, then go to Step 2**

**Prothioconazole-S-methyl (M01) (winter cereals, 2 x 200 g as/ha – winter cereals, SEU, Step 2)**

**STEPS 1-2 in FOCUS**

**FOCUS Surface water Tool for Exposure Predictions Step 2**

*developed by Michael Klein*

Program version: Version 3.2  
Date of this simulation: 18/01/2021, 17:04:25

**OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION**

*Comments: metabolite*

Active substance:	M01_4
Compound for PEC calculation:	SEU_cereals winter
Application rate (g/ha) of a.i.:	200.00
Crop Interception:	average crop cover (20 %)
Application/crop type:	cereals, winter
Number of applications per season:	2
Application interval (d):	14.00
Region and season of application:	South Europe, Mar. - May
Molecular mass of active ingredient (g/mole):	344.30
Molecular mass of calc. compound (g/mole):	358.30
Maximum observed in water/sediment studies (%)	12.70
Maximum observed in soil studies (%)	14.60
DT50 soil (d) parent compound:	1.20
Water solubility (mg/L):	1000.00
KOC assessed compound(L/kg):	2526.00
KOC parent compound(L/kg):	1765.00
DT50 water(d):	1000.00
DT50 sediment (d):	1000.00
DT50 soil (d):	15.70

**SCENARIO DATA USED IN THE CALCULATION**

Distance to the water body (m):	1.00
Spraydrift for multiple applications (% of application):	2.4380
Spraydrift for single application (% of application):	2.7590
Runoff + drainage(% of application):	4.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

**RESULTS OF THE CALCULATION**

Number of application per season considered for this run: 2

Equivalent application rate for drift (g/ha):	26.43
Equivalent application rate for runoff/drainage(g/ha):	24.31
Equivalent app. rate for runoff/drainage of parent compound(g/ha):	21.15
Loading to water body per drift event(mg/m <sup>2</sup> ):	0.0644
Loading to water body via runoff/drainage (mg/m <sup>2</sup> ):	1.2542
fraction of substance entering water body in water phase:	0.2289
fraction of substance entering water body in sediment:	0.7711
Loading to water body via runoff/drainage of parent substance(mg/m <sup>2</sup> ):	0.0839
fraction of parent substance entering water body in water phase:	0.2982
fraction of parent substance entering water body in sediment:	0.7018
Total Loading to water body via drift (mg/m <sup>2</sup> ):	0.1289 ( 8.7853%)
Total Loading to water body via water phase(mg/m <sup>2</sup> ):	0.2871 ( 19.5725%)
Total Loading to water body via sediment phase (mg/m <sup>2</sup> ):	0.9671 ( 65.9202%)
Total Loading into water phase via Parent's runoff (mg/m <sup>2</sup> ):	0.0250 ( 1.7064%)
Total Loading into sediment phase via Parent's runoff (mg/m <sup>2</sup> ):	0.0589 ( 4.0156%)
Maximum PECSW (µg/L):	1.1532
Maximum PECSW occurring on day:	18
Maximum PECsed (µg/kg dry sediment):	28.2415
Maximum PECsed occurring on day:	19

Table: Calculated Concentrations in the water body (multiple application)

Time after max. peak(d)	PECsw (µg/L)		PECsed(µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	1.1532	---	28.2415	---
1	1.1180	1.1356	28.2219	28.2317
2	1.1173	1.1266	28.2024	28.2219
4	1.1157	1.1216	28.1633	28.2024
7	1.1134	1.1186	28.1048	28.1731
14	1.1080	1.1146	27.9688	28.1049
21	1.1026	1.1115	27.8334	28.0369
28	1.0973	1.1086	27.6987	27.9692
42	1.0867	1.1031	27.4312	27.8344
50	1.0807	1.1000	27.2795	27.7577
100	1.0439	1.0811	26.3502	27.2849

## RESULTS OF THE CALCULATION FOR THE RESPECTIVE SINGLE APPLICATION PATTERN

Number of application per season considered for this run:	1
Equivalent application rate for drift (g/ha):	26.43
Equivalent application rate for runoff/drainage(g/ha):	24.31
Loading to water body per drift event(mg/m <sup>2</sup> ):	0.0729
Loading to water body via runoff(mg/m <sup>2</sup> ):	0.8150
fraction of substance entering water body in water phase:	0.2289
fraction of substance entering water body in sediment phase:	0.7711
Total Loading to water body via drift (mg/m <sup>2</sup> ):	0.0729 ( 8.2135%)
Total Loading to water body via water phase(mg/m <sup>2</sup> ):	0.1866 ( 21.0134%)
Total Loading to water body via sediment phase (mg/m <sup>2</sup> ):	0.6284 ( 70.7731%)
Maximum PECSW (µg/L):	0.7614

Maximum PECSW occurring on day:	4
Maximum PECsed (µg/kg dry sediment):	18.7166
Maximum PECsed occurring on day:	5

Table: Calculated Concentrations in the water body (respective single application pattern)

Time after max. peak(d)	PECsw (µg/L)		PECsed(µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	0.7614	---	18.7166	---
1	0.7410	0.7512	18.7036	18.7101
2	0.7404	0.7459	18.6907	18.7036
4	0.7394	0.7429	18.6648	18.6907
7	0.7379	0.7411	18.6260	18.6713
14	0.7343	0.7386	18.5359	18.6261
21	0.7308	0.7366	18.4461	18.5811
28	0.7272	0.7347	18.3569	18.5362
42	0.7202	0.7310	18.1796	18.4468
50	0.7162	0.7290	18.0791	18.3960
100	0.6918	0.7165	17.4632	18.0827

**Prothioconazole-desthio (M04) (spring cereals, 2 x 200 g as/ha – spring cereals, Step 1)**

**STEPS 1-2 in FOCUS**

**FOCUS Surface water Tool for Exposure Predictions Step 1**

*developed by Michael Klein*

Program version: Version 3.2  
Date of this simulation: 18/01/2021, 17:05:35

**OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION**

*Comments: metabolite*

Active substance:	M04_5
Compound for PEC calculation:	NEU_cereals spring
Application rate (g/ha) of a.i.:	200.00
Application/crop type:	cereals, spring
Number of applications per season:	2.00
Application interval (d):	14.00
Molecular mass of active ingredient (g/mole):	344.30
Molecular mass of calc. compound (g/mole):	312.20
Maximum observed in water/sediment studies (%)	54.60
Maximum observed in soil studies (%)	57.10
KOC of parent compound(L/kg):	1765.00
Water solubility (mg/L):	1000.00
KOC compound(L/kg):	574.00
DT50 water/sediment (d):	1000.00

**SCENARIO DATA USED IN THE CALCULATION**

Distance to the water body (m):	1.00
Spraydrift (% of application):	2.7590
Runoff + drainage(% of application):	10.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

**RESULTS OF THE CALCULATION**

Equivalent app. rate for drift (g/ha):	99.02
Equivalent app. rate for runoff/drainage(g/ha):	103.55
Equivalent app. rate for runoff/drainage(g/ha) of parent:	99.02
Loading to water body via drift (mg/m <sup>2</sup> ):	0.5464
Loading to water body via runoff/drainage(mg/m <sup>2</sup> ):	40.5144
fraction of substance entering water body in water phase:	0.5665
fraction of substance entering water body in sediment phase:	0.4335

Table: Calculated Concentrations in the water body

Time (d)	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	78.3212		439.1096	
1	77.4779	77.8996	444.7232	441.9164
2	77.4242	77.6753	444.4150	443.2428
4	77.3170	77.5229	443.7994	443.6750
7	77.1564	77.4002	442.8775	443.5307
14	76.7829	77.1849	440.7338	442.6677
21	76.4112	76.9889	438.6006	441.6673
28	76.0414	76.7982	436.4776	440.6350
42	75.3071	76.4233	432.2625	438.5456
50	74.8906	76.2114	429.8722	437.3489
100	72.3396	74.9096	415.2291	429.9286

Maximum PEC<sub>sw</sub> values in water and sediment are calculated from sum of individual applications.

**Compare with ecotox endpoints. If TER values are less than regulatory triggers, then go to Step 2**

**Prothioconazole-desthio (M04) (spring cereals, 2 x 200 g as/ha – spring cereals, NEU, Step 2)**

**STEPS 1-2 in FOCUS**

**FOCUS Surface water Tool for Exposure Predictions Step 2**

*developed by Michael Klein*

Program version: Version 3.2  
Date of this simulation: 18/01/2021, 17:05:37

**OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION**

*Comments: metabolite*

Active substance:	M04_5
Compound for PEC calculation:	NEU_cereals spring
Application rate (g/ha) of a.i.:	200.00
Crop Interception:	average crop cover (20 %)
Application/crop type:	cereals, spring
Number of applications per season:	2
Application interval (d):	14.00
Region and season of application:	North Europe, Mar. - May
Molecular mass of active ingredient (g/mole):	344.30
Molecular mass of calc. compound (g/mole):	312.20
Maximum observed in water/sediment studies (%)	54.60
Maximum observed in soil studies (%)	57.10
DT50 soil (d) parent compound:	1.20
Water solubility (mg/L):	1000.00
KOC assessed compound(L/kg):	574.00
KOC parent compound(L/kg):	1765.00
DT50 water(d):	1000.00
DT50 sediment (d):	1000.00
DT50 soil (d):	22.70

**SCENARIO DATA USED IN THE CALCULATION**

Distance to the water body (m):	1.00
Spraydrift for multiple applications (% of application):	2.4380
Spraydrift for single application (% of application):	2.7590
Runoff + drainage(% of application):	2.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

