

**FINAL** REGISTRATION REPORT

**Part B**

**Section 8**

**Environmental Fate**

Detailed summary of the risk assessment

Product code: **CHR/F/PYRA 250 EC**

Product name(s): **Etiuda 250 EC, Fermata 250 EC**

Chemical active substance(s):

**Pyraclostrobin, 250 g/L**

Central Zone

Zonal Rapporteur Member State: Poland

**CORE ASSESSMENT**

Applicant: Innvigo Sp. z o.o.

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**MS Finalisation date: 15/12/2022**

## Version history

When	What
December 2021	Dossier sent for evaluation
May 2022	Updates based on feedback from zRMS Poland
September 2022	zRMS evaluation of dRR
December 2022	Final version prepared by zRMS after Commenting period

## Table of Contents

<b>8</b>	<b>Fate and behaviour in the environment (KCP 9).....</b>	<b>4</b>
8.1	Critical GAP and overall conclusions.....	5
8.2	Metabolites considered in the assessment.....	9
8.3	Rate of degradation in soil (KCP 9.1.1).....	10
8.3.1	Aerobic degradation in soil (KCP 9.1.1.1) .....	10
8.3.2	Anaerobic degradation in soil (KCP 9.1.1.1).....	11
8.4	Field studies (KCP 9.1.1.2).....	12
8.4.1	Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1). 12	
8.4.2	Soil accumulation testing (KCP 9.1.1.2.2) .....	12
8.5	Mobility in soil (KCP 9.1.2) .....	12
8.5.1	Column leaching (KCP 9.1.2.1).....	14
8.5.2	Lysimeter studies (KCP 9.1.2.2).....	14
8.5.3	Field leaching studies (KCP 9.1.2.3) .....	14
8.6	Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3) .....	14
8.7	Predicted Environmental Concentrations in soil (PEC <sub>soil</sub> ) (KCP 9.1.3) .....	17
8.7.1	Justification for new endpoints .....	17
8.7.2	Active substance(s) and relevant metabolite(s) .....	17
8.7.2.1	PEC <sub>soil</sub> of CHR/F/PYRA 250 EC.....	21
8.8	Predicted Environmental Concentrations in groundwater (PEC <sub>gw</sub> ) (KCP 9.2.4) .....	21
8.8.1	Justification for new endpoints .....	21
8.8.2	Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1).....	21
8.9	Predicted Environmental Concentrations in surface water (PEC <sub>sw</sub> ) (KCP 9.2.5) .....	24
8.9.1	Justification for new endpoints .....	25
8.9.2	Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5) .....	25
8.10	Fate and behaviour in air (KCP 9.3, KCP 9.3.1) .....	34
<b>Appendix 1</b>	<b>Lists of data considered in support of the evaluation .....</b>	<b>35</b>
<b>Appendix 2</b>	<b>Detailed evaluation of the new Annex II studies .....</b>	<b>37</b>
<b>Appendix 3</b>	<b>Additional information provided by the applicant (e.g. detailed modelling data).....</b>	<b>37</b>

zRMS comments:

The text highlighted in grey was provided by the evaluator.

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

New and additional informations are highlighted in yellow.

## 8.1 Critical GAP and overall conclusions

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

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15
Use- No. <sup>(e)</sup>	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: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha <sup>(f)</sup>	ZRM's 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			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Winter wheat (TRZAW)	F	<i>Mycosphaerella graminicola</i> , <i>Fusarium avenaceum</i> , <i>Pyrenophora tritici</i> , <i>Puccinia striiformis</i> , <i>Blumeria graminis</i> , <i>Phaeosphaeria nodorum</i> , <i>Puccinia recondita</i>	Spray, medium sprayer	Spring BBCH 25-69	a) 2 b) 2	21	a) 1 l/ha b) 2 l/ha	a) 0,25 kg a.s./ha b) 0,5 kg a.s/ha	100- 400	35		A
2	PL	Winter tritiale (TTLWI)	F	<i>Rhynchosporium secalis</i> , <i>Blumeria graminis</i> , <i>Pyrenophora tritici- repentis</i> , <i>Mycosphaerella graminicola</i> , <i>Fusarium avenaceum</i>	Spray, medium sprayer	Spring BBCH 25-69	a) 2 b) 2	21	a) 1 l/ha b) 2 l/ha	a) 0,25 kg a.s./ha b) 0,5 kg a.s/ha	100- 400	35		A
3	PL	Winter rye (SECCW)	F	<i>Rhynchosporium secalis</i> , <i>Puccinia recondita</i> , <i>Mycosphaerella graminicola</i> , <i>Blumeria graminis</i>	Spray, medium sprayer	Spring BBCH 25-69	a) 2 b) 2	21	a) 1 l/ha b) 2 l/ha	a) 0,25 kg a.s/ha b) 0,5 kg a.s/ha	100- 400	35		A
4	PL	Spring barley (HORVS)	F	<i>Pyrenophora teres</i> , <i>Blumeria graminis</i> , <i>Rhynchosporium secalis</i> , <i>Cochliobolus sativus</i> , <i>Puccinia hordei</i>	Spray, medium sprayer	Spring BBCH 25-59	a) 2 b) 2	21	a) 1 l/ha b) 2 l/ha	a) 0,25 kg a.s/ha b) 0,5 kg a.s/ha	100- 400	35		A

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15
Use- No. <sup>(e)</sup>	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: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha <sup>(f)</sup>	ZRM's 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			
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
1														
2														
Minor uses according to Article 51 (zonal uses)														
1	PL	Spring Rye (SECCS)	F	<i>Rhynchosporium secalis</i> , <i>Puccinia recondita</i> , <i>Mycosphaerella graminicola</i> , <i>Blumeria graminis</i> , <i>Phaeosphaeria nodorum</i>	Spray, medium sprayer	Spring BBCH 25-69	a) 2 b) 2	21	a) 1 l/ha b) 2 l/ha	a) 0,25 kg a.s/ha b) 0,5 kg a.s/ha	100- 400	35		A
2														
Minor uses according to Article 51 (interzonal uses)														
1														
2														

**Remarks table heading:**

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008

(c) g/kg or g/l

(d) Select relevant

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

(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

<b>Remarks</b>	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
<b>columns:</b>	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	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	10	For specific uses other specifications might be possible, e.g.: g/m <sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
			13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

\* 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

Column 15: zRMS conclusion.

<b>A</b>	Acceptable
<b>R</b>	Acceptable with further restriction
<b>C</b>	To be confirmed by cMS
<b>N</b>	Not acceptable / evaluation not possible
<b>n.r.</b>	Not relevant for section 3

**Table 8.1-2: Assessed (critical) uses during approval of Clethodim-pyraclostrobin 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 situ- ation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: develop- mental 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 ap- plications (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		
I	EU	cereals	F	Septoria tritici, Lepto- sphaeria nodorum, Puc- cinia recondita, Puc- cinia striiformis, Puc- cinia hordei, Fusarium species, R. secalis, P. teres, Microdochium nivale	SP	25-69	2	21	a) 1.00  b) 2.00	a) 250  b) 500	200 - 400	35	

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 Clethodim-pyraclostrobin potentially relevant for exposure assessment**

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
BF 500-3 “des-methoxy” 500M07	357		Soil: 95.8 %  Water: 2.3 %  Sediment: 65.7 %	Sediment
BF 500-6 “azoxy” 500M01	611		Soil: 30.9 %  Sediment: 6.5 %	Soil  Potential leaching to groundwater  Sediment
BF 500-7 “azo” 500M02	596		Soil: 12.5 %  Sediment: 6.3 %	Soil  Potential leaching to groundwater  Sediment
BF 500-11 “M277” 500M60	277		Water: 44.5 % (photolysis study), 11.4 %  Sediment: 0.6 %	Surface Water
BF 500-13 “M2427” 500M62	247		Water: 16.8 % (photolysis study), 15.7%  Sediment: 2.1 %	Surface Water
BF 500-14 „M387TypeA” 500M76	387		Water: 14.8 % (photolysis study), 11.4%  Sediment: 0.7 %	Surface Water

### 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 substance.

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

The degradation of pyraclostrobin in aerobic soil studies is characterised by a rather low mineralisation rate (about 5% TAR within 100 days) and a formation of high amounts of bound residues (about 55% TAR within 100 days). The same metabolites, BF 500-6 and BF 500-7, were found in all soil types. BF 500-6 generally exceeded 10% TAR (maximum 31% TAR), whereas BF 500-7 slightly exceeded 10% TAR only in one of all investigated soils. Bound residues increased with time and the major portion of radioactivity was associated with insoluble humins and high-molecular humic acids. A release of pyraclostrobin or metabolites could not be observed, neither with harsh extraction methods (NaOH) nor with intensive activity of soil-eating animals (earthworms). Photolytical degradation leads to the same degradation products, however, all metabolites were formed in amounts less than 10% TAR.

