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#### CP 9 FATE AND BEHAVIOUR IN THE ENVIRONMENT

Spiroxamine was included in Annex I to Council Directive 91/414/EEC in 1999 (Directive 1999/7)/EC. Entry into Force on 1 September 1999). Spiroxamine was then renewed in 2012; the rapporteur Dember State was Germany and the co-rapporteur Member State was Hungary. This Supplementary Dossier contains data which were not submitted at the time of the Annex I inclusion of spiroxamine under Council Directive 91/414/EEC and which were therefore not evaluated during the first EU review. However, all studies submitted for the first approval and subsequent first renewal of spiroxamine have also been summarised according to current guidance and included in the dossior. Where studies meet relevant validity criteria, new robust study summaries are provided in the appropriate dossier section. However, where studies do not meet relevant validity criteria and are not considered acceptable, less detailed suppose maries may have been provided alongside a discussion of potential study defreencies. All relied upon study reports are submitted in Document K for this second renewal of approval dossier or in Document K for the first renewal submissions.

All data which were already submitted by Bayer of (former Bayer CropScience) for the Amex L'inclusion and first renewal under Council Directive 1/414/EEC are contained in the draft Re-Assessment Report (RAR) 2010 and its revised RAR 2017, and are included in the Baseline Dossier provided by Bayer AG.

This formulation is registered throughout Europe under trade names such as HELIX, MPLLSE GOLD, INUT 460 EC, INPUT CLASSIC, KROTON, PROLINE MAX, 460 EC, Prosaro Plus, ROMBUS POWER, THESORUS, THESORUS, 460 EC. Prothoconazole — Spiroxamine EC 460 (160+300 g/L) was already a representative formulation of Bayer AG for the first renewal of spiroxamine under Council Directive 91/414/EEC.

Spiroxamine consists of four isomers two distereomers, each with its corresponding two enantiomers which are in a 1:1 ratio) as shown in the schematic below. The isomer comendature presented in some historical documentation may differ with respect to the A/B and corresponding trans/cis notation due to a discrepancy in referencing, which is discussed in detail in position paper M-761468-01-1 (see CA 1.7/01). The stereo assignments depicted here, together with the A and B notation will be used exclusively going forward to ensure continuity of information throughout the dossier. The outcome of the chiral analysis of spiroxamine degradation is organing at time of submission and will be provided, along with a definition of any Uncertainty Factor (UF) in Poc N3, at a pater date.



The representative formulated product Prothioconazole + Spiroxamine EC 460 (160+300 g/L) also contains the active substance prothioconazole. The active substance prothioconazole is not the primary focus of the renewal of the active substance spiroxamine and is the subject of a separate renewal evaluation which is in progress at the time of writing.

#### **CP 9.1** Fate and behaviour in soil

Use of the representative formulated product Prothioconazole + Spiroxamine EC 460 (260+300 g/L) can potentially lead to measurable amounts reaching soil therefore, the fate and behaviour is soil of Prothioconazole + Spiroxamine EC 460 (160+300 g/L) is addressed.

The formulated product Prothioconazole + Spiroxamane EC 460 (160+300 g/L), containing the active substance spiroxamine (500 g/L), is applied as a broadcast foliar spray to various crops. Consequently, the fate and behaviour of the active substance resulting from use of the formulated product. Prothioconazole + Spiroxamine EC 460 (160+300 g/L) can be extrapolated from the studies on the active substance itself and therefore no additional laboratory studies, in the late and behaviour have been performed on the formulation.

The route of degradation of spiroxamine was consistent in all studies and driven via de-alkylation of the amine moiety and/or oxidation reactions of the alkylchains resulting in identification of the soil metabolites M01 (spiroxamine-desethyl) M02 spiroxamine desproyl) and M03 (spiroxamine N-oxide; please see Figure 9.1-1). The only notable new observation versus the previous evaluation was that of M06 (spiroxamine-acid), previously M06 was observed only at a maximum of 9.5% previously; the most recent data show M06 at a maximum of 5.3% AR at the final time point in the Refesol-02A soil thus triggering further evaluation and risk assessment. Studies to define the modelling parameters for M06 are currently on-going and conservative endpoints are used to provide a preliminary view of potential M06 exposure but will be updated upon study completion.

Figure 9.1-1: Rerobic soil degradation pathway for Spiroxamine

## **CP 9.1.1** Rate of degradation in soil

For information on the rate of degradation in soil please refer to Document MCA, Section 7.1.2. An



assessment of the statistical difference of the kinetic evaluation of the lab and field studies was performed using the EFSA endpoint XL. This assessment determined that the field studies were statistically different to the lab dataset and as such modelling endpoints are taken from the field studies in isolation

#### **CP 9.1.1.1** Laboratory studies

The rate of degradation in soil of the active substance spiroxamine and its major metabolities, as defined in CA 7.4.1 (i.e. metabolites M01 (spiroxamine-desethyl), M02 (spiroxamine-despropyl) M03 (spiroxamine-N-oxide) and M06 (spiroxamine-acid)), in laboratory studies is evaluated under CA 21.2.1 of the corresponding active substance dossier. As it is possible to extrapolate the behaviour of the active substance resulting from use of the formulated product Prothio onazole + Spiroxamine F. 460 (160+300 g/L) from the study on the active substance itself, additional laboratory studies investigating the rate of degradation in soil have not been performed.

A summary of the fate and behaviour of the active substance and associated significant metaborities in laboratory soil degradation studies is presented under CA 7-7.2.

CP 9.1.1.2 Field studies

#### Soil dissipation studies CP 9.1.1.2.1

Soil dissipation behaviour of the expresentative formulation Prothiconazole + Spiroxamine EC 460 (160+300 g/L) can be extrapolated from the studies designed of evaluate the active substance addressed under CA 7.1.2.2.1. The dissipation rate of spiroxamine has been determined in five studies across eighteen European sites. Full details of the studies and derivation of the rate of dissipation according to the latest guidance is available under CA 7.2.2.2.1.

#### Soil accomulation studies CP 9.1.1.2.2

Soil accumulation rudies with the representative formulation Prothiocong ole + Spiroxamine EC 460 (160+300 g/L) have not been conducted as behaviour can adequately addressed in the same manner as for the active substance and relevant metabolites (i.e. metabolites M01 (spiroxamine-desethyl), M02 (spiroxamine-despropyl) and M03 (spiroxamine-N-oxide) as described under CA 7.1.2.2.2.

## Appility in the soil

#### **CP 9.1.2.1** Laborátory studies

Studies investigating the soil sorption properties of the active substance spiroxamine and major metabolites as defined in CA 7.40 (i.e. metabolites MM (spiroxamine-desethyl), M02 (spiroxamine-despropyl), M03 (spiroxamine-Noxide) and 1006 (spiroxame-acid)), are evaluated under CA 7.1.3.1 of the corresponding active substance dossier. As it is possible to extrapolate the behaviour of the active substance resulting from use of the formulated product Prothioconazole + Spiroxamine EC 460 (160+300 g/L) from the studies on the active substance and metabolites themselves, additional soil sorption studies have not been performed.

The high sorption displayed by spiroxamine and its metabolites is reflected in the outcome of column leaching studies investigating the leaching behaviour of aged residue of spiroxamine in soil. These studies demonstrated that in soil column studies, aged residues of spiroxamine did not significantly leach to the column percolate with only 0.2 %AR being found in the leachate.

A summary of the behaviour of the active substance and its metabolites (addressed under CA 7.1.3.1.1 and CA 7.1.3.1.2, respectively) in soil sorption studies is presented under CA 7.1.3.1

#### Lysimeter studies

Lysimeter studies with the representative formulation Prothioconazole + Spiroxamine EC 460 (160+300



g/L) were not conducted as lysimeter studies with the active substance are not triggered (CA 7.1.4.2).

Adequate soil sorption parameters for the active substance spiroxamine and all major soil metabotics (as defined under Point CA 7.4.1) are provided under Points CA 7.1.3.1.1 and CA 7.1.3.1.2. Furthermore, determination of the predicted environmental concentration in groundwater conducted under Point CP 9.2.4 do not indicate groundwater concentrations exceeding the relevant trigger levels, consequently lysimeter and/or field leaching studies with the active substance or any metabolites are not required.

#### **CP 9.1.2.3** Field leaching studies

Field leaching studies with the representative formulation Prothic conazole + Spiroxamine 12 460 (160+300 g/L) have not been conducted as these have not been triggered (CA 7) 4.3)

#### CP 9.1.3 Estimation of concentrations in soil

The Predicted Environmental Concentrations in soil (PECs) have been calculated for the active substance spiroxamine and major metabolite, as defined in CA 7.4.1, along with the intact formulation (self following foliar applications of Prothioconazole + Spiroxamine EC 460 (160+300 g/L) in accordance with the representative GAP.

The critical Good Agricultural Practice (GAP) for the representative formulation Prothicoonazole + Spiroxamine EC 460 (160+300 g/L) is presented in document D1, with relevant agronomic parameters are summarised in Table 9.1.3.

<b>Table 9.1.3-1:</b>	GAP fox P	rothioconazole	+Spiroxamine	EC 460°	(160°+300 g/L)

					. 9	
	GAP details			<b>Applicati</b>	on timing	
			La La	rly O 🖔		ite
Cron	Appan rate	Growth	Crop inter-	Effective	Crop inter-	Effective
Crop	as/ha)	% stage	~ ception	Øappln ≰ate	@ ception	appln rate
		4	(%) <sup>a</sup>	(g/han)a) 🗸	<sup>y</sup> (%) <sup>a)</sup>	(g/ha) a)
Winter cere- %	2x 150=375 C			. 2 8		
als (spring	(14 60 min in 🗐	<b>3</b> 0-69 °)	80, GS30	02x 75	90 (GS 40+)	2x 37.5
appln only	terval		0	_		
Spring sere-	2x 150 975 (14 d⁄min in 3			Ŋ		
als (spring	(14 d⁄min in 📉	30-69°) 🛇	80 (GS30+)	~2x 75	90 (GS 40+)	2x 37.5
appln only) b)	ærval) 🍫			2		

a) Representative of the worst case application rate.

The predicted environmental concentration in soil was calculated using a risk envelope approach based upon the traximum proposed are rate following the recommendations of the FOCUS Soils Group (FOCUS 1997). Calculations assume any substance teaching the soil surface is distributed uniformly to a depth of 5 cm (with no medianical incorporation). The bulk density of soil is assumed to be 1.5 g/cm<sup>3</sup>.

## Predicted environmental concentrations in soil (PECs) – formulation

The initial producted environmental concentration in soil of the representative formulated product Prothioconazole Spirovamine EC 460 (1669300 g/L) is presented in Table 9.1.3-2. Since the formulation components other than the active substance will dissipate rapidly in the environment, it is only necessary to consider the initial concentration for Prothioconazole + Spiroxamine EC 460 (160+300 g/L).

b) Barley, oats, wheat, ryo, tritical

c) Encompassing barley and oals at GS-30-61

FOCUS (1997). Soil persistence models and EU registration. European Commission Document 7617/VI/96.



Table 9.1.3-2: Worst-case initial PECs for Prothioconazole + Spiroxamine EC 460 (160+300 g/L) needed for environmental risk assessment

Стор	Formulation application rate (L/ha)	Application timing (growth stage)	Crop interception (%)	Soil concentration (mg Prothicona- zole + Spirox amine EC 469 (160-300 g/3/kg dw soil)
Winter and spring cereals (spring ap- plication only)	1.25 L/ha Prothio- conazole + Spirox- amine EC 460 (160+300 g/L) (equivalent to 1230 g/ha) <sup>A</sup>	30-0	8 minimum	0.328

A Based on a Prothioconazole + Spiroxamine EC 400 (160+1000 g/L) formulation relative density of 0.984 g/mls see CP

The maximum initial concentration of the formulated product Prothioconazore + Spiroxamine EC 460 (160+300 g/L) in soil following application is 0.328 g formulation for the formulation of the formulated product Prothioconazore + Spiroxamine EC 460 (160+300 g/L) in soil following application is 0.328 g formulation of the formulated product Prothioconazore + Spiroxamine EC 460 (160+300 g/L) in soil following application is 0.328 g formulation of the formulated product Prothioconazore + Spiroxamine EC 460 (160+300 g/L) in soil following application is 0.328 g formulation of the fo

# Predicted environmental concentrations in soil PECs active substance spiroxamine and metabolites

The predicted environmental concentrations in solt of the active substance and of major metabolites, as defined under Point 7.4.1. (on the basis of the studies investigating the fate and behaviour of the active substance in soil under Point 7.4.1.), have been calculated below based on the key endpoints presented in Table 9.1.3-3 and the uses of the tepresentative formulation Prothioconazole + Spiroxamine EC 460 (160+300 g/L) described in Table 9.1.3-1.



Table 9.1.3-3: Summary of parameters used for determination of PECs

Component	Endpoint	Value	Comment &
Spiroxamine (mw 297.5 g/mol),	Aerobic DT <sub>50</sub> / DT <sub>90</sub> soil (days)	56.6 / 393 (FOMC: α=1.297; β=80.06)	Worst case persistence field DT values from KCA 7.1.2.2 1/12 See Table 7.1.2.2
	DT <sub>90field</sub> > 1 year	Yes	i.e. PECs a cumulation
Metabolite M01 (spirox- amine-desethyl, (mw 269.4 g/mol, molar ratio 0.906))	Aerobic DT <sub>50</sub> / DT <sub>90</sub> soil (days)	223 / 742 Q (SFO)	Worst Case persistence field DT values from SCA 7.02.2.162
	Maximum occurrence in soil (%)		See Table 9.4.1-1
	DT <sub>90field</sub> > 1 year	Yes Yes	i. PECs accumulation
Metabolite M02 (spirox- amine- despropyl, (mw 255.4 g/mol, molar ratio 0.858))	Aerobic DT <sub>50</sub> DT <sub>90</sub> soul	1607/5334 (SFQ)	Worst case persistence first DT values from KCA 20.2.2.02 See Table 7.1.2.2.1-71
	Maximum occurrence in soil (%)	<b>3</b> .2	See Table 7.4.1-1
	T <sub>90field</sub> 1 year	Of Yes	PECS accumulation required
Metabolite M03 (spirox- amine- N-oxide, (mw 313.5 g/mol, molar ratio 1.054))	Aerobic DT <sub>50</sub> DT <sub>90</sub> Soil	107/358 (SFQ)	Worst case persistence lab VT values from KCA 7.1.2.1.1/09 see Table 7.1.2.1.1-1
	Maximum occurrence in	\$\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\tilde{\mathcal{O}}\math	See Table 7.4.1-1
	DT <sub>90</sub> d > 1 year	Y	i.e. PECs accumulation required
Metabolite M06 (spirox-amine-acid, (mw 3253 g/mol, molas)	Aerobic DT DT DT Soil	1000 / 3320 S (SEA)	Worst case persistence lab DT values from KCA 7.1.2.1.1/09
ratio 1.101))	Maximum occurrence in		see Table 7.1.2.1.1-1
	soil (%)	5.3	See Table 7.4.1-1 i.e. PECs accumulation
	DT Sossield > 1 Pear	Yes	required

The predicted environmental concentrations in sort of each metabolite was calculated using a pseudo application rate per cop using the following equation:

 $A_{\text{metabolite}}(g/ha) = A_{\text{parent}} \times \frac{\text{maximum metabolite observed (\%)}}{100} \times \text{molar correction factor}$   $A_{\text{parent}} \times A_{\text{parent}} \times A_{\text{par$ 

The calculation of pseudo application rates for the metabolites for each use are shown in Table 9.1.3-4. The application rate that represents the worst case scenario for spiroxamine is an application to cereals at 375 g a.s./ha.



Table 9.1.3-4: Pseudo application rates for metabolites of spiroxamine used in the PEC<sub>SOIL</sub> calculations

Crop / application rate	Metabo- lite	Max. soil load per applica- tion (g a.s./ha)	Maximum observed in soil (%)	Molar correction factor	Pseudo applica- tion rate per ap- plication (g a.s./ha)
Cereal/ 375 g a.s./ha	M01	75	12.0	0.9406	8.15
Cereal/ 375 g a.s./ha	M02	75	9.2	Ø.858	5.92
Cereal/ 375 g a.s./ha	M03	75	73	<b>⊘</b> ₹.054	\$24 Ø
Cereal/ 375 g a.s./ha	M06	75	<sub>e</sub> 5.3		4.38

The initial predicted environmental concentration for parent in soil offer application was calculated using the following equation, assuming the soil deposit journiformly distributed in the top 5 cm soil layer and that the soil bulk density is 1.5 g/cm<sup>3</sup> (FOCUS 1997):

$$PEC_{SOIL} (mg/kg) = \frac{A \times (1 - F)}{100 \times d \times p}$$

Where:

A = Application rate (g.a.s./ha)F = Fraction intercepted by crop d = Depth of field soil layer (5 cm)  $\rho$  = Dry bulk density  $(1.5 \text{ g/cm}^3)$ 

For the metabolites, the effective dose was calculated accounting for molecular weight and maximum observed occurrence in soil Short and long-term (seasonal) predicted concentrations in soil of the active substance spiroxamine metabolites were calculated using SFO kinetics based on worst-case persistence DT50 values (see Table 9.1.3 3) using the following equation:

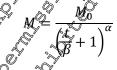
Where:

Initial PEC<sub>SOI</sub> Soil BEC ironediately after application

k = first order degradation/dissipation rate constant (ln(2)/half-life)

t specified time point after application (days)

For the active substance Spiroxamine, short and long term (seasonal) predicted concentrations in soil were calculated using FOMC kinetics based on worst-case persistence  $DT_{50}$  values (see Table 9.1.3-3) using the following equation:



where

M = total amount of chemical present at time t $M_0 =$  total amount of chemical present at time t = 0

 $\alpha$  = shape parameter determined by coefficient of variation of k values

 $\beta = 10$  location parameter

For metabolite concentrations, degradation between applications was not taken into account (worst-case).



## **PECs**<sub>accumulation</sub>

In addition to the seasonal PECs calculations, the potential accumulation (PECs,accumulation) in soil ollowing repeated annual applications was calculated for metabolite where DT<sub>90field</sub> > 1 year i.e. the active, substance spiroxamine and metabolites M01 (spiroxamine-desethyl), M02 (spiroxamine-despropyl), M03 (spiroxamine-N-oxide) and M06 (spiroxamine-acid).

For parent spiroxamine, accumulation calculations were based on application every year as a worst case. The decay of each annual application was modelled on a daily basis for up to 100 years from first apply cation using FOMC degradation kinetics. The total daily sidue was the sum of the individual residues from each application. The calculation was carried out for 100 years assuming in exporation to 5 cm depth and with tillage to 20 cm depth. Although soil ridgesidues are technically still increasing due to the use of FOMC kinetics, a 100 years of repeated annual applications is considered sufficiently worst-case.

For parent spiroxamine metabolites M01 (spiroxamine-desether), M02 (spiroxamine-despropyl) M03 (spiroxamine-N-oxide) and M06 (spiroxamine-acid), accumulation calculations were similarly conducted but using SFO kinetics and a shorter time period Accumulation PECs for MV6 are provided based on the default DT<sub>50</sub> and is considered worst case; an ongoing OECD307 study is being conducted to provide realistic  $DT_{50}$  and refine the presented conservative assessment.

PECs, accumulation was calculated as the sum of the PECs, plates, concentration before the first annual application in the last year and the PEC in (calculated for 5 cm soil depth) mmediately after the last application:

$$PEC_{s,ini} = PEC_{s,pla}$$

$$PEC_{s,accomulation} = PEC_{s,pla}$$

$$PEC_{s,pla}$$

Where:

Depth of the field so Dayer for incorperation (§  $d_{inc}$ 

ρ

The resulting worst-case predicted engronmental concentrations in soil of the active substance are presented by Table 9.1.3. Condetable in State of the match of the interior of the second of the sec The resulting worst-case predicted environmental concentrations in soil of the act sented in Table 9.1.3-9. Table 9.1.3-9.



Table 9.1.3-5: Worst-case PECs (initial, short/long-term and TWA) for spiroxamine following application of Prothioconazole + Spiroxamine EC 460 (160+300 g/L) to cereals

		Conc	centration in so	il (mg aðkg soil	dw)
Time		1 x 375g	a.s./ha	<b>®</b> 2 x 375 g	a.s./ĥa A
		Actual	TWA	Actual ,	O TWA
Initial (after last appln)		0.100	\$ - @	) 0.181 J	
	24h	0.098	0.099	0.17&	0.180
Short term	2d	0.097	0.09	o 0.1476	0.978
	4d	0.994	<b>9</b> 997 ×	0.171	©0.176
	7d	O.090	£0.095	0.164	0,172
	14d	A 0.08	0.600	© 0,149 O	<b>0</b> .164
Longtorm	21d	0,074	Ø.086 🖓	°√0.136∜	0.15
Long term	28d Q,	0.068	0.082	Ö 0.186 Ö	0.151
	5.60V	0.033	Ø72 Ô	0.100	<b>©</b> 0.134
	\$00d \		0.058	& 0.0€ €	0.111
Plateau concentration (20 cm)		\$ 0.010		0019 O	-
PEC <sub>accumulation</sub> (PEC <sub>act</sub> +PEC <sub>soil plateau</sub> )		(after 100 g/s)	\$\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	©0.200 (when 100 yrs)	-

A For concentrations of the active substance, degradation between applications was taken into account.