**RESULTS OF THE CALCULATION**

Number of application per season considered for this run: 2

Equivalent application rate for drift (g/ha):	99.02
Equivalent application rate for runoff/drainage(g/ha):	82.84
Equivalent app. rate for runoff/drainage of parent compound(g/ha):	79.22
Loading to water body per drift event(mg/m <sup>2</sup> ):	0.2414
Loading to water body via runoff/drainage (mg/m <sup>2</sup> ):	2.4226
fraction of substance entering water body in water phase:	0.5665
fraction of substance entering water body in sediment:	0.4335
Loading to water body via runoff/drainage of parent substance(mg/m <sup>2</sup> ):	0.1572
fraction of parent substance entering water body in water phase:	0.2982
fraction of parent substance entering water body in sediment:	0.7018
Total Loading to water body via drift (mg/m <sup>2</sup> ):	0.4828 ( 15.7646%)
Total Loading to water body via water phase(mg/m <sup>2</sup> ):	1.3723 ( 44.8083%)
Total Loading to water body via sediment phase (mg/m <sup>2</sup> ):	1.0503 ( 34.2933%)
Total Loading into water phase via Parent's runoff (mg/m <sup>2</sup> ):	0.0469 ( 1.5310%)
Total Loading into sediment phase via Parent's runoff (mg/m <sup>2</sup> ):	0.1103 ( 3.6028%)
Maximum PECSW (µg/L):	5.9290
Maximum PECSW occurring on day:	18
Maximum PECsed (µg/kg dry sediment):	33.1316
Maximum PECsed occurring on day:	19

Table: Calculated Concentrations in the water body (multiple application)

Time after max. peak(d)	PECsw (µg/L)		PECsed(µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	5.9290	---	33.1316	---
1	5.7721	5.8505	33.1087	33.1201
2	5.7681	5.8103	33.0857	33.1087
4	5.7601	5.7872	33.0399	33.0857
7	5.7481	5.7730	32.9713	33.0514
14	5.7203	5.7536	32.8117	32.9714
21	5.6926	5.7379	32.6528	32.8917
28	5.6650	5.7231	32.4948	32.8122
42	5.6103	5.6946	32.1810	32.6540
50	5.5793	5.6786	32.0030	32.5641
100	5.3893	5.5812	30.9129	32.0094

## RESULTS OF THE CALCULATION FOR THE RESPECTIVE SINGLE APPLICATION PATTERN

Number of application per season considered for this run:	1
Equivalent application rate for drift (g/ha):	99.02
Equivalent application rate for runoff/drainage(g/ha):	82.84
Loading to water body per drift event(mg/m <sup>2</sup> ):	0.2732
Loading to water body via runoff(mg/m <sup>2</sup> ):	1.4663
fraction of substance entering water body in water phase:	0.5665
fraction of substance entering water body in sediment phase:	0.4335
Total Loading to water body via drift (mg/m <sup>2</sup> ):	0.2732 ( 15.7049%)
Total Loading to water body via water phase(mg/m <sup>2</sup> ):	0.8306 ( 47.7502%)
Total Loading to water body via sediment phase (mg/m <sup>2</sup> ):	0.6357 ( 36.5449%)
Maximum PECSW (µg/L):	3.6670



Maximum PECSW occurring on day:	4
Maximum PECsed (µg/kg dry sediment):	20.5350
Maximum PECsed occurring on day:	5

Table: Calculated Concentrations in the water body (respective single application pattern)

Time after max. peak(d)	PECsw (µg/L)		PECsed(µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	3.6670	---	20.5350	---
1	3.5775	3.6223	20.5207	20.5278
2	3.5750	3.5993	20.5065	20.5207
4	3.5701	3.5859	20.4781	20.5065
7	3.5627	3.5775	20.4356	20.4852
14	3.5454	3.5658	20.3367	20.4356
21	3.5283	3.5561	20.2382	20.3862
28	3.5112	3.5470	20.1403	20.3370
42	3.4773	3.5294	19.9458	20.2389
50	3.4581	3.5195	19.8355	20.1832
100	3.3403	3.4592	19.1598	19.8394

**1,2,4-triazole (M13) (winter oilseed rape, 2 x 160 g as/ha – winter oilseed rape, Step 1)**

**STEPS 1-2 in FOCUS**

**FOCUS Surface water Tool for Exposure Predictions Step 1**

*developed by Michael Klein*

Program version: Version 3.2  
Date of this simulation: 21/04/2021, 09:51:27

**OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION**

*Comments: metabolite*

Active substance:	M13_2
Compound for PEC calculation:	SEU_OSR winter
Application rate (g/ha) of a.i.:	160.00
Application/crop type:	oil seed rape, winter
Number of applications per season:	2.00
Application interval (d):	14.00
Molecular mass of active ingredient (g/mole):	344.30
Molecular mass of calc. compound (g/mole):	69.10
Maximum observed in water/sediment studies (%)	41.80
Maximum observed in soil studies (%)	1.00E-05
KOC of parent compound(L/kg):	1765.00
Water solubility (mg/L):	730000.00
KOC compound(L/kg):	83.00
DT50 water/sediment (d):	1000.00

**SCENARIO DATA USED IN THE CALCULATION**

Distance to the water body (m):	1.00
Spraydrift (% of application):	2.7590
Runoff + drainage(% of application):	10.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

**RESULTS OF THE CALCULATION**

Equivalent app. rate for drift (g/ha):	13.42
Equivalent app. rate for runoff/drainage(g/ha):	3.21E-06
Equivalent app. rate for runoff/drainage(g/ha) of parent:	13.42
Loading to water body via drift (mg/m <sup>2</sup> ):	0.0741
Loading to water body via runoff/drainage(mg/m <sup>2</sup> ):	2.6845
fraction of substance entering water body in water phase:	0.9004
fraction of substance entering water body in sediment phase:	0.0996

Table: Calculated Concentrations in the water body

Time (d)	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	8.3037		6.6871	
1	8.2733	8.2885	6.8669	6.7770
2	8.2676	8.2795	6.8621	6.8208
4	8.2562	8.2707	6.8526	6.8391
7	8.2390	8.2608	6.8384	6.8418
14	8.1991	8.2399	6.8053	6.8318
21	8.1594	8.2197	6.7723	6.8175
28	8.1200	8.1997	6.7396	6.8021
42	8.0415	8.1600	6.6745	6.7704
50	7.9971	8.1375	6.6376	6.7521
100	7.7247	7.9988	6.4115	6.6380

Maximum PEC<sub>sw</sub> values in water and sediment are calculated from sum of individual applications.

**Compare with ecotox endpoints. If TER values are less than regulatory triggers, then go to Step 2**

1,2,4-triazole (M13) (winter oilseed rape, 2 x 160 g as/ha – winter oilseed rape, SEU, Step 2)

## STEPS 1-2 in FOCUS

### FOCUS Surface water Tool for Exposure Predictions Step 2

*developed by Michael Klein*

Program version: Version 3.2  
Date of this simulation: 21/04/2021, 09:51:33

#### OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

*Comments: metabolite*

Active substance:	M13_2
Compound for PEC calculation:	SEU_OSR winter
Application rate (g/ha) of a.i.:	160.00
Crop Interception:	full canopy (75 %)
Application/crop type:	oil seed rape, winter
Number of applications per season:	2
Application interval (d):	14.00
Region and season of application:	South Europe, Mar. - May
Molecular mass of active ingredient (g/mole):	344.30
Molecular mass of calc. compound (g/mole):	69.10
Maximum observed in water/sediment studies (%)	41.80
Maximum observed in soil studies (%)	1.00E-05
DT50 soil (d) parent compound:	1.20
Water solubility (mg/L):	730000.00
KOC assessed compound(L/kg):	83.00
KOC parent compound(L/kg):	1765.00
DT50 water(d):	1000.00
DT50 sediment (d):	1000.00
DT50 soil (d):	1000.00

#### SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m):	1.00
Spraydrift for multiple applications (% of application):	2.4380
Spraydrift for single application (% of application):	2.7590
Runoff + drainage(% of application):	4.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

#### RESULTS OF THE CALCULATION

Number of application per season considered for this run: 2

Equivalent application rate for drift (g/ha):	13.42
Equivalent application rate for runoff/drainage(g/ha):	8.03E-07
Equivalent app. rate for runoff/drainage of parent compound(g/ha):	3.36
Loading to water body per drift event(mg/m <sup>2</sup> ):	0.0327
Loading to water body via runoff/drainage (mg/m <sup>2</sup> ):	0.0000
fraction of substance entering water body in water phase:	0.9004
fraction of substance entering water body in sediment:	0.0996
Loading to water body via runoff/drainage of parent substance(mg/m <sup>2</sup> ):	0.0133
fraction of parent substance entering water body in water phase:	0.2982
fraction of parent substance entering water body in sediment:	0.7018
Total Loading to water body via drift (mg/m <sup>2</sup> ):	0.0654 ( 83.0886%)
Total Loading to water body via water phase(mg/m <sup>2</sup> ):	0.0000 ( 0.0001%)
Total Loading to water body via sediment phase (mg/m <sup>2</sup> ):	0.0000 ( 0.0000%)
Total Loading into water phase via Parent's runoff (mg/m <sup>2</sup> ):	0.0040 ( 5.0431%)
Total Loading into sediment phase via Parent's runoff (mg/m <sup>2</sup> ):	0.0093 ( 11.8682%)
Maximum PECSW (µg/L):	0.2416
Maximum PECSW occurring on day:	18
Maximum PECsed (µg/kg dry sediment):	0.1948
Maximum PECsed occurring on day:	19

Table: Calculated Concentrations in the water body (multiple application)