**Table 8.3.1-1: Summary of aerobic degradation rates for Pyraclostrobin - laboratory studies**

Pyraclostrobin, Laboratory studies, aerobic conditions										
Soil type	Label	pH	t. °C	MWHC %	DT <sub>50</sub> (d)	DT <sub>90</sub> (d)	DT <sub>50</sub> (d) 20°C pF2/10kPa	r <sup>2</sup>	Kinetic model	Evaluated on EU level y/n Reference
Loamy sand	Totyl	7.3	20	40	12	143	-	0.99	bi-phasic (best fit)	Yes: SANCO/1420/2001
Loamy sand	Chlorophenyl	7.5	20	40	14	152	-	0.996	bi-phasic (best fit)	
Loamy sand	-	5.4	20	40	101	-	-	0.99	bi-phasic (best fit)	
Loamy sand	-	6.5	20	40	50	163	-	0.98	bi-phasic (best fit)	
Loamy sand	-	5.6	20	40	38	-	-	0.98	bi-phasic (best fit)	
Loam	0	7.7	20	40	85	-	-	0.98	bi-phasic (best fit)	
Loamy sand	-	5.4	20	20	137	-	-	0.99	bi-phasic (best fit)	
Loamy sand	-	5.4	5	40	-	-	-	-	-	
Loamy sand	-	5.4	30	40	86	-	-	0.98	bi-phasic (best fit)	
Loamy sand	-	5.4	20	40	-	-	-	-	-	
Geometric mean (n=10)							Not used			
pH-dependency:							No			

**Table 8.3.1-2: Summary of aerobic degradation rates for BF 500-6 - laboratory studies**

BF 500-6, Laboratory studies, aerobic conditions										
Soil type	Label	pH	t. °C	MWHC %	DT <sub>50</sub> (d)	DT <sub>90</sub> (d)	DT <sub>50</sub> (d) 20°C pF2/10kPa	r <sup>2</sup>	Kinetic model	Evaluated on EU level y/n Reference
Loamy sand	Totyl	7.3	20	40	129	428	-	0.99	bi-phasic (best fit)	Yes: SANCO/1420/2001
Loamy sand	Chlorophenyl	7.5	20	40	166	552	-	0.996	bi-phasic (best fit)	
Geometric mean (n=2)							Not used			
pH-dependency:							No			

**Table 8.3.1-3: Summary of aerobic degradation rates for BF 500-7 - laboratory studies**

BF 500-6, Laboratory studies, aerobic conditions										
Soil type	Label	pH	t. °C	MWHC %	DT <sub>50</sub> (d)	DT <sub>90</sub> (d)	DT <sub>50</sub> (d) 20°C pF2/10kPa	r <sup>2</sup>	Kinetic model	Evaluated on EU level y/n Reference
Loamy sand	Totyl	7.3	20	40	112	372	-	0.99	bi-phasic (best fit)	Yes: SANCO/1420/2001
Loamy sand	Chlorophenyl	7.5	20	40	159	529	-	0.996	bi-phasic (best fit)	
Geometric mean (n=2)							Not used			
pH-dependency:							No			

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

Under anaerobic conditions, a very fast de-methoxylation took place, forming the metabolite BF 500-3 in high amounts (max. 96% TAR within 7 days). This reaction is supposed to be the first step also in the aerobic soil degradation, however, in aerobic soil the further reaction to BF 500-6, BF 500-7 and bound residues is too fast to detect this short-lived intermediate. In anaerobic soil, however, the further reactions of BF 500-3 are slowed down considerably.

**Table 8.3.2: Summary of anaerobic degradation rates for pyraclostrobin- laboratory studies**

Pyraclostrobin, Laboratory studies, aerobic conditions										
Soil type	Label	pH	t. °C	MWHC %	DT <sub>50</sub> (d)	DT <sub>90</sub> (d)	DT <sub>50</sub> (d) 20°C pF2/10kPa	r <sup>2</sup>	Kinetic model	Evaluated on EU level y/n Reference
Sandy loam	Totyl	7.5	20	flooded	2	5	-	0.981	SFO	Yes: SANCO/1420/2001
Loamy sand	Chlorophenyl	7.2	20	flooded	3	9	-	0.980	SFO	
Major metabolites						BF 500-3 max. 95.8%				

## 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)

The laboratory rate studies showed that under certain conditions the DT50-value of pyraclostrobin in soil can be greater than 60 days. This is the trigger value given by EEC Directive 91/414 amended by EC Directive 95/36 that requires the performance of field soil dissipation studies.

Pyraclostrobin, Field studies – Modelling endpoints						
Soil type	Location	pH	Depth	DT <sub>50</sub> (d) 20°C pF2/10kPa	Fit/r <sup>2</sup> /err (%)	Evaluated on EU level y/n Reference
Sandy loam	Spain, Manzanilla	7.6	0-50 cm	-	-	Yes: Kellner, O., Zagnmeister, W., 1999, 1999/11301  Kellner, O., Zagnmeister, W., 1999, 1999/11292
Sandy loam	Spain, Alcala de Rio	7.6	0-50 cm	-	-	
Loamy sands	Sweden, Bjarred	5.8	0-50 cm	20.6	SFO/0.888/20.2	
Loamy sands	Germany, Meckenheim	6.2	0-50 cm	12.5	SFO/0.994/5.1	
Loamy silt	Germany, Bad Sass	6.8	0-50 cm	26.5	SFO/0.997/3.3	
Loamy sand	Germany Grobharrie	5.6	0-50 cm	15.3	SFO/0.845/22.0	
Geometric mean (n=4)				18		
pH-dependency				No		

### 8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Soil accumulation studies are not required according to SANCO/1420/2001.

## 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 substance.

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

Pyraclostrobin						
Soil type	OC (%)	pH (-)	K <sub>f</sub> (mL/g)	K <sub>foc</sub> (mL/g)	1/n (-)	Evaluated on EU level y/n Reference
Sand	0.8	6.4	60	7500	0.896	Yes: SANCO/1420/2001
Loamy sand	1.9	5.6	304	16000	1.025	
Sandy loam	1.8	7.3	142	7889	1.012	
Loamy sand	0.5	5.9	30	6000	0.861	
Sandy loam	0.6	5.3	54	9000	0.873	
Sandy loam	3.9	7.6	368	9436	1.005	
Arithmetic mean (n = 6)				9304	0.95	
pH-dependency				No		

**Table 8.5-2: Summary of soil adsorption/desorption for BF 500-3**

BF 500-3						
Soil type	OC (%)	pH (-)	K <sub>f</sub> (mL/g)	K <sub>foc</sub> (mL/g)	1/n (-)	Evaluated on EU level y/n Reference
Sand/ Loamy sand	2.5	5.8	268	10700	0.942	Yes: SANCO/1420/2001
Sandy loam	1.5	7.5	63.5	4240	0.688	
Loamy sand	1.1	6.5	74.3	6750	0.802	
Loamy sand	0.4	5.8	47.3	11800	0.942	
Loam	0.5	5.2	60.1	12000	0.773	
Sandy clay loam	3.4	7.5	354	10400	0.831	
Arithmetic mean (n = 6)				9315	0.830	
pH-dependency				No		

**Table 8.5-3: Summary of soil adsorption/desorption for BF 500-6**

BF 500-6						
Soil type	OC (%)	pH (-)	K <sub>f</sub> (mL/g)	K <sub>foc</sub> (mL/g)	1/n (-)	Evaluated on EU level y/n Reference
Sand/ Loamy sand	2.5	5.8	84	3360	-	Yes: SANCO/1420/2001
Sandy loam	1.5	7.5	248	16550	-	
Loamy sand	1.1	6.5	350	31830	-	
Loamy sand	0.4	5.8	366	91650	-	
Loam	0.5	5.2	634	126800	-	
Sandy clay loam	3.4	7.5	630	18500	-	
Arithmetic mean (n = 6)				48115	-	
pH-dependency				No		

**Table 8.5-4: Summary of soil adsorption/desorption for BF 500-7**

BF 500-7						
Soil type	OC (%)	pH (-)	K <sub>f</sub> (mL/g)	K <sub>foc</sub> (mL/g)	1/n (-)	Evaluated on EU level y/n Reference
Sand/ Loamy sand	2.5	5.8	101	4020	-	Yes: SANCO/1420/2001
Sandy loam	1.5	7.5	450	29950	-	
Loamy sand	1.1	6.5	418	37950	-	
Loamy sand	0.4	5.8	544	135900	-	
Loam	0.5	5.2	750	149900	-	
Sandy clay loam	3.4	7.5	543	15950	-	
Arithmetic mean (n = 6)				62278	-	
pH-dependency				No		

### 8.5.1 Column leaching (KCP 9.1.2.1)

Laboratory studies:

Column leaching:

Aged residue leaching:

0% in leachate, all radioactivity in top soil layer

0% in leachate, all radioactivity in top soil layer

The mobility of pyraclostrobin in soil and its metabolites were evaluated during the Annex I inclusion. No additional column leaching studies have been performed.

Pyraclostrobin as well as its metabolites showed very high K<sub>oc</sub> values. In aged and non-aged column leaching studies, no residues were found in any of the leachates and all radioactivity remained in the top soil layer.

### 8.5.2 Lysimeter studies (KCP 9.1.2.2)

Field studies:

Lysimeter/Field leaching studies:

based on K<sub>oc</sub> and DT<sub>50</sub> values, no leaching expected  
 Studies are not required.