Table 9.1.3-6: Worst-case RECs (initial, short/long-term and TWAF for metabolite M01 following application of Prothioconazole 4 Spiroxamine EC 460 (160+300 g/L) to coreals

Time &		Concentration on soil (mg as/kg soil dw)			
Time of the state		,10x 373g	a.s./ha	2 x 375 g	a.s./ha <sup>A</sup>
3, 4,		Actual S	TWA	Actual	TWA
Initial		0.01	- 1	0.022	-
	2 <sup>4</sup> 4		0.011	0.022	0.022
Short term	\$2d \$	, <b>30</b> .011, J	0.011	0.022	0.022
	Q 4d	\$ 0.00Y	0.011	0.021	0.022
4 5	, Fa	<b>0</b> 011	0.011	0.021	0.021
	14d Ø	0.010	0.011	0.021	0.021
Long torm	2 Hel _	0.010	0.011	0.020	0.021
	\$28d <sup>ũ</sup>	0.010	0.010	0.020	0.021
	50d	0.009	0.010	0.019	0.020
	100d	0.008	0.009	0.016	0.019
Long term  Plateau concentration (20 cm)		0.004	-	0.008	
PEC <sub>accumulation</sub> (PEC <sub>act</sub> +PEC <sub>soil plateau</sub> )		0.015 (after 4th yr)	-	0.030 (after 4th yr)	-

A For metabolite concentrations, degradation between applications was not taken into account (worst-case).



Table 9.1.3-7: Worst-case PECs (initial, short/long-term and TWA) for metabolite M02 following application of Prothioconazole + Spiroxamine EC 460 (160+300 g/L) to cereals

		Conc	centration in so	il (mg aðkg soil	dw)
Time		1 x 375g	a.s./ha	<b>∞</b> 2 x 375 g	a.s./ha A
		Actual	TWA	Actual ,	O TWA ~
Initial		0.008	Ö - (	0.016	
	24h	0.008	0.008	0.016	0.016
Short term	2d	0.008	0.000	° 0.046 °	0.0016
	4d	0.608	9008 ×	0.016	©0.016
	7d	0.008 °	0.008	0.015	0.016
	14d		0.608	0,015	<b>0</b> .015
Longtonn	21d	0,007	<b>©</b> .008	\$\int_0.014\times	0.01
Long term	28d 🔍	(\$\sqrt{0.00}\)	(\$\int_{\infty}^{\infty} 0.0 <b>0</b>	Ö 0.04 2	0.015
	5.0d	0.006	D 07	0.013	° 0.014
	\$00d \( \tilde{\chi} \)	Ø.005 Ş	@0.006\	& 0.0 <b>1</b> 0 €	0.013
Plateau concentration (5 cm)		S 0.003		<b>9</b> 005 O	-
PEC <sub>accumulation</sub> (PEC <sub>act</sub> +PEC <sub>soil plateau</sub> )		(adher 2ndzyr)	\$\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2	0.021 (after 37 yr)	-

A For metabolite concentrations, degradation between applications was not aken into account (worst-case).

Table 9.1.3-8: Worst-case RECs (initial, short/long-term and TWAV for metabolite M03 following application of Prothioconazole + Spiroxamine EC 460 (160+300 g/L) to cereals

Time & S		Concentration on soil (mg as/kg soil dw)			
Time & S		, 10 <sup>3</sup> 375g	a.s./ha	2 x 375 g	a.s./ha <sup>A</sup>
		Actual 0	TWA	Actual	TWA
Initial Q S		0.008	'ZQ	0.017	-
	241/1 ^	y 0;008 ~ (	0.008	0.017	0.017
Short term	\$2d <i>\$</i>	. Ø.008. Ø	800.0	0.016	0.017
	4d	© 0.008	800.0	0.016	0.016
The state of the s	Äd Q	<b>0</b> ,008	0.008	0.016	0.016
	14d@	0.008	0.008	0.015	0.016
Langton O	2 He 0	0.007	0.008	0.015	0.016
Long term  Plateau concentration (20 cm)	%28d <sup>ũ</sup>	0.007	0.008	0.014	0.015
	50d	0.006	0.007	0.012	0.014
	100d	0.004	0.006	0.009	0.012
Plateau concentration (20 cm)		0.002	-	0.005	-
PEC <sub>accumulation</sub> (PEC <sub>act</sub> +PEC <sub>soil plateau</sub> )		0.010 (after 2nd yr)	-	0.022 (after 2nd yr)	-

A For metabolite concentrations, degradation between applications was not taken into account (worst-case).



Table 9.1.3-9: Worst-case PECs (initial, short/long-term and TWA) for metabolite M06 following application of Prothioconazole + Spiroxamine EC 460 (160+300 g/L) to cereals

		Conc	centration in so	il (mg asokg soil	dw)
Time		1 x 375g	a.s./ha	<b>®</b> 2 x 375 g	a.s./ĥa A
		Actual	TWA	Actual	O TWA .
Initial		0.006	Ö - (	چ 0.012 کی	
	24h	0.006	0.006	0.012	0.010
Short term	2d	0.006	0.000	° 0.042	0.012
	4d	0.996	<b>9</b> 006	0.012	90.012
	7d	© 7.006 ©	0.006	0.012	0.012
	14d	A 0.000	0.606	0,012	<b>0</b> :012
I and town	21d	0,006	Ø.006 <del>\$\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}\frac{1}{2}</del>	0.012	0.01
Long term	28d 💸	0.006	0.00	Ö 0.041 0	0.012
	5,954	0.006	<b>1 3</b> 006 <b>3</b>	0.011	° €0.011
	\$00d	Ø.005 S	© 0.006	° 0.010 €	0.011
Plateau concentration (20 cm)		\$ 0.007	~ ~ ~	0013 O	-
PEC <sub>accumulation</sub> (PEC <sub>act</sub> +PEC <sub>soil plateau</sub> )		(anter 15 m/s)	\$\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	0.025 (after Syrs)	-

A For metabolite concentrations, degradation between applications was not taken into account (worst-case).

Table 9.1.3-10: Overview of unitial DECs following single (1x \$7.5 g/kg), multiple (2x 375 g/hg) and repeated annual applications for a period of 100 years of 2x 375 g/hg to cereals O

		, ~
	Oncentration to soil (60	g as/kg soil dw)
		ha A,B Repeated annual application of 2x 375 g/ha
Spiroxamine Spiroxamine	00 7 7 0.1810	0.019 (background) 0.069 (peak) after 100 yrs annual use
M01 (spitexamine-de-		0.008 (background) 0.030 (peak) plateau after 4 yrs annual use
M02 (spiroxamine-despropyl),	0.016	0.005 (background) 0.021 (peak) plateau after 3 yrs annual use
M03 (spiroxamine-Nox-) 0.00	0.017	0.005 (background) 0.022 (peak) plateau after 3 yrs annual use

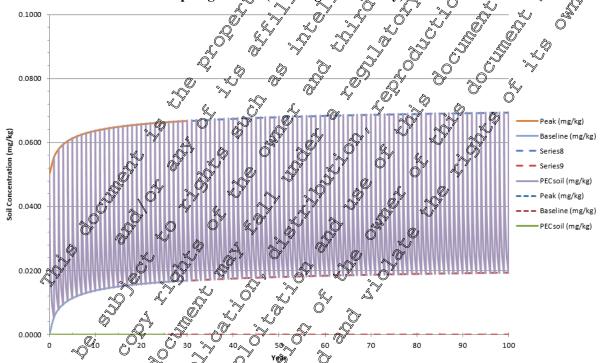


	Concentration in soil (mg as/kg soil dw)				
Substance	1x 375 g/ha	2 x 375 g a.s./ha <sup>A,B</sup>	Repeated annual application of 2x 375 g na		
M06 (spiroxamine-acid)	0.006	0.012	0.013 (background) 0.025 (peak) plateau after 20 yrs annual		

A For concentrations of the active substance, degradation between applications was siken into account.

The predicted accumulation of spiroxamine in soil over a 100-year period after application to cereals is illustrated in Figure 9.1.3-1.

Figure 9.1.3-1: Accumulation of spiroxamine in soil following repeated annual application to winter or spring cereals (2x.3/75 g/ha annually)



Following application of 2x 375 g/ha to cereats, worst-case PEC in soil of the active substance spiroxamine and metabolites M01 (spiroxamine-desethy), M02 (spiroxamine-desproyl), M03 (spiroxamine-N-oxide) and M06 (spiroxamine-acid) were 0.18 f, 0.022, 0.016, 0.017 and 0.012 mg/kg soil dw respectively. Following worst-case repeated annual applications to cereals (i.e. 2x 375 g/ha annually), worst-case peak accumulated PEC ar soil were 0.069, 0.030, 0.021, 0.022 and 0.025 mg/kg soil dw respectively.

# Predicted environmental concentrations in soil (PEC<sub>S</sub>) – active substance prothioconazole and metabolites

The representative formulated product Prothioconazole + Spiroxamine EC 460 (160+300 g/L) also contains the active substance prothioconazole. The active substance prothioconazole is not the primary focus of the renewal of the active substance spiroxamine and is the subject of a separate renewal evaluation which is in progress at the time of writing.

B For metabolite concentrations, degradation between applications was not taken into account (worst-case).



According to the current evaluation documents for the active substance prothioconazole (i.e. EFSA 2007<sup>2</sup>, p.77/98), the definition of the residue for environmental risk assessment in soil lists prothioconazole and metabolites M01 (prothioconazole-S-methyl) and M04 (prothioconazole-desthio).

The predicted environmental concentration in soil of prothioconazole and metabolites M01 (proflioconazole-S-methyl) and M04 (prothioconazole-desthio) are addressed by reference to the existing RAR for spiroxamine, volume 3, Annex B.9 (8-Aug-2017) which provides the following Table 94.3-11 from page 324; Table B.9.7-14) showing PECs following 2x 200 g prothioconazole/ha applications to cereals using existing parameters as needed for environmental risk assessment:

Table 9.1.3-11: PECsoil values for Prothioconazele and Spiroxamine EC 460

-					
Compound	maximum (mg/kg soil)	Q	21d-TWA (mg/kg soil)	Q,	Reference
Cereals:2x 1.25 L product/ (2 x 0.200 kg Protl	ha nioconazole, 2 x 0,375	kg Spirox			
Prothioconazole	0.084		∕ <u>Q.</u> 028 🕰	Shad	
Prothioconazole-desthio	0075	y 40"	~ 0.066O ×	MEF-68	& Zer®, 2008, 1474, 28
Prothioconazole-S-methyl	0):021	· \$ 4	7 0.008 J	(scelerio	
Spiroxamine	0.288		272	Roepke	
KWG 4168-desethy1	@ <del>0.023 </del> 0.118**		© 0.02,6	MEF@8	/274
KWG 4168-despropyl	© 0.014 0.116**	4 0	0.03		© <sup>1</sup>

<sup>\*\*</sup> According to Open Point 27 of the Evaluation Table initial PECs value for the metaborites M01 (-desethyl) and M02 (-despropyl) were recalculated.

Using the existing list of endpoints (LoEP) for profinioconazole, following 2x 200 g prothioconazole/ha applications to cereals the maximum initial predicted environmental concentration in soil of prothioconazole and metabolites MOI (profinioconazole S-methyl) and MO4 (prothioconazole-desthio) are 0.081, 0.075 and 0.02 Dmg/kg soil, respectively.

For procedural reasons studies listed in the Table CP A 3-1 below are included in the current dossier as available data or information previously submitted but not necessarily evaluated. However, these reports have been fully supersoded by newer studies. Consequently, no summaries of the reports have been included in the dossier.

Table CP 9.1.3-1: Studies previously submitted and not relied upon for the risk assessment

1 11010 01 711		proposity submitted and not reness upon for the risk assessment
	Documents Qo.	Date Title of of of
KCP 🗳	M-304009-	2008 Predicted environmental concentrations of spiroxamine in soil (PECsoil) -
9.1.3/01	02-1	Q Use in cereats in Europe

#### CP 9.2 Pate and behaviour in water and sediment

Use of the representative formulated product Prothioconazole + Spiroxamine EC 460 (160+300 g/L) can potentially lead to amounts reaching surface water during treatments by spray drift or *via* soil drainage and fun-off therefore the rate and behaviour in water and sediment of Prothioconazole + Spiroxamine FC 460 (160+300 g/L) is addressed.

<sup>&</sup>lt;sup>2</sup> EFSA Scientific Report (2007) 106, 1-98, Conclusion on the peer review of prothioconazole.



The representative formulated product Prothioconazole + Spiroxamine EC 460 (160+300 g/L) also contains the active substance prothioconazole. The active substance prothioconazole is not the primary focus of the renewal of the active substance spiroxamine and is the subject of a separate renewal evaluation which is in progress at the time of writing.

#### **CP 9.2.1** Aerobic mineralisation in surface water

As it is possible to extrapolate the behaviour of the active substance resulting from use of the formulated product Prothioconazole + Spiroxamine EC 460 (160+300 g/L) from the study on the active substance itself, additional laboratory studies investigating the aerobic mineralisation in surface water of Prothioconazole + Spiroxamine EC 460 (160+300 g/L) have not been performed.

#### **CP 9.2.2** Water/sediment study

As it is possible to extrapolate the behaviour of the active substance resulting from use of the formulated product Prothioconazole + Spiroxamine EC 400 (160+300 g/L) from the study of the active substance itself, additional laboratory studies investigating the behaviour of Prothioconazole + Spiroxamine FC 460 (160+300 g/L) in water/sediment studies have not been performed.

## CP 9.2.3 Irradiated water sediment study.

As it is possible to extrapolate the Schaviour of the active substance resulting from use of the formulated product Prothioconazole + Spiroxamine EC 460 (160-300 g/L) from the study of the active substance itself, additional laboratory studies investigating the behaviour of Prothioconazole + Spiroxamine EC 460 (160+300 g/L) in irradiated water/sed/ment studies have not been performed.

#### CP 9.2.4 Estimation of concentration on groundwater

# CP 9.2.4.1 Calculation of concentrations in groundwater

The Predicted Environmental Concentrations in graundwater (PEC<sub>GW</sub>) to lowing foliar applications of Prothioconazole + Sprioxanone ECO460 (460+300 g/L) have been calculated for the active substance spiroxamine and major metabolites, as defined in CA 74.1, in accordance with the representative GAP.

The representative formulated product Prothioconazole + Spiroxamine EC 460 (160+300 g/L) also contains the active substance prothioconazole. The active substance prothioconazole is not the primary focus of the renewal of the active substance spiroxamine and is the subject of a separate renewal evaluation which is in progress at the time of writing.

The predicted environmental concentration of the active substance spiroxamine and significant metabolite in groundwater (PE $_{\rm CW}$ ) is determined using the standardised recommendations of the FOCUS working group on surface water scenarios (FQCUS  $2000^3$ ,  $2014^4$  and EC  $2014^5$ ). The PECs are provided in one existing modelling study included in the last evaluation which is therefore included for completeness but which has been superseded by a new modelling report conducted to modern requirements CP 92.4.1/02 (M-76314701-1).

FOCUS (2009). 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.

<sup>&</sup>lt;sup>4</sup> \* FOCUS (2014). Generic guidance for Tier 1 FOCUS groundwater assessments, version 2.2. FOCUS groundwater scenarios working group.

EC (2014). Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU, Report of the FOCUS Ground Water Work Group, EC Document Reference Sanco/13144/2010 version 3, 613 pp.

4



Substance	Report 1	eference	Document no.	Comment		
Spiroxamine	KCP 9.	2.4.1/01	<u>M-304049-01-1</u>	Submitted for first renewal of spirox o amine, 2010. Reviewed under UP. Consid-		
				ered valid and acceptable.	ř	
Spiroxamine	KCP 9.	2.4.1/02	<u>M-763143-01-1</u>	New data not verreviewed under UP.		
PECgw FOC	U <b>S (spirox</b> a	amine)				
Data Point:		KCP 9.2.4.1	/01			
D 41						

#### PECgw FOCUS (spiroxamine)

Data Point:	KCP 9.2.4.1/01
Report Author:	
Report Year:	2008
Report Title:	Predicted environmental concentrations of spiroxamine in groundways rectavge
	(PECgw) based on calculations with FOCUS PEARCE and OCUS PELMO - Use
	in cereals in Europe
Report No:	MEF-08/272 1 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2
Document No:	M-304049-01
Guideline(s) followed in	I not applicable A A A A A A A A A A A A A A A A A A A
study:	
Deviations from current	LNI
test guideline:	
Previous evaluation:	yes Sevaluated and accepted 4 6
	RÄR (2010) 💍 🎸 🧒 💆
GLP/Officially recog-	Ono, not Conducted under GLP/Officially recognised testing facilities
nised testing facilities:	
Acceptability/Reliability/	Yes V & V

#### Executive summar

This study was previous considered during the evaluation of spirox mine (RAR (2010)) and is therefore included again for completeness. This study presents the EFC modelling conducted on the representative for the last evaluation, however, the PEC modelling reported in this study is superseded by the new PEC modelling performed in study KCP1 95.4.1/02 (M-763143.01-1)

Data Point:  Report Author:  Report Year:  Report Title  A modeling assessment of spiroxamine and its Mmetabolites in groundwater  Report No:  Document No:  Guideline(s) followed for study:  Deviations from current test guideline:  Previous evaluation:  A modeling assessment of spiroxamine and its Mmetabolites in groundwater  FOCUS 2000, 2014), EFSA (2014)  FOCUS 2000, 2014), EFSA (2014)  Substitute of the spiroxamine and its Mmetabolites in groundwater  FOCUS 2000, 2014), EFSA (2014)  Substitute of the spiroxamine and its Mmetabolites in groundwater  FOCUS 2000, 2014), EFSA (2014)  Substitute of the spiroxamine and its Mmetabolites in groundwater  FOCUS 2000, 2014), EFSA (2014)  Substitute of the spiroxamine and its Mmetabolites in groundwater  FOCUS 2000, 2014), EFSA (2014)  Substitute of the spiroxamine and its Mmetabolites in groundwater  FOCUS 2000, 2014), EFSA (2014)
Report Title A modelling assessment of spiroxamine and its Mmetabolites in groundwater  Report No. 0471836-GW2  Document No: M-75143-05-1  Guideline(s) followed for study: Deviations from current test guideline: None Previous evaluation: No, not previously submitted
Report Title A modelling assessment of spiroxamine and its Mmetabolites in groundwater  Report No. 0471836-GW2  Document No: M-75143-05-1  Guideline(s) followed for study: Deviations from current test guideline: None Previous evaluation: No, not previously submitted
Report Title
Document No:  Guideline(s) followed for study:  Deviations from current test guideline:  Previous evaluation:  No, not previously submitted
Guideline (s) followed in study:  Deviations from current test guideline:  Previous evaluation:  No, not previously submitted
Study:  Deviations from current test guideline:  Previous evaluation:  None yes the provious evaluation:  None yes the provious evaluation of the previous e
Deviations from current None Y test guideline: None Y Tervious evaluation: None Y Terv
test guideline:  Previous evaluation:   No, not previously submitted
Previous evaluation: A No, not previously submitted
GI P/Officially record Pot applicable
GLI/OTHERRY ICCUE
mised testing facilities.
Acceptability/R hability: YeO

# Executive summary

The leaching behaviour of spiroxamine and its metabolites M01 (spiroxamine-desethyl), M02 (spiroxamine-despropyl) and M03 (spiroxamine-N-oxide) following application of Prothioconazole + Spiroxamine EC 460 (160+300 g/L) formulation applied as a foliar spray to winter and spring cereal crops was examined in accordance with the FOCUS groundwater scenarios workshop guidelines (FOCUS, 2000) and 2014) and the EFSA guidance for protected crops (EFSA, 2014).



The following field uses were simulated in accordance with the supported uses of the Prothioconazole+ Spiroxamine EC 460 (160+300 g/L) formulation:

- Two applications (BBCH 30 onwards) at a rate of 375 g a.s./ha to winter cereals
- Two applications (BBCH 30 onwards) at a rate of 375 g a.s./ha to spring cereals

Simulations for the field uses were conducted using the FOCUS groundwater cenarios in the FOCUS PEARL (version 4.4.4), FOCUS PELMO (version 5.5.3) and FOCUS MAGRO (version 5.4) no dels.