Time after max. peak(d)	PECsw (µg/L)		PECsed(µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	0.2416	---	0.1948	---
1	0.2348	0.2382	0.1947	0.1948
2	0.2346	0.2364	0.1946	0.1947
4	0.2343	0.2354	0.1943	0.1946
7	0.2338	0.2348	0.1939	0.1944
14	0.2326	0.2340	0.1930	0.1939
21	0.2315	0.2334	0.1920	0.1934
28	0.2304	0.2328	0.1911	0.1930
42	0.2282	0.2316	0.1893	0.1920
50	0.2269	0.2310	0.1882	0.1915
100	0.2192	0.2270	0.1818	0.1882

## RESULTS OF THE CALCULATION FOR THE RESPECTIVE SINGLE APPLICATION PATTERN

Number of application per season considered for this run:	1
Equivalent application rate for drift (g/ha):	13.42
Equivalent application rate for runoff/drainage(g/ha):	8.03E-07
Loading to water body per drift event(mg/m <sup>2</sup> ):	0.0370
Loading to water body via runoff(mg/m <sup>2</sup> ):	0.0000
fraction of substance entering water body in water phase:	0.9004
fraction of substance entering water body in sediment phase:	0.0996
Total Loading to water body via drift (mg/m <sup>2</sup> ):	0.0370 ( 99.9999%)
Total Loading to water body via water phase(mg/m <sup>2</sup> ):	0.0000 ( 0.0001%)
Total Loading to water body via sediment phase (mg/m <sup>2</sup> ):	0.0000 ( 0.0000%)
Maximum PECSW (µg/L):	0.1546

Maximum PEC <sub>SW</sub> occurring on day:	4
Maximum PEC <sub>sed</sub> (µg/kg dry sediment):	0.1251
Maximum PEC <sub>sed</sub> occurring on day:	5

Table: Calculated Concentrations in the water body (respective single application pattern)

Time after max. peak(d)	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	0.1546	---	0.1251	---
1	0.1507	0.1527	0.1250	0.1250
2	0.1506	0.1517	0.1249	0.1250
4	0.1504	0.1511	0.1247	0.1249
7	0.1501	0.1507	0.1245	0.1248
14	0.1493	0.1502	0.1239	0.1245
21	0.1486	0.1498	0.1233	0.1242
28	0.1479	0.1494	0.1227	0.1239
42	0.1465	0.1487	0.1215	0.1233
50	0.1457	0.1483	0.1208	0.1229
100	0.1407	0.1457	0.1167	0.1208

**Prothioconazole-triazolylketone (M42) (winter cereals, 2 x 200 g as/ha – winter cereals, Step 1)**

**STEPS 1-2 in FOCUS**

**FOCUS Surface water Tool for Exposure Predictions Step 1**

*developed by Michael Klein*

Program version: Version 3.2  
Date of this simulation: 18/04/2021, 08:18:11

**OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION**

*Comments: metabolite*

Active substance:	M42_3
Compound for PEC calculation:	NEU_cereals winter
Application rate (g/ha) of a.i.:	200.00
Application/crop type:	cereals, winter
Number of applications per season:	2.00
Application interval (d):	14.00
Molecular mass of active ingredient (g/mole):	344.30
Molecular mass of calc. compound (g/mole):	185.70
Maximum observed in water/sediment studies (%)	9.10
Maximum observed in soil studies (%)	1.00E-05
KOC of parent compound(L/kg):	1765.00
Water solubility (mg/L):	1000.00
KOC compound(L/kg):	1.00
DT50 water/sediment (d):	1000.00

**SCENARIO DATA USED IN THE CALCULATION**

Distance to the water body (m):	1.00
Spraydrift (% of application):	2.7590
Runoff + drainage(% of application):	10.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

**RESULTS OF THE CALCULATION**

Equivalent app. rate for drift (g/ha):	9.82
Equivalent app. rate for runoff/drainage(g/ha):	1.08E-05
Equivalent app. rate for runoff/drainage(g/ha) of parent:	9.82
Loading to water body via drift (mg/m <sup>2</sup> ):	0.0542
Loading to water body via runoff/drainage(mg/m <sup>2</sup> ):	1.9633
fraction of substance entering water body in water phase:	0.9987
fraction of substance entering water body in sediment phase:	0.0013

Table: Calculated Concentrations in the water body

Time (d)	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	6.7160		0.0654	
1	6.7111	6.7136	0.0671	0.0662
2	6.7065	6.7112	0.0671	0.0667
4	6.6972	6.7065	0.0670	0.0668
7	6.6833	6.6995	0.0668	0.0669
14	6.6509	6.6833	0.0665	0.0668
21	6.6187	6.6671	0.0662	0.0666
28	6.5867	6.6510	0.0659	0.0665
42	6.5231	6.6190	0.0652	0.0662
50	6.4870	6.6007	0.0649	0.0660
100	6.2660	6.4883	0.0627	0.0649

Maximum PEC<sub>sw</sub> values in water and sediment are calculated from sum of individual applications.

**Compare with ecotox endpoints. If TER values are less than regulatory triggers, then go to Step 2**



**Prothioconazole-triazolylketone (M42) (winter cereals, 2 x 200 g as/ha – winter cereals, NEU, Step 2)**

**STEPS 1-2 in FOCUS**

**FOCUS Surface water Tool for Exposure Predictions Step 2**

*developed by Michael Klein*

Program version: Version 3.2  
Date of this simulation: 18/04/2021, 08:18:14

OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

*Comments: metabolite*

Active substance:	M42_3
Compound for PEC calculation:	NEU_cereals winter
Application rate (g/ha) of a.i.:	200.00
Crop Interception:	average crop cover (20 %)
Application/crop type:	cereals, winter
Number of applications per season:	2
Application interval (d):	14.00
Region and season of application:	North Europe, Mar. - May
Molecular mass of active ingredient (g/mole):	344.30
Molecular mass of calc. compound (g/mole):	185.70
Maximum observed in water/sediment studies (%)	9.10
Maximum observed in soil studies (%)	1.00E-05
DT50 soil (d) parent compound:	1.20
Water solubility (mg/L):	1000.00
KOC assessed compound(L/kg):	1.00
KOC parent compound(L/kg):	1765.00
DT50 water(d):	1000.00
DT50 sediment (d):	1000.00
DT50 soil (d):	1000.00

SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m):	1.00
Spraydrift for multiple applications (% of application):	2.4380
Spraydrift for single application (% of application):	2.7590
Runoff + drainage(% of application):	2.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

RESULTS OF THE CALCULATION

Number of application per season considered for this run: 2

Equivalent application rate for drift (g/ha):	9.82
Equivalent application rate for runoff/drainage(g/ha):	8.63E-06
Equivalent app. rate for runoff/drainage of parent compound(g/ha):	7.85
Loading to water body per drift event(mg/m <sup>2</sup> ):	0.0239
Loading to water body via runoff/drainage (mg/m <sup>2</sup> ):	0.0000
fraction of substance entering water body in water phase:	0.9987
fraction of substance entering water body in sediment:	0.0013
Loading to water body via runoff/drainage of parent substance(mg/m <sup>2</sup> ):	0.0156
fraction of parent substance entering water body in water phase:	0.2982
fraction of parent substance entering water body in sediment:	0.7018
Total Loading to water body via drift (mg/m <sup>2</sup> ):	0.0479 ( 75.4341%)
Total Loading to water body via water phase(mg/m <sup>2</sup> ):	0.0000 ( 0.0005%)
Total Loading to water body via sediment phase (mg/m <sup>2</sup> ):	0.0000 ( 0.0000%)
Total Loading into water phase via Parent's runoff (mg/m <sup>2</sup> ):	0.0046 ( 7.3257%)
Total Loading into sediment phase via Parent's runoff (mg/m <sup>2</sup> ):	0.0109 ( 17.2397%)
Maximum PECSW (µg/L):	0.2101
Maximum PECSW occurring on day:	18
Maximum PECsed (µg/kg dry sediment):	0.0021
Maximum PECsed occurring on day:	19

Table: Calculated Concentrations in the water body (multiple application)

Time after max. peak(d)	PECsw (µg/L)		PECsed(µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	0.2101	---	0.0021	---
1	0.2099	0.2100	0.0021	0.0021
2	0.2097	0.2099	0.0021	0.0021
4	0.2094	0.2097	0.0021	0.0021
7	0.2090	0.2095	0.0021	0.0021
14	0.2080	0.2090	0.0021	0.0021
21	0.2070	0.2085	0.0021	0.0021
28	0.2060	0.2080	0.0021	0.0021
42	0.2040	0.2070	0.0020	0.0021
50	0.2029	0.2064	0.0020	0.0021
100	0.1960	0.2029	0.0020	0.0020

#### RESULTS OF THE CALCULATION FOR THE RESPECTIVE SINGLE APPLICATION PATTERN

Number of application per season considered for this run:	1
Equivalent application rate for drift (g/ha):	9.82
Equivalent application rate for runoff/drainage(g/ha):	8.63E-06
Loading to water body per drift event(mg/m <sup>2</sup> ):	0.0271
Loading to water body via runoff(mg/m <sup>2</sup> ):	0.0000
fraction of substance entering water body in water phase:	0.9987
fraction of substance entering water body in sediment phase:	0.0013
Total Loading to water body via drift (mg/m <sup>2</sup> ):	0.0271 ( 99.9994%)
Total Loading to water body via water phase(mg/m <sup>2</sup> ):	0.0000 ( 0.0006%)
Total Loading to water body via sediment phase (mg/m <sup>2</sup> ):	0.0000 ( 0.0000%)

Maximum PECSW (µg/L):	0.1418
Maximum PECSW occurring on day:	4
Maximum PECsed (µg/kg dry sediment):	0.0014
Maximum PECsed occurring on day:	5