The mobility in soil of pyraclostrobin and its metabolites were evaluated during Annex I inclusion. No additional studies have been performed. Neither the active substance nor its metabolites revealed any risk for groundwater contamination. Lysimeter studies were therefore considered unnecessary.

### 8.5.3 Field leaching studies (KCP 9.1.2.3)

Field studies:

Lysimeter/Field leaching studies:

based on K<sub>oc</sub> and DT<sub>50</sub> values, no leaching expected  
 Studies are not required.

The mobility in soil of pyraclostrobin and its metabolites were evaluated during Annex I inclusion. No additional studies have been performed. Neither the active substance nor its metabolites revealed any risk for groundwater contamination. Lysimeter/Field leaching studies were therefore considered unnecessary.

## 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 substance.

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

Pyraclostrobin Distribution ( pond:max. sediment 53% after 14d; river: max sediment 62% after 2d, decreasing to 10% after 100d; irradiated system: max sediment 18.3% after 7d)					
Water/sediment system	DegT50 whole syst. (d)	DegT90 whole syst. (d)	DissT50 water (d)	DissT90 water (d)	Evaluated on EU level y/n Reference
Pond	27/29	89	3/8.7	41	Yes:SANCO/1420/2001
River	29	96	1	9	
Irradiated water	-	-	5	-	

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

Metabolite in Water/sediment system	Max. in water/sediment % after d (system, label)	Evaluated on EU level y/n Reference
BF 500-3	Max. in water: 2.3 % after 61 d (river, mean of both labels) Max. in sediment: 65.7 % after 14 d (river, mean of both labels) Irradiated system: Not found	SANCO/1420/2001
BF 500-6	Max. in water: Not found in water Max. in sediment: 6.5 % after 61 d (pond, mean of both labels) Irradiated system: Not found	
BF 500-7	Max. in water: Not found in water Max. in sediment: 6.3 % after 61 d (pond, mean of both labels) Irradiated system: Not found	
BF 500-11	Max. in water: 7.1 % after 33 d Max. in sediment: 15.5 % at 61 d (pond, ring) Irradiated system: max. water 11.4 % after 21 d, max. sediment 0.6 % after 62 d (both totyl-label)	
BF 500-13	Max. in water: Not found in water Max. in sediment: Not found in sediment Irradiated system: max. water 15.7 % after 62 d, max. sediment 2.1 % after 45 d (both totyl-label)	
BF 500-14	Max. in water: Not found in water Max. in sediment: Not found in sediment Irradiated system: max. water 11.4 % after 14 d, max. sediment 0.7 % after 7 d (both chlorophenyl-label)	

**Table 8.6-3: Summary of degradation in water/sediment of observed metabolites under realistic light and temperature conditions**

time after treatment	% TAR								
	total	BF500-14 (500M76) Rf 0.18	unknown Rf 0.26	BF 500-11 (500M60) Rf 0.31	BF 500-13 (500M62) Rf 0.44	BF 500-12 (500M59) Rf 0.27	pyraclostrobin Rf 0.80	BF 500-3 (500M07) Rf 0.89	others*
<b>water</b>									
0 h	89.4	0.1	0.1	0.2			85.2	2.4	1.5
3 h	91.4	1.3	0.1	0.9		0.8	84.0	2.7	1.6
6 h	90.6	1.4	0.1	1.1		0.9	82.4	2.8	1.9
9 h	83.8	1.7	0.2	1.2		1.2	75.5	2.6	1.5
1 d	81.2	2.7	0.2	2.1	0.4	1.7	68.7	2.6	2.8
2 d	80.9	4.7	0.3	3.7	0.6	3.1	61.0	3.0	4.4
3 d	78.4	6.6	0.5	5.7	1.2	3.9	51.0	3.0	6.5
7 d	69.1	8.5	0.7	7.8	2.2	3.3	34.2	2.7	9.7
10 d	63.4	10.8	1.3	10.4	3.7	2.2	17.3	2.3	15.4
14 d	59.6	9.7	1.6	10.3	4.1	1.8	14.0	2.4	15.1
21 d	57.3	8.6	3.0	11.4	7.0	1.0	5.4	3.3	17.6
30 d	55.9	5.6	4.7	10.5	10.5		2.1	5.0	17.7
45 d	51.5	2.3	5.9	5.5	14.0	0.6	0.8	4.7	17.6
62 d	46.2	1.7	5.9	3.9	15.7	0.9	0.9	4.1	13.1
<b>Sediment</b>									
1 d	9.9	0.1				0.1	8.9	0.6	0.2
3 d	18.1	0.3	0.1			0.2	15.0	1.4	0.9
7 d	25.6	0.5	0.3	0.1	0.4	0.3	18.3	4.0	1.7
14 d	24.7	0.6	0.8	0.2	0.8	0.2	6.4	12.4	3.2
30 d	26.6	0.4	1.7	0.3	1.8		0.9	16.9	4.7
45 d	24.2	0.6	1.9	0.5	2.1		0.5	14.3	4.3
62 d	21.5	0.5	1.8	0.6	1.9		0.3	12.7	3.8



**Table 8.6-4: Summary of degradation in water/sediment of observed metabolites under irradiated conditions**

Substance		DT <sub>50</sub> [days] (first order)
pyraclostrobin	(water)	5
BF 500-11	(water)	20
BF 500-13	(water)	-*
BF 500-14	(water)	14
pyraclostrobin	(sediment)	4
BF 500-3	(sediment)	99

\* no reasonable calculation possible

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

zRMS  
Comments:

Calculations of PECs for active substance and its metabolites BF 500-6 and BF 500-7 were accepted.  
For PECs calculations the worst-case field DT<sub>50</sub> of 55 days was used according to the SANCO/1420/2001. Regarding the metabolites BF 500-6 and BF 500-7 worst-case default DT<sub>50</sub> values of 1000 days were used.  
  
The crop interception of 20% was accepted.  
  
The maximum initial and accumulative (if relevant) PECs values for active substance and its metabolites for multiple application are presented in following table:

Crop	Winter and spring cereals	
Application rate g a.s./ha	2 x 250.0 21 d interval	
Compound	PECs, ini	PEC <sub>accumulation</sub>
	mg a.s/kg	
Pyraclostrobin	0.4713	nr
BF 500-6	0.2195	1.0740
BF 500-7	0.0865	0.4231

nr – not relevant as DT<sub>90</sub> < 1 year

Calculation of PECs for formulation was corrected by the evaluator:

PEC<sub>sformulation</sub> = 1.1346 mg/kg.

These values will be used in further risk assessment.

nr – not relevant as DT<sub>90</sub> < 1 year

Calculation of PECs for formulation was corrected by the evaluator:

$$PEC_{\text{formulation}} = 1.1346 \text{ mg/kg.}$$

These values will be used in further risk assessment.

### 8.7.1 Justification for new endpoints

Not deemed necessary

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

According to the residue definition provided in the SANCO/1420/2001, the active substance Pyraclostrobin and its major soil metabolites BF 500-6 and BF 500-7 are considered for environmental exposure assessment in soil.

Cereals are considered to represent the worst case scenario in predicting the environmental concentration in soil as it has a higher application rate.

**Table 8.7.2-1: Input parameters related to application for PEC<sub>soil</sub> calculations**

Use No.	1-4, minor 1
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Crop	Winter and spring cereals (BBCH 25-69)
Application rate (g as/ha)	Pyraclostrobin: 250
Number of applications/interval	2/21
Crop interception (%)	20
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm (no tillage)

**Table 8.7.2-2: Input parameter for Pyraclostrobin and relevant metabolites for PEC<sub>soil</sub> calculation**

Compound	Molecular weight (g/mol)	Max. formation fraction <sup>a)</sup> or occurrence <sup>b)</sup> (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Pyraclostrobin	387.8	-	<b>55</b> (SFO, maximum field)	Yes <i>SANCO/1420/2001</i>
BF 500-6	611.5	30.9	1000 (SFO, default)	
BF 500-7	595.5	12.5	1000 (SFO, default)	

<sup>a</sup> Not averaged endpoint representing the absolute worst case, in agreement with other selected DT<sub>50</sub> values  
<sup>b</sup> maximum occurrence

**Table 8.7-2-3: PEC<sub>soil</sub> for Pyraclostrobin- multiple applications**

PEC <sub>soil</sub> (mg/kg)		Cereals	
		Multiple applications	
		Actual	TWA
Initial		<b>0.4713</b>	-
Short term	24h	<b>0.4654</b>	<b>0.4684</b>
	2d	<b>0.4596</b>	<b>0.4654</b>
	4d	<b>0.4482</b>	<b>0.4596</b>
Long term	7d	<b>0.4315</b>	<b>0.4511</b>
	14d	<b>0.3951</b>	<b>0.4321</b>
	21d	<b>0.3617</b>	<b>0.4141</b>
	28d	<b>0.3312</b>	<b>0.3974</b>
	50d	<b>0.2510</b>	<b>0.3514</b>
	100d	<b>0.1337</b>	<b>0.2863</b>
Plateau concentration (5 cm) after year 10		<b>0.0048</b>	-
PEC <sub>accumulation</sub> (PEC <sub>act</sub> + PEC <sub>soil</sub> plateau)		<b>0.4764</b>	-