The input parameters for the calculations are defined in Table 9.2.4.1.1 and were selected based on recommendations from FOCUS (FOCUS, 2000 and 2014).

These results demonstrate that spiroxamine can be used safely as proposed without the risk of piro amine and its metabolites M01 (spiroxamine-deseth, M02 (spiroxamine-deseth, M02 (spiroxamine-deseth, M03 (spiroxamine-des amine-N-oxide) exceeding acceptable levels in goundwater.

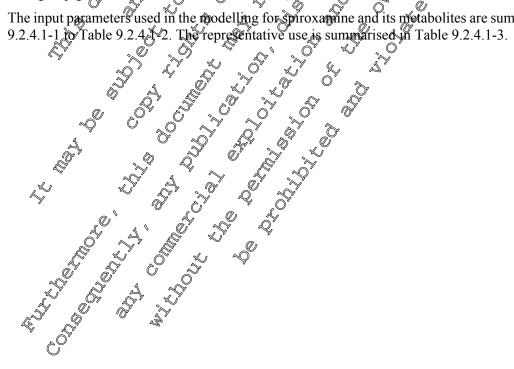
The predicted 80th percentile average annual concentrations for spiroxamme following application to winter and spring cereals were lower than the 0.1 µg/L regulatory (threshold in groundwater at 14m depth for all crop / scenario combinations. The PEC<sub>G</sub> values for metabolites MO (spiroxamine desetty), M02 (spiroxamine-despropyl) and M03 (spiroxamine-N-oxide) following annual application spiroxamine to crops were <0.001 µg/L, which is expected due to the high K<sub>OC</sub> of spir wamine and its metabolites, as well as being in accordance of values submitted previously. All values are below the 0.1 μg/L regulatory threshold in groundwater at 1 m depth for all the available frop / Seenario combinations.

#### Study design

The purpose of this study was to assess the potential for leaching of spiroxamine and its metabolites M01, M02 and M03 following application of the Prothioconazole + Spiroxanine EC 460 (160+300 g/L) formulation to winter and spring cereals, in accordance with the EU representative GAP.

The predicted environmental concentrations in groundwater (PEC<sub>GW</sub>) for the field uses were determined using the FOCUS PEARL (wersion 4.4.4) FOCUS PELMO (Version 5.5.3) and FOCUS MACRO (version 5.5.4) ground water models and scenarios in accordance with the POCUS groundwater scenarios workgroup gui@lines@FOCUS, 2000 and 2014).

The input parameters used in the modelling for spiroxamine and its metabolites are summarised in Table



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#### Document MCP – Section 9: Fate and behaviour in the environment Prothioconazole + Spiroxamine EC 460 (160+300 g/L)

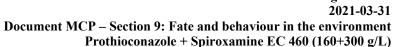
Table 9.2.4.1-1: Physico-chemical parameters used in modelling for spiroxamine

Parameter	Value	Remarks
Physico-chemical		
Molecular weight (g/mol)	297.5	MCA Renewal of Approval dossfer, see CA 1.7
Water solubility at 20°C (mg/L)	470	MCA Renewal of Approvat dossier see
Vapour pressure at 20°C (Pa)	4.5 x 10 <sup>-3</sup>	MCA Renewal of Approval dessier, see
Molar enthalpy of vaporization (kJ/mol)	95	
Diffusion coefficient in water (m <sup>2</sup> /d)	4.3 x 40-5 (200°C) (PEARL)	FOOUS recommendation A
(m <sup>2</sup> /s)		
Diffusion coefficient in gas $(m^2/d)$	0.43 (20°C)	
Degradation in soil		
DT <sub>50</sub> soil (d)	43.80 5	Geometric media of uncropped field data in=81, submitted in MCA Renewal of Ap- proper dossier, see data point CA 7.1.2.1.1, Table 7.1, 22.1-72
Temperature correction function  Reference temperature  PELMO:  PEARL: (kJ/mol)  PEARL: (kJ/mol)	20 5 2,58 55.4 5	FOCUS recommendation
Moisture correction function  Reference musture (-)  PEARL/PELMO: moisture exponent (-)	0.49	
Sorption to soil		
K <sub>FOC</sub> (mL/g)		Goometric mean (n= 8) calculated from in- dividual values, see data point CA 7.1.3.1, Table 7.1.3.1-1
K <sub>FOM</sub> (mL/g)	2884 5 6	Calculated K <sub>F</sub> oc / 1.724
Freundlick exponent 1/n (-)	0.892	Arithmetic mean (n=8) calculated from individual values submitted in MCA Renewal of Approval dossier see CA 7.1.3.1
Cron management related parameters		
Crop uptake factor (-)	0.67	Crop uptake factor calculated by Briggs equation, see Appendix 2
Washoff Factor (1/10) (PEARL)	0.0001	Default
Washoff Cactor (Vm) (MACRO)	0.05	Default
Foliar DT <sub>50</sub>	10	Default



Table 9.2.4.1-2: Input parameters used in groundwater modelling for the metabolites of spiroxamine

D	M01 (spiroxamine-desethyl)		M02 (spiroxamine-	despropy (f)	M03 (spiroxaj	nine-N-oxide
Parameter	Value	Remarks	Value	Remarks 6	Value &	Remarks
Molecular weight (g/mol)	269.4	Based on structure	269.4	Remarks Based on structure	Value 313.9	Remarks Based on structure
Water solubility at 20°C (mg/L)	14.8	MCA Renewal of Approval dossier, see CA 2.5	269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4 269.4	MCA Renewal of Approval	1000	WICA Renewal of Approval dossier, see CA 2.5
Vapour pressure at 20°C (Pa)	0	(FOCUS, 2014)	Br and	OCUS 2014)		Default value (FQ@S, 2014)
$K_{FOC}$ (mL/g)	3271	Geometric mean (n=4) submitted in MOA Renewal of Appropriate data point (A 7.1.3.1.2, Table 7 0.3.1.2-1)	269AC JIDDE	Geometric mean (n=4) submitted in MCA Renewal of Approval dossier see data point CA 7.1.3 1.2, Table 1.3.1.2-1.  Arithmetic mean (n=4) submitted in MCA Renewal of Approval dossier see CA 7.1.3 1.2.  Geometric mean (n=10) of laboratory values submitted in MCA Renewal of Approval dossier, see data point CA 7.1.2.1.1, Table 7.1.2.1.1-2	CUMER LES	Geometric mean (n=4), submitted in MCA Renewal of Approval dossier, see data point CA 7.1.3.1.2, Table 7.1.3.1.2-1
1/n	0.848	Arithmetic mean (154), submitted in MCA Renewal of pproval dossier see (27.1.3.1.0)	0.878	Arithmene mean (n=4) submitted in MCARenewal of Approval dossier see CA	0.900	Arithmetic mean (n=4), submitted in MCA Renewal of Approval dossier see CA 7.1.3.1
DT <sub>50</sub> soil @ 20°C & pF2 (days)	168.6	Geotheric mean (n=10) of a- boratory values, submitted in MCA Renewal of Approval dossier, see data point A 7.1.2.1.1, Table 7.1.2.1.4-2		Geometric mean (n=10) of laboratory values submitted in MCA Renewal of Approval dossier, see data point CA 7.1.2.1.1, Table 7.1.2.1.1-2	46.4	Geometric mean (n=7) of laboratory values submitted in MCA Renewal of Approval dossier, see data point CA 7.1.2.1.1, Table 7.1.2.1.1-2
Coll	seducin	Court Ape Brown				





Domorroston	M01 (spiroxamine-desethyl)		M02 (spiroxamine-	despropyl)	M03 (spiroxamine-N-oxide)	
Parameter	Value	Remarks	Value	Remarks	<b>V</b> alue	Remarks
Plant uptake factor	0	Default value	0	Default value	0	Default value
Formation fraction	0.183	Arithmetic mean (n=10), of laboratory values; submitted in MCA Renewal of Approval dossier, see CA 7.1.2	0.138	Arithmetic mean (n=10), of (n- borntory values;) submitted in MCA Renewal of Approval dossice see CA 3.1.2	@149 @170 @170	Anthmetic thean (n=7), of laborator values, submitted in MCA Renewal of Approval cossier see CA 7.1.2
MACRO conversion fraction	0.1657	Mwparent) ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	1.185xxx 3 3 3 5 5	Transfer of the state of the st	1025°	0.149 (ff x (MWmetabolite/ MWparent)
Washoff Factor (1/m) (PEARL)	0.0001		0.000 P	Default COCO	0.000	Default
Foliar DT <sub>50</sub> (d)	10	Defaulto Defaulto	10,0	Default 1	10	Default

Default Defaul



Table 9.2.4.1-3: Supported use of Prothioconazole+ Spiroxamine EC 460 (160+300 g/L) formulation

	<b>GAP</b> details		Early a	application	Late a	pplication 4
Crop	Appln	Growth stage	Int. (%)	Effective ap-	Int (%)	Effective ap
	rate (g	(PHI)		pln rate (g	Ž.	pln rate (g
	as/ha)			as/ha)	4	∠ as/ha) y
Winter sown	2x 150-	30-69	80	2x 75 🐇	🦻 90 (GS 🕝	2x, 30.5
cereals b	375 (14 d		(GS30+)	's L	(40+) ≰	
	min inter-		\\$\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\		W W	%
	val)		4	O	Z)	
Spring sown	2x 150-	30-69	8 <b>O</b> O	2x/38	90 (@S	, × 2x & 7.5 🙋
cereals b	375 (14 d		$(G_{\bullet})^{3}(0+)$		<b>4</b> 0+)	√ d. 1
	min inter-					
	val)		L S°			

Applications made to winter and spring cereals were simulated using the relevant FOCUS scenarios in FOCUS PEARL (version 4.4.4) and FOCUS PELMO (version 5.5.3). In FOCUS MACKO (version 5.5.4), simulations were performed using the Chateaudin scenario.

The groundwater models account for crop interception using different prethods. For consistency, the internal interception routines of the models were disabled and the approximation rates were manually adjusted for crop interception, in accordance with FOCUS recommendation (FOCUS 2000 and 2014).

The calculation of the adjusted application rates is shown in Table 9.2.43-4

Table 9.2.4.1-4: Calculation of exposure to soil for use in groundwater simulations

Scenario	FOOUS dates for	Applicati	on timing				
	@ emergence harvest		<b>Late</b>				
Wingi	Wing Cereals (FOCUS winter cereals), 2x 395 g as Da (14 demin interval) GS30-69						
Châteaudun (C)	26-Oct/15/Jul	15-Apr (105), 29-Apr (1190)	31-May (151), 14-Jun (165)				
Hamburg (H)	1 Nov/10 Aug &	4 May (124), 18 May (138)	08-Jun (159), 22-Jun (173)				
Jokioinen (🗘	20-Sep/75-Aug	14-May (134), 28-May (148)	26-Jun (177), 10-Jul (191)				
Kremsminster (K)	5-XV/10-Ang	24 (1128), 8-May (128)	11 Jun (162), 25-Jun (176)				
Okehamption (N)	17-Oct/1-Aug	21 Apr <sub>((111)</sub> , 5 May (125)	24-May (144), 7-Jun (158)				
Piacenza (P)	1-D@/1-Juk/ 3@Nov/30-Jun	19-Mar (78) 2-Apr (92)	12-May (132), 26-May (146)				
Porto (O)		30-Jan (30), 13-Feb (44)	04-May (124), 18-May (138)				
Sevilla (S) <u>⊀</u>	90-No Q31-May	6-Jan (6), 20-Jan (20)	14-Mar (73), 28-Mar (87)				
Thiva (T🎾 🍍	Ø 30-Nov/30-Mm &	18-Jan (18), 1-Feb (32)	13-Apr (103), 27-Apr (117)				
		Expliest appln @GS30 with 2 <sup>nd</sup> appln 14 days later	2 <sup>nd</sup> appln @GS69 with 1 <sup>st</sup> appln 14 days prior				
Spring	cereals (FOC) spring ceret	(14 d min ir					
Châteaudun (C) "	10-Mar/20-Jul		12-Jun (159), 22-Jun (173)				
Hamburg (H)	Apr/20-Aug	28-Apr (118), 12-May (132)	18-Jun (165), 28-Jun (179)				
Jokioinen 🔏 🧸	8-May/25-Aug	5-Jun (156), 19-Jun (170)	07-Jul (184), 17-Jul (198)				
Kremsmünster (K)	1-Apr 20-Aug"	27-Apr (117), 11-May (131)	18-Jun (165), 28-Jun (179)				
Okehannition (N)	L <sub>a</sub> 1_√or/20_ Aug	22-Apr (112), 6-May (125)	08-Jun (155), 18-Jun (169)				
Porto (O)	40-Mar/20-Jul	16-Apr (106), 30-Apr (120)	12-Jun (159), 22-Jun (173)				
Porto (O)		Earliest appln @GS30 with 2 <sup>nd</sup> appln 14 days later	2 <sup>nd</sup> appln @GS69 with 1 <sup>st</sup> appln 14 days prior				



#### Results and discussion

The PEC<sub>GW</sub> (80<sup>th</sup> percentile annual average leachate concentration at 1 m soil depth) values, modelled using FOCUS PEARL, PELMO and MACRO for spiroxamine and its metabolites M01 (spiroxamine-desethyl), M02 (spiroxamine-despropyl) and M03 (spiroxamine-N-oxide) following application of the Prothioconazole+ Spiroxamine EC 460 (160+300 g/L) formulation to winter and spring cereals, are provided in Table 9.2.4.1-5 to Table 9.2.4.1-9.

Table 9.2.4.1-5: PEC<sub>GW</sub> following annual application of spiroxamine in accordance with the GAP, using the FOCUS PEARL model and early application.

			e e	/\V ./	- ~ .
		80th	Percentile PECGW	at 1 m Soil Depth	ig/L) 🗣 🔏
Crop	Scenario	Spiroxamine	M91 (spirox- amine-desethyl)	M02 (spirox amare-despro- y pylo	M03 (spirox) amine-N-oxide)
	Châteaudun	<0.001	Ø.001 <u>%</u>	\$ <b>\$00</b> 001 \$	<0.001
	Hamburg	<0.001	~ <0.00V	₹0.001 <sub>€</sub>	O < Q Q 0001 0 7
Winter	Jokioinen	<0.001	<0.001	( 0.000° «	√ <0.001,©
cereals	Kremsmünster	< 0.00 10	'y′ ,≤ <b>©</b> .001,	O <0.001 S	<0.00
(early	Okehampton	<0.00 (*)	<b>20.00</b>	<b>©</b> !001	<0.001
applica-	Piacenza	< <b>%</b> ,001 °C'	> <0.00√ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	₹0.00 <u>1</u>	\$©.001
tion)	Porto	<₩.001	© <© 901 S		<b>№</b> 0.001
	Sevilla		Ø.001, Ø	<0.901	<0.001
	Thiva	< 0.001	<0.001	♥ × 🔊 .001,	© <0.001
Spring	Châteaudun	<b>≥</b> 0×001 ~ €	@ <0.001	£0.0 <b>0</b> €	< 0.001
cereals	Hamburg 🦠	<sup>2</sup> √0.001©		<0.001 ×	< 0.001
(early	Jokioinen	<0.001	©0.0010°	<0.001	< 0.001
applica-	Kremsmünster	© <0.001	<0.001 <0.001 <0.001	0.001	< 0.001
tion)	Okehan oton	. 89:001	~ <0.001 <sub>@₁</sub>	<0.001	< 0.001
	Porto O	0.001	y \$0.001 Q	<0.001	< 0.001

Table 9.2.4.1-6: PEC<sub>GW</sub> following annual application of spiroxamine in accordance with the GAP using the FOCUS PEARL mode and late application

	~	SOth	Percentile PECGW	at 1 m Soil Depth (µ	ıg/L)
Crop	Scepario	Spiroxamine &	amme-desetayi)	M02 (spirox- amine-despro- pyl)	M03 (spirox- amine-N-oxide)
	Thâtea dun		<0.001	< 0.001	< 0.001
Æ	👢 Hamburg 🔍	\$\tag{0.00}	Ø.001	< 0.001	< 0.001
Winter © cereals	″ Jokioiner®	<0.091	0.001	< 0.001	< 0.001
	121011101114	0.001 0.001	<0.001	< 0.001	< 0.001
(early	Okehampton C	♥ × <b>0</b> .001	<0.001	< 0.001	< 0.001
applica-	Piacenza ®		<0.001	< 0.001	< 0.001
tion)	Porto <sub>s \</sub>	0° <0001 0°	< 0.001	< 0.001	< 0.001
	Sevilla	© <0.001 <sub>Q</sub> ,	< 0.001	< 0.001	< 0.001
	Thiwa 💍	\$\times \lambda \sqrt{0.00HQ}	< 0.001	< 0.001	< 0.001
Spring ©	Châteaudun	<0.001	< 0.001	< 0.001	< 0.001
Spring © cereals	<b>A</b> rambu <u>r</u> g	<0.001	< 0.001	< 0.001	< 0.001
(earl	Jokiomen 🛴	<0.001	< 0.001	< 0.001	< 0.001
applica-	Kremsmünstæ	< 0.001	< 0.001	< 0.001	< 0.001
tion)	Okehampton	< 0.001	< 0.001	< 0.001	< 0.001
U	Porto	< 0.001	< 0.001	< 0.001	< 0.001



Table 9.2.4.1-7: PEC<sub>GW</sub> following annual application of spiroxamine in accordance with the GAP, using the FOCUS PELMO model and early application

		80th Per	centile PEC <sub>GW</sub>	at 1 m Soil Dept	th (µg/L)
Crop	Scenario	Spiroxamine	M01 (spi- roxamine-	M02(spi- roxamine-	M03 (spi- roxamine-
			desethyl)	despropyl)	oxide
	Châteaudun	< 0.001	< 0.001	<0.001	O <0.001
	Hamburg		§ <0.001	<0.001 🖔	<sup>y</sup> <0.001 ≤9
	Jokioinen	<0.001	<0.001	<0.001	\$0.00k
Winter cereals	Kremsmünster	<0.001	<0.0010	<0.000	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
(early application)	Okehampton	<0.00	<0.001	。 <0,001	> <000001 _ @
(willy upproduced)	Piacenza	<0.001	<0.001 g	<sup>₽</sup> < <b>Q</b> 001, 6	€0.001
	Porto	<0.001	@0.001°~	$\sim 0.001$	、 <<0.0 <b>%</b> C
	Sevilla	<b>₩</b> 0.001 <b>©</b>	√×0.001	<0.00	< 0.001
	Thiva	<0.00	C < 0.000 1 7	<0.901	<0.001 °
	Châteaudun	-\$\square                                                                                                                                                                                                                                                                                                                                                   \q	<0.001	Ø.001 <sup>□</sup>	©0.001@
Spring cereals (early application)	Hamburg 🗸	~9.001 <u>~</u> ″	©0.001	~~~0.00 <del>%</del>	<0.06
	Jokioinen 💇	«×0.0Qd	<0.00P	<0.00 Å	> <0 <b>⊙</b> 01
	Kremsmünster	% < 0.6 <b>0</b> 01	\$ <0@01 \$	/ < <b>©</b> 001 &	<b>€</b> 0.001
	Okehampton "	o <0.001 °	<0%.001	&0.001 \$	ू≪₹0.001
	Porto 🛇	<b>2</b> 0.001	\$0.00 <u>₹</u>	Q<0.00P	<i>&gt;&gt;</i> <0.001

Table 9.2.4.1-8: PEC<sub>GW</sub> following annual application of spiroxamine in accordance with the GAP; using the FOCUS RELMO model and late application

			<u>~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~</u>		
		₹ 80tl	Percentile PEC	w at 1 m Soil De	pth (μg/L)
Crop	Scenario	Spirox-	MbT (spirox- Amineate- sethyl)	M02 (spirox- an@ne- despropyl)	M03 (spirox- amine-N-oxide)
80	Châte@udun O	<b>₹</b>	Ø.001 28	<0.001	< 0.001
Ö	Hamburg 🔾	_<0.001	<i>"©</i> *<0.001	<0.001	< 0.001
	Jokioinen	© <0.00T	<0.001	< 0.001	< 0.001
Winter vereals	& remsn@nster	<0.001 (	O* <6.001 , O	< 0.001	< 0.001
(late application)	Okeltampton	(a) .001 <sub>4</sub>	%≤0.001∆°	< 0.001	< 0.001
(into approximent)	Piacenza	√×0.0940°	0<0.001	< 0.001	< 0.001
	Porto	~02 <b>0</b> 1	<0.0001	< 0.001	< 0.001
	Sevolla 😞	<u></u> ≤©001 ∘ €	<b>%</b> 001	< 0.001	< 0.001
	A Priva	Ø.001&	<b>⊘</b> <0.001	< 0.001	< 0.001
	Châteaudyn	~~<0.00°	« <0.001	< 0.001	< 0.001
Spring cereals	Hamburg	<0.001	<0.001	< 0.001	< 0.001
(laterapplication)	Joknoinen 💙	<b>60</b> %001 💫	< 0.001	< 0.001	< 0.001
(late application)	Krerksmünster	\$0.00°	< 0.001	< 0.001	< 0.001
	Okehampton	Z <sub>1</sub> <0.001	< 0.001	< 0.001	< 0.001
	A Porto S	<0.0001	< 0.001	< 0.001	< 0.001
(late application)					



Table 9.2.4.1-9: PEC<sub>GW</sub> following annual application of spiroxamine in accordance with the GAP, using the FOCUS MACRO model application to Châteaudun

		80th Percentile PEC <sub>GW</sub> at 1 m Soil Depth (μg/L)				
Сгор	Application window	Spirox- amine	M01 (spi- roxamine- desethyl)	M02 (spirox- amine- despropyl)	Mos (spines	
Winter canala	Early	< 0.01	< 0.01	<0.014	< 001	
Winter cereals	Late	< 0.01	<0,01	<0.01	√ <b>3</b> 0.01 <b>√</b>	
Spring cereals	Early	< 0.01	<0.01	<b>&lt;Ø</b> ∕01	£ <0.01 / (	
	Late	< 0.01	<0.01	<b>6</b> 0.01	~ <0.00 ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	

#### **Conclusions**

Predicted environmental concentrations of spiroxamine and its metabolites MO (spiroxamine-desethyl), M02 (spiroxamine-despropyl) and MO (spiroxamine-N-oxide) in groundwater have been generated in accordance with FOCUS guidelines FOCUS (2000 and 2014) and in accordance with the FU representative uses of the spiroxamine Prothioconazole+ Spiroxamine FC 460 (160+300 g/L) on conter and spring cereals.