Table: Calculated Concentrations in the water body (respective single application pattern)

Time after max. peak(d)	PECsw (µg/L)		PECsed(µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	0.1418	---	0.0014	---
1	0.1417	0.1418	0.0014	0.0014
2	0.1416	0.1417	0.0014	0.0014
4	0.1414	0.1416	0.0014	0.0014
7	0.1411	0.1414	0.0014	0.0014
14	0.1404	0.1411	0.0014	0.0014
21	0.1397	0.1408	0.0014	0.0014
28	0.1391	0.1404	0.0014	0.0014
42	0.1377	0.1397	0.0014	0.0014
50	0.1370	0.1394	0.0014	0.0014
100	0.1323	0.1370	0.0013	0.0014

### **Azoxystrobin and its metabolites**

Azoxystrobin (winter oilseed rape, 2 x 120 g as/ha – winter oilseed rape, Step 1)

## STEPS 1-2 in FOCUS

### FOCUS Surface water Tool for Exposure Predictions Step 1

*developed by Michael Klein*

Program version: Version 3.2  
Date of this simulation: 18/01/2021, 17:09:27

#### OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

*Comments: OSR, winter*

Active substance:	Azoxy 1
Application rate (g/ha) of a.i.:	120.00
Application/crop type:	oil seed rape, winter
Number of applications per season:	2.00
Application interval (d):	14.00
Water solubility (mg/L):	6.00
KOC compound(L/kg):	391.50
DT50 water/sediment (d):	205.00

#### SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m):	1.00
Spraydrift (% of application):	2.7590
Runoff + drainage(% of application):	10.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

#### RESULTS OF THE CALCULATION

Equivalent app. rate for drift (g/ha):	120.00
Equivalent app. rate for runoff/drainage(g/ha):	120.00
Equivalent app. rate for runoff/drainage(g/ha) of parent:	0.00E+00
Loading to water body via drift (mg/m <sup>2</sup> ):	0.6622
Loading to water body via runoff/drainage(mg/m <sup>2</sup> ):	24.0000
fraction of substance entering water body in water phase:	0.6570
fraction of substance entering water body in sediment phase:	0.3430

Table: Calculated Concentrations in the water body

Time (d)	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	54.7696		205.7819	
1	53.8303	54.3000	210.7456	208.2637
2	53.6486	54.0197	210.0342	209.3267

---

4	53.2870	53.7436	208.6187	209.3262
7	52.7492	53.4325	206.5132	208.5710
14	51.5154	52.7812	201.6828	206.3298
21	50.3104	52.1576	196.9653	203.9914
28	49.1336	51.5482	192.3582	201.6567
42	46.8620	50.3617	183.4647	197.0633
50	45.6114	49.7013	178.5686	194.4941
100	38.5169	45.8328	150.7937	179.3920

Maximum PEC<sub>sw</sub> values in water and sediment are calculated from sum of individual applications.

**Compare with ecotox endpoints. If TER values are less than regulatory triggers, then go to Step 2**

**Azoxystrobin (winter oilseed rape, 2 x 120 g as/ha – winter oilseed rape, NEU, Step 2)**

## **STEPS 1-2 in FOCUS**

### **FOCUS Surface water Tool for Exposure Predictions Step 2**

*developed by Michael Klein*

Program version: Version 3.2  
Date of this simulation: 18/01/2021, 17:09:29

#### OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

*Comments: OSR, winter*

Active substance:	Azoxy 1
Application rate (g/ha) of a.i.:	120.00
Crop Interception:	full canopy (75 %)
Application/crop type:	oil seed rape, winter
Number of applications per season:	2
Application interval (d):	14.00
Region and season of application:	North Europe, Mar. - May
Water solubility (mg/L):	6.00
KOC assessed compound(L/kg):	391.50
KOC parent compound(L/kg):	0.00E+00
DT50 water(d):	1000.00
DT50 sediment (d):	205.00
DT50 soil (d):	78.00

#### SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m):	1.00
Spraydrift for multiple applications (% of application):	2.4380
Spraydrift for single application (% of application):	2.7590
Runoff + drainage(% of application):	2.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

#### RESULTS OF THE CALCULATION

Number of application per season considered for this run:	2
Equivalent application rate for drift (g/ha):	120.00
Equivalent application rate for runoff/drainage(g/ha):	30.00
Loading to water body per drift event(mg/m²):	0.2926
Loading to water body via runoff/drainage (mg/m²):	1.0904
fraction of substance entering water body in water phase:	0.6570

fraction of substance entering water body in sediment:	0.3430
Total Loading to water body via drift (mg/m <sup>2</sup> ):	0.5851 ( 34.9226%)
Total Loading to water body via water phase(mg/m <sup>2</sup> ):	0.7164 ( 42.7578%)
Total Loading to water body via sediment phase (mg/m <sup>2</sup> ):	0.3740 ( 22.3196%)
Maximum PEC <sub>SW</sub> (µg/L):	3.8143
Maximum PEC <sub>SW</sub> occurring on day:	18
Maximum PEC <sub>sed</sub> (µg/kg dry sediment):	14.2424
Maximum PEC <sub>sed</sub> occurring on day:	19

Table: Calculated Concentrations in the water body (multiple application)

Time after max. peak(d)	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	3.8143	---	14.2424	---
1	3.6477	3.7310	14.2195	14.2310
2	3.6418	3.6879	14.1965	14.2195
4	3.6301	3.6619	14.1508	14.1966
7	3.6126	3.6445	14.0824	14.1623
14	3.5720	3.6184	13.9242	14.0827
21	3.5318	3.5962	13.7677	14.0038
28	3.4921	3.5751	13.6130	13.9254
42	3.4141	3.5344	13.3088	13.7704
50	3.3703	3.5117	13.1381	13.6828
100	3.1090	3.3748	12.1193	13.1523

## RESULTS OF THE CALCULATION FOR THE RESPECTIVE SINGLE APPLICATION PATTERN

Number of application per season considered for this run:	1
Equivalent application rate for drift (g/ha):	120.00
Equivalent application rate for runoff/drainage(g/ha):	30.00
Loading to water body per drift event(mg/m <sup>2</sup> ):	0.3311
Loading to water body via runoff(mg/m <sup>2</sup> ):	0.5790
fraction of substance entering water body in water phase:	0.6570
fraction of substance entering water body in sediment phase:	0.3430
Total Loading to water body via drift (mg/m <sup>2</sup> ):	0.3311 ( 36.3773%)
Total Loading to water body via water phase(mg/m <sup>2</sup> ):	0.3805 ( 41.8020%)
Total Loading to water body via sediment phase (mg/m <sup>2</sup> ):	0.1986 ( 21.8206%)
Maximum PEC <sub>SW</sub> (µg/L):	2.0831
Maximum PEC <sub>SW</sub> occurring on day:	4
Maximum PEC <sub>sed</sub> (µg/kg dry sediment):	7.7619
Maximum PEC <sub>sed</sub> occurring on day:	5

Table: Calculated Concentrations in the water body (respective single application pattern)

Time after max. peak(d)	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	2.0831	---	7.7619	---
1	1.9879	2.0355	7.7494	7.7557
2	1.9847	2.0109	7.7369	7.7494
4	1.9783	1.9962	7.7120	7.7369
7	1.9688	1.9865	7.6747	7.7182



---

14	1.9467	1.9721	7.5885	7.6749
21	1.9248	1.9600	7.5032	7.6318
28	1.9032	1.9485	7.4189	7.5891
42	1.8606	1.9263	7.2531	7.5046
50	1.8368	1.9138	7.1600	7.4569
100	1.6943	1.8392	6.6048	7.1678

**R234886 (winter cereals, 2 x 150 g as/ha – winter cereals, Step 1)**  
**(PEC<sub>sw</sub> calculations based on K<sub>foc</sub> of 21 mL/g)**

## **STEPS 1-2 in FOCUS**

### **FOCUS Surface water Tool for Exposure Predictions Step 1**

*developed by Michael Klein*

Program version:

Version 3.2

Date of this simulation:

18/01/2021, 17:10:46

#### OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

*Comments: Azoxy metabolite*

Active substance:	R234886_4
Compound for PEC calculation:	SEU_cerals winter
Application rate (g/ha) of a.i.:	150.00
Application/crop type:	cereals, winter
Number of applications per season:	2.00
Application interval (d):	14.00
Molecular mass of active ingredient (g/mole):	403.40
Molecular mass of calc. compound (g/mole):	389.40
Maximum observed in water/sediment studies (%)	18.10
Maximum observed in soil studies (%)	28.80
KOC of parent compound(L/kg):	391.50
Water solubility (mg/L):	57.00
KOC compound(L/kg):	21.00
DT50 water/sediment (d):	1000.00

#### SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m):	1.00
Spraydrift (% of application):	2.7590
Runoff + drainage(% of application):	10.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

#### RESULTS OF THE CALCULATION

Equivalent app. rate for drift (g/ha):	26.21
Equivalent app. rate for runoff/drainage(g/ha):	41.70
Equivalent app. rate for runoff/drainage(g/ha) of parent:	26.21
Loading to water body via drift (mg/m <sup>2</sup> ):	0.1446
Loading to water body via runoff/drainage(mg/m <sup>2</sup> ):	13.5817
fraction of substance entering water body in water phase:	0.9728
fraction of substance entering water body in sediment phase:	0.0272

Table: Calculated Concentrations in the water body

Time (d)	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	44.5213		9.2482	
1	44.4773	44.4993	9.3402	9.2942
2	44.4465	44.4806	9.3338	9.3156
4	44.3849	44.4482	9.3208	9.3215
7	44.2927	44.4013	9.3015	9.3170
14	44.0783	44.2934	9.2565	9.2980
21	43.8650	44.1861	9.2116	9.2767
28	43.6527	44.0793	9.1671	9.2548
42	43.2311	43.8667	9.0785	9.2108
50	42.9920	43.7459	9.0283	9.1856
100	41.5276	43.0007	8.7208	9.0296

Maximum PEC<sub>sw</sub> values in water and sediment are calculated from sum of individual applications.