**Table 8.7-2-4: PEC<sub>soil</sub> for Pyraclostrobin- single application**

PEC <sub>soil</sub> (mg/kg)		Cereals	
		Single application	
		Actual	TWA
Initial		0.2667	-
Short term	24h	0.2633	0.2650
	2d	0.2600	0.2633
	4d	0.2536	0.2601
Long term	7d	0.2441	0.2552
	14d	0.2235	0.2445
	21d	0.2047	0.2343
	28d	0.1874	0.2247
	50d	0.1420	0.1978
	100d	0.0756	0.1516
Plateau concentration (5 cm) after year 10		0.0027	-
PEC <sub>accumulation</sub> (PEC <sub>act</sub> + PEC <sub>soil plateau</sub> )		0.2694	-

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

**Table 8.7-2-5: PEC<sub>soil</sub> for BF 500-6- multiple applications**

PEC <sub>soil</sub> (mg/kg)		Cereals	
		Multiple Applications	
		Actual	TWA
Initial		0.2195	-
Short term	24h	0.2195	0.2195
	2d	0.2195	0.2195
	4d	0.2195	0.2195
Long term	7d	0.2194	0.2195
	14d	0.2193	0.2195
	21d	0.2191	0.2194
	28d	0.2188	0.2194
	50d	0.2175	0.2193
	100d	0.2130	0.2187
Plateau concentration (5 cm) after year 10		0.8546	-
PEC <sub>accumulation</sub> (PEC <sub>act</sub> + PEC <sub>soil plateau</sub> )		1.0740	-

**Table 8.7-2-6: PEC<sub>soil</sub> for BF 500-6- single application**

PEC <sub>soil</sub>	Cereals
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(mg/kg)		Single application	
		Actual	TWA
Initial		0.1098	-
Short term	24h	0.1098	0.1098
	2d	0.1098	0.1098
	4d	0.1098	0.1098
Long term	7d	0.1098	0.1098
	14d	0.1097	0.1098
	21d	0.1096	0.1098
	28d	0.1094	0.1097
	50d	0.1088	0.1097
	100d	0.1066	0.1094
Plateau concentration (5 cm) after year 10		0.4275	-
PEC <sub>accumulation</sub> (PEC <sub>act</sub> + PEC <sub>soil plateau</sub> )		0.5373	-

**Table 8.7-2-7: PEC<sub>soil</sub> for BF 500-7- multiple applications**

PEC <sub>soil</sub> (mg/kg)		Cereals	
		Multiple Applications	
		Actual	TWA
Initial		0.0865	-
Short term	24h	0.0865	0.0865
	2d	0.0865	0.0865
	4d	0.0865	0.0865
Long term	7d	0.0864	0.0865
	14d	0.0864	0.0864
	21d	0.0863	0.0864
	28d	0.0862	0.0864
	50d	0.0857	0.0864
	100d	0.0839	0.0861
Plateau concentration (5 cm) after year 10		0.3366	-
PEC <sub>accumulation</sub> (PEC <sub>act</sub> + PEC <sub>soil plateau</sub> )		0.4231	-

**Table 8.7-2-8: PEC<sub>soil</sub> for BF 500-7- single application**

PEC <sub>soil</sub> (mg/kg)		Cereals	
		Single application	
		Actual	TWA
Initial		0.0433	-

Short term	24h	0.0433	0.0433
	2d	0.0432	0.0433
	4d	0.0432	0.0433
Long term	7d	0.0432	0.0432
	14d	0.0432	0.0432
	21d	0.0432	0.0432
	28d	0.0431	0.0432
	50d	0.0429	0.0432
	100d	0.0420	0.0431
Plateau concentration (5 cm) after year 10		0.1684	-
PEC <sub>accumulation</sub> (PEC <sub>act</sub> + PEC <sub>soil plateau</sub> )		0.2117	-

### 8.7.2.1 PEC<sub>soil</sub> of CHR/F/PYRA 250 EC

Table 8.7-2-9: PEC<sub>soil</sub> for CHR/F/PYRA 250 EC on cereals

Active substance/ reparation	Application rate (g/ha)	PEC <sub>act</sub> (mg/kg)	PEC <sub>twa21 d</sub> (mg/kg)	Tillage depth (cm)	PEC <sub>soil,plateau</sub> (mg/kg)	PEC <sub>accu</sub> = PEC <sub>act</sub> + PEC <sub>soil,plateau</sub> (mg/kg)
Pyraclostrobin	2 × 1063.7	2.27-1.1346	-	5	N/A	N/A

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

zRMS Comments:	<p>Calculations of PEC<sub>gw</sub> for active substance and its metabolites BF 500-6 and BF 500-7 were accepted.</p> <p>Calculations of PEC<sub>gw</sub> for active substance and its relevant metabolites were provided with PUF = 0.</p> <p>The recommended FOCUS models were used: FOCUS PELMO and FOCUS PEARL.</p> <p>Following the current EU guidance [EFSA (2014)], the geometric mean of the sorption coefficient (<math>K_{foc}</math>) should be used, but for calculations of PEC<sub>gw</sub> for active substance and its metabolites the arithmetic mean <math>K_{foc}</math> were used according to the SANCO/1420/2001. This approach was accepted.</p> <p>The PEC<sub>gw</sub> values for active substance and its metabolites were below the trigger value of 0.1 µg/L.</p>
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### 8.8.1 Justification for new endpoints

No new endpoints were established.

### 8.8.2 Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1)

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

Use No.	1-3	2 4, 1 minor
Crop	Winter cereals	Spring cereals
Application rate (g)	Pyraclostrobin: 250	Pyraclostrobin: 250

as/ha)		
Number of applications/interval (d)	2/21	2/21
Relative application date	96 days before harvest	20 days after emergence
Crop interception (%)	20	20
Frequency of application	annual	annual
Models used for calculation	FOCUS PEARL v4.4.4. FOCUS PELMO v5.5.3.	FOCUS PEARL v4.4.4. FOCUS PELMO v5.5.3.

**Table 8.8-2: Input parameters related to active substance Pyraclostrobin and its metabolites for PEC<sub>gw</sub> calculations**

Compound	Pyraclostrobin	BF 500-6	BF 500-7	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	387.8	305.8	297.8	SANCO/1420/2001-Final DAR 2001
Water solubility (g/mol):	1.9	0.003	0.005	SANCO/1420/2001-Final DAR 2001
Saturated vapour pressure (Pa):	$2.6 \times 10^{-8}$	$1 \times 10^{-10}$	$1 \times 10^{-10}$	SANCO/1420/2001-Final DAR 2001
DT <sub>50</sub> in soil (d)	18 (geo mean)*	1000 (default)	1000 (default)	SANCO/1420/2001-Final DAR 2001
Transformation rate	-	0.03037 (from parent)	0.02957 (from parent)	SANCO/1420/2001-Final DAR 2001
K <sub>foc</sub> (mL/g)	9304 (arithmetic mean)	48115 (arithmetic mean)	62278 (arithmetic mean)	SANCO/1420/2001-Final DAR 2001
1/n	0.95 (arithmetic mean)	1	1	SANCO/1420/2001-Final DAR 2001
Plant uptake factor	0 (default)	0 (default)	0 (default)	SANCO/1420/2001-Final DAR 2001
Formation fraction	-	1 (from parent)	1 (from parent)	SANCO/1420/2001-Final DAR 2001

\*Please refer to Appendix 3

**Table 8.8-2: PEC<sub>gw</sub> for Pyraclostrobin and its metabolites on winter cereals (with FOCUS PEARL 4.4.4)**

Crop Scenario		80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)		
		Pyraclostrobin	BF 500-6	BF 500-7
Winter Cereals	Châteaudun	<0.0000001 <0.001	<0.0000001 <0.001	<0.0000001 <0.001
	Hamburg	<0.0000001 <0.001	<0.0000001 <0.001	<0.0000001 <0.001
	Jokioinen	<0.0000001 <0.001	<0.0000001 <0.001	<0.0000001 <0.001
	Kremsmünster	<0.0000001 <0.001	<0.0000001 <0.001	<0.0000001 <0.001
	Okehampton	<0.0000001 <0.001	<0.0000001 <0.001	<0.0000001 <0.001
	Piacenza	<0.0000001 <0.001	<0.0000001 <0.001	<0.0000001 <0.001
	Porto	<0.0000001 <0.001	<0.0000001 <0.001	<0.0000001 <0.001
	Sevilla	<0.0000001 <0.001	<0.0000001 <0.001	<0.0000001 <0.001
	Thiva	<0.0000001 <0.001	<0.0000001 <0.001	<0.0000001 <0.001