The predicted 80th percentile average annual concentrations for spiroxamine following application to winter and spring cereals were lower than the 0.1 µg/L regulatory threshold in groundwater at 1 m depth for all crop / scenario combinations. The PEC values for petabolites Mo1, M02 and M03 following annual application spiroxamine to crops were also lower than the 0.1 µg/L regulatory threshold in groundwater at 1 m depth for all the available crops / scenario combinations.

These results demonstrate that spiroxamme can be used safely as proposed without the risk of spiroxamme and its metabolites M01 M02 and M00 exceeding acceptable levels in groundwater.

#### Assessment and conclusion by applicant:

The study was conducted to guideline(s) FOCUS 2000 2014) and EFSA (2014) (required guidelines). The study is considered valid for use in the risk assessment.

PEC<sub>GW</sub> calculations for M06 have not been presented as critical studies to define modelling inputs are currently on-going. In studies in estigating the route of degradation of the active substance spiroxamine in soil (presented under CA 75.1.1), the metabolite M06 is only observed >5% AR in one out of ten soils and only of the very last sampling point (in all other soils and all other sampling points the observed level of metabolite M06 was <5%). Due to the low levels of M06 observed, it was difficult to obtained reliable degradation rate constants from the parent applied studies. Consequently, estimated PEC<sub>GW</sub> from conservative input parameters were found to be provide unreasonable estimates of leaching when compared to the outcome of the soil column studies (see KCA 7.1.4.1) where only 0.2% of AR were observed in leachate. PEC<sub>GW</sub> for M06 will be provided upon completion of the studies.

## PECgw FQCUS (prothiceonazole)

The representative formulated product Prothioconazole + Spiroxamine EC 460 (160+300 g/L) also contains the active substance prothioconazole. The active substance prothioconazole is not the primary focus of the representative substance spiroxamine and is the subject of a separate renewal evaluation which is in progress at the time of writing.

According to the current evaluation documents for the active substance prothioconazole (i.e. EFSA



2007<sup>6</sup>, p.77/98), the definition of the residue for environmental risk assessment in groundwater lists prothioconazole and metabolites M01 (prothioconazole-S-methyl) and M04 (prothioconazole-desthig).

The predicted environmental concentration in groundwater of prothioconazole and metabolites M01 (prothioconazole-S-methyl) and M04 (prothioconazole-desthio) are addressed by reference to the existing LoEP (EFSA 2007, p.75-76/98) which considered 3x 200 g prothioconazole/ha applications to reals using existing parameters and gave PECgw <0.001 µg/L for prothioconazole and metabolites M01 (prothioconazole-S-methyl) and M04 (prothioconazole-desthio) at all nine POCUS scenario locations.

#### **CP 9.2.4.2** Additional field tests

Based on the results of the FOCUS groundwater modelling assessment (Document M-CP, Section 9.2.4.1), additional field testing is not required.

# CP 9.2.5 Estimation of concentrations in surface water and sediment

The Predicted Environmental Concentrations in surface water (PEC) have been calculated for the active substance spiroxamine and major metabolites, as defined in (CA 7.44) along with the formulation following foliar applications of Protherconazole + Spiroxamine & 460 (160 500 g/C) in accordance with the representative GAP.

The predicted environmental concentration of the formulated product Prothiocorazole + Spiroxamine EC 460 (160+300 g/L), the active substance spiroxamine and significant metabolite in surface water (PECsw) is determined using the sandardised recommendations of the FOCUS working group on surface water scenarios (FOCUS 2001, 2007, 2007, 2012, and 2012). The PECs are provided in one existing modelling study included in the last valuation and sincluded here for completeness but which has been superseded by two new modelling reports conducted to modern requirements CP 9.2.5/02 (M-763144-01-1) and CV 9.2.5/03 (N-63146-01-1).

Substance	Report reference	Document no.	
Spiroxamine ?	KQP 9.2,5001 C	<u>M-304053-01-1</u>	Submitted for first renewal of spirox-
			amine 2010. Reviewed under UP. Consid-
			ered valid and acceptable.
Spiroxamine	K 0 9.2,50 2	M-√6314⊕01-1	New data not yet reviewed under UP.
Spiroxamine	KSCP 9.25/03	<u>M-7634,46-014</u>	Ž <sup>y</sup>

#### PECsw formulation

The initial predicted environmental concentration in surface water of the representative formulated product Prothoconazole + Spiroxamine EC 460 (160+300 g/L) is presented in Table 9.2.5-1. Since the formulation components other than the active substance are assumed to dissipate rapidly in the environment it is only necessary to consider the initial concentration for Prothioconazole + Spiroxamine EC

FOSA Santific Report 2007) 106, 1-98, Conclusion on the peer review of prothioconazole.

<sup>&</sup>lt;sup>7</sup> CCUS 2001 FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of the Focus Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev 2 245 pg

<sup>&</sup>lt;sup>8</sup> CUS (2007). Landscape and Mitigation Factors in Aquatic Ecological Risk Assessment. Volume 1. Extended Summary and Recommendations. SANCO/10422/2005, version 2.0, September 2007.

FOCUS (2011). Generic Guidance for FOCUS surface water Scenarios. Version 1. January 2011.

FOCUS (2012). Generic guidance for FOCUS surface water scenarios, ver 1.2, December 2012.

FOCUS (2015). Generic Guidance for FOCUS surface water Scenarios. Version 1.4. May 2015.



460 (160+300 g/L).

**Table 9.2.5-1:** Worst-case initial PECsw for Prothioconazole + Spiroxamine EC 460 (160+300 g/L) needed for environmental risk assessment

	Formulation	Mitigation dis	PECsw (μg Pro 46	othioconaz (le + S <sub> </sub> 50 (160+300 g/L)/L	
Сгор	application rate	Mitigation dis- tance (m)	Water body Gype Ditch	Water body type Pond	Water body type Spream
Winter and	1.25 L/ha Prothioconazole	Default 5	7.902 2.142	0.2694	2.142 C
spring cereals (spring application only)	+ Spiroxamine EC 460 (160+300 g/L) (equivalent to 1230 g/ha) <sup>B</sup>	10 0	0° 1.436 2,	1676	1.136

Calculated using the FOCUS drift calculator v.1 Apr 2001) with the Greals, winter and cereal spring applies drift

The maximum initial concentration of the formulated product Protheconagole + Spiroxamine EC 460 (160+300 g/L) in surface water following application with to applied mitigation and to consideration of no spray buffer zones of 5 and 10 m is 7 902, 2,142 and 1.136 ag/L. respectively.

PECsw FOCUS steps: 1-2 (spiroxamine)

Data Point:	KCP,9/2.5/0 N
Report Author:	
Report Year:	2008
Report Title:	Predicted environmental concentrations of spiroxamine in surface water and sedi-
	ment (PECson PECsed) based on the tiered POCUSsw approach - Use in cereals
	in byrope & O V O
Report No:	MEF-08/273 0
Document No:	<u>M-304053-01-1/</u>
Guideline(s) followed in	not applicable To the control of the
study:	
Deviations from current	Oone O
test guideline:	
Previous Valuation: 🔍 🛇	yes evaluated and accepted
	RAŘ (2010) 🐥 🔊
GLP Officially recognition	No, not conducted under GLP/Officially recognised testing facilities
nised testing facilities:	
Acceptability/R@iability:	Yes

# Executive summary

This stude was previous considered during the evaluation of spiroxamine (RAR (2010)) and is therefore included again for completeness. This study presents the PEC modelling conducted on the representative for the last evaluation, however, this PEC modelling is superseded by the new PEC modelling performed in study KCP1 9.2.5/02 (M-763144-01-1) and KCP1 9.2.5/03 (M-763146-01-1).

loadings and considering a worst-case single application 
Based on a Prothioconazole + Spiroxamuse EC460 (1604)00 g/L formulation relative density of 0.84 g/ml, see CP В



Data Point:	KCP 9.2.5/02
Report Author:	
Report Year:	2021
Report Title:	A modelling assessment of spiroxamine and its metabolites in surface water using
	FOCUS surface water steps 1 & 2
Report No:	0471836-SW1
Document No:	<u>M-763144-01-1</u>
Guideline(s) followed in	FOCUS (2000, 2014), EFSA (2014)
study:	
Deviations from current	None V Q Q Q Q
test guideline:	
Previous evaluation:	No, not previously submitted
GLP/Officially recog-	not applicable
nised testing facilities:	
Acceptability/Reliability:	Yes & Q Q X X X Y

#### **Executive summary**

The potential for spiroxamine and its metabolites M01 (spiroxamine-desethyl) M02 (spiroxamine-desethyl

The following open field uses were simulated in accordance with the supported uses of the Prothioconazole + Spiroxamine EC 460 760+300 g/L formulation:

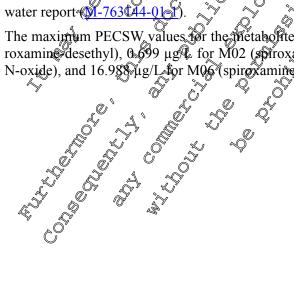
- Two applications (BBCHOO onwards) as a rate of 375 g a.s. That to winter cereals
- Two applications (BBCH 30 onwards) at a rate of 3/3 g a.s./ha to spring sereals

Simulations for the open field uses of the Prothic Conazole + Sprioxamine EG 460 (160+300 g/L) formulation were conducted using Steps 1-2 in FOCUS in accordance with the FOCUS guidance for surface water modelling (FOCUS, 2001 and 2015). A refinement of the values generated at Steps 1-2 to more realistic concentrations was performed for spiroxamine using FOCUS Step 3 and Step 4 in another study (see CP 9.2.5/83).

The input parameters for the calculations were selected based on recommendations from FOCUS (FOCUS 2007, 2017, 2012, 2015) and EFSA (2004), and studies submitted with the MCA 7 renewal of approval dossier.

The global maximum PEC<sub>SW</sub> and PEC<sub>SED</sub> values for spiroxonine and its metabolites at Step 2 are provided in Table 9.2.5-2 Detailed values and time weighted averages (TWA) are provided in the surface water report 101-763 144-01.

The maximum PECSW values for the metabolites at Step 2 for cereals were 0.826  $\mu$ g/L for M01 (spiroxamine-desethyl), 0.699  $\mu$ g/L for M02 (spiroxamine-despropyl), 1.882  $\mu$ g/L for M03 (spiroxamine-N-oxide), and 16.988  $\mu$ g/L for M06 (spiroxamine-acid).





<b>Table 9.2.5-2: Globa</b>	l maximum PECsy	v and PEC <sub>SED</sub>	for spiroxa	ımine and	its metabolites
-----------------------------	-----------------	--------------------------	-------------	-----------	-----------------

Cron	Compound	Global maxi	imum at Step 2
Crop	Compound	PECsw (μg/L)	PEC <sub>SED</sub> (μg/kg)
	Spiroxamine	5.194	97.213 (b)
	M01 (spiroxamine-de-		26 162 S
	sethyl)	0.826	26.462
Cereals	M02 (spiroxamine-		18/480
2x 375 g/ha, GS30-69	despropyl)	0.699	2 9.700 / V
	M03 (spiroxamine-N-ox-		
	ide)	1.882	© 60.404 ×
	M06 (spiroxamine-acid)	16.988	0.542 °

#### Study design

The purpose of this study was to predict the environmental concentrations of spiroxamine and its metabolites M01 (spiroxamine-desethyl), M02 (spiroxamine-desproyer), M03 (spiroxamine-N-oxide) and M06 (spiroxamine-acid) in surface water and sediment following application to winter and spring coreals, made in accordance with the EU representative GAP.

Conservative predicted environmental concentrations for spiroxamine and its metabolites in surface water and sediment (PEC<sub>SW</sub> and PEC<sub>SED</sub>) following application to open field crops were simulated using Steps 1-2 in FOCUS (version 3.2). A refinement of these values generated to Steps 2 to more realistic concentrations were calculated for spiroxamine using the FOCUS step 3 surface water scenarios with the FOCUS suite of surface water models was performed in in another study (see CP 9.2.4.1/02). The modelling simulations were carried out in accordance with the FOCUS guidance for surface water modelling (FOCUS, 2001 and 2015).

The input parameters used in the modelling for spiroxamine and its metabolites are summarised in Table 9.2.5-3 to Table 9.2.6.4.

Table 9.2.5-3: Physico-chemical parameters used in modelling for spiroxamine

Parameter Value Value	Remarks D
Physico-chemical	\$\times_{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\tin}\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\tetx{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\tin}\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\ti}}\\ \ti}\\\ \text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\tex{\tex
Wolcedian weight (grain)	MCA Renewal of Approval dossier, see CA
Molecular weight (g/mol) 297.5 3 4 4 7 6	MCA Renewal of Approval dossier, see CA 2.5
Vapour pressure (Pa) 2.84 (40°) (2.0°C)	MCA Renewal of Approval dossier, see CA 2.2
Degradation in soil	
DT <sub>50</sub> soil (d) 428	Geometric mean of uncropped field data (n= 8), submitted in MCA Renewal of Approval dossier, see data point CA 7.1.2.1.1, Table 7.1.2.2.1-72



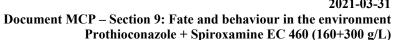
Parameter	Value	Remarks
Sorption to soil	•	
K <sub>FOC</sub> (mL/g)	4111	Geometric mean (n= 8) calculated from individual values, see data point CA 7.1.31, Table 7.1.3.1-1
K <sub>FOM</sub> (mL/g)	2384	Calculated K <sub>Foc</sub> A 724
Degradation in aquatic systems		
DT <sub>50</sub> whole system (Step 1)	157.9	Geometric mean (n=6) submitted in MCA Renewal of Approval dossier, see data point CA 7.2.2.3, Yable 3.2.2.3, 23.
DT <sub>50</sub> water (d) (Step 2)	1000& & &	FOOUS recommendations water set to con-
DT <sub>50</sub> sediment (d) (Step 2)	137.9	FOCION recommendation, Sédiment set to whole system degradation value.
		Geometric mean (n=6) submitted in MCA Renewal of Approval dosafer, see data point CA 7.2.2.3, Table 2.2.3, 23.  FOCUS recommendation, Sediment set to conservative assumption  FOCUS recommendation, Sediment set to whole system degradation value.



Table 9.2.5-4: Input parameters used in STEPs 1-2 for the metabolites of spiroxamine

Parameter	M01 (spiroz	kamine-desethyl)	M02 (spiro	xamine-despropyl)	Md3 (spire	oxamine-N-oxide	M06 (spin	examine-aixid)
rarameter	Value	Remarks	Value	Remarks	Value	Remarks	Value	Remarks S
Molecular weight (g/mol)	269.4	Based on structure	255.4	Based on structure	\$13.5 \$13.5	Based on structure of	327.5	Based on structure
Water solubility (mg/L)	14.8	MCA Renewal of Approval dossier, see CA 2.5	46.6	MCA Renewal of Approval dossor, see CA			. 4	Default value
K <sub>FOC</sub> (mL/g)	3271	newal of Approval of sier, see data point CA 7.1.3.1.2 Table 7.1.3.1.2	2693	7.1.3.10, Table 7 7.4.9.1.2-1	1677 2697	74.3.1.2, Table 3	3.2	Preliminary value, submitted in MCA Renewal of Approval dossier see CA 7.1.3.1
DT <sub>50</sub> soil @ 20°C & pF2 (days)	108.0	of laboratory values submitted in MCA Renewal of approval dossier, see data point CA 7 12.1.1, Table	219.101 2000	Geometric mean (n=10) of laborator values submitted in MCA Re- newal of Approval dos- sice, see data point CA 7.1.2.1.1 Table	0 5 0 5 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Geometric mean (n=7)	479 6	Geometric mean (n=4) of laboratory values submit- ted in MCA Renewal of Approval dossier, see CA 7.1.2.1.1
Max % observed in soil	[12.0]	From MCA Rolewal of Approval, dossier, See Table 24.1-1	9.2	From MCA RenewaDof Approval dossrer, see Table 7.4.1.0	7.2	From MCA Renewal of Approval dossier, see Table 7.4.1-1		From MCA Renewal of Approval dossier, see Ta- ble 7.4.1-1

Approval dossier see 9.2 Approva Table 7.4





						A	200°	
Danamatan	M01 (spiroz	xamine-desethyl)	M02 (spiro	xamine-despropyl)	M03 (spire	oxamine-N-oxide)	M06 (spi	roxamin@aeid)
Parameter	Value	Remarks	Value	Remarks	Value	Remarks	Value	Remarks (
DT <sub>50</sub> water (d)	1000		1000	o E	1000 .	var sies. Sto	<b>393.</b> 6	FOCOS recommendation, water set to whole system degradation value
DT <sub>50</sub> sediment (d)	1000	FOCUS default value (worst-case)	1000	FOCUS default value	Ligon Ligon	FOCUS default value	1000	FOCUS recommendation, sediment set to conservative assumption
DT <sub>50</sub> total system (d)	1000	(worst cuse)	1000	(worst-case) in the state of th	1009		293.6	Geometric mean (n=5) submitted in MCA Renewal of opproval dossier, see data point CA 7.2.2.3, Table 7.2.2.3-23
Max % observed in water/sediment	4.3	From Mc Renewal of Approval dossier see	~ ~ ~	From MCA Regewal of Approval Cossier, see Table 7.4.1-1	W " - W	Approval dossier see	44.5	From MCA Renewal of Approval dossier, see Table 7.4.1-1

The property of the problem of the p



<b>Table 9.2.5-5:</b>	Supported use of Prothioconazole + Spiroxamine EC 460 (160+300 g/L)

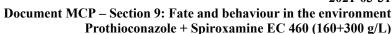
Стор	Application rate (g a.s./ha)	Number of applications	Interval between applications	BBCH growth stage at applica- tion
Winter cereals	375	2	14 days	<b>3</b> 0-69
Spring cereals	375	2	14 days	34969

At Step 2, seasons of application were estimated based on the earliest and latest likely dates that applications would be made, in accordance with the BBCH growth ranges proposed in the EU representative GAP. In accordance with FOCUS guidance (FOCUS, 2001 and 2015), where there are multiple applications, Step 2 simulations were performed based or both the multiple and the respective single application rates and the worst-case PEC<sub>SW</sub> and PEC<sub>SED</sub>, alues were selected for input into the environmental risk assessment. The regions of use and seasons for application used in the Step 2 modelling are presented in Table 9.2.5-6.

Crop	Zone (Step 2)	Season V V	Interception .
	Rorth Europe	Mar-May	Full (7 <b>%</b> )
	North Europe ()	Jon-Sep	Full (70%)
Winter cereals	South Enrope	Oct-Pob	Full (70%)
	South Eaglobe	IMSO-Mav≥ √ √	Full (70%) Full (70%)
	Noth Europa		Full (70%)
4/1/		Jun Sep	Full (70%)
Spring cereats		Oct-Feb	Full (70%)
L R S	South Europe	Mar-May	Full (70%)

## Results and discussion

Summaries of the maximum PECs and PECsED values for spiroxamine and its metabolites M01 (spiroxamine-desethyl), M02 (spiroxamine-desethyl), M03 (spiroxamine-N-oxide) and M06 (spiroxamine-acid) at FOCUS steps 1 and 2 as calculated by the DOCUS surface water models, are provided in Table 9.2.5-7 and Table 9.2.5-8 for PECsW and PECsD values, respectively. Detailed values and time weighted averages (TWA) are provided in the surface water report (M-763144-01-1).