**Compare with ecotox endpoints. If TER values are less than regulatory triggers, then go to Step 2**

**R234886 (winter cereals, 2 x 150 g as/ha – winter cereals, SEU, Step 2)**  
**(PEC<sub>sw</sub> calculations based on K<sub>foc</sub> of 21 mL/g)**

## **STEPS 1-2 in FOCUS**

### **FOCUS Surface water Tool for Exposure Predictions Step 2**

*developed by Michael Klein*

Program version:	Version 3.2
Date of this simulation:	18/01/2021, 17:10:50

#### OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

*Comments: Azoxy metabolite*

Active substance:	R234886_4
Compound for PEC calculation:	SEU_cerals winter
Application rate (g/ha) of a.i.:	150.00
Crop Interception:	average crop cover (20 %)
Application/crop type:	cereals, winter
Number of applications per season:	2
Application interval (d):	14.00
Region and season of application:	South Europe, Mar. - May
Molecular mass of active ingredient (g/mole):	403.40
Molecular mass of calc. compound (g/mole):	389.40
Maximum observed in water/sediment studies (%)	18.10
Maximum observed in soil studies (%)	28.80
DT50 soil (d) parent compound:	78.00
Water solubility (mg/L):	57.00
KOC assessed compound(L/kg):	21.00
KOC parent compound(L/kg):	391.50
DT50 water(d):	1000.00
DT50 sediment (d):	1000.00
DT50 soil (d):	110.40

#### SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m):	1.00
Spraydrift for multiple applications (% of application):	2.4380
Spraydrift for single application (% of application):	2.7590
Runoff + drainage(% of application):	4.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

#### RESULTS OF THE CALCULATION

Number of application per season considered for this run:	2
---	---

Equivalent application rate for drift (g/ha):	26.21
Equivalent application rate for runoff/drainage(g/ha):	33.36
Equivalent app. rate for runoff/drainage of parent compound(g/ha):	20.97
Loading to water body per drift event(mg/m <sup>2</sup> ):	0.0639
Loading to water body via runoff/drainage (mg/m <sup>2</sup> ):	2.4932
fraction of substance entering water body in water phase:	0.9728
fraction of substance entering water body in sediment:	0.0272
Loading to water body via runoff/drainage of parent substance(mg/m <sup>2</sup> ):	1.5240
fraction of parent substance entering water body in water phase:	0.6570
fraction of parent substance entering water body in sediment:	0.3430
Total Loading to water body via drift (mg/m <sup>2</sup> ):	0.1278 ( 3.0830%)
Total Loading to water body via water phase(mg/m <sup>2</sup> ):	2.4252 ( 58.5104%)
Total Loading to water body via sediment phase (mg/m <sup>2</sup> ):	0.0679 ( 1.6383%)
Total Loading into water phase via Parent's runoff (mg/m <sup>2</sup> ):	1.0013 ( 24.1579%)
Total Loading into sediment phase via Parent's runoff (mg/m <sup>2</sup> ):	0.5227 ( 12.6104%)
Maximum PECSW (µg/L):	13.4409
Maximum PECSW occurring on day:	18
Maximum PECsed (µg/kg dry sediment):	2.8198
Maximum PECsed occurring on day:	19

Table: Calculated Concentrations in the water body (multiple application)

Time after max. peak(d)	PECsw (µg/L)		PECsed(µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	13.4409	---	2.8198	---
1	13.4278	13.4344	2.8179	2.8189
2	13.4185	13.4288	2.8159	2.8179
4	13.3999	13.4190	2.8120	2.8159
7	13.3721	13.4049	2.8062	2.8130
14	13.3074	13.3723	2.7926	2.8062
21	13.2430	13.3399	2.7791	2.7994
28	13.1789	13.3077	2.7656	2.7927
42	13.0516	13.2435	2.7389	2.7792
50	12.9794	13.2070	2.7238	2.7715
100	12.5373	12.9820	2.6310	2.7243

#### RESULTS OF THE CALCULATION FOR THE RESPECTIVE SINGLE APPLICATION PATTERN

Number of application per season considered for this run:	1
Equivalent application rate for drift (g/ha):	26.21
Equivalent application rate for runoff/drainage(g/ha):	33.36
Loading to water body per drift event(mg/m <sup>2</sup> ):	0.0723
Loading to water body via runoff(mg/m <sup>2</sup> ):	1.3013
fraction of substance entering water body in water phase:	0.9728
fraction of substance entering water body in sediment phase:	0.0272
Total Loading to water body via drift (mg/m <sup>2</sup> ):	0.0723 ( 5.2639%)
Total Loading to water body via water phase(mg/m <sup>2</sup> ):	1.2659 ( 92.1557%)
Total Loading to water body via sediment phase (mg/m <sup>2</sup> ):	0.0354 ( 2.5804%)

Maximum PECSW (µg/L):	7.0800
Maximum PECSW occurring on day:	4
Maximum PECsed (µg/kg dry sediment):	1.4853
Maximum PECsed occurring on day:	5

Table: Calculated Concentrations in the water body (respective single application pattern)

Time after max. peak(d)	PECsw (µg/L)		PECsed(µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	7.0800	---	1.4853	---
1	7.0729	7.0764	1.4843	1.4848
2	7.0680	7.0734	1.4833	1.4843
4	7.0582	7.0683	1.4812	1.4833
7	7.0436	7.0608	1.4781	1.4817
14	7.0095	7.0437	1.4710	1.4781
21	6.9755	7.0266	1.4638	1.4746
28	6.9418	7.0096	1.4568	1.4710
42	6.8747	6.9758	1.4427	1.4639
50	6.8367	6.9566	1.4347	1.4599
100	6.6038	6.8381	1.3858	1.4350

**R234886 (winter cereals, 2 x 150 g as/ha – winter cereals, Step 1)**  
**(PEC<sub>sed</sub> calculations based on K<sub>foc</sub> of 490 mL/g)**

## **STEPS 1-2 in FOCUS**

### **FOCUS Surface water Tool for Exposure Predictions Step 1**

*developed by Michael Klein*

Program version: Version 3.2  
Date of this simulation: 22/03/2021, 22:45:30

#### OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

*Comments: Azoxy metabolite*

Active substance:	R234886_4_s
Compound for PEC calculation:	SEU_cerals winter
Application rate (g/ha) of a.i.:	150.00
Application/crop type:	cereals, winter
Number of applications per season:	2.00
Application interval (d):	14.00
Molecular mass of active ingredient (g/mole):	403.40
Molecular mass of calc. compound (g/mole):	389.40
Maximum observed in water/sediment studies (%)	18.10
Maximum observed in soil studies (%)	28.80
KOC of parent compound(L/kg):	391.50
Water solubility (mg/L):	57.00
KOC compound(L/kg):	490.00
DT50 water/sediment (d):	1000.00

#### SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m):	1.00
Spraydrift (% of application):	2.7590
Runoff + drainage(% of application):	10.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

#### RESULTS OF THE CALCULATION

Equivalent app. rate for drift (g/ha):	26.21
Equivalent app. rate for runoff/drainage(g/ha):	41.70
Equivalent app. rate for runoff/drainage(g/ha) of parent:	26.21
Loading to water body via drift (mg/m <sup>2</sup> ):	0.1446
Loading to water body via runoff/drainage(mg/m <sup>2</sup> ):	13.5817
fraction of substance entering water body in water phase:	0.6048
fraction of substance entering water body in sediment phase:	0.3952

Table: Calculated Concentrations in the water body

Time (d)	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	27.8645		134.1741	
1	27.6548	27.7597	135.5087	134.8414
2	27.6357	27.7025	135.4149	135.1516
4	27.5974	27.6595	135.2273	135.2363
7	27.5401	27.6206	134.9464	135.1722
14	27.4068	27.5470	134.2932	134.8959
21	27.2741	27.4781	133.6432	134.5865
28	27.1421	27.4106	132.9963	134.2698
42	26.8800	27.2773	131.7119	133.6309
50	26.7313	27.2019	130.9836	133.2655
100	25.8208	26.7376	126.5218	131.0027

Maximum PEC<sub>sw</sub> values in water and sediment are calculated from sum of individual applications.