**Table 8.8-5: PEC<sub>gw</sub> for Pyraclostrobin and its metabolites on spring cereals (with FOCUS PEARL 4.4.4)**

Crop Scenario		80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)		
		Pyraclostrobin	BF 500-6	BF 500-7
Spring Cereals	Châteaudun	<0.0000001 <0.001	<0.0000001 <0.001	<0.0000001 <0.001
	Hamburg	<0.0000001 <0.001	<0.0000001 <0.001	<0.0000001 <0.001
	Jokioinen	<0.0000001 <0.001	<0.0000001 <0.001	<0.0000001 <0.001
	Kremsmünster	<0.0000001 <0.001	<0.0000001 <0.001	<0.0000001 <0.001
	Okehampton	<0.0000001 <0.001	<0.0000001 <0.001	<0.0000001 <0.001
	Porto	<0.0000001 <0.001	<0.0000001 <0.001	<0.0000001 <0.001

**Table 8.8-6: PEC<sub>gw</sub> for Pyraclostrobin and its metabolites on winter cereals (with FOCUS PELMO 5.5.3)**

Crop Scenario		80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)		
		Pyraclostrobin	BF 500-6	BF 500-7
Winter Cereals	Châteaudun	<0.0001 <0.001	<0.0001 <0.001	<0.0001 <0.001
	Hamburg	<0.0001 <0.001	<0.0001 <0.001	<0.0001 <0.001
	Jokioinen	<0.0001 <0.001	<0.0001 <0.001	<0.0001 <0.001
	Kremsmünster	<0.0001 <0.001	<0.0001 <0.001	<0.0001 <0.001
	Okehampton	<0.0001 <0.001	<0.0001 <0.001	<0.0001 <0.001
	Piacenza	<0.0001 <0.001	<0.0001 <0.001	<0.0001 <0.001
	Porto	<0.0001 <0.001	<0.0001 <0.001	<0.0001 <0.001
	Sevilla	<0.0001 <0.001	<0.0001 <0.001	<0.0001 <0.001

	Thiva	<0.0001 <0.001	<0.0001 <0.001	<0.0001 <0.001
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**Table 8.8-7: PEC<sub>gw</sub> for Pyraclostrobin and its metabolites on spring cereals (with FOCUS PELMO 5.5.3)**

Crop Scenario		80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)		
		Pyraclostrobin	BF 500-6	BF 500-7
Spring Cereals	Châteaudun	<0.0001 <0.001	<0.0001 <0.001	<0.0001 <0.001
	Hamburg	<0.0001 <0.001	<0.0001 <0.001	<0.0001 <0.001
	Jokioinen	<0.0001 <0.001	<0.0001 <0.001	<0.0001 <0.001
	Kremsmünster	<0.0001 <0.001	<0.0001 <0.001	<0.0001 <0.001
	Okehampton	<0.0001 <0.001	<0.0001 <0.001	<0.0001 <0.001
	Porto	<0.0001 <0.001	<0.0001 <0.001	<0.0001 <0.001

The results of the groundwater simulation with FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3 for Pyraclostrobin and its metabolites not exceed the threshold value of 0.1 µg/L in any relevant scenarios an assessment on the relevance of these metabolites in groundwater was not triggered.

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

zRMS

Comments:

Calculations of PEC<sub>sw</sub> and PEC<sub>sed</sub> for active substance and its metabolites were accepted.

The recommended FOCUS models were used: FOCUS Step 1 & 2, Step 3 and Step 4. The mitigation measures were proposed: vegetated buffer strip, non-sprayed strip and drift reduction nozzles (50%).

For PEC<sub>sw</sub> and PEC<sub>sed</sub> calculations the worst-case crop interception of 0% was taken into consideration.

The max PEC<sub>sw</sub> value for R4 stream scenario for pyraclostrobin (0.1344 µg/L) is above the RAC value (0.0616 µg/L) if 20 m vegetative strip with 20 m no spray buffer and 50% nozzle reduction were considered.

As this scenario is not relevant for Poland, therefore it was not considered The GAP table is only for PL. In accordance with the PL national requirements – only D3, D4 and R1 scenarios were taken into consideration.

For spring cereals the R1 scenario from the winter cereals was used.

The max PEC<sub>sw</sub> for Poland are presented in the table below:

Crop	Application rate g a.s./ha	Vegetative strip (m)	No spray buffer (m)	Max PEC <sub>sw</sub> (µg/L)
Winter cereals	2 x 250	20	20 and 50% DRT	0.05981 R1 stream
Spring cereals	2 x 250	20	20 and 50% DRT	0.05981 R1 stream

Metabolites of pyraclostrobin:



For metabolites BF 500-3, BF 500-6, BF 500-7, BF 500-11, BF 500-13 and BF 500-14. the worst case was considered: default DT<sub>50</sub> of 1000 days was used for water, sediment and the whole system.

PEC<sub>sw</sub> and PEC<sub>sed</sub> values for metabolites were calculated in Step 1 & 2.

The PEC<sub>sw</sub> assessment for formulation was corrected. The calculations PEC<sub>sw</sub> was calculated using SWASH Drift calculator. The PEC<sub>sw</sub> values are presented below:

Formulation	Application rate g form/ha	Distance (m)	PEC <sub>sw</sub> (µg /L)
CHR/F/PYRA 250 EC	1063.7	1	6.8339
		5	1.8524
		10	0.9824
		15	0.7163
		20	0.5104

The relevant mitigation measure will be recommended in ecotoxicological section.

### 8.9.1 Justification for new endpoints

No new endpoints were established.

### 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	CHR/F/PYRA 250 EC	
Use No.	1-3	2-4, 1 minor
Crop	Winter cereals	Spring cereals
Application rate (kg as/ha)	Pyraclostrobin: 0.25	Pyraclostrobin: 0.25
Number of applications/interval (d)	2/21	2/21
Application window	March- May	March- May
Application method	Ground spray	Ground spray
CAM (Chemical application method)	Appl. foliar linear	Appl. foliar linear
Soil depth (cm)	4	4
Models used for calculation	STEPS 1-2 in FOCUS v3.2 FOCUS SWASH v3.1, FOCUS PRZM v3.3.1, FOCUS MACRO v5.5.3, FOCUS TOXWA v3.3.1, SWAN 4.0.1, SWAN 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 CHR/F/PYRA 250 EC**

Crop	Scenario	Application window used in modelling
Winter cereals	D1	20 March – 10 May

Crop	Scenario	Application window used in modelling
	D2	30 March – 20 May
	D3	11 April – 1 June
	D4	13 March – 3 May
	D5	10 March – 30 April
	D6	16 January – 8 March
	R1	19 April – 9 June
	R3	14 March – 4 May
	R4	6 January – 26 February
Spring cereals	D1	22 May – 12 July
	D3	21 April – 11 June
	D4	13 May – 3 July
	D5	3 April – 24 May
	R4	3 April – 24 May

As *Spring cereals* does not include R1 scenario relevant in PL *Winter wheat* covers risk for this scenario.

**Table 8.9-2:** Input parameters related to active substance **clothianpyr** and its metabolites for PEC<sub>sw/sed</sub> calculations

[illegible]

Compound	Pyraclostrobin	BF 500-3	BF 500-6	BF 500-7	BF 500-11	BF 500-13	BF 500-14
Plant Uptake	0 (default)	Not required for Step 1-2	Not required for Step 1-2	Not required for Step 1-2	Not required for Step 1-2	Not required for Step 1-2	Not required for Step 1-2
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	Not required for Step 1-2	Not required for Step 1-2	Not required for Step 1-2	Not required for Step 1-2	Not required for Step 1-2	Not required for Step 1-2
DT <sub>50,soil</sub> (d)	18 (geo. mean)	1	1000 (default)	1000 (default)	1	1	1
DT <sub>50,water</sub> (d)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)
DT <sub>50,sed</sub> (d)	29	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)
DT <sub>50,whole system</sub> (d)	29	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 0.01  Total system: 67.7	Soil: 30.9  Total system: 6.5	Soil: 12.5  Total system: 6.3	Soil: 0.001  Total system: 12.0	Soil: 0.001  Total system: 17.8	Soil: 0.001  Total system: 12.1
Formation fraction in soil (%)	-	1 (from parent)	1 (from parent)	-	-	-	-

#### PEC<sub>sw/sed</sub>

**Table 8.9-3: FOCUS Step 1,2 and Step 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Pyraclostrobin following single two applications of CHR/F/PYRA 250 EC**

Scenario	Waterbody	Max PEC <sub>sw</sub> (µg/L)*	Dominant entry route	21 d- PEC <sub>sw, twa</sub> (µg/L)**	Max PEC <sub>sed</sub> (µg/kg)*
<b>FOCUS</b>					
<b>Winter cereals</b>					
Step 1	---	17.03	runoff/drainage	10.15	1160
Step 2	---	2.18	runoff/drainage	1.41	163.78
Northern Europe	March-May	2.18	runoff/drainage	1.41	163.78
Step 3					
D1	ditch	1.391	drainage	0.487	5.671
D1	stream	1.169	drainage	0.014	0.242
D2	ditch	1.405	drainage	0.361	5.385
D2	stream	1.213	drainage	0.288	3.780
D3	ditch	1.373	drainage	0.073	1.356

Scenario  FOCUS	Waterbody	Max PEC <sub>sw</sub> (µg/L)*	Dominant entry route	21 d- PEC <sub>sw, twa</sub> (µg/L)**	Max PEC <sub>sed</sub> (µg/kg)*
D4	pond	0.065	drainage	0.051	0.710
D4	stream	1.036	drainage	0.002	0.048
D5	pond	0.070	drainage	0.057	0.703
D5	stream	1.207	drainage	0.007	0.119
D6	ditch	1.383	drainage	0.334	4.090
R1	pond	0.078	runoff	0.061	1.001
R1	stream	0.893	runoff	0.019	5.652
R3	stream	1.263	runoff	0.028	2.676
R4	stream	0.897	runoff	0.031	6.648
<b>Spring cereals</b>					
Step 1	---	17.03	runoff/drainage	10.15	1160
Step 2	---	2.18	runoff/drainage	1.41	163.78
Northern Europe	March-May	2.18	runoff/drainage	1.41	163.78
Step 3					
D1	ditch	1.763	drainage	0.957	10.21
D1	stream	1.201	drainage	0.051	1.031
D3	ditch	1.373	drainage	0.075	1.383
D4	pond	0.070	drainage	0.056	0.643
D4	stream	1.152	drainage	0.010	0.18328
D5	pond	0.066	drainage	0.053	0.668
D5	stream	1.184	drainage	0.005	0.086
R4	stream	0.900	runoff	0.069	7.943

\* single applications should be marked.