Maximum PEC<sub>SW</sub> for spiroxamine and its metabolites - FOCUS Step 1-2 **Table 9.2.5-7:** 

2         N         Jun-Sep, full int. (70%)         3.673         0.444         40974         4.086         49.945         3.449         0.236         0.498         0.696         5.536           2         S         Oct-Feb, full int. (70%)         5.194         0.826         0.699         1.882         16.988         3.449         0.436         0.367         1.047         9.403           2         S         Mar-May, full int. (70%)         5.194         0.826         0.699         1.882         16.988         3.449         0.436         0.367         1.047         9.403           Spring cereals, 2x 375 g/ha, GS30-69         1.882         16.988         3.449         0.436         0.367         1.047         9.403           2         N         Mar-May, full int. (70%)         3.673         0.444         0.374         1.086         9.945         3.449         0.236         0.198         0.606         5.536           2         N         Jun-Sep, full int. (70%)         3.673         0.446         0.374         0.386         9.945         3.449         0.236         0.198         0.606         5.536           2         S         Oct-Feb, full int. (70%)         5.494         0.826         0.699	EO	<b>A</b> =:	A		<b>N</b> .f. 1.			- 100			- ala az - 1- %		<u>,</u>
2 S Mar-May, full int. (70%) 5.194 0.826 0.699 1.882 6.988 3.449 0.436 0.367 1.047 9.403  Spring cereals, 2x 375 g/ha, GS30-69  1		Area	Application timing	~~-		ipie appin (	μg/L) Ma2 «	NACC		SII	igie appin ()	ig/L)	, MOC
2 S Mar-May, full int. (70%) 5.194 0.826 0.699 1.882 16.988 3.449 0.436 0.367 1.047 9.403				spx	IVIUI	IVIU2	INIU3	N1U6	spx V	MUI		14163	<b>SIMINO</b>
2 S Mar-May, full int. (70%) 5.194 0.826 0.699 1.882 16.988 3.449 0.436 0.367 1.047 9.403		ereals 2x	375 g/ha_GS30-69 (spring ar	nlications of	1lv)			N. C.S.	110	600			<u></u>
2 S Mar-May, full int. (70%) 5.194 0.826 0.699 1.882 16.988 3.449 0.436 0.367 1.047 9.403	1		is to gring, esse of (spring a)			5.983	16.452	139.85¢		1 <u>~ °</u>		1,022	T~ -
2 S Mar-May, full int. (70%) 5.194 0.826 0.699 1.882 16.988 3.449 0.436 0.367 1.047 9.403	2	N	Mar-May, full int. (70%)			0.374	10086	2.945	3.449	9.236	0.198	0.606	5.536
2 S Mar-May, full int. (70%) 5.194 0.826 0.699 1.882 16.988 3.449 0.436 0.367 1.047 9.403		N				<b>1</b> 0374	J.086	©9.945 (	3.449	0.236	0.198/		5.536
2 S Mar-May, full int. (70%) 5.194 0.826 0.699 1382 6.988 3.449 0.436 0.367 1.047 9.403  Maximum (step 2) 5.194 0.826 0.699 1.882 16.988 3.449 0.436 0.367 1.047 9.403  Spring cereals, 2x 375 g/ha, GS30-69  1 45.436 7 7 54 5.983 16.452 39.851		S	Oct-Feb, full int. (70%)	5.194	0.826	© 0.699	1.882	16,988	3.449	0.436	a 0.367	1.047	9.403
2 N Mar-May, full int. (70%) 3673 0.444 20.374 1.086 9 9.945 3.449 0.236 3.198 0.606 5.536 2 N Jun-Sen full int. (70%) 3673 0.444 0.374 1.086 9 9.45 3.449 0.236 0.198 0.606 5.536		S	Mar-May, full int. (70%)	5.194		0.699	1882	16.988	×3.449		0.367	1.047	9.403
2 N Mar-May, tull int. (70%) 3673 0.444 20.374 1.086 9.945 3.449 20.236 20.198 0.606 5.536						£0.699 👡	9 001		3.449	0.436	0,367	<sub>1.047</sub>	9.403
2 N Mar-May, tull int. (70%) 3673 0.444 20.374 1.086 9.945 3.449 20.236 20.198 0.606 5.536	Spring ce	ereals, 2x	375 g/ha, GS30-69	a K	/ .f	0.	Pr.	-0,0		1700 E		N. N.	
2 N Mar-May, tull int. (70%) 3673 0.444 20.374 1.086 9.945 3.449 20.236 20.198 0.606 5.536	1			45.470	7,101	5.983	<b>26</b> :452	139.851	\$ <sup>5</sup> C	- "C	-0 (M)	-	-
2 N Jun-Sep, full int. (70%) \$ 3,673   0.4448   0.374   1.886   9.945   3.449   0.236   0.198   0.606   5.536   2 S Oct-Feb, full int. (70%) \$ 3.494   0.826   0.699   1.882   16.988   3.449   0.436   0.367   1.047   9.402   2 S Mar-May, full int. (70%) \$ 9.194   0.826   0.699   1.882   16.988   3.449   0.436   0.367   1.047   9.402   3 Maximum (step 2) 5.194   0.826   0.699   1.882   16.988   3.449   0.436   0.367   1.047   9.402   3 Maximum (step 2) 5.194   0.826   0.699   1.882   16.988   3.449   0.436   0.367   1.047   9.402   3 Maximum (step 2) 5.194   0.826   0.699   1.882   16.988   3.449   0.436   0.367   1.047   9.402   3 Maximum (step 2) 5.194   0.826   0.699   1.882   16.988   3.449   0.436   0.367   1.047   9.402   3 Maximum (step 2) 5.194   0.826   0.699   1.882   16.988   3.449   0.436   0.367   1.047   9.402   3 Maximum (step 2) 5.194   0.826   0.699   1.882   16.988   3.449   0.436   0.367   1.047   9.402   3 Maximum (step 2) 5.194   0.826   0.699   1.882   16.988   3.449   0.436   0.367   1.047   9.402   3 Maximum (step 2) 5.194   0.826   0.699   1.882   16.988   3.449   0.436   0.367   1.047   9.402   3 Maximum (step 2) 5.194   0.826   0.699   1.882   16.988   3.449   0.436   0.367   1.047   9.402   3 Maximum (step 2) 5.194   0.826   0.699   1.882   16.988   3.449   0.436   0.367   1.047   9.402   3 Maximum (step 2) 5.194   0.826   0.699   1.882   16.988   3.449   0.436   0.367   1.047   9.402   3 Maximum (step 2) 5.194   0.826   0.699   1.882   16.988   3.449   0.436   0.367   1.047   9.402   3 Maximum (step 2) 5.194   0.826   0.699   1.882   16.988   3.449   0.436   0.367   1.047   9.402   3 Maximum (step 2) 5.194   0.826   0.699   1.882   16.988   3.449   0.436   0.367   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047   1.047	2		Mar-May, full int. (70%)	\$\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	√ U. <del>444</del> &		1.000	9.945 <sup>©\$</sup>	3.449	Q=296	<b>3</b> 9.198	0.000	5.536
2 S Oct-Feb, full int. (70%) 5.494 0.826 0.699 1.882 16.988 3.449 0.436 0.367 1.047 9.402 2 S Mar-May, full int. (70%) 5.194 0.826 0.699 1.882 16.988 3.449 0.436 0.367 1.047 9.402  Maximum (step 2) 5.194 0.826 0.699 1.882 16.988 3.449 0.436 0.367 1.047 9.403  Maximum (step 2) 5.194 0.826 0.699 1.882 16.988 3.449 0.436 0.367 1.047 9.403	2	N	Jun-Sep, full int. (70%)	D <sup>™</sup> 3.673\ <sup>©</sup>	0.444	0,374	1086	9.945	s @ 449				5.536
2 S Mar-May, full into (70%) \$194 0.826 0.699 1.882 16988 3.3449 0.436 0.367 1.047 9.403    Maximum (step 2)   5.194   0.826   0.699   0.882   16.988   3.449 0.436   0.367   1.047   9.403	2	S	Oct-Feb, full int. (70%)	5.194	0Ç826	<b>0.699</b>	%¥1.882 <sub>% (</sub>	16.988	3.4495				9.403
Maximum (step 2) 5.194 0.826 0.826 16.988 3.449 3 0.436 0.367 1.047 9.403  Rutting to the copy the problem of the copy that it is a state of the copy that	2	S	Mar-May, full int (70%)	§.194	O 0.826 &	0.699	1.882	16.988	3(449	<u></u> $0.436$			9.403
They be gub jeck thay history and use owner the risk conner the gub ication of the owner the risk for this document land of the owner the risk for the germination of the conner characteristics and who late the permitse ion and who late the risk for the permitse in the permitse			Maximum (step 2)	5.194	0.826	0,699	≥ 10882	<b> 16.988</b> 🛭	3.449	<b>6.436</b>	0.367	1.047	9.403
			Thurs this comme	docume docume	exploit exploit								

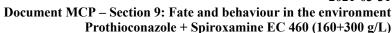




Table 9.2.5-8: Maximum PEC<sub>SED</sub> for spiroxamine and its metabolites - FOCUS Step 1-2

							×			-0	·O\
FO-	Area	Application timing		Multi	ple appln (µ	ıg/kg)	4	⊜ <sup>©°</sup> Single	appln (µg	ýkg) 🐧	, b /
CUS			spx	M01	M02	M03 M06	spx 💎	<sup>™</sup> M01	M02	M03	M06
Step			-								
Winter ce	ereals, 2	x 375 g/ha, GS30-69 (spring ap	plications or	nly)		. I C				9,	
1			1620.000	226.618	157.147	266.202 24.464		- ®×	~- V		√ © -
2	N	Mar-May, full int. (70%)	117.133	13.949	9.727	17.06% 0.31%	65,950	<i>≈7,0</i> ≥76	<b>3</b> .117	© 9.508 € 9	⊃້"0.177
2	N	Jun-Sep, full int. (70%)	117.133	13.949	9.72°	\$ 15067 0.317	\$5.950	~7.376 <u></u>	5.117\$	9.50	0.177
2	S	Oct-Feb, full int. (70%)	197.213	26.462	a. 18.480	Ø30.404√ 0.542√	110,408	13.935	9. <b>6</b> 8Ĭ	~ <b>√1</b> 6.895	0.300
2	S	Mar-May, full int. (70%)	197.213	26.462	18,480	30,404 0.542	<u>_1</u> 00.408 ₃ _	3.935	9.681	<sup>™</sup> 16.895	0.300
		Maximum (step 2)	197.213	26,462	<b>≈18.480</b>	<b>30.</b> 404	11.0408C	13.935	9.681	16.895	0.300
Spring ce	ereals, 2x	x 375 g/ha, GS30-69		<b>D</b>					J. W. B.	o S	
1			1620.000	226.618	157,147	266.202 ~4A64		- J	- ~~~		-
2	N	Mar-May, full int. (70%)	117053	1 <b>269</b> 49	چ9.727 ج	0.317°		7.376	5.1 <b>9</b> 7°	9.508	0.177
2	N	Jun-Sep, full int. (70%)	ĴÎ7.133 <sub>←</sub>	\$ 13.94 <b>9</b>	√° 9.7270	17.067 0.317	65.950	√9.376 × ×	JS.117	9.508	0.177
2	S	Oct-Feb, full int. (70%)	197.243	26.462	182480	<b>6</b> 9.404 0.542	√¥10.408 °	13.935	9.681	16.895	0.300
2	S	Mar-May, full int. (76%)	195.213	26.462	₩18.480 «	60.404 0.542		13@35	9.681	16.895	0.300
		Maximum (step 2)	197.213∜	26.462	18,489	60.304 0.542	10.408	33.935	9.681	16.895	0.300

#\$ 157,147 266,202 4. 19949 9.727 077.067 0.315 13.949 9.727 077.067 0.315 13.949 9.727 077.067 0.315 13.949 9.727 077.067 0.315 13.949 9.727 077.067 0.315 13.949 9.727 077.067 0.315 13.949 9.727 077.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.315 13.949 17.067 0.



### **Conclusions**

Predicted environmental concentrations of spiroxamine and its metabolites M01 (spiroxamine-descrivt) M02 (spiroxamine-despropyl), M03 (spiroxamine-N-oxide) and M06 (spiroxamine-acid) in surface water and sediment have been generated in accordance with FOCUS and EFSA guidance, for the use of formulation Prothioconazole + Spiroxamine EC 460 (160+300 g/L) on winter and spring cereals.

The maximum PEC<sub>SW</sub> values for the metabolites at Step 2 for cereals were \$826 \text{ \text{ug/L} foom01 \text{ spirox}} amine-desethyl), 0.699 µg/L for M02 (spiroxamine-despropyl), 1.882 µg/L for M03 (spiroxamineide), and 16.988 µg/L for M06 (spiroxamine-acid).

The global maximum PEC<sub>SW</sub> and PEC<sub>SED</sub> values for proxamine and its metabolites at Step vided in Table 9.2.5-9.

Global maximum PECswand PECsED for spiroxamin and its metabo **Table 9.2.5-9:** lites - FOCUS Step 2

Crop	Compound Global maximum at Step 2 <sup>a</sup> C
Стор	A SI ECSA (hg/kg/ / Yecset) (hg/kg/)
	Spiroxamine & \$7.194 \$1.194 \$1.197.213
	M01 (spipokaming de- )
	ASPETRYI)
Cereals	M02 (spiroxamine 3 3 4 5 6 6 9 5 4 8 6 8 6 8 6 8 6 8 6 8 6 8 6 8 6 8 6 8
2x 375 g/ha, GS30-69	~~despřopvl)
	M09 (spiroxamine) N-ox-(
	[ © Oide)
	M06 (spiroxamine-activ)

.s steps 3-4 (spinoxamine) The study was conducted to guideline(s) FOCUS 2005, 2015 (required guideline). The study is considered valid for use in the risk occurrent.



Data Point:	KCP 9.2.5/03
Report Author:	
Report Year:	2021
Report Title:	A modelling assessment of spiroxamine using FOCUS surface water steps & 4 -
	Application of PTZ + SPX EC 460 (160+300 g/L) to cereals
Report No:	0471836-SW3
Document No:	<u>M-763146-01-1</u>
Guideline(s) followed in	FOCUS (2000, 2014), EFSA (2014)
study:	
Deviations from current	None V Q Q Q Q
test guideline:	
Previous evaluation:	No, not previously submitted
GLP/Officially recog-	not applicable
nised testing facilities:	
Acceptability/Reliability:	Yes & S & S & S & S & S & S & S & S & S &

## **Executive summary**

The potential to refine values generated at Step 1-2 (see CP 92.5/02) for sproxamine to more redistic concentrations was performed using FCUS Step 3 and Step 4.

The following open field uses were simulated in accordance with the supported uses of the Prothioconazole + Spiroxamine EC 460 (160 200 a/L) formulation azole + Spiroxamine EC 460 (160\(\frac{2}{3}\)00 g/L) formulation:

- Two applications (BBCH 30 69) at a rate @ 375 g.a.s./have winter cereals
- Two applications (BBCH 30 69) at a rate of 370 g a.s. ha to spring cereals

The input parameters for the calculations were selected based on recommendations from FOCUS (FO-CUS 2001, 2007, 2011, 2012, 2015) and EFSA (2004), and studies submitted in the appropriate section of the MCA 7.

EQSW and PECSED values for spiroxamine at Step 3 and 4 are provided in Table The global maximum 9.2.5-10.

Global maximum PECswand PECsed for spiroxamine – FOCUS Step 3 Table 9.2.5 10:

Use S				Maximum PECsw (μg/L)
Winter cereals, earl	y 2x 375 g a.s./ha		(4 . a	2.370 <sup>a</sup> )
Winter cereals, late	2 x 375 g a.s./			2.994
Spring cereals, each	y, 2 x 375 g a/ha			3.139
Spring cereals date,	2 03/75 g/g/s./ha	Č, O, C		2.834

a) Maximum value resulted from single application

The maximum PECsw values for spiro summer at FOCUS Step 4 are presented in Table 9.2.5-11.



**Table 9.2.5-11:** Global maximum PEC<sub>SW</sub> and PEC<sub>SED</sub> for spiroxamine – FOCUS Step 4

Use	Mitigation	Maximum PECsw@ (μg/L)
Winter cereals, early, 2 x 375 g	20 m VFS + 20 m SDBZ + 0% SDRT	0.397
a.s./ha	20 m VFS + 30 m SDBZ + 0% SDRT	0.397
Winter cereals, late, 2 x 375 g	20 m VFS + 20 m SDBZ + 0% SDRT	0.303
a.s./ha	20 m VFS + 30 m SDBZ + 0% SDRT	0241
Spring cereals, early, 2 x 375 g	20 m VFS + 20 m SDBZ + 0% SDRT	
a.s./ha	20 m VFS + 30 m Stor Z + 0% SDR	© 0.372 V
Spring cereals, late, 2 x 375 g	20 m VFS + 20 m <sub>s</sub> SĎBZ + 0% SΦνΓ	( 0.2 <b>3</b>
a.s./ha	20 m VFS + 30 SDBZ + 0% SDRT	0.227 °

VFS = vegetated filter strip, SDBZ = spray drift buffer zone SDRT = spray drift reduction technology

## Study design

The purpose of this study was to predict the environmental concentrations of sparoxamine and its metabolites M01 (spiroxamine-desethyl), M02 (spiroxamine desproyl), M03 (spiroxamine-N-oxide) and M06 (spiroxamine-acid) in surface water, and sediment following application of winter and spring cereals, made in accordance with the EU representative GOVP.

A refinement of values generated at Steps 12 to more realistic. Oncentrations were estculated for spiroxamine using the FOCUS Step 30 urface water scenarios withothe FOCUS suite of surface water models (MACRO version 5.5.4, PRZM version 4.37, SPIN version 2.2 and TOXSW Oversion 5.5.3) in the SWASH version 5.3 shell. Mingation was added a Step 4 using the SWAN version 5.0.0 tool. The The input parameters used in the modelling for spirokamine are summarised in Pable 9.2.5-12. modelling simulations were carried out in accordance with the FOCUS guidance for surface water mod-



**Table 9.2.5-12:** Physico-chemical parameters used in modelling for spiroxamine

Parameter	Value	Remarks
	Physico-chemic	al
Molecular weight (g/mol)	297.5	From A 1.7
Water solubility (mg/L)	470	From CA 2.25
Vapour pressure (Pa)	0.0047 (20°C)	From CA 2.2
	Degradation in so	
DT <sub>50</sub> soil (d)	43.8	Geometric mean of uncropped field data (n=0) 8), under CA 1.2.2.1/12, see Table 7.1.2.24- 72
Temperature correction function	<sub>4</sub> €″	
Reference temperature (°C)	20	
MACRO: (K <sup>-1</sup> )	0.95	
PRZM: Q <sub>10</sub> (-)	€2.58 &°	FOCUS recommendation W
Moisture correction function		
Reference moisture (-)	pF2 0	
PRZM/MACRO: moisture exponent (-)	\$\tag{\tag{\tag{\tag{\tag{\tag{\tag{	
	Souption (Soi	
$K_{FOC}$ (mL/g)	414	Geometric mean (n=8) calculated from individual values summarised ander C\$\tilde{Q}\$7.1.3.1, See Fable 7.\$\tilde{Q}\$1.1.2
K <sub>FOM</sub> (mL/g)	2384 ©	Calculated 100 / 1,724
Freundlich exponent 1/n (-)	\$\tag{92} \tag{92}	Arithmetic mean (n=8) calculated from individual values summarised under CA 7.1.3.1.
Deg	gradation in aquatic	systems V
DT <sub>50</sub> whole system	radation in aguatic	
DT <sub>50</sub> water (d)	1000	See Table 7.2.2.3-23  COUS recommendation, water set to conservative assumption
DT <sub>50</sub> sedimen(vd)	157.9	FOCUS recommendation, sediment set to whose system degradation value
$DT_{50} \operatorname{crop}(\mathfrak{G})$	) 'O'10 'O'	
Temperature correction function		FOCUS recommendation
Reference temperature (°C)	\$\frac{20}{20}\display \text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\tin}\ext{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\texi{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\texi\tin\text{\text{\text{\texi}\text{\text{\text{\text{\text{\text{\texi}\text{\text{\texi}\text{\text{\text{\texi}\text{\text{\text{\texi}\text{\text{\texi}\text{\texi{\texi}\text{\texi}\tin\texi{\texi{\texi{\texi{\texi{\texi{\texi{\texi{\texi{\texi{\t	To confinentation
TOXSWA: activation energy (J/mot)	65400	
Crop uptake factor (-)	0.47	Based on Briggs equation and measured logK <sub>OW</sub> A
Wash off coefficient ( mn <sup>-1</sup> ) A MACRO (mm <sup>-1</sup> )	0.5	FOCUS recommendation

For spiroxamine log(K, or) values of 2.79 (diastereomer A) and 2.98 (diastereomer B) were determined at pH 7 (Krohn, 1995). Using Bargs' relation, the corresponds to a PUF of 0.52 (diastereomer A) and 0.43 (diastereomer B). As the molar A According to EFSA (2013), European Commission (2014) and FOCUS (2014), the Briggs relation can be used to derive the



masses are identical for both isomers, the mole fractions are 0.53 for diastereomer A and 0.46 for diastereomer B (Krohn, 1994). Therefore:  $PUF_{SPX} = 0.53 * 0.52 + 0.43 * 0.46 = 0.47$ .