**Compare with ecotox endpoints. If TER values are less than regulatory triggers, then go to Step 2**



**R234886 (winter cereals, 2 x 150 g as/ha – winter cereals, SEU, Step 2)**  
**(PEC<sub>sed</sub> calculations based on K<sub>foc</sub> of 490 mL/g)**

## **STEPS 1-2 in FOCUS**

### **FOCUS Surface water Tool for Exposure Preditions Step 2**

*developed by Michael Klein*

Program version:	Version 3.2
Date of this simulation:	22/03/2021, 22:45:33

#### OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

*Comments: Azoxy metabolite*

Active substance:	R234886_4_s
Compound for PEC calculation:	SEU_cerals winter
Application rate (g/ha) of a.i.:	150.00
Crop Interception:	average crop cover (20 %)
Application/crop type:	cereals, winter
Number of applications per season:	2
Application interval (d):	14.00
Region and season of application:	South Europe, Mar. - May
Molecular mass of active ingredient (g/mole):	403.40
Molecular mass of calc. compound (g/mole):	389.40
Maximum observed in water/sediment studies (%)	18.10
Maximum observed in soil studies (%)	28.80
DT50 soil (d) parent compound:	78.00
Water solubility (mg/L):	57.00
KOC assessed compound(L/kg):	490.00
KOC parent compound(L/kg):	391.50
DT50 water(d):	1000.00
DT50 sediment (d):	1000.00
DT50 soil (d):	110.40

#### SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m):	1.00
Spraydrift for multiple applications (% of application):	2.4380
Spraydrift for single application (% of application):	2.7590
Runoff + drainage(% of application):	4.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

#### RESULTS OF THE CALCULATION

Number of application per season considered for this run:	2
---	---

Equivalent application rate for drift (g/ha):	26.21
Equivalent application rate for runoff/drainage(g/ha):	33.36
Equivalent app. rate for runoff/drainage of parent compound(g/ha):	20.97
Loading to water body per drift event(mg/m <sup>2</sup> ):	0.0639
Loading to water body via runoff/drainage (mg/m <sup>2</sup> ):	2.4932
fraction of substance entering water body in water phase:	0.6048
fraction of substance entering water body in sediment:	0.3952
Loading to water body via runoff/drainage of parent substance(mg/m <sup>2</sup> ):	1.5240
fraction of parent substance entering water body in water phase:	0.6570
fraction of parent substance entering water body in sediment:	0.3430
Total Loading to water body via drift (mg/m <sup>2</sup> ):	0.1278 ( 3.0830%)
Total Loading to water body via water phase(mg/m <sup>2</sup> ):	1.5080 ( 36.3803%)
Total Loading to water body via sediment phase (mg/m <sup>2</sup> ):	0.9852 ( 23.7684%)
Total Loading into water phase via Parent's runoff (mg/m <sup>2</sup> ):	1.0013 ( 24.1579%)
Total Loading into sediment phase via Parent's runoff (mg/m <sup>2</sup> ):	0.5227 ( 12.6104%)
Maximum PECSW (µg/L):	8.3937
Maximum PECSW occurring on day:	18
Maximum PECsed (µg/kg dry sediment):	40.9105
Maximum PECsed occurring on day:	19

Table: Calculated Concentrations in the water body (multiple application)

Time after max. peak(d)	PECsw (µg/L)		PECsed(µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	8.3937	---	40.9105	---
1	8.3491	8.3714	40.8821	40.8963
2	8.3433	8.3588	40.8538	40.8821
4	8.3317	8.3481	40.7972	40.8538
7	8.3144	8.3374	40.7125	40.8114
14	8.2742	8.3158	40.5154	40.7126
21	8.2341	8.2953	40.3193	40.6142
28	8.1943	8.2750	40.1242	40.5161
42	8.1151	8.2349	39.7367	40.3207
50	8.0703	8.2121	39.5169	40.2097
100	7.7954	8.0721	38.1708	39.5248

## RESULTS OF THE CALCULATION FOR THE RESPECTIVE SINGLE APPLICATION PATTERN

Number of application per season considered for this run:	1
Equivalent application rate for drift (g/ha):	26.21
Equivalent application rate for runoff/drainage(g/ha):	33.36
Loading to water body per drift event(mg/m <sup>2</sup> ):	0.0723
Loading to water body via runoff(mg/m <sup>2</sup> ):	1.3013
fraction of substance entering water body in water phase:	0.6048
fraction of substance entering water body in sediment phase:	0.3952
Total Loading to water body via drift (mg/m <sup>2</sup> ):	0.0723 ( 5.2639%)
Total Loading to water body via water phase(mg/m <sup>2</sup> ):	0.7871 ( 57.3000%)
Total Loading to water body via sediment phase (mg/m <sup>2</sup> ):	0.5142 ( 37.4360%)

Maximum PECSW (µg/L):	4.4229
Maximum PECSW occurring on day:	4
Maximum PECsed (µg/kg dry sediment):	21.5490
Maximum PECsed occurring on day:	5

Table: Calculated Concentrations in the water body (respective single application pattern)

Time after max. peak(d)	PECsw (µg/L)		PECsed(µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	4.4229	---	21.5490	---
1	4.3978	4.4103	21.5340	21.5415
2	4.3947	4.4033	21.5191	21.5340
4	4.3886	4.3975	21.4893	21.5191
7	4.3795	4.3917	21.4447	21.4968
14	4.3583	4.3803	21.3409	21.4448
21	4.3372	4.3695	21.2376	21.3929
28	4.3162	4.3588	21.1348	21.3412
42	4.2745	4.3376	20.9307	21.2383
50	4.2509	4.3256	20.8149	21.1798
100	4.1061	4.2519	20.1059	20.8191

**R401553 (spring cereals, 2 x 150 g as/ha – spring cereals, Step 1)**

## **STEPS 1-2 in FOCUS**

### **FOCUS Surface water Tool for Exposure Predictions Step 1**

*developed by Michael Klein*

Program version: Version 3.2  
Date of this simulation: 18/01/2021, 17:11:53

#### OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

*Comments: Azoxy metabolite*

Active substance:	R401553_5
Compound for PEC calculation:	NEU_cereal spring
Application rate (g/ha) of a.i.:	150.00
Application/crop type:	cereals, spring
Number of applications per season:	2.00
Application interval (d):	14.00
Molecular mass of active ingredient (g/mole):	403.40
Molecular mass of calc. compound (g/mole):	213.20
Maximum observed in water/sediment studies (%)	8.90
Maximum observed in soil studies (%)	17.00
KOC of parent compound(L/kg):	391.50
Water solubility (mg/L):	560.00
KOC compound(L/kg):	142.60
DT50 water/sediment (d):	1000.00

#### SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m):	1.00
Spraydrift (% of application):	2.7590
Runoff + drainage(% of application):	10.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

#### RESULTS OF THE CALCULATION

Equivalent app. rate for drift (g/ha):	7.06
Equivalent app. rate for runoff/drainage(g/ha):	13.48
Equivalent app. rate for runoff/drainage(g/ha) of parent:	7.06
Loading to water body via drift (mg/m <sup>2</sup> ):	0.0389
Loading to water body via runoff/drainage(mg/m <sup>2</sup> ):	4.1065
fraction of substance entering water body in water phase:	0.8402
fraction of substance entering water body in sediment phase:	0.1598

Table: Calculated Concentrations in the water body

Time (d)	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	11.6313		16.4012	
1	11.6025	11.6169	16.5452	16.4732
2	11.5945	11.6077	16.5337	16.5063
4	11.5784	11.5971	16.5108	16.5143
7	11.5544	11.5839	16.4765	16.5055
14	11.4984	11.5552	16.3968	16.4710
21	11.4428	11.5270	16.3174	16.4331
28	11.3874	11.4990	16.2384	16.3943
42	11.2774	11.4434	16.0816	16.3161
50	11.2151	11.4119	15.9927	16.2715
100	10.8330	11.2174	15.4479	15.9951

Maximum PEC<sub>sw</sub> values in water and sediment are calculated from sum of individual applications.

**Compare with ecotox endpoints. If TER values are less than regulatory triggers, then go to Step 2**

**R401553 (spring cereals, 2 x 200 g as/ha – spring cereals, NEU, Step 2)**

## **STEPS 1-2 in FOCUS**

### **FOCUS Surface water Tool for Exposure Predictions Step 2**

*developed by Michael Klein*

Program version:	Version 3.2
Date of this simulation:	18/01/2021, 17:11:56

#### OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

*Comments: Azoxy metabolite*

Active substance:	R401553_5
Compound for PEC calculation:	NEU_cereal spring
Application rate (g/ha) of a.i.:	150.00
Crop Interception:	average crop cover (20 %)
Application/crop type:	cereals, spring
Number of applications per season:	2
Application interval (d):	14.00
Region and season of application:	North Europe, Mar. - May
Molecular mass of active ingredient (g/mole):	403.40
Molecular mass of calc. compound (g/mole):	213.20
Maximum observed in water/sediment studies (%)	8.90
Maximum observed in soil studies (%)	17.00
DT50 soil (d) parent compound:	78.00
Water solubility (mg/L):	560.00
KOC assessed compound(L/kg):	142.60
KOC parent compound(L/kg):	391.50
DT50 water(d):	1000.00
DT50 sediment (d):	1000.00
DT50 soil (d):	1.10

#### SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m):	1.00
Spraydrift for multiple applications (% of application):	2.4380
Spraydrift for single application (% of application):	2.7590
Runoff + drainage(% of application):	2.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

#### RESULTS OF THE CALCULATION

Number of application per season considered for this run:	2
---	---

Equivalent application rate for drift (g/ha):	7.06
Equivalent application rate for runoff/drainage(g/ha):	10.78
Equivalent app. rate for runoff/drainage of parent compound(g/ha):	5.64
Loading to water body per drift event(mg/m <sup>2</sup> ):	0.0172
Loading to water body via runoff/drainage (mg/m <sup>2</sup> ):	0.0173
fraction of substance entering water body in water phase:	0.8402
fraction of substance entering water body in sediment:	0.1598
Loading to water body via runoff/drainage of parent substance(mg/m <sup>2</sup> ):	0.2051
fraction of parent substance entering water body in water phase:	0.6570
fraction of parent substance entering water body in sediment:	0.3430
Total Loading to water body via drift (mg/m <sup>2</sup> ):	0.0344 ( 13.3919%)
Total Loading to water body via water phase(mg/m <sup>2</sup> ):	0.0146 ( 5.6724%)
Total Loading to water body via sediment phase (mg/m <sup>2</sup> ):	0.0028 ( 1.0785%)
Total Loading into water phase via Parent's runoff (mg/m <sup>2</sup> ):	0.1348 ( 52.4686%)
Total Loading into sediment phase via Parent's runoff (mg/m <sup>2</sup> ):	0.0704 ( 27.3886%)
Maximum PECSW (µg/L):	0.7242
Maximum PECSW occurring on day:	18
Maximum PECsed (µg/kg dry sediment):	1.0243
Maximum PECsed occurring on day:	19