\*\* twa-time as required by ecotox

#### FOCUS Step 4

**Table 8.9-4: Global maximum PEC<sub>sw</sub> values for pyraclostrobin, following two applications of CHR/F/PYRA 250 EC to winter and spring cereals according to the central zone GAP according to surface water Step 4**

PEC <sub>sw</sub> (µg/L)	Scenario	Winter cereals	Spring cereals
Nozzle reduction	Vegetative strip (m)	None-20	None-20
	No spray buffer (m)	20	20
None	D1 ditch	0.09501	0.1191
50 %		0.04749	0.05933

PEC <sub>sw</sub> (µg/L)	Scenario	Winter cereals	Spring cereals
Nozzle reduction	Vegetative strip (m)	<del>None</del> 20	<del>None</del> 20
	No spray buffer (m)	20	20
None	D1 stream	<b>0.1089</b>	<b>0.1119</b>
50 %		0.05442	0.05592
None	D2 ditch	<b>0.09601</b>	-
50 %		0.04799	-
None	D2 stream	<b>0.1130</b>	-
50 %		0.05649	-
None	D3 ditch	<b>0.09376</b>	<b>0.09378</b>
50 %		0.04686	0.04687
None	D4 pond	0.02607	0.02820
50 %		0.01300	0.01407
None	D4 stream	<b>0.09646</b>	<b>0.1073</b>
50 %		0.04821	0.05363
None	D5 pond	0.02812	0.02646
50 %		0.01403	0.01320
None	D5 stream	<b>0.1124</b>	<b>0.1103</b>
50 %		0.05620	0.05512
None	D6 ditch	<b>0.09447</b>	-
50 %		0.04722	-
None	R1 pond	0.02841	Covered by winter cereals.
50 %		0.0156	
None	R1 stream	<b>0.08320</b>	Covered by winter cereals.
50 %		0.05981	
None	R3 stream	<b>0.1177</b>	-
50 %		0.05884	-
None	R4 stream	<b>0.1315</b>	<b>0.1344</b>
50 %		<b>0.1315</b>	<b>0.1344</b>

## Conclusions

PEC<sub>sw</sub> values for pyraclostrobin from STEP 4 are lower than RAC = 0.0616 µg/L (Acute toxicity for fish *O. mykiss*) when using 20 m buffer zone and 50 % nozzle reduction beside PEC<sub>sw</sub> for R4 stream scenario. It is not considered as relevant scenario for Poland, therefore it can be neglected.

## Metabolites of Pyraclostrobin

**Table 8.9-5: FOCUS Step 1,2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for BF 500-3 following single two applications of CHR/F/PYRA 250 EC**

Scenario FOCUS	Waterbody	Max PEC <sub>sw</sub> (µg/L)*	Dominant entry route	21 d- PEC <sub>sw, twa</sub> (µg/L)**	Max PEC <sub>sed</sub> (µg/kg)*
<b>Winter cereals</b>					
Step 1	---	10.63	runoff/drainage	7.98	742.13
Step 2	---	1.40	runoff/drainage	1.05	106.91
Northern Europe	March-May	1.40	runoff/drainage	1.05	106.91
<b>Spring cereals</b>					
Step 1	---	10.63	runoff/drainage	7.98	742.13
Step 2	---	1.40	runoff/drainage	1.05	106.91
Northern Europe	March-May	1.40	runoff/drainage	1.05	106.91

**Table 8.9-6: FOCUS Step 1,2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for BF 500-6 following single two applications of CHR/F/PYRA 250 EC**

Scenario FOCUS	Waterbody	Max PEC <sub>sw</sub> (µg/L)*	Dominant entry route	21 d- PEC <sub>sw, twa</sub> (µg/L)**	Max PEC <sub>sed</sub> (µg/kg)*
<b>Winter cereals</b>					
Step 1	---	0.99	runoff/drainage	0.76	364.48
Step 2	---	0.15	runoff/drainage	0.14	68.70
Northern Europe	March-May	0.15	runoff/drainage	0.14	68.70
<b>Spring cereals</b>					
Step 1	---	0.99	runoff/drainage	0.76	364.48
Step 2	---	0.15	runoff/drainage	0.14	68.70
Northern Europe	March-May	0.15	runoff/drainage	0.14	68.70

**Table 8.9-7: FOCUS Step 1,2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for BF 500-7 following single two applications of CHR/F/PYRA 250 EC**

Scenario FOCUS	Waterbody	Max PEC <sub>sw</sub> (µg/L)*	Dominant entry route	21 d- PEC <sub>sw, twa</sub> (µg/L)**	Max PEC <sub>sed</sub> (µg/kg)*
<b>Winter cereals</b>					
Step 1	---	0.51	runoff/drainage	0.29	179.84
Step 2	---	0.10	runoff/drainage	0.05	32.30
Northern Europe	March-May	0.10	runoff/drainage	0.05	32.30
<b>Spring cereals</b>					
Step 1	---	0.51	runoff/drainage	0.29	179.84
Step 2	---	0.10	runoff/drainage	0.05	32.30
Northern Europe	March-May	0.10	runoff/drainage	0.05	32.30

**Table 8.9-8: FOCUS Step 1,2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for BF 500-11 following single two applications of CHR/F/PYRA 250 EC**

Scenario FOCUS	Waterbody	Max PEC <sub>sw</sub> (µg/L)*	Dominant entry route	21 d- PEC <sub>sw, twa</sub> (µg/L)**	Max PEC <sub>sed</sub> (µg/kg)*
<b>Winter cereals</b>					
Step 1	---	14.71	runoff/drainage	14.60	0.00
Step 2	---	2.12	runoff/drainage	2.10	0.00
Northern Europe	March-May	2.12	runoff/drainage	2.10	0.00
<b>Spring cereals</b>					
Step 1	---	14.71	runoff/drainage	14.60	0.00
Step 2	---	2.12	runoff/drainage	2.10	0.00
Northern Europe	March-May	2.12	runoff/drainage	2.10	0.00

**Table 8.9-9: FOCUS Step 1,2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for BF 500-13 following single two applications of CHR/F/PYRA 250 EC**

Scenario FOCUS	Waterbody	Max PEC <sub>sw</sub> (µg/L)*	Dominant entry route	21 d- PEC <sub>sw, twa</sub> (µg/L)**	Max PEC <sub>sed</sub> (µg/kg)*
<b>Winter cereals</b>					
Step 1	---	19.45	runoff/drainage	19.31	0.00
Step 2	---	2.80	runoff/drainage	2.78	0.00
Northern Europe	March-May	2.80	runoff/drainage	2.78	0.00

Scenario  FOCUS	Waterbody	Max PEC <sub>sw</sub> (µg/L)*	Dominant entry route	21 d- PEC <sub>sw, twa</sub> (µg/L)**	Max PEC <sub>sed</sub> (µg/kg)*
<b>Spring cereals</b>					
Step 1	---	19.45	runoff/drainage	19.31	0.00
Step 2	---	2.80	runoff/drainage	2.78	0.00
Northern Europe	March-May	2.80	runoff/drainage	2.78	0.00

**Table 8.9-10: FOCUS Step 1,2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for BF 500-14 following single two applications of CHR/F/PYRA 250 EC**

Scenario  FOCUS	Waterbody	Max PEC <sub>sw</sub> (µg/L)*	Dominant entry route	21 d- PEC <sub>sw, twa</sub> (µg/L)**	Max PEC <sub>sed</sub> (µg/kg)*
<b>Winter cereals</b>					
Step 1	---	20.74	runoff/drainage	20.59	0.00
Step 2	---	2.99	runoff/drainage	2.96	0.00
Northern Europe	March-May	2.99	runoff/drainage	2.96	0.00
<b>Spring cereals</b>					
Step 1	---	20.74	runoff/drainage	20.59	0.00
Step 2	---	2.99	runoff/drainage	2.96	0.00
Northern Europe	March-May	2.99	runoff/drainage	2.96	0.00

## Conclusions

PEC<sub>sw</sub> values for pyraclostrobin metabolites from STEP 1-2 are lower than RACs threshold value estimated for each metabolite.