A PUF of 0.47 is used for spiroxamine in the risk assessment.

Table 9.2.5-13: Supported use of the PTZ + SPX EC 460 (460g/L) formulation

Стор	F G or I a)	Number of applications	Application rate (g a.s./ha)	Interval be- tween appli- cations (days)		PID
Winter cereals	F	2	375	₹14	BBCH 30-69	"S'n.a «J"
Spring cereals	F	2	375	<i>≨</i> 14	© BBCH 30-6€	≈ n.a♥ (

a) Outdoor of field use (F), greenhouse application (G) or indoor application (I) n.a = not applicable

The foliar application method was selected so that a crop interception value would be determined by the model based on the growth stage.

In accordance with FOCUS guidance, where there are multiple applications. Step 3 simulations were performed based on both the multiple and the respective single application rates and the worst case PECsw and PECsed values were selected for apput into the environmental risk as sissenful.

Due to the wide range of BBCH stages within the requested GAP, several potential application periods have been used for modelling, based on simings from application and various growth stages was operefore set up for each scenario, as specified in Table 9.2.5-14. The actual application dates were then determined automatically in PRZM and MACRO using the Pesticide Application Tiping calculator (PAT).

The application timings for selected for the beginning (early) and end (late) of the application windows relative to emergence and harvest are provided in Eable 9.2.5-143



Application timings for uses on winter and spring cereals in surface water simulations Table 9.2.5-14:

Scenario o	details	FOCUS	S default					SWASH	application	n window (s	tart dale)		, OD		
			ites			Early	season	000		`.			Late season		
				Windo	w 1 (a)	Windo	w 2 (b)	Windo	w 3 (c)	Winde	w 1 (d)	Wingle	św 2 (e)√ 🎾	Windo	w 3 (f)
Scenario	Crop no.	Emer- gence	Harvest	Start	End	Start	End	Start	W 3 (C)	Start	End	Start	Lai -	Start	End
	110.	genee	I	Wint	er sown cere	als (FOCUS	winter cæê	Mc) 2v 375	Pac/ha (1/Ca	1 min int)	20 60		100	<del>}</del>	<b>)</b>
D1	n.a.	25-Sep	26-Aug	25-Mar (84)	8-May (128)	n.a.	winter cox	E Ing.	n.a.	Par.	30-09 Januar.	8-Jun (159) . :	22-Ful (203)	(193)	25-Aug (237)
D2	n.a.	25-Oct	7-Aug	4-Apr (94)	18-May (138)	n.a.	n.a.	n.a.	n.æ	n.a	n.a.	16-Jun 2	30-100	11-Jul (192)	24-Aug (236)
D3	n.a.	21-Nov	15-Aug	16-Apr (106)	30-May (150)	n.a.	≫n.a.	O <sup>©</sup> n.a.	n.a.	n.a.	n.a.	8-Jul	21-Aug	31-Jul	13-Sep (256)
D4	n.a.	22-Sep	21-Aug	18-Mar (77)	1-May (121)	n.a.	GOA.	n.a.	T BO	O.A.	O TANA.	(189) \$\sigma (1	(233) (9 Jul (200)	9-Jul (190)	22-Aug (234)
D5	n.a.	10-Nov	15-Jul	15-Mar	28-Apr (108)	n.a.	n.a.	n.a.	n.a.e	n.a.	n.æ.	5-May %(125)	18-Jun (169)	2-Jun (153)	16-Jul (197)
D6	n.a.	30-Nov	30-Jun	P6-Feb		n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	<i>y</i>	6-May (126)	27-Apr (117)	10-Jun (161)
R1	n.a.	12-Nov	31°-Jul	24-Apr (114)	7∜Jun <a href="#">√ (158) €</a>	Oza.	na.	DÛ.a.	(D).a.		Da.	2-Jun (153)	16-Jul (197)	25-Jun (176)	8-Aug (220)
R3	n.a.	1-Dec	1-Jul	19-Mar	2-May (0)	n.a.	nact	n.a.).	n.a.	n <sub>a</sub> .	n.a.	1-May (121)	14-Jun (165)	25-May (146)	9-Jul (190)
R4	n.a.	10-Nov	15-Jul	24-Jan (24)J	© 9-Mar (1060)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	27-Apr (117)	10-Jun (161)	2-Jun (153)	16-Jul (197)
t2:2 Applicatio Early sease Late seaso every	2x 375 g/ha ( on windows s on – window n – window y year oplicable	(code used westarted on vivial started on vivial	intrivative application modell ppDate 3.06 andow 3/GS6	ing runs) ):  Substitute of the substitute of th	minespray, r	plication with	Dirw (30 da	+ (no. of a	applications	– 1) x minin	num appln in	iterval, i.e. 4	4 days). Trea	atments were	conducted
	Co.	DECTIO		Marier E	De Bi									2-Jun (153)	



# Document MCP – Section 9: Fate and behaviour in the environment Prothioconazole + Spiroxamine EC 460 (160+300 g/L)

Scenario o	details	FOCUS	S default					SWASH	application	n window (s	start date)				a103
			ites			Early	season		 A	] <b>*</b> ` ` ` `		Late	season		0
				Windo	w 1 (a)	Windo	w 2 (b)	Windo	w 3 (c) 💞	Wind	ow 1 (d)	Wind	ow 2 (e)(>	y Windo	w 3 (f)
Scenario	Crop no.	Emer- gence	Harvest	Start	End	Start	End	Start	<b>E</b> nd	Start	End	Start	End	Start	End
	110.	genee		Sprir	o sown cere	als (FOCUS	snring cere	als), 2x <b>©</b> 5 g	as/haa(14 d	l min int) GS	30-69	<del>                                     </del>			
D1	1	5-May	4-Sep	27-May (147)	10-Jul (191)	n.a.	n.a.	n.a.	Gr.a.	A.A.	830-69 . On.a.	29-Jun (174)	2 Aug (218)	(199)	31-Au (243)
D3	1	1-Apr	20-Aug	28-Apr (118)	11-Jun (162)	n.a.	n ap	n a.	ni.a	naz	nca.	30 May (150)	13-Gal (194)	28-9en (179)	11-Au (223)
D4	2	26-Apr	26-Aug	18-May (138)	1-Jul (182)	n.a.	Pn.a.	n.a.	n.a.	O⊳ na «	na ?	14- Jun		****	22-Au (234)
D5	1	15-Mar	20-Jul	Q_Apr	23_May	H.a.	n.a.	On a	Wan a	- × 40 a	n.a. c	9-May (129)	\$22_Iun	A_Iun	18-Iu
R4	1	15-Mar	20-Jul	9-Apr (99)	23-May	n.a.O	n.C.	n.a	They the			9-May	22 Pain (173)	4-Jun (155)	18-Ju (199)
		Z.E. W	ry Pe				on an	n.a. in foliar linear l	O C	•					
			re 1												



The length of the application windows were calculated using the equation below:

Length of window (days) =  $30 + ((n-1) \times interval between applications (days))$ 

Where:

number of applications n

## Step 4 – application of mitigation measures

Results and discussion

Summaries of the maximum PECsw and PECson Values for spiroxagine at FOCUS Step. 2 and 4 as calculated by the FOCUS surface water models, are provided in Table 9.2.5.18.



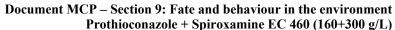
Maximum PEC<sub>SW</sub> and PEC<sub>SED</sub> for following application of 2 x 375 g a.s./ha spiroxamine to winter cereals – FOCUS step 3 **Table 9.2.5-15:** 

C						16.	(7) V	A	
G • -					PECsw	μg/L)	Late applicat		
			Early applica	tion (GS30-55)			Late applicat	ion (GS55-69)	Ĉ
Scenario	Water body	Initial	Main route of entry	21-day TWA	Maximum PECsed   (110/kga)	Liverial	Late applicat  Main route of entry	ion (GS55-69)  21-30ay TWA	<b>Maximun</b> PEC <sub>SED</sub>
			entry		μg/kg)				(hg/kg)
				Multiple applicat	1011/2/1/20 / 5 5/110		NO 210°		0,
D1	Ditch	2.370	Spray drift		8.203	<u> </u>	Spray Dift	0.45°	18.040
D1	Stream	1.843	Spray drift	0.022	V 11.0	2.0911	Spray drift	0.453	
D2	Ditch	2.392	Spray drift	0,621,5	7.449	2.094	Spray drift	1.884	19.800
D2	Stream	2.113	Spray drift	0.308	6.332	©2.619 ×		1.591	16.000
D3	Ditch	2.361	Spray drift	0.208	<b>Z</b> 276	2.372	Spray drift	0.374	3.751
D4	Pond	0.100	Spray drift	0,080	1.231	0013	Spray don't	0.092	1.333
D4	Stream	1.745	Spray drið	0.003	0.075	2.043	Spood drift	© 0.048	0.584
D5	Pond	0.113	Sprayedrift	0.0920	1.332	0,112	Spray drift	0.092	1.326
D5	Stream	1.885	Spray drift	Q <b>®</b> 11	0.163,1	<b>2</b> .204	Spray drift	0.069	0.804
D6	Ditch	2 <b>3</b> 34 (	Spray drift	© 0.252 √ V	3,034	2.383	Språy drift	1.075	9.824
R1	Pond	0.184	Runoff	\$\bullet 0\d\$\bullet \\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	3.042	0.296	Runoff	0.255	4.042
R1	Stream	1.555	⊗pray drift	& <b>0</b> .086	9.7 <b>8</b> 3	\$ 1.562 d		0.093	23.260
R3	Stream	2.185	Spravarift	J 0.078	<b>ॐ</b> 340 √	2.203	Spray drift	0.081	2.434
R4	Stream	1.666	Runoff 0	P. P.O.	9.325 °	2.203 2.562	Spray drift	0.117	8.281
	Jrthermore	Countries	cumericati Puòlicati Lial permi	0.0011 0.252 0.037 0.078 0.078 0.078	he late				



# **Document MCP – Section 9: Fate and behaviour in the environment** Prothioconazole + Spiroxamine EC 460 (160+300 g/L)

D1	Ditch Stream Ditch Stream Ditch Pond Stream Pond Stream Pond Stream Ditch Pond Stream Stream Stream	2.370 1.843 2.392 2.113 2.361 0.081 1.745 0.081 1.885 2.334 0.08	Spray drift	21-day TWA  Single application 0.200 0.005 0.005 0.508 0.114 0.060 0.003	Maximum PECsix (μg/kg) on 1x 375 g/hg 2,523 0.078 7.267 7.267 7.6312 0.757 0.052	2.391 2.090 2.393 2.129 2.0081 2.043	Spray drift	21 day TWA	0.490 1.300 11.440 9.527 2.625 0.820 0.442
D1	Ditch Stream Ditch Stream Ditch Pond Stream Pond Stream Pond Stream Ditch	2.370 1.843 2.392 2.113 2.361 0.081 1.745 0.081 1.885 2.334	Spray drift	21-day TWA  Single application 0.200 0.005 0.005 0.508 0.114 0.060 0.003	PECsity (µg/kg) on 1x 375 g/hg 2,523 0.078 7.267 7.267 7.613 0.757 0.052	2.391 2.090 2.129 2.393 2.0081 2.043	Spray drift	1.286 0089 \$1.303 1.44 0.206 0.063 0.068	0.490 1.300 11.440 9.527 2.625 0.820 0.442
D1	Ditch Stream Ditch Stream Ditch Pond Stream Pond Stream Pond Stream Ditch	2.370 1.843 2.392 2.113 2.361 0.081 1.745 0.081 1.885 2.334	Spray drift	Single application  0.200  0.005  0.508  0.1145  0.060  0.003	PECsity (µg/kg) on 1x 375 g/hg 2,523 0.078 7.267 7.267 7.613 0.757 0.052	2.391 2.090 2.393 2.129 2.0081 2.043	Spray drift	1.286 0089 \$1.303 1.44 0.206 0.063 0.068	0.490 1.300 11.440 9.527 2.625 0.820 0.442
D1 D2 D2 D3 D4 D4 D5 D5	Stream Ditch Stream Ditch Pond Stream Pond Stream Pond Stream Ditch	2.370 1.843 2.392 2.113 2.361 0.081 1.745 0.081 1.885 2.334	Spray drift	Single application  0.200  0.005  0.508  0.1145  0.060  0.003	(µg/kg) on 1x 375 g/hg 2,523 0.078 7.267 6.312 7.613 0.757 0.052	2.391 2.090 2.993 2.129 2.0081 2.043	Spray drift	1.286 0089 \$1.303 1.44 0.206 0.063 0.068	0.490 1.300 11.440 9.527 2.625 0.820 0.442
D1 D2 D2 D3 D4 D4 D5 D5	Stream Ditch Stream Ditch Pond Stream Pond Stream Pond Stream Ditch	1.843 2.392 2.113 2.361 0.081 1.745 0.081 1.885 2.334	Spray drift	0.200 0.005 0.007 0.508 0.114 0.060 0.003	0.0757 0.0757 0.0757	2.391 2.090 2.993 2.129 2.0081 2.043	Spray drift	1.286 0089 1.303 1.44 0.206 0.063 0.068	11.440 9.527 2.625 0.820 0.442
D1 D2 D2 D3 D4 D4 D5 D5	Stream Ditch Stream Ditch Pond Stream Pond Stream Pond Stream Ditch	1.843 2.392 2.113 2.361 0.081 1.745 0.081 1.885 2.334	Spray drift	0.005 0.007 0.508 0.114 0.060 0.003	7.267 6.312 7.613 0.757 0.824	2.093 2.129 2.002 2.002 2.043	Spray drift	0089 1.303 0.206 0.063 0.068	11.440 9.527 2.625 0.820 0.442
D2 D2 D3 D4 D4 D5	Ditch Stream Ditch Pond Stream Pond Stream Ditch Ditch	2.392 2.113 2.361 0.081 1.745 0.081 1.885 2.334 c	Spray drift	0.001 0.1145 0.060 0.003	7.267 6.312 7.613 0.757 0.852 0.824	2.093 2.129 2.002 2.002 2.043	Spray drift	0089 1.303 0.206 0.063 0.068	11.440 9.527 2.625 0.820 0.442
D2 D3 D4 D4 D5	Stream Ditch Pond Stream Pond Stream Ditch	2.113 2.361 0.081 1.745 0.081 1.885 2.334 c	Spray drift	0.001 0.1145 0.060 0.003	6.312 7.613 0.757 0.852 0.824	2.129 2.302 2.0081 2.043	Spray drift Spray, drift Spray, drift Spray, drift Spray, drift	0.206 0.063 0.028	9.527 2.625 0.820 0.442
D3 D4 D4 D5	Ditch Pond Stream Pond Stream Ditch	2.361 0.081 1.745 0.081 1.885 2.334 c	Spray drift Spray drift Spray drift Spray drift Spray drift Spray drift	0.060	7.613 0.757 0.824	2.052 ° 0.081 ° 2.043 ° 0.081	Spray drift Spray drift Spray drift Spray drift	0.206 0.063 0.028°	2.625 0.820 0.442
D4 D4 D5	Pond Stream Pond Stream Ditch	0.081 1.745 0.081 1.885 2.334	Spray drift Spray drift Spray drift Spray drift Spray drift	0.060	0.757 0.824 0.824	2.0430	Spray drift Spray drift Spray don't	0.063 0.028	0.820 0.442
D4 D5	Stream Pond Stream Ditch	1.745 0.081 1.885 2.334	Spray drift Spray drift Spray drift Spray drift	0.003	0.824	2.043	Spray drift Spray don't	0.028°	0.442
D5	Pond Stream Ditch	0.081 1.885 2.334 C	Spray drift Spray drift Spray drift	0.002	0.824	J000181	Spray don't	- W.V.	
D.f	Stream Ditch	1.885 2.334 °C	Spray drift	0802	0.055			a 063	0.006
D5 D6 R1 R1 R3 R4	Ditch	2.334 🚓 Ĉ	Spra@drift	0.003	0.055	1 ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~		-7000	0.826
D6 R1 R1 R3 R4	Ditch Pond Stream Stream	2.334 © 0.080 0 \$1\$55	Spray drift	~~~~ 0.0510°°°		2.204	Spow drift	© 0.040	0.623
R1 R1 R3 R4	Pond Stream Stream	0.0810 1 <b>9</b> 55	■ Shray drift 9	0.02.0	0.757	2383	Spray drift	0.731	6.705
R1 R3 R4	Stream Stream	×1,\$955		DE 00066	1.363	<b>D</b> .169	Runoff	0.144	2.213
R3 R4	Stream	51/01 //	Spray drift	50.029 J	3,637	1.562	Spray drift	0.061	13.670
R4		2.185	Spray drift	<u>0.029</u>	3.510	2003	Spray drift Spray drift	0.051 0.113	1.392 6.618
	Tr may	The cope	Spray driggs Spray drift Spray drift Spray drift Spray drift Spray drift Carry	on in on or in and and and	Tiologie				

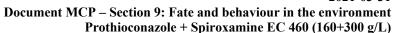




Maximum PEC<sub>SW</sub> and PEC<sub>SED</sub> following application of 2 x 375 g a.s./ha spiroxagame to spring cereals - FOCUS Step **Table 9.2.5-16:** 

			9	* *	<u> </u>	- P			<u>Ore</u>
					PECsw	(Qug/L)		~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	<u> </u>
			Early applica	tion (GS30-55)	\$ 00 p	. رو (	<b>∫</b> Late applicat	ion (GS55-69)\^\	»·
Scenario	Water body	Initial	Main route of entry	21-day I WA	Maximum PDCsed (µg/kg)	° Initial	Main route of	21-day TWA	Maximum PECsed (µg/kg)
				Multiple applicati	on 2x 375 g/ha		a ¥ . 1		A CO
D1	Ditch	3.139	Spray drift	2.020	\$ \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	2894	Spray drift	1.805	16.340
D1	Stream	2.096	Spray drift	<b>®</b> 156	2.930		Spray drift	0.09 <b>%</b>	1.912
D3	Ditch	2.369	Spray drift	√© 0.227¢	2.257	2.375	Spray drift	0:264	2.730
D4	Pond	0.111	Spray drift <sup>ℵ</sup>	0.XQ94	§ 1.134 💖	%CH4 > 3	Spray difft	a 0.093	1.258
D4	Stream	1.937	Spray drift	\$ 0.020 s	° 0,260	2.048	Spray drift	0.049	0.567
D5	Pond	0.106	Spray drift	0.088	Ør.180	0,104	Spray drift	<b>9</b> 94	1.186
D5	Stream	1.989	Spray drift		0.147	(2.209, C	Sprayarift	0.069	0.775
R4	Stream	3.063	Runoff	\$ 0.309 \$ 1 P	_ 7. <b>2</b> 86 🖼	1.9610	_ Nunoff &	0.287	6.842
		200	" 10" " C	Single application	n <b>⊘l</b> x 375 g/ha ″				
D1	Ditch	2417	Spray drift	<b>10.400</b>	8. <b>88</b> 8	2.414 6	Spray drift	1.396	9.939
D1	Stream	<b>2</b> .096	SprayOdrift	0.094	, %1.686 &	2,096	Spray drift	0.090	1.688
D3	Ditch	2.369	Spray drift C	Q 129 3	0 1.728	£ 2.375	Spray drift	0.172	2.171
D4	Pond	0.081	Spray drift	0.063	0912	0.081	Spray drift	0.063	0.724
D4	Stream	1.937	Spow drift	0.008	0.135	2.048	Spray drift	0.028	0.441
D5	Pond	0.082	Spray drift	09.063 S	0.747	, \\ 0.082	Spray drift	0.064	0.744
D5	Stream	Q1.989	SprayQhrift	0.005	0.086	2.209	Spray drift	0.040	0.619
R4	Stream	1.566	Spray drift	0.207	5.437	1.810	Runoff	0.272	6.819

Summaries of the PEsw and PECsed values for Spirox angle following application of infrigation measures at Step 4 are provided in Table 9.2.5-17 to Table 9.2.5-18.