Table: Calculated Concentrations in the water body (multiple application)

Time after max. peak(d)	PECsw (µg/L)		PECsed(µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	0.7242	---	1.0243	---
1	0.7183	0.7212	1.0236	1.0239
2	0.7178	0.7196	1.0229	1.0236
4	0.7168	0.7185	1.0214	1.0229
7	0.7153	0.7174	1.0193	1.0218
14	0.7118	0.7155	1.0144	1.0193
21	0.7084	0.7137	1.0095	1.0169
28	0.7050	0.7119	1.0046	1.0144
42	0.6982	0.7085	0.9949	1.0095
50	0.6943	0.7065	0.9894	1.0067
100	0.6706	0.6945	0.9557	0.9896

#### RESULTS OF THE CALCULATION FOR THE RESPECTIVE SINGLE APPLICATION PATTERN

Number of application per season considered for this run:	1
Equivalent application rate for drift (g/ha):	7.06
Equivalent application rate for runoff/drainage(g/ha):	10.78
Loading to water body per drift event(mg/m <sup>2</sup> ):	0.0195
Loading to water body via runoff(mg/m <sup>2</sup> ):	0.0173
fraction of substance entering water body in water phase:	0.8402
fraction of substance entering water body in sediment phase:	0.1598
Total Loading to water body via drift (mg/m <sup>2</sup> ):	0.0195 ( 52.8881%)
Total Loading to water body via water phase(mg/m <sup>2</sup> ):	0.0146 ( 39.5854%)
Total Loading to water body via sediment phase (mg/m <sup>2</sup> ):	0.0028 ( 7.5265%)
Maximum PECSW (µg/L):	0.4111

Maximum PECSW occurring on day:	4
Maximum PECsed (µg/kg dry sediment):	0.5815
Maximum PECsed occurring on day:	5

Table: Calculated Concentrations in the water body (respective single application pattern)

Time after max. peak(d)	PECsw (µg/L)		PECsed(µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	0.4111	---	0.5815	---
1	0.4078	0.4095	0.5811	0.5813
2	0.4075	0.4086	0.5807	0.5811
4	0.4069	0.4079	0.5799	0.5807
7	0.4061	0.4073	0.5787	0.5801
14	0.4041	0.4062	0.5759	0.5787
21	0.4022	0.4052	0.5731	0.5773
28	0.4002	0.4042	0.5703	0.5759
42	0.3964	0.4022	0.5648	0.5731
50	0.3942	0.4011	0.5617	0.5716
100	0.3807	0.3943	0.5426	0.5618



**R402173 (winter oilseed rape, 2 x 120 g as/ha – winter oilseed rape, Step 1)**  
**(PEC<sub>sw</sub> calculations based on K<sub>foc</sub> of 25 mL/g)**

## **STEPS 1-2 in FOCUS**

### **FOCUS Surface water Tool for Exposure Predictions Step 1**

*developed by Michael Klein*

Program version: Version 3.2  
Date of this simulation: 22/03/2021, 22:12:37

#### OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

*Comments: Azoxy metabolite*

Active substance:	R402173_2
Compound for PEC calculation:	SEU_OSR winter
Application rate (g/ha) of a.i.:	120.00
Application/crop type:	oil seed rape, winter
Number of applications per season:	2.00
Application interval (d):	14.00
Molecular mass of active ingredient (g/mole):	403.40
Molecular mass of calc. compound (g/mole):	333.30
Maximum observed in water/sediment studies (%)	2.40
Maximum observed in soil studies (%)	17.00
KOC of parent compound(L/kg):	391.50
Water solubility (mg/L):	61.00
KOC compound(L/kg):	25.00
DT50 water/sediment (d):	1000.00

#### SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m):	1.00
Spraydrift (% of application):	2.7590
Runoff + drainage(% of application):	10.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

#### RESULTS OF THE CALCULATION

Equivalent app. rate for drift (g/ha):	2.38
Equivalent app. rate for runoff/drainage(g/ha):	16.86
Equivalent app. rate for runoff/drainage(g/ha) of parent:	2.38
Loading to water body via drift (mg/m <sup>2</sup> ):	0.0131
Loading to water body via runoff/drainage(mg/m <sup>2</sup> ):	3.8469
fraction of substance entering water body in water phase:	0.9677
fraction of substance entering water body in sediment phase:	0.0323

Table: Calculated Concentrations in the water body

Time (d)	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	12.4532		3.1023	
1	12.4431	12.4481	3.1108	3.1066
2	12.4345	12.4435	3.1086	3.1081
4	12.4173	12.4347	3.1043	3.1073
7	12.3915	12.4217	3.0979	3.1046
14	12.3315	12.3916	3.0829	3.0975
21	12.2718	12.3616	3.0680	3.0901
28	12.2124	12.3317	3.0531	3.0827
42	12.0945	12.2723	3.0236	3.0679
50	12.0276	12.2385	3.0069	3.0595
100	11.6179	12.0300	2.9045	3.0074

Maximum PEC<sub>sw</sub> values in water and sediment are calculated from sum of individual applications.

**Compare with ecotox endpoints. If TER values are less than regulatory triggers, then go to Step 2**

**R402173 (winter oilseed rape, 2 x 120 g as/ha – winter oilseed rape, SEU, Step 2)**  
**(PEC<sub>sw</sub> calculations based on K<sub>foc</sub> of 25 mL/g)**

## **STEPS 1-2 in FOCUS**

### **FOCUS Surface water Tool for Exposure Predictions Step 2**

*developed by Michael Klein*

Program version:	Version 3.2
Date of this simulation:	22/03/2021, 22:12:40

#### OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

*Comments: Azoxy metabolite*

Active substance:	R402173_2
Compound for PEC calculation:	SEU_OSR winter
Application rate (g/ha) of a.i.:	120.00
Crop Interception:	full canopy (75 %)
Application/crop type:	oil seed rape, winter
Number of applications per season:	2
Application interval (d):	14.00
Region and season of application:	South Europe, Mar. - May
Molecular mass of active ingredient (g/mole):	403.40
Molecular mass of calc. compound (g/mole):	333.30
Maximum observed in water/sediment studies (%)	2.40
Maximum observed in soil studies (%)	17.00
DT50 soil (d) parent compound:	78.00
Water solubility (mg/L):	61.00
KOC assessed compound(L/kg):	25.00
KOC parent compound(L/kg):	391.50
DT50 water(d):	1000.00
DT50 sediment (d):	1000.00
DT50 soil (d):	4.70

#### SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m):	1.00
Spraydrift for multiple applications (% of application):	2.4380
Spraydrift for single application (% of application):	2.7590
Runoff + drainage(% of application):	4.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

#### RESULTS OF THE CALCULATION

Number of application per season considered for this run:	2
---	---

Equivalent application rate for drift (g/ha):	2.38
Equivalent application rate for runoff/drainage(g/ha):	4.21
Equivalent app. rate for runoff/drainage of parent compound(g/ha):	0.59
Loading to water body per drift event(mg/m <sup>2</sup> ):	0.0058
Loading to water body via runoff/drainage (mg/m <sup>2</sup> ):	0.1053
fraction of substance entering water body in water phase:	0.9677
fraction of substance entering water body in sediment:	0.0323
Loading to water body via runoff/drainage of parent substance(mg/m <sup>2</sup> ):	0.0432
fraction of parent substance entering water body in water phase:	0.6570
fraction of parent substance entering water body in sediment:	0.3430
Total Loading to water body via drift (mg/m <sup>2</sup> ):	0.0116 ( 7.2454%)
Total Loading to water body via water phase(mg/m <sup>2</sup> ):	0.1019 ( 63.6306%)
Total Loading to water body via sediment phase (mg/m <sup>2</sup> ):	0.0034 ( 2.1210%)
Total Loading into water phase via Parent's runoff (mg/m <sup>2</sup> ):	0.0284 ( 17.7418%)
Total Loading into sediment phase via Parent's runoff (mg/m <sup>2</sup> ):	0.0148 ( 9.2612%)
Maximum PECSW (µg/L):	0.5167
Maximum PECSW occurring on day:	18
Maximum PECsed (µg/kg dry sediment):	0.1290
Maximum PECsed occurring on day:	19

Table: Calculated Concentrations in the water body (multiple application)

Time after max. peak(d)	PECsw (µg/L)		PECsed(µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	0.5167	---	0.1290	---
1	0.5159	0.5163	0.1289	0.1289
2	0.5156	0.5160	0.1288	0.1289
4	0.5149	0.5156	0.1286	0.1288
7	0.5138	0.5151	0.1284	0.1287
14	0.5113	0.5138	0.1277	0.1284
21	0.5088	0.5126	0.1271	0.1280
28	0.5064	0.5113	0.1265	0.1277
42	0.5015	0.5089	0.1253	0.1271
50	0.4987	0.5075	0.1246	0.1268
100	0.4817	0.4988	0.1203	0.1246

#### RESULTS OF THE CALCULATION FOR THE RESPECTIVE SINGLE APPLICATION PATTERN

Number of application per season considered for this run:	1
Equivalent application rate for drift (g/ha):	2.38
Equivalent application rate for runoff/drainage(g/ha):	4.21
Loading to water body per drift event(mg/m <sup>2</sup> ):	0.0066
Loading to water body via runoff(mg/m <sup>2</sup> ):	0.0934
fraction of substance entering water body in water phase:	0.9677
fraction of substance entering water body in sediment phase:	0.0323
Total Loading to water body via drift (mg/m <sup>2</sup> ):	0.0066 ( 6.5648%)
Total Loading to water body via water phase(mg/m <sup>2</sup> ):	0.0904 ( 90.4212%)
Total Loading to water body via sediment phase (mg/m <sup>2</sup> ):	0.0030 ( 3.0140%)