PEC<sub>sw/sed</sub> of CHR/F/PYRA 250 EC

**PEC<sub>sw</sub> for the formulation CHR/H/CLETO EC was estimated in FOCUS Swash 5.3.**

Method of calculation	FOCUS 4
Application rate	$2 \times 1063.7 \text{ g a.s./ha}$
Main routes of entry	Drift 0%
Resulting PEC <sub>sw</sub> for CHR/H/CLETO EC CHR/F/PYRA	5.9701 µg/L

#### Calculation of drift loading into surface water



**Input**

Application Rate (g ai/ha):  Crop:   
 Number of Applications:  Waterbody:   
 Use FOCUS (step 3) or mitigation distances (m)?

**Info: Dimensions of receiving water body and field site (m)**

Width:  Depth:  Length:   
 Distance: Crop <--  --> Top of bank <--  --> Water

**Info: Drift regression terms to provide overall 90th percentile drift data**

Regression parameters A:  B:  C:  D:   
 Distance for change in regression (m)

**Output: Drift deposition in water body per drift event**

Drift percentile per event  based on a total of  applications.  

	at edge nearest field	farthest from field	areic mean
Distance from crop: (m)	<input type="text" value="1.00"/>	<input type="text" value="2.00"/>	
% of application rate:	<input type="text" value="2.4376"/>	<input type="text" value="1.2104"/>	<input type="text" value="1.6838"/>

**Output: Drift loading onto water body**

Mass loading per drift event:  mg per m2 of water surface area.  
 Nominal concentration in water,  
 resulting from drift event:  ug/L (for comparison with modelling result)

**Data sources:**  
 Spray drift data are from BBA, (2000) and AgDRIFT 1.11, (1999).  
 Calculations of percentile drift are from spreadsheet of Travis, (1998).  
 Regressions of drift curves and spreadsheet calculations are by Russell and Yon, (2000 and 2001).

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

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

Compound	Pyraclostrobin
Photochemical oxidative degradation in air	<p>derived by the Atkinson model</p> <p>DT<sub>50</sub> (h): &lt; 2h, derived by the Atkinson model (24h day, AOP)</p> <p>Quantum yield of direct phototransformation : <math>2.17 \times 10^{-1}</math></p>
Volatilisation	<p>Vapour pressure (Pa): <math>2.6 \times 10^{-8}</math> (20 °C)</p> <p>Henry's Law Constant (Pa m<sup>3</sup>/mol): <math>5.307 \times 10^{-6}</math> (20 °C)</p>
Metabolites	-

The vapour pressure at 20 °C of the active substance ~~Clethodim~~ **Pyraclostrobin** is < 10<sup>-5</sup> Pa. Hence, Pyraclostrobin is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the Pyraclostrobin due to volatilization with subsequent deposition is not considered.

The atmospheric half-life of Pyraclostrobin indicates that the compound is not persistent in the atmosphere according to the representative criterion of potential long term transport of plant protection products (DT<sub>50</sub> in air > 2 d).

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

### List of data submitted by the applicant and 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 9.1.1.2	Adamczak, A.	2021	<i>Normalisation of the degradation rate constant of Pyraclostrobin.</i> <i>Unpublished</i> <i>GLP-No</i>	N	Chemiroł
KCP 9.1.3	Adamczak, A.	2021	<i>CHR/F/PYRA Predicted environmental concentration of pyraclostrobin and its metabolites in soil, ground water and surface water</i> <i>Unpublished</i> <i>GLP-No</i>	N	Chemiroł
KCP 9.2.4.1	Adamczak, A.	2021	<i>CHR/F/PYRA Predicted environmental concentration of pyraclostrobin and its metabolites in soil, ground water and surface water</i> <i>Unpublished</i> <i>GLP-No</i>	N	Chemiroł
KCP 9.2.5	Adamczak, A.	2021	<i>CHR/F/PYRA Predicted environmental concentration of pyraclostrobin and its metabolites in soil, ground water and surface water</i> <i>Unpublished</i> <i>GLP-No</i>	N	Chemiroł

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

<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>
KCP 9.1.1.2.1/01	Kellner, O. Zangmeister, W.	1999	<i>Field soil dissipation of BAS 500 F (304428) in formulation BAS 500 01 F (1998 - 1999).</i> 1999/11301, EU/FA/049/98 GLP Unpublished	N	BASF
KCP 9.1.1.2.1/02	Kellner, O. Zangmeister, W.	1999	Field soil dissipation of BAS 500 F (304428) in formulation BAS 500 01 F. 1999/11292, DE/FA/045/97 GLP Unpublished	N	BASF

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

No new data submitted in the framework of this application.

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

zRMS Comments:	The submitted normalisation of the degradation rate constant of pyraclostrobin was accepted. $DT_{50}$ (20°C, pF2) = 18 d This endpoint was used in exposure assessment.
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Reference: KCP 9.1.1.2

Report *Normalisation of the degradation rate constant of Pyraclostrobin.*, Adamczak, A., 2021

GLP: No

Acceptability: Yes

Following the recommendations of FOCUS work group on degradation kinetics FOCUS 2005, *Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration* degradation rate constants originating from Kellner, O., Zagnmeister, W., 1999, 1999/11301 and Kellner, O., Zagnmeister, W., 1999, 1999/11292 unprotected studies presented in DAR 2001 of active substance Pyraclostrobin. The half-lives were calculated on the basis of the normalized degradation rate constants.

**Table A1 Concentration of Pyraclostrobin in soil of the field trials after modification of LOQ data for kinetic modelling following FOCUS**

<b>D05/02/97</b>							
DAT	0	14	26	53	96	173	350
Residue [g ha <sup>-1</sup> ]	206	140	107	40	18	7.5	-
<b>D08/01/97</b>							
DAT	0	12	26	64	98	182	362
Residue [g ha <sup>-1</sup> ]	193	152	123	54	30	xxx	7.5
<b>DU2/02/97</b>							
DAT	0	12	29	57	96	174	347
Residue [g ha <sup>-1</sup> ]	208	92	105	59	7.5	-	-
<b>ALO/01/98</b>							
DAT	0	14	30	60	98	182	349
Residue [g ha <sup>-1</sup> ]	166	61	36	37	24	7.5	-
<b>ALO/02/98</b>							
DAT	0	15	30	63	99	182	356
Residue [g ha <sup>-1</sup> ]	194	53	60	53	48	23	7.5
<b>HUS/02/98</b>							
DAT	0	16	31	59	100	177	351
Residue [g ha <sup>-1</sup> ]	200	88	102	56	34	7.5	-

DAT = days after treatment

A single first-order kinetic approach was applied to the estimation and normalisation of the degradation rate constants of Pyraclostrobin.

$$C_t = C_{\text{initial}} e^{-k_{\text{act}} t} \quad (a)$$

$$k_{\text{act}} = f_{\text{temp}} * f_{\text{moist}} * k_{\text{ref}} \quad (b)$$

with	$C_t$	concentration at time t	[g ha <sup>-1</sup> ]
	$C_{\text{initial}}$	concentration at time 0	[g ha <sup>-1</sup> ]
	$k_{\text{act}}$	estimated actual degradation rate constant (at current soil temperature and moisture conditions)	[d <sup>-1</sup> ]
	t	time after application	[d]
	$f_{\text{temp}}$	temperature correction factor	[.]
	$f_{\text{moist}}$	moisture correction factor	[.]
	$k_{\text{ref}}$	estimated degradation rate constant at reference conditions (soil temperature 20°C, soil moisture at pF2)	[d <sup>-1</sup> ]

The parameters  $C_{\text{initial}}$  and  $k_{\text{ref}}$  were estimated with the program ModelMaker v.3 by Marquardt optimization procedure. The degradation rate constant resulting from the estimation procedure was used to derive the DT<sub>50</sub> value.

$$DT_{50} = \frac{\ln(2)}{k_{\text{ref}}}$$

The degradation rate constants were corrected for differences between actual daily soil moisture and a reference soil moisture at pF2 using modified Walker equation as recommended by FOCUS 2000, *FOCUS groundwater scenarios in the EU review of active substances*. The correction factor for soil moisture is calculated using equation:

$$f_{\text{moist}} = \begin{cases} \left( \frac{\theta_{\text{act}}}{\theta_{\text{ref}}} \right)^B & \text{for } \theta_{\text{ref}} > \theta_{\text{act}} \\ 1 & \text{for } \theta_{\text{ref}} \leq \theta_{\text{act}} \end{cases}$$

where	$f_{\text{moist}}$	moisture correction factor
	$\theta_{\text{act}}$	actual soil moisture (volumetric water content)
	$\theta_{\text{ref}}$	reference soil moisture at pF2
	B	exponent of the moisture response function, B = 0.7

The daily actual soil moisture used for the moisture correction of the different field trials was estimated with the FOCUS-PEARL. For each site a PEARL scenario was created. A soil depth of 0.5 m and 0.025 m discretization scheme were selected for each scenario.