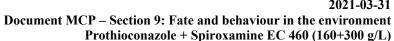


Maximum PEC<sub>SW</sub> and PEC<sub>SED</sub> following application of 2 x 375 g a.s./ha spiroxapame to winter cereals - FOCUS Step 4 **Table 9.2.5-17:** 

					PECsw	(Cug/L)			-0 <sup>9</sup>
			Early applicat	tion (GS30-55)	- OO.	) 	Late application	ion (CS55-69) 21-day TWA	
Scenario	Water body	_	Main route of		Maximum	√O »	Main route of		<b>Maximum</b>
		Initial	entry	21-day TWA	PPCsed (µg/kg)	° Initial	entry O	21-day TWA	PECSED
					μg/kg)		T P	21-10 TWA	(µg/kg)
D.1	D'. I	0.200	Multiple applicati	on 2x 375 g/ha	m VFS \ 20 m S	DBZ + 0% SDR			2.105
D1	Ditch	0.208	Drainage	0.082	0.968	0.399	S Diamago	0.10/	2.103
D1	Stream	0.190	Spray drift	60003	0.055	0.211	Spray drift	0.023	0.263
D2	Ditch	0.244	Drainage	0.067	0.852 0.699 V	0.303	Drainage	0,196	2.274
D2	Stream	0.213	~p-wj		\$ 0.699 V	253	Spray drift	0.170	2.054
D3	Ditch	0.179	Spray drift	0.023	U_@\\	[ a >> 0.205 (C)	Drainage (	0.041	0.440
D4	Pond	0.058	Drainage .	0.0480	<b>0</b> .754	0.006	Drainage	<b>Q</b> 055	0.814
D4	Stream	0.179	Spray drift	0.601	0.011	0.209	1,4,80	0.007	0.089
D5	Pond	0.066	Drainage	0.002	0.875	0.066	Drainage &	0.055	0.811
D5	Stream	0.193	Spray drift	0.002	0.024	0.224	Spray drift	0.010	0.123
D6	Ditch	0.193	Drainage	0.028	0.351	0.243	Drainage	0.116	1.166
R1	Pond	¥9.065	Ru@ff	0.059	1.033	0.092	Runoff	0.079	1.214
R1	Stream	<b>≫</b> 0.239	Runoff	0.039	0.668	0.241	Runoff	0.021	1.379
R3	Stream	0.237	Runedi	°>0.016 √>	0.554	0.229	Spray drift	0.014	0.193
R4	Stream	0.397	Rounoff	0,022	0.832	0.166	Spray drift	0.027	0.584
D5   Stream   0.193									
	Course	Ny TITO C.	D						



						A		, ,	I TOP
					PECsw	(μg/ <b>L</b> )		<u>_</u> 9	
			Early applicat	tion (GS30-55)		a V	Late applicat	ion (GS55-69)	<u> </u>
Scenario	Water body		Main route of		Maximum 1	•	Main route of	i day TWA	Maximum
		Initial	entry	21-day TWA	PECSER	IIIIIII 🔊	entry _	212day TWA	PECSED
					(µg/kg)	2°			🌿 🕏 (μg/kg)
		T		n 1x 375 g/ha; 20	m VFS + 20 m	DBZ + 0% SDRT			<u>,</u> ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
D1	Ditch	0.200	Drainage	0.023	0.29	\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\		0.137	€1.233
D1	Stream	0.190	Spray drift	0.001	0.012	0.2 <b>4</b>	Spray drift⊙		O <sup>™</sup> 0.193
D2	Ditch	0.244	Drainage	0.069	6 5 0.833 0 5 T	0.244	Drainage Drainage	\$ 0.139 C	1.323
D2	Stream	0.213	Spray drift	0.053	0.699	0.214	Spræy drift	0.420	1.227
D3	Ditch	0.179	Spray drift	0.013 \$	0.182	9. <b>20</b> 5	O Drainage S	0.023	0.300
D4	Pond	0.046	Drainage	0.035	0.446	30.046 ×	Drainage	0.036	0.483
D4	Stream	0.179	Spray dirit	0.000	<b>QCD08</b>	0.200°	Spray drift	0.004°	0.065
D5	Pond	0.046	Drainage	0.036	0.486	00046	Drainage Drainage	0.036	0.487
D5	Stream	0.193	Spray drið	©0.001	0.008	© 0.224 O	Spon drift	0.006	0.092
D6	Ditch	0.174	Spray drift	0.006	~0.086 °	0.243	O Drainage	0.079	0.788
R1	Pond	0.04	Runoff		0.544	<b>3</b> 0.057	Runoff	0.048	0.682
R1	Stream	≥0\$265 @	Spray drift	₩ 0.007 J	0.253	0.166	S@ray drift	0.013	0.801
R3	Stream	0.229	Spray drift	S 0.000	0.259		Spray drift	0.009	0.147
R4	Stream	0.171	€ Runoff	£00009	0.374	© 0.166	Spray drift	0.025	0.583
					0 m VES+ 20 m/S			•	<b>r</b>
D1	Ditch	0.167	Drainage		0.775 C	<b>9</b> .239	Drainage	0.147	1.684
D1	Stream	0.130	Spray drift	0.003	- (2)	0.143	Spray drift	0.018	0.210
D2	Ditch	©0.192 ©	Drainage .	0.0530	€0.678	0.241	Drainage	0.155	1.816
D2	Stream	0.144	Spray drift	<b>10,037</b>	0.4890	0.174	Spray drift	0.122	1.565
D3	Ditch (	0.133		0.018	<u> </u>	0.163	Drainage	0.033	0.352
D4	Rond	0.049	Dainage O		0.634	0.055	Drainage	0.046	0.685
D4	Stream	0/122	Spray dru	<b>9</b> .001	0.011	0.145	Spray drift	0.006	0.071
D5	Pond	0.055	Drawage .	0.046	0.686	0.055	Drainage	0.046	0.682
D5	Stream		Spray drift	0001	0.020	0.155	Spray drift	0.008	0.098
D6	Ditch O	0.156	Drain@e	<b>№</b> 0.022	0.280	0.192	Drainage	0.092	0.934
R1	Pond	0.057	Rumoff		0.922	0.084	Runoff	0.072	1.106
R1	Stream	0.339	Runoff	0.019	0.666	0.241	Runoff	0.020	1.373
R3	Stream	C0.237	Runorf	0.015	0.539	0.160	Spray drift	0.012	0.180
·	Stream Stream	C0.237	100 m						
	COMP. OFF								





						A		<b>)</b>	
					PECsw	(μg/ <b>L</b> )	a Í	- @. Š	
			Early applicate	tion (GS30-55)			Late applicat	ion (GS55-69)	ð
Scenario	Water body	Initial	Main route of entry	21-day TWA	Maximum PECseb (µg/kg)	Initial	Main route of entry	Zi <sup>2</sup> day T <b>Y</b>	Maximum PECsed ≿ ∅(μg/kg)
R4	Stream	0.397	Runoff	0.022	a 0.829	Q.265	\$ °RunofÔ ♥	30.026 S	0.581
			Single applicatio	n 1x 375 g/ha; 20	m√VFS + 20 m SI	DBZ%ĴŰ% SDŖŒ			~ C
D1	Ditch	0.160	Drainage	0.018	0,232	0.192	Trainage O		○ 0.972
D1	Stream	0.130	Spray drift	0.00	& \$\int 0.009 \\ \sigma \int \int 0.009 \\ \sigma \int \int \int 0.009 \\ \sigma \int \int \int 0.009 \\ \sigma \int \int \int \int 0.009 \\ \sigma \int \int \int \int \int \int \int \int	<sub>3</sub> 0.₽43 ≥	Spray Dift	, \$ 0.010 , C	0.151
D2	Ditch	0.192	Drainage	0×052 ©	,0,654	√ 0.192   √ 0.192   √ 0.192   √ 0.192   √ 0.192   √ 0.192   √ 0.192   √ 0.192   √ 0.192   √ 0.192   √ 0.192   √ 0.192   √ 0.192   √ 0.192   √ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓ 0.192   ✓	Dramage	0.408	1.042
D2	Stream	0.144	Spray drift	0.037	Ø.489 " <sub>\(\right\)</sub>	9.56°,	Spray drift	a 0.084	0.923
D3	Ditch	0.133	Spray drift	_ 0.0×0	0.1 <b>4</b> §	~ @0.163 ~ ~	Drainage	0.018	0.236
D4	Pond	0.038	Drainage	0.029	<b>9</b> 372	D.0380	Prainage	<b>0.0</b> \$0°	0.402
D4	Stream	0.122	Spray drift		~ 0.006 °	<b>0014</b> 5^	Spray dent	350.003	0.051
D5	Pond	0.038	<b>Drainag</b>	0.029	0.405	0.038	Dramage	0.030	0.406
D5	Stream	0.132	Spray drift	0.000	~C0.006	0,155	Spray drift	0.005	0.072
D6	Ditch	0.1180	Spray driff		0.069	<b>№</b> 192 (	Drainage	0.062	0.621
R1	Pond	≥0 <b>9</b> 038 @	Runoff	© 0.029 √ V	0.494	0.051	Qunoff	0.043	0.614
R1	Stream	<b>€</b> 0.115	Spray drift		0.251 OF	05133	\$ Runoff	0.012	0.797
R3	Stream	0.159	Spray drift	& <b>®</b> 0006	0.25%	\$ 0.160 d	Spray drift	0.008	0.137
R4	Stream	0.171	Romoff	0.009	<b>10</b> :372	0.163	Runoff	0.025	0.580

R4 Stream 0.171 Report 0.009 0.372 0.11

VFS = vegetative filter strip, SDBZ = spray drift buffs zone, SDBZ = spray drift buffs zone, SDBZ = spray drift buffs zone, SDBZ = spray drift reduction technology

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VFS = vegetative filter strip, SDBZ = spray drift buffs zone, SDBZ = spray drift reduction technology

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VFS = vegetative filter strip, SDBZ = spray drift buffs zone, SDBZ = spray drift reduction technology

Report 1.000 0.11

VFS = vegetative filter strip, SDBZ = spray drift buffs zone, SDBZ =



Table 9.2.5-18: Maximum PEC<sub>SW</sub> and PEC<sub>SED</sub> following application of 2 x 375 g a.s./ha spiroxapaine to spring cereals - FOCUS Step

	3-10. Maximum 1 ECsw and 1 Ecsep following application of 2 x 373 g a.s./na spiroxagame to spring certais - 1-0-003 Step 3-									
					- And	Oug/L)			<u> </u>	
		Early application (GS30-55)					<b>⊃</b>   Late application   Late   Lat	application (CS55-69)		
Scenario	Water body	Initial	Main route of entry	21-day TWA	Maximum PECsed (μg/kg)	° Initial	Main route of		Maximum PEC <sub>SED</sub> (μg/kg)	
			Multiple applicati	on 2x 375 g/ha	m VFS ± 20 m S	DBZ + 0%SDRT			~\$\\	
D1	Ditch	0.297	Drainage	0.185	2.077 V	0 <u>3</u> 95	Drainage	0.171	2.086	
D1	Stream	0.211	Spray drift	<b>6023</b>	0.261	0.Ž11	Spray drift		0.240	
D3	Ditch	0.182	Spray drift	é 0.025 &	<b>10,28</b> 1	0.194	Drainage	<b>Q.02</b> 9	0.343	
D4	Pond	0.065	Drainage *	0.05	§ 0.775 ℃		Drainage Drainage	0.055	0.784	
D4	Stream	0.200	Spray drif	0.003	0,00	0.210	Spray drift	0.007	0.089	
D5	Pond	0.062	Drainage		Ø.800 O	0.006	Drainage	<b>9.0</b> 55	0.808	
D5	Stream	0.205	Spray drift		0.022	0.224 C	Spra Carift	0.010	0.123	
R4	Stream	0.372	Runoff	\$ \$0.039 \disp\{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\partition{\parti		0.2270	A. Runoff &	0.038	0.776	
Single Application to 375 g/ha 20 m M/S + 20 m SDRZ + (% SDRT)										
D1	Ditch	0,244	Drainage	0.137	1,233	× 0.244 6	Drainage	0.137	1.231	
D1	Stream	Ø:211		0.01/2	\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	0.201	Spray drift	0.013	0.193	
D3	Ditch	0.182	Spray drift C	0.014	0.201	© 0.194 V	Drainage	0.019	0.257	
D4	Pond	0.046	Drainage	0.036	Q. <b>9</b> 63	0.046	Drainage	0.036	0.469	
D4	Stream	0.200	Sprow drift	0.0019	0.020	0.210	Spray drift	0.004	0.065	
D5	Pond	0.046	√Drainage <sup>™</sup>	0.936	0.481	<u>~</u> 0.046	Drainage	0.036	0.484	
D5	Stream	@0.205	Spray Wrift	1 0.001 <sub>0</sub>	0.013	0.224	Spray drift	0.006	0.092	
R4	Stream	0.173	Runoff ,	0.629	0.615	0.224	Runoff	0.035	0.772	
	<b>100</b>	,	Multiple applicati	on 28375 g/hg; 20	m VFS 20 m S	SDBZ + 0% SDRT	1			
D1	Ditch	0.236	Dramage	0.1460	₹.661	0.219	Drainage	0.135	1.668	
D1	Stream	0.143\$	Spray drift	81039	0.208	0.143	Spray drift	0.010	0.192	
D3	Ditch	×0.438	P Drainage	\$\int 0.020 @\frac{1}{2}	0.225	0.154	Drainage	0.023	0.274	
D4	Pond	0.054	Arainage 3		0.652	0.055	Drainage	0.046	0.659	
D4	Stream ~	0.138	Spray drift	% <b>0</b> .002	0.032	0.145	Spray drift	0.006	0.071	
D5	Pone	~ √10.051 ~ «C	Draipage	0.043	0.673	0.055	Drainage	0.046	0.680	
D5	Stream	0.1400	ray drift	- 100	0.018	0.155	Spray drift	0.008	0.098	
R4	Stream	20Q 72	Runo	0.039	0.820	0.227	Runoff	0.037	0.772	

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Document MCP – Section 9: Fate and behaviour in the environment Prothioconazole + Spiroxamine EC 460 (160+300 g/L)

					PECsw	μg/E			In The
			Early application (GS30-55)			La		Late application (GS55-69)	
Scenario	Water body	Initial	Main route of entry	21-day TWA	Maximum PECsend (µg/kg)	Initial	Nain route of entry	ZI-day TXXX	Maximum PECsed (μg/kg)
			Single applicatio	n 1x 375 g/ha; 20	m VFS + 20 m St	DBZ + 0% SDRT	2.		<b>*</b>
D1	Ditch	0.192	Drainage	0.107	0.972	~~~ 0.192 × ×	Drawnage	0.107	£©0.971
D1	Stream	0.143	Spray drift	0.010	\$ 0\151 \q	0.143	🐰 🕏 pray drift 🔾	(C)010 (	O 0.151
D3	Ditch	0.138	Drainage	0.041	& \$\int 0.158_\)	<sub>3</sub> 0.954 ≥		, \$ 0.015, ©	0.202
D4	Pond	0.038	Drainage	@ 0x930 @	, 0, <b>38</b> 6	√°0.038√	Diainage ?	0.030	0.391
D4	Stream	0.138	Spray drift	0.001	Ø:016 , N	. 0.048 ×	Spray drift	0.003	0.051
D5	Pond	0.038	Drainage	<sub>6</sub> 0.030	0.404	~ @0.038 ~ ~ ~	Drainage	0.030	0.403
D5	Stream	0.140	Spray drift	0.001	0.010	D. 1550	Spray drift	<b>9.30</b> 5	0.072
R4	Stream	0.173	Runoff	0.030	0.612	00224	Runoff	0.035	0.768

R4 Stream 0.173 Ranoff 0.000 0.612 0.0224 Ranoff STREAM OF STREAM



## **Conclusions**

Predicted environmental concentrations of spiroxamine in surface water and sediment have been generated in accordance with FOCUS and EFSA guidance, for the use of PTZ + SPX EC 460 (460 generated) on winter and spring cereals.

The global maximum PEC<sub>SW</sub> and PEC<sub>SED</sub> values for spiroxamine and its metabolites at Step 3 are provided in Table 9.2.5-19, and Step 4 are presented in Table 9.2.5-20.

Table 9.2.5-19: Global maximum PEC<sub>SW</sub> and PEC<sub>SW</sub> for spiroxamine - FOCUS Step 3

Use	4	Maxmum PECsw/µg/L)
Winter cereals, early, 2 x 375 g a.s./ha	[4 <sup>©</sup> ]	2.370° × × × ×
Winter cereals, late, 2 x 375 g a.s./ha		2.990 0
Spring cereals, early, 2 x 375 g a.s./ha	. 💜 .	3,339 2 2 2
Spring cereals, late, 2 x 375 g a.s./ha		2.834

a) Maximum value resulted from single application

Table 9.2.5-20: Maximum PEC<sub>SW</sub> and PEC<sub>SED</sub> for spirocamine FOCUS Step 4

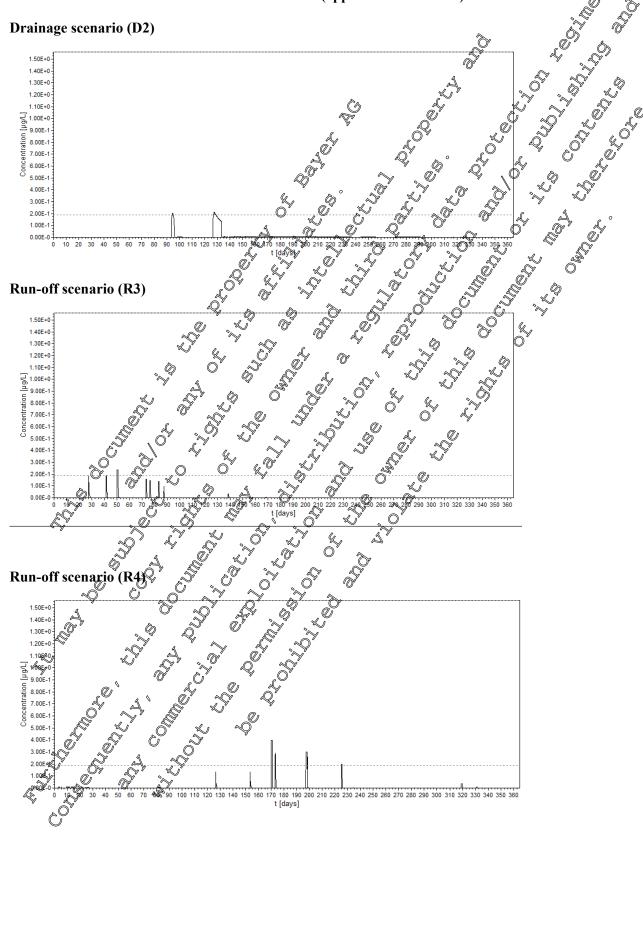
Use	Maximum PECsw (µg/L)
Winter cereals, early, 2 x 375 g	20,m VFS,+20 m SDBZ +20% SD T
a.s./ha	20 m VFS + 30 0 SDBZ 0% SDRT 0 0 0.397
Winter cereals, late, 2 x 375 g	20 m XFS + 20 m SDBZ + 0% SDRT 0.303
a.s./ha	20 nOVFS +30 m SpBZ + 6% SDRT
Spring cereals, early, 2 x 37 g g	20m VFS 20 m SDBZ + 0% SDRT
a.s./ha	20 m VFS + 30 m SDB2 + 0% SDRT V 0.372
Spring cereals, late, 2 x 75 g	20 m VFS + 20 m SDBZ + 0% SDRT 0.275
a.s./ha	$\bigcirc$ 20 $\bigcirc$ VFS $\bigcirc$ 0 m $\bigcirc$ BZ $\pm$ 0% SD $\bigcirc$ $\bigcirc$ 0.227

VFS = vegetated filter strip, SDBZ = spray drift buffer zone, SDBT = spray drift feduction technology

In order to provide for their refinement to Step 3 and 4 SW modelling. PPAT profiles can be considered. Example EPAT profiles for are shown in Figure 9.2.5-1 below which show the exposure profile for drainage (D) and run-off (R) scenario are mainly driven by spray drift. A more detailed evaluation of the exposure profiles can be conducted, on request.



Figure 9.2.5-1: Example exposure profile following 2x 375 g/ha to winter cereals with mitigation of 20 m VFS + 20 m SDBZ (application window a)





## **Assessment and conclusion by applicant:**

The study was conducted to guideline(s) FOCUS 2001, 2015 (required guideline). The study is considered valid for use in the risk assessment.