Maximum PECSW (µg/L):	0.3968
Maximum PECSW occurring on day:	4
Maximum PECsed (µg/kg dry sediment):	0.0991
Maximum PECsed occurring on day:	5

Table: Calculated Concentrations in the water body (respective single application pattern)

Time after max. peak(d)	PECsw (µg/L)		PECsed(µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	0.3968	---	0.0991	---
1	0.3963	0.3966	0.0990	0.0991
2	0.3961	0.3964	0.0989	0.0990
4	0.3955	0.3961	0.0988	0.0989
7	0.3947	0.3957	0.0986	0.0988
14	0.3928	0.3947	0.0981	0.0986
21	0.3909	0.3938	0.0977	0.0984
28	0.3890	0.3928	0.0972	0.0981
42	0.3852	0.3909	0.0962	0.0977
50	0.3831	0.3898	0.0957	0.0974
100	0.3701	0.3832	0.0925	0.0957

**R402173 (winter oilseed rape, 2 x 120 g as/ha – winter oilseed rape, Step 1)**  
**(PEC<sub>sed</sub> calculations based on K<sub>foc</sub> of 200 mL/g)**

## **STEPS 1-2 in FOCUS**

### **FOCUS Surface water Tool for Exposure Predictions Step 1**

*developed by Michael Klein*

Program version: Version 3.2  
Date of this simulation: 22/03/2021, 22:40:13

#### OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

*Comments: Azoxy metabolite*

Active substance:	R402173_2_s
Compound for PEC calculation:	SEU_OSR winter
Application rate (g/ha) of a.i.:	120.00
Application/crop type:	oil seed rape, winter
Number of applications per season:	2.00
Application interval (d):	14.00
Molecular mass of active ingredient (g/mole):	403.40
Molecular mass of calc. compound (g/mole):	333.30
Maximum observed in water/sediment studies (%)	2.40
Maximum observed in soil studies (%)	17.00
KOC of parent compound(L/kg):	391.50
Water solubility (mg/L):	61.00
KOC compound(L/kg):	200.00
DT50 water/sediment (d):	1000.00

#### SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m):	1.00
Spraydrift (% of application):	2.7590
Runoff + drainage(% of application):	10.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

#### RESULTS OF THE CALCULATION

Equivalent app. rate for drift (g/ha):	2.38
Equivalent app. rate for runoff/drainage(g/ha):	16.86
Equivalent app. rate for runoff/drainage(g/ha) of parent:	2.38
Loading to water body via drift (mg/m <sup>2</sup> ):	0.0131
Loading to water body via runoff/drainage(mg/m <sup>2</sup> ):	3.8469
fraction of substance entering water body in water phase:	0.7895
fraction of substance entering water body in sediment phase:	0.2105

Table: Calculated Concentrations in the water body

Time (d)	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	10.1672		20.2469	
1	10.1510	10.1591	20.3019	20.2744
2	10.1439	10.1533	20.2879	20.2847
4	10.1299	10.1451	20.2598	20.2792
7	10.1088	10.1341	20.2177	20.2619
14	10.0599	10.1092	20.1198	20.2153
21	10.0112	10.0847	20.0224	20.1672
28	9.9628	10.0602	19.9255	20.1189
42	9.8666	10.0117	19.7331	20.0223
50	9.8120	9.9841	19.6240	19.9673
100	9.4778	9.8140	18.9555	19.6276

Maximum PEC<sub>sw</sub> values in water and sediment are calculated from sum of individual applications.

**Compare with ecotox endpoints. If TER values are less than regulatory triggers, then go to Step 2**

**R402173 (winter oilseed rape, 2 x 120 g as/ha – winter oilseed rape, SEU, Step 2)**  
**(PEC<sub>sed</sub> calculations based on K<sub>foc</sub> of 200 mL/g)**

## **STEPS 1-2 in FOCUS**

### **FOCUS Surface water Tool for Exposure Predictions Step 2**

*developed by Michael Klein*

Program version: Version 3.2  
Date of this simulation: 22/03/2021, 22:40:18

#### OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

*Comments: Azoxy metabolite*

Active substance:	R402173_2_s
Compound for PEC calculation:	SEU_OSR winter
Application rate (g/ha) of a.i.:	120.00
Crop Interception:	full canopy (75 %)
Application/crop type:	oil seed rape, winter
Number of applications per season:	2
Application interval (d):	14.00
Region and season of application:	South Europe, Mar. - May
Molecular mass of active ingredient (g/mole):	403.40
Molecular mass of calc. compound (g/mole):	333.30
Maximum observed in water/sediment studies (%)	2.40
Maximum observed in soil studies (%)	17.00
DT50 soil (d) parent compound:	78.00
Water solubility (mg/L):	61.00
KOC assessed compound(L/kg):	200.00
KOC parent compound(L/kg):	391.50
DT50 water(d):	1000.00
DT50 sediment (d):	1000.00
DT50 soil (d):	4.70

#### SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m):	1.00
Spraydrift for multiple applications (% of application):	2.4380
Spraydrift for single application (% of application):	2.7590
Runoff + drainage(% of application):	4.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

#### RESULTS OF THE CALCULATION

Number of application per season considered for this run: 2



Equivalent application rate for drift (g/ha):	2.38
Equivalent application rate for runoff/drainage(g/ha):	4.21
Equivalent app. rate for runoff/drainage of parent compound(g/ha):	0.59
Loading to water body per drift event(mg/m <sup>2</sup> ):	0.0058
Loading to water body via runoff/drainage (mg/m <sup>2</sup> ):	0.1053
fraction of substance entering water body in water phase:	0.7895
fraction of substance entering water body in sediment:	0.2105
Loading to water body via runoff/drainage of parent substance(mg/m <sup>2</sup> ):	0.0432
fraction of parent substance entering water body in water phase:	0.6570
fraction of parent substance entering water body in sediment:	0.3430
Total Loading to water body via drift (mg/m <sup>2</sup> ):	0.0116 ( 7.2454%)
Total Loading to water body via water phase(mg/m <sup>2</sup> ):	0.0831 ( 51.9092%)
Total Loading to water body via sediment phase (mg/m <sup>2</sup> ):	0.0222 ( 13.8424%)
Total Loading into water phase via Parent's runoff (mg/m <sup>2</sup> ):	0.0284 ( 17.7418%)
Total Loading into sediment phase via Parent's runoff (mg/m <sup>2</sup> ):	0.0148 ( 9.2612%)
Maximum PECSW (µg/L):	0.4235
Maximum PECSW occurring on day:	18
Maximum PECsed (µg/kg dry sediment):	0.8418
Maximum PECsed occurring on day:	19

Table: Calculated Concentrations in the water body (multiple application)

Time after max. peak(d)	PECsw (µg/L)		PECsed(µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	0.4235	---	0.8418	---
1	0.4209	0.4222	0.8412	0.8415
2	0.4206	0.4215	0.8406	0.8412
4	0.4200	0.4209	0.8395	0.8406
7	0.4191	0.4203	0.8377	0.8397
14	0.4171	0.4192	0.8337	0.8377
21	0.4151	0.4182	0.8296	0.8357
28	0.4131	0.4172	0.8256	0.8337
42	0.4091	0.4151	0.8176	0.8297
50	0.4068	0.4140	0.8131	0.8274
100	0.3930	0.4069	0.7854	0.8133

## RESULTS OF THE CALCULATION FOR THE RESPECTIVE SINGLE APPLICATION PATTERN

Number of application per season considered for this run:	1
Equivalent application rate for drift (g/ha):	2.38
Equivalent application rate for runoff/drainage(g/ha):	4.21
Loading to water body per drift event(mg/m <sup>2</sup> ):	0.0066
Loading to water body via runoff(mg/m <sup>2</sup> ):	0.0934
fraction of substance entering water body in water phase:	0.7895
fraction of substance entering water body in sediment phase:	0.2105
Total Loading to water body via drift (mg/m <sup>2</sup> ):	0.0066 ( 6.5648%)
Total Loading to water body via water phase(mg/m <sup>2</sup> ):	0.0738 ( 73.7646%)
Total Loading to water body via sediment phase (mg/m <sup>2</sup> ):	0.0197 ( 19.6706%)

Maximum PECSW (µg/L):	0.3249
Maximum PECSW occurring on day:	4
Maximum PECsed (µg/kg dry sediment):	0.6467
Maximum PECsed occurring on day:	5

Table: Calculated Concentrations in the water body (respective single application pattern)

Time after max. peak(d)	PECsw (µg/L)		PECsed(µg/kg dry sediment)	
	Actual	TWA	Actual	TWA
0	0.3249	---	0.6467	---
1	0.3233	0.3241	0.6462	0.6464
2	0.3231	0.3237	0.6458	0.6462
4	0.3227	0.3233	0.6449	0.6458
7	0.3220	0.3229	0.6435	0.6451
14	0.3204	0.3220	0.6404	0.6435
21	0.3189	0.3212	0.6373	0.6420
28	0.3173	0.3205	0.6342	0.6404
42	0.3143	0.3189	0.6281	0.6373
50	0.3125	0.3180	0.6246	0.6356
100	0.3019	0.3126	0.6034	0.6248

### A 3.3 EPAT Graphical Output

Winter cereals (2 x 200 g a.s./ha, 14-day application interval, BBCH GS 30-69 – early application timing)

Step 4 – 20 metre spray drift buffer and 20 metre runoff vegetated filter strip

#### R4 Stream