The degradation rate constants were also corrected for differences between actual daily temperatures and a reference temperature 20 °C using the Q<sub>10</sub>-rule.

$$f_{\text{temp}} = \begin{cases} Q_{10}^{\frac{T_{\text{act}} - T_{\text{ref}}}{10}} & \text{for } T_{\text{act}} > 0^\circ\text{C} \\ 0 & \text{for } T_{\text{act}} \leq 0^\circ\text{C} \end{cases}$$

where	$f_{\text{temp}}$	temperature correction factor	[.]
	$T_{\text{act}}$	actual soil temperature	[°C]
	$T_{\text{ref}}$	reference temperature (20°C)	[°C]
	$Q_{10}$	factor of increase of degradation rate with an increase in temperature of 10°C ( $Q_{10} = 2.2$ , FOCUS recommendation)	[.]

The optimization was evaluated based on visual assessment and statistical goodness-of-fit measures. The basic statistical indices for model evaluation were coefficient of determination and the minimum error to pass the Chi<sup>2</sup> test as recommended by the FOCUS group of degradation kinetics.

$$\text{err} = 100 \cdot \sqrt{\frac{1}{\chi^2_{\text{tabulated}}} \cdot \sum \frac{(C - O)^2}{O^2}}$$

where

err	measurement error percentage
C	calculated value
O	observed value
$\bar{O}$	mean of all observed values
$\chi^2_{\text{tabulated}}$	tabulated Chi <sup>2</sup> value based on m degrees of freedom (number of measurements after averaging of replicates minus number of parameters according to FOCUS) and probability $\alpha$ (5 % according to FOCUS)

The tabulated Chi<sup>2</sup> assuming a significance level of 5%, was obtained from Excel using the CHI-INV function.

The evaluation of the CTB criteria is summarized in table below. The trials D05/02/97, D08/01/97, DU2/02/97 and HUS/02/98 match the criteria completely, allowing normalisation of the degradation rate constants. The field trials ALO/01/98 and ALO/02/98 violate the requirement for a single first-order model and were therefore excluded from the calculation of normalized degradation times.

**Criterion 1:** Check that only a non-significant fraction of the dose can have leached out of the soil layers that were sampled (consider the amount of rainfall and concentration measured in the deepest sampled layer).

The residues of BAS 500 F in the lowest sampled layer are always lower or equal to the detection limit. Therefore it can be concluded that all trials fulfill the criterion that only a non-significant fraction of the dose has leached out of the soil layers that were sampled.

**Criterion 2:** Check that only a non-significant fraction of the dose disappeared via processes at the soil surface such as volatilisation or photochemical transformation (consider the period between spraying and the first significant rainfall event; check additionally that there is no initial fast decline followed by a slower decline; a recovery in the field that is much lower than the dose is also an indication of losses at the soil surface).

**Volatilization:** Volatilization is not to be expected a significant loss route for BAS 500 F because of the very low the vapor pressure of  $2.6 \times 10^{-10}$  hPa at 20°C.

**Phototransformation:** The soil photolysis study of BAS 500 F shows that the presence of light does not have a strong influence on the degradation of BAS 500 F on soil. When incubated at 40% MWC the soil photolytic half-life was 36.9 days (continuous radiation) and the half-life of the dark control samples (aerobic soil metabolism) was 31.7 days. Incubating the soil at 80% MWC decreased the half-life of BAS 500 F in the irradiated and the dark control samples (8.9 days and 10.4 days, respectively). The irradiated soil samples were subjected to 0 to 15 days of continuous illumination, which is equivalent to 30 days of 12 hr light and 12 h darkness per day.

**Recovery:** Moderate recovery rates were observed for the initial samplings of the different field trials, but the first-order degradation kinetics are not influenced by the low initial value. Therefore, the low recoveries may be regarded as a problem of the application technique and the sampling of initial soil samples rather than an indication of significant surface losses that would influence the calculation of the half-life.

**Phases of degradation:** The visual assessment of the fitted curve to the observed residues indicates a bi-phasic degradation behavior for the trials ALO/01/98 and ALO/02/98. There is no clear indication that these findings can be attributed to losses at the soil surface, i.e., other causes such as changes in the environmental settings during the experiment should also be considered for the interpretation. As no clear conclusion can be drawn regarding the cause of the bi-phasic behavior the field trials ALO/01/98 and ALO/02/98 were excluded from the calculation of degradation times.

For the trials D05/02/97, D08/01/97, DU2/02/97 and HUS/02/98 it can be concluded that only a non-significant fraction of the dose disappeared via processes at the soil surface.

**Criterion 3:** Check that the decrease of the total amount with time corresponds reasonably well with first-order kinetics (either via curve-fitting or via applying a simulation model); if there is much scatter in the relationship between total amount with time (probably due to an inadequate sampling strategy) the estimation of a transformation rate in soil may be not acceptable.

The field trials ALO/01/98 and ALO/02/98 present a bi-phasic degradation behaviour and a single first-order model could not be fitted adequately to the data. The trials were therefore excluded from the calculation of degradation times.

For the trials D05/02/97, D08/01/97, DU2/02/97 and HUS/02/98 a single first-order model could be fitted to the data. The coefficients of determination for the respective fits (Table A.4) give much evidence for a successful estimation according to first-order kinetics.

**Criterion 4:** Check whether the soil has been characterized (organic matter, clay etc.).

The soil characteristics are described in detail in the reports of the field dissipation study.

**Criterion 5:** Check whether the location can be considered representative with respect to soil type and climate for European conditions.

The sites of the field dissipation studies are located in Europe and have been selected to cover the range of agroclimatic conditions across Europe (Sweden (north), Germany (middle), Spain (south)) and agricultural soil (sand - clay).

**Criterion 6:** Check whether meteorological data are available, and whether a correction for the difference between the actual soil temperature (mean temperature measured during the day in top soil layer) and 20°C has been made (an acceptable alternative is temperature during the day in air measured on location, or nearby weather station).

Meteorological data are available and have been used in the standardisation procedure.

<p><b>Criterion 7:</b> Check whether the dose is reported and whether the formulated product is relevant (no granulate or slow release).</p> <p>The dose is reported. The trials were performed using the formulated product BAS 500 01 F (EC formulation) which is a typical type of formulation for end use products of BAS 500 F. Therefore, the degradation behaviour of BAS 500 F under field conditions could satisfactorily be investigated with the formulations used and therefore is relevant.</p>
<p><b>Criterion 8:</b> If inverse modelling was used, check whether the model used is acceptable.</p> <p>The model used is identical to the subroutines in FOCUS-PEARL, which is a simulation model recommended by FOCUS for EU-registration (FOCUS 2000: "FOCUS groundwater scenarios in the EU review of active substances" Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference Sanco/321/2000 rev.2, 202 pp.).</p>
<p><b>Criterion 9:</b> Check whether analytical procedure was documented well and whether recovery was acceptable.</p> <p>The analytical procedure has been documented well and the recovery was acceptable.</p>
<p><b>Criterion 10:</b> Check history of pesticide use on plot. In preceding years no active ingredient or structure analog should be used.</p> <p>No active ingredient and no structural analog have been used in the preceding years.</p>
<p><b>Criterion 11:</b> Check method of application. Pesticide should not be applied below soil surface.</p> <p>The pesticide has been applied onto the bare soil surface.</p>
<p><b>Criterion 12:</b> Check method of sampling. Method of sampling should be adequate.</p> <p>The method of sampling is described in detail in the reports of the field studies and is seen to be adequate.</p>
<p><b>Criterion 13:</b> Check influence of crop. Uptake of pesticide by crop should be negligible.</p> <p>Application was onto bare soil and crops were not present during the field studies.</p>

The estimated parameters (initial concentrations and normalized degradation rate constants) and the goodness-of-fit measures for the different field trials are presented below.

Field trial	C <sub>initial</sub> [g ha <sup>-1</sup> ]	k <sub>ref</sub> [d <sup>-1</sup> ]	DT <sub>50</sub> (20°C, pF2) [d]	r <sup>2</sup>	err [%]
D05/02/97	204.9	0.0554*	12.5	0.994	5.1
D08/01/97	191.0	0.0262*	26.5	0.997	3.3
DU2/02/97	183.0	0.0452*	15.3	0.845	22.0
ALO/01/98	Bi-phasic degradation: single first-order model not applicable				
ALO/02/98	Bi-phasic degradation: single first-order model not applicable				
HUS/02/98	178.8	0.0337*	20.6	0.888	20.2
<b>Geometric mean</b>			<b>18.0</b>		

r<sup>2</sup> = coefficient of determination; err = minimum error to pass  $\chi^2$  test

\* = significantly different from zero at P = 0.05

The field trials ALO/01/98 and ALO/02/98 were excluded for the calculation of degradation times as they showed a bi-phasic degradation behaviour and a single first-order model could therefore not be fitted adequately to the data.

The high coefficients of determination and minimum error values of the other field trials give evidence of successful estimations. For D05/02/97 and HUS/02/98 a stronger deviation from the optimum can be observed which is mainly caused by differences to a single high residual value at the second sampling date. This finding must be attributed to the stronger natural variability of field data and is no indication for deficits in the model fits. The residual plots of the respective trials support this interpretation as no apparent systematic error can be observed.