# PECsw FOCUS (prothioconazole)

The representative formulated product Prothioconazole + Spiroxamine EC 460 (160+300 g/L) also con tains the active substance prothioconazole. The active substance prothioconazole is get the primary fo cus of the renewal of the active substance spiroxamine and is the subject of a separate renewal evaluation which is in progress at the time of writing.

According to the current evaluation documents for the active substance prothioconazole Q.e. ELSA 2007<sup>12</sup>, p.77/98), the definition of the residue for environmental risk assessment in soil lists protractionazole and metabolites M01 (prothioconazole-S-meths) and M04 (prothioconazole-desthio) and in surface water lists prothioconazole and metabolites MO4 (prothioconazole-desthio) and M13 (prothioconazole-124 triazole).

The predicted environmental concentration to surface water of prothiocorrazole and metabolites M01 (prothioconazole-S-methyl), M04 (prothioconazole-desthio) and M13 (prothioconazole-124) triazole) are addressed by reference to the existing RAR for spiroxamine, volume 3 Annex B.9 (8-Aug-2017) which provides the following tables (from pages 199200) showing PECs according to FOCUS step-2 for prothioconazole and metabolites M01 (prothioconazole-S-methyl), M04 (prothioconazole-desthio) and M13 (prothioconazole-124 triazole) with additional PECsW according to FOCUS steps 3 and 4 (considering no spray buffer distances of 5 m and implementation of yegetative filter strips of 5, 10 and 20 m) based on the existing Loup for prothic onazole as no ded for environmental risk assessment:

Maximum and 21d TWA aquatic PEC values according to FOCUS STEP 2 **Table 9.2.5-21:** For application of prothioconaxole on coreals between March and May (Schad & Zerbe, 2008, MEF-08, 252), 4

		<b>V</b>	<u> </u>	<u> </u>		<i>Q</i>		
Scenario a	Prothio	conazol©	Prothice	nazolo thio 2m-twa	Prothioc	mazole-S-	Prothioc	
~~~~			o des	thio 🥿 🐪		hyl	tria	zole
	PEC	210 twa	PEC <sub>sw</sub>	2∱a-twa≼	PECQ"	21d-twa	PECsw	21d-twa
**	$(\mu g/1)$	2 for twa	(µg/L)	PEC	(µg/L)	PECsw	(µg/L)	PEC <sub>sw</sub>
	2.	<sup>(γ)</sup> (μg/ <b>L</b> )	`\\ \\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	(µg/b)		(µg/L)		(µg/L)
NE	Ø2.048 Å	0.059	4.138		©0.382	0.300	0.262	0.243
NE SE  a) NE: Northers	, 2.048	263	7.36	0 - 0	0.670	0.542	0.262	0.243
a) NE: Norther	Europe SE:	Southern Eu	rope					
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EFSA Scientific Report (2007) 106, 1-98, Conclusion on the peer review of prothioconazole.



Table 9.2.5-22: Prothioconazole-desthio: Maximum concentration of FOCUS STEP 3 and FOCUS STEP 4, with non-sprayed buffer zone at 5 m (Schad & Zerbe, 2008, MEF-08/252(



Table 9.2.5-23: Desthio: Maximum PEC<sub>SW</sub> concentration at FOCUS STEP 4, with run-off reductuins (Schad & Zerbe, 2008, MEF-08/252)

Scenario	Distance	Reduction	PECsw	
	(m)	(%)	(mag/L)	
spring cereals	•	•	Ş	4 , 4
R4 Roujan - stream	5	60/85	0.335	
	10	60/85	0.335	
	10	<b>80</b> /95	© 0.176√	
winter cereals	<u>.</u>			
R1 Weiherbach - stream	5	€ 60/85 °C	0.499	
	10	© 60/85	(Q499	
	10	80/95	0.261	2 0
R3 Bologna - stream	5	60/85	0.504	
	10 📞	© 60/8 <b>3</b> ° ~	0,994	7
	10	<u> 8</u> 8 8 7 7	© 264 L	4
R4 Roujan - stream	5 4	© 0/85 Q ,	0.5620	
	10	60/85	0.562	
	10 0 0		QQ94	

Note – possible typo in table above. It is assumed the third entry for each scenario corresponds to a VFS distance of 20 m (rather than a duplicate entry of 10 m)

Using the existing LoEP for prothioconazole and with the sep 4 ontigation levels applied above, the maximum initial predicted environmental concentration in surface water of prothioconazole and metabolites M01 (prothioconazole-S-metryl), M04 (prothioconazole-desthio) and M13 (prothioconazole-124 triazole) are 2.048, 0.670, 0.294 and 0.262 µg (prothioconazole-title).

## CP 9.3 Fare and behaviour in air.

# CP 9.3.1 Route and rate of degradation in air and transport via air

The fate and behaviour in air of the representative formulation Prothioconazole + Spiroxamine EC 460 (160+300 g/L) can be extrapolated from the active substance studies addressed under CA 7.3.

Based or an overall vapour pressure value for the whole active substance (i.e. combined A and B isomers) of  $4.7 \times 10^{-3}$  Pa  $(20^{\circ})$  and individual vapour pressure values of  $3.0 \times 10^{-3}$  and  $6.0 \times 10^{-3}$  Pa  $(20^{\circ}C)$  for the A and B diastereoisomers (see Point CA 2.2), respectively and calculated Henry's law constant for the whole active substance of  $4 \times 10^{-3}$  Pa  $(40^{\circ}C)$  and individual Henry's law constants of  $2.5 \times 10^{-3}$  and  $5.0 \times 10^{-3}$  Pa  $(40^{\circ}C)$  for the A and B diastereoisomers (see Point CA 2.2), respectively, piroxamine is semi-volatile and may have a potential to volatilise from plant, soil and water surfaces.

However, experimentally in studies investigating the amount of active substance volatilised under field conditions, it was shown that the amount volatilised was ca. 2% after 24 hrs. Any volatilisation of the active substance from the laboratory soil studies under Point CA 7.1.1. was also very low (<1% AR), although some colatilisation was observed from water surfaces in the water/sediment study (under Point CA 7.2.2.3). However, the substance opinochemical oxidative degradation half-life (using the Atkinson equation) in air of the active substance opinoxamine is <3 hours and therefore, if present, spiroxamine will not persist in the atmosphere.

Consequently the predicted environmental concentration of the active substance in air is expected to be negligible and is no calculated.

## CP 9.

Use of the representative formulated product Prothioconazole + Spiroxamine EC 460 (160+300 g/L)



can potentially lead to amounts reaching surface water during treatments by spray drift or *via* soil drainage and run-off, and therefore potentially reaching Water Treatment Plants (WTPs) where disinfection processes have the potential to modify the active substance or metabolites during treatment. In order to address the potential for harmful compounds being formed during the disinfection process, an assessment of potential exposure at WTPs is presented.

# **Impact of WTP Exposure**

Data Point:	KCP 9.4/01
Report Author:	
Report Year:	2021
Report Title:	Spiroxamine: Effects of water treatment on parent and metabolites in drinking
	water
Report No:	0471836-WT1
Document No:	<u>M-764010-01-1</u> 0 0 0 0 0
Guideline(s) followed in	None None
study:	
Deviations from current	None Of the State
test guideline:	
Previous evaluation:	No, not previously submitted 2 2 2 2
GLP/Officially recog-	not applicable
nised testing facilities:	
Acceptability/Reliability:	Yes V

# **Executive Summary**

Under Regulation (EC) No 1107/2009, it is necessary to show that active substances for use in plant protection products have no parmful effect on human or animal health through drinking water. The presence and potential levels of active substance and any metabolites in drinking water should therefore be investigated to assess the risk of formation of harmful substances such as nitrosamines, dioxins and furans during drinking water drinfection processes.

In this paper, the potential for formation of such substances resulting from treatment of water containing spiroxamine and its metabolites has been looked at. A review of the degradation pathways of spiroxamine in water and soil has been performed. Spiroxamine degrades to major metabolites M01 (spiroxamine-desethyl), M02 (spiroxamine-desthyl), M03 (spiroxamine-N-oxide) and M06 (spiroxamine-acid), minor metabolites, bound residues and carbon dioxide in soil, either via microbial processes. In water/sediment spiroxamine degrades to major metabolites, M06 (spiroxamine-acid), minor metabolites, bound residues and carbon dioxide, via microbial processes.

Groundwater and surface water are the most common sources of drinking water in Europe. The predicted environmental concentrations (PECs) of spiroxamine and its major metabolites in surface water and groundwater have been estimated and were found to be present at very low levels. In addition, the concentrations of spiroxamine and its metabolites in surface water are estimated for small edge of field water bodies. Drinking water is abstracted from much larger waterbodies so a dilution factor for typical large waterbodies has been estimated and drinking water concentrations calculated.

Based on the consentrations and the various steps in the drinking water treatment process, an assessment has been made on the likelihood of water treatment by-products of spiroxamine or its metabolites being present in drinking water.

It is very like that during the drinking water treatment processes prior to disinfection (sand filtration, coagulation) redimentation filtration and carbon filtration), spiroxamine and its metabolites will be removed due to their very high propensity to adsorb to organic material.

Since levels of spiroxamine and its metabolites will be negligible in drinking water prior to disinfection processes, it is very unlikely that disinfection by-products of spiroxamine and its metabolites will be present in drinking water.



## Predicted environmental concentrations in drinking water (PECDW) and its sources

The main sources of drinking water in Europe are groundwater and surface water, with surface water combined with artificial recharge and river bank filtration only accounting for a very minor contribution. This paper has therefore focussed on groundwater and surface water as sources of drinking water.

## Groundwater (PEC<sub>GW</sub>)

The leaching behaviour of spiroxamine and its metabolites, was examined in accordance with the FQ-CUS groundwater scenarios workshop guidelines (FOCUS 2000 and 2014).

Simulations of spiroxamine and its metabolites, M01 (spiroxamine-desethyl), M02 (spiroxamine-despropyl) and M03 (spiroxamine-N-oxide) following application to field crops were conducted with the FOCUS groundwater scenarios in FOCUS PEARL (version 4.44), FOCUS FELMO (version 5.5.53) and FOCUS MACRO (version 5.5.4) in accordance with the FOCUS groundwater scenarios workshop guidelines (FOCUS, 2000 and 2014).

The following uses were simulated in accordance with the supported uses of the spirox mine see Table 9.4-1:

Table 9.4-1: Modelled uses for spiroxamine

Crop	FOCUS Scenario	BBCH range	Application rate oper application (gos./ha)	Crop inter	Soil loading per applica- &tjon (g a.s./ha)
Winter cereals	Winter cereals	BBCH-30 on-	3756		37.5
Spring cereals	Springxereals	BASCH 30con- wards	€ 2075 V	J 90 J	37.5

The predicted 80th percentile average annual concentrations in groundwater at 1 m depth for spirox-amine and its metabolites M01 (spiroxamine-desethyl) M02 (spiroxamine-despropyl) and M03 (spiroxamine-N-oxide) were <0.001 μg/L for all uses and all scenarios: derefore, are all significantly below the 0.1 μg/L regulatory threshold. In studies investigating the poute of degradation of the active substance spiroxamine as soil spresented under CA 1.1.13 the metabolite M06 is only observed >5% AR in one out of ten soils and only at the very last sampling point (in all other soils and all other sampling points the observed level of metabolite M06 was 5%). Due to the low levels of M06 observed, it was difficult to obtain rehable degradation rate constants from the parent applied studies. Consequently, estimated PEC<sub>GW</sub> from conservative input parameters were found to be provide unreasonable estimates of leaching when compared to the outcome of the soil column studies (see KCA 7.1.4.1) where only 0.2% of AR were observed in leachate. Potential inputs via groundwater for metabolite M06 (spiroxamine-acid) are currently being defined as the studies required to define the modelling input parameters are underway and modelling using conservative assumptions result in unrealistic estimates of PEC<sub>GW</sub>. It should be noted that exposure of spiroxamine and its metabolite via groundwater are not expected and that exposure of the WTP with residues would be predominantly via surface water.

## Surface water (PEC<sub>SW</sub>)

The potential for spiroxamine and its metabolites M01 (spiroxamine-desethyl), M02 (spiroxamine-desproyl), M03 (spiroxamine-N-oxide) and M06 (spiroxamine-acid) to reach surface water, was examined in accordance with FOCUS guidance for surface water modelling (FOCUS (2001 and 2015)).

Applications prade to the winter and spring cereals were simulated using Steps 1-2 in FOCUS in accordance with FOCUS guidance for surface water modelling (FOCUS (2001 and 2015)). A refinement of the values generated at Steps 1-2 to more realistic concentrations were calculated for spiroxamine only using FOCUS Step 3. FOCUS Step 4 was used to apply mitigation measures.

The maximum  $PEC_{SW}$  values for spiroxamine at FOCUS Step 4 are presented in CP 9.2.5/03 but represented in Table 9.4-2.



<b>Table 9.4-2:</b>	Maximum PEC <sub>sw</sub>	values for	spiroxamine –	- FOCUS Step 4
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Use	Mitigation	Maximum PECsw (μg/L
Winter cereals 2 x 375 g	20 m VFS + 20 m NSBZ + 0% SDRT	0.397
a.s./ha	20 m VFS + 30 m NSBZ + 0% SDRT	> 0.397
Samina cancela 2 - 275 a c a /ha	20 m VFS + 20 m NSBZ + 0% SDRT	0.372
Spring cereals 2 x 375 g a.s./ha	20 m VFS + 30 m NSBZ + 0% SDRT	0.372

a) Maximum value resulted from single application

The overall maximum PEC<sub>SW</sub> values for the metabolites at Step 2 for the field uses are presented in CP 9.2.5/02 but re-presented in Table 9.4-3:

Table 9.4-3: Overall maximum PECSW values for the metabolites of piroximine for field uses – FOCUS Step 2

Compound	O Verall maximum PECsw (μg(L)
M01 (spiroxamine-desethyl)	
M02 (spiroxamine-despropyl)	\$\tag{70.699}\$
M03 (spiroxamine-N-oxide)	
M06 (spiroxamine-acid)	

Please note that assumptions at Step 2 are extremely conservative and that further reductions in PEC<sub>sw</sub> would be expected at Step 3 and 4 (not presented).

# Drinking water abstracted from surface water

PEC<sub>SW</sub> values have been assessed with the standard FOCUS scenarios. These valculations are performed with receiving water bodies, such as ditches, wonds and streams (Table 9.4-4), however, these types of water body are generally not used as a source of winking water in Europe. Therefore, a dilution will take place, before the substance of interest eaches major rivers or lakes serving as drinking water supplies. Characteristics of some typical European rivers and lakes are shown in Table 9.4-5.

Table 9.4-4: Water volume of small water bodies in model scenarios

Scenario 🖔	🗎 Dimensions a. 👸	Volume
Ditch &	Length 100 m Depth 0.3 m Wighth: 1 ca	30000 L (30 m3)
Pond	Depth: On Diameter 30 mg	706858 L (707 m3)
Stream	Length. 100 m	30000 L (30 m3)

Table 9.4-5: Characteristics of European rivers and lakes

Name of waterbody	© Outflow (m3/s)	Volume
Danube S S S S S S S S S S S S S S S S S S S	6700	-
Knine & // &	2300	-
Elbe	870	-
Loire &	930	-
Average rive Outflow	2700	-
Lake Constance	-	4.8 x 1010 m3

Dilution Dactors of 10<sup>7</sup> and 10<sup>9</sup> can be applied to PEC<sub>SW</sub> for the pond scenarios and the ditch or stream scenarios, respectively if a major lake (e.g. Lake Constance) is used as a drinking water supply, as follows:

VFS = vegetated filter strip, SDBZ = spray drift buffer zone, SDRT = spray drift reduction technology



Pond scenarios dilution factor =  $4.8 \times 10^{10} \text{ m}^3 / 707 \text{ m}^3 = 6.8 \times 10^7$ 

Ditch/stream dilution factor =  $4.8 \times 10^{10} \text{ m}^3 / 30 \text{ m}^3 = 1.6 \times 10^9$ 

A dilution factor of 10<sup>5</sup> and 10<sup>6</sup> can be applied to PEC<sub>SW</sub> for the pond scenarios and the ditch or fream scenarios, respectively if a river with an average outflow is used as a drinking water supply. These dilution factors are calculated as follows:

Total outflow over 7 hours =  $2700 \text{ m}^3/\text{s} \times 7 \text{ hours } \times 3600 \text{ s} = 6.8 \times 10^7 \text{ m}^3$ 

Pond scenarios dilution factor =  $6.8 \times 10^7 \text{ m}^3 / 707 \text{ m}^3 = 9 \times 10^5 \text{ m}^3$ 

Ditch/stream scenarios dilution factor =  $6.8 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3 = 2.3 \times 10^7 \text{ m}^3 / 30 \text{ m}^3$ 

Thus a dilution factor of 10<sup>5</sup> can be applied as a worst case assumption. However, considering the original estimated concentrations of spiroxamine or as metabolites in surface water, any consideration of dilution demonstrates an extremely low risk that transformation products of spiroxamine could cause adverse effects as they are considerably below the maximum drinking water limit of 0.1 µg/L.

## **Drinking water treatment processes**

In Europe, groundwater generally undergoes the following treatment prior to use a drinking water:

No treatment or treatment without disinfection (cg vo % alv drinking water)

Treatment with disinfection (ca 40% all drinking water)

When groundwater is disinfected, the most common treatment methods before disinfection are aeration with rapid sand filtration or carbon/filtration.

Only 40% of drinking water from disinfected from disinfected from disinfected.

Almost all surface water (cq 45% all drinking water) is disinfected prior to use as drinking water. Surface water is most likely to undergo coagulation/sedimentation/fibrration or carbon filtration prior to disinfection.

A total of 62% of dripking water from disinfected surface water (ca 28% of all drinking water) is chlorine disinfected

Disinfection is most commonly performed with chlorine and hypochlorite with chlorine dioxide and chloramine each accounting for less/than of disinfection methods.

UV treatment accounts for ca 16% of disinfection methods and only 2% of disinfection methods use ozone.

## Removal of spiroxamine and its metabolites before disinfection

The  $K_{FOC}$  values for spikoxamine and  $W_{S}$  metabolites (please see CP 9.1.2) are as follows:

Table 9.4-6: KFOC values for spiroxamine and its metabolites

Compound O A A A A	K <sub>FOC</sub> (mL/g)
Spiroxamine	4111
M01 (spiroxamine desettry)	3271
M02 (spiroxamine-despropy)	2695
MOS (spirozamine-19-oxide)	1677
M06 (spooxamine-acid)	Study ongoing

Based on these  $K_{FOC}$  values it can be seen that all of these compounds are slightly mobile or immobile from the McCall classification. It is therefore very likely that spiroxamine and its metabolites will be



removed from drinking water through the sand filtration, coagulation/sedimentation/filtration or carbon filtration process. Studies on the sorption behaviour of M06 (spiroxamine-acid) are ongoing, however, this affinity is also expected to hold true for this compound. Nevertheless, even if the experimentally derived K<sub>FOC</sub> value is low, dilution and degradation will occur as discussed previously, yielding concen trations so low that any transformation products from disinfection will not pose Frisk to human health

The overall predicted concentration of spiroxamine and its metabolites in ground water and subface water indicate an overall very low risk to human health irrespective of what reaction pocesses occur. during water treatment.

### **Conclusions**

An assessment has been made on the likelihood of water treatment by-products of spiroxamine or je metabolites being present in drinking water. The most common sources of drinking water in Europe are groundwater and surface water.

Spiroxamine degrades to major metabolites M01 (Spiroxamine-desethyl) M02 spiroxamine-despropyl), M03 (spiroxamine-N-oxide), M06 (spiroxamine-acid), min@ metabolites, bound@esidu@ and carbon dioxide in soil, either via microbial or photolytic processes. In petagic and water/sediment systems spiroxamine degrades to major metabolites MOV (spiroxamine desettovi), MO2 (spiroxamine desettovi), M03 (spiroxamine-N-oxide), M06 (spiroxamine-acid), mixor metabolites, bound residues and carbon dioxide, either via microbial or photolytic processes.

The PECs of spiroxamine and its major metabolites or surface water and groundwater have been estimated and were found to be present at very low levels. It is also very likely that during the drinking water treatment processes prior to disinfection (sand filtration, coagulation/sedimentation/filtration or carbon filtration), spiroxamme and its metabolites will be removed due to their relatively high propensity to adsorb to organic material. For those metabolite@which have a low Kroc, dantion and degradation will occur to levels so low that any transformation products from distrifection will not pose a risk to human health.

Since levels of spiroxamine and its metabolites will be negligible in drinking water prior to disinfection processes, it is very unlikely that disinfection by products of spiroxamine and its metabolites will be present in drinking water.

# Assessment and conclusion by applicant.

The study is considered valid for use in the risk assessment.