FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: CHR/F/SCORPIO 325 SC

Product name(s): Clapton 325 SC, Scarp 325 SC

Chemical active substances:

Difenoconazole, 125 g/L
Azoxystrobin, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: 09.2023

MS Finalisation date: 11/2025

This document describes the acceptable use conditions required for registration according to Art. 34 and Art. 33 of Regulation 1107/2009 of CHR/F/SCORPIO 325 SC containing azoxystrobin and difenoconazole in POLAND.

Scorpion 325 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for registration data of Scorpion 325 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Scorpion 325 SC has expired. Innvigo Sp. z o.o. refers to above mentioned studies within this document.

Version history

When	What
July 2023	Submission to the Polish Ministry of Agriculture and Rural Development
November 2023	Submission to the evaluation unit
January 2024	Documentation update provided by the applicant
October 2024	Correction of documentation as requested by zRMS provided by the applicant
January 2025	Correction of documentation as requested by zRMS provided by the applicant
July 2025	zRMS dRR evaluation
September 2025	Updated aquatic risk assessment by the Applicant
October 2025	Corrected mixture toxicity for aquatic organisms by the Applicant
November 2025	zRMS fonalised evaluation

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9 Ecotoxicology (KCP 10)

Review Comments:

This is the application for registration plant protection product - CHR/F/SCORPIO 325 SC (Clapton 325 SC, Scarp 325 SC), according to Article 33 of Regulation 1107/2009 based on unprotected data for compositionally comparable formulation - Scorpion 325 SC (acc. Art. 34 of Reg. 1107/2009). Further detail are given in separative document titled: Compositions comparison in accordance with Article 34 - CHR/F/SCORPIO 325 SC only for PL authority. CHR/F/SCORPIO 325 SC is a suspension concentrate type formulation (SC) containing 125 g/L difenoconazole and 200 g/ha azoxystrobin and is used as a fungicide in numbers of crops.

This Part B document only reviews data and additional information that has not previously been considered within the EU review process.

Since this document is based on the information provided by the applicant, all review comments, additions and corrections have been made using commenting boxes or highlighted in grey.

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	PL	*Winter oilseed rape (BRSNW)*	F	*Phoma lingam, Alternaria brassicae, Verticillium longisporum*	Spray, medium sprayer	Autumn, spring BBCH 14-29 -BBCH 31-55	a)1 b)2	min. 90/120	a) 0.9-1.0 l/ha b) 1.8-2.0 l/ha	a) 0.2925-0.325 kg a.s./ha (AZX 0.18-0.2 kg a.s./ha + DIF 0.1125-0.125 kg a.s/ha) b) 0.585-0.65 kg a.s./ha (AZX 0.36-0.4 kg a.s./ha + DIF 0.225-0.25 kg a.s/ha)	200-400	n/a		A	A	R	A	A	A	A
2	PL	*Winter oilseed rape (BRSNW)*	F	*Sclerotinia sclerotiorum, Botryotina fuckeliana, Alternaria brassicae*	Spray, medium sprayer	Spring BBCH 61-69	a)1 b)1	n/a	a) 0.9-1.0 l/ha b) 0.9-1.0 l/ha	a) 0.2925-0.325 kg a.s./ha (AZX 0.18-0.2 kg a.s./ha + DIF 0.1125-	200-400	n/a		A	A	R	A	A	A	A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
										0.125 kg a.s/ha) b) 0.2925-0.325 kg a.s./ha (AZX 0.18-0.2 kg a.s./ha + DIF 0.1125-0.125 kg a.s/ha)										
3	PL	*Sugar beet (BEAVX)*	F	*Cercospora beticola, Ramularia beticola, Erysiphe betae.*	Spray, medium sprayer	Spring BBCH 39-49	a)1 b)1	n/a	a) 0.8-1.0 l/ha b) 0.8-1.0 l/ha	a) 0.26-0.325 kg a.s./ha (AZX 0.16-0.2 kg a.s./ha + DIF 0.1-0.125 kg a.s/ha) b) 0.26-0.325 kg a.s./ha (AZX 0.16-0.2 kg a.s./ha + DIF 0.1-0.125 kg a.s/ha)	200-400	n/a		A	A	R	A	A	A	A
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)																				
4																				
5																				
Minor uses according to Article 51 (field uses)																				
6	PL	*Spring oilseed rape (BRSNS), ~~Sinapis alba (SINAL)~~,* Mustard (3MUSC) *Papaver somniferum (PAPSO), ~~Glycine max~~*	F	*Sclerotinia sclerotiorum, Alternaria brassicace, Leptosphaeria maculans, Alternaria brassicicola, Botrytis cinerea, Fusarium sp., Fusarium oxysporum, Septoria glycines,*	Spray, medium sprayer	Autumn, spring OSR, mustard, poppy, flax, hemp, sunflower BBCH 14-29 -BBCH	a)1 b)2	min. 90/120	a) 0.9-1.0 l/ha b) 1.8-2.0 l/ha	a) 0.2925-0.325 kg a.s./ha (AZX 0.18-0.2 kg a.s./ha + DIF 0.1125-0.125 kg a.s/ha)	200-400	n/a	Mammals: soybean – no safe – BBCH 40-49 Pumpkin – no safe- BBCH 10-49	A	A	R	A	A	A	A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
		Soybean (GLXMA), ~~Helianthus annuus~~ Sunflower (HELAN), ~~Cucurbita pepo~~ Pumpkin (CUUPE) (seed production only), ~~Linum usitatissimum~~ Flax (LIUUT) - technical and seed production, ~~Cannabis sativa~~ Hemp CNISA) - technical and seed production		*Cercospora sojina, Alternaria helianthin, Diaporthe helianthin, Golovinomyces cichoracearum, Alternaria alternata, Golovinomyces orontii, Melampsora lini, Septoria cannabis,*		31-69 Soybean BBCH 14-29; BBCH 31-39 BBCH 50-69 Pumpkin BBCH 50-69				b) 0.585-0.65 kg a.s./ha (AZX 0.36-0.4 kg a.s./ha + DIF 0.225-0.25 kg a.s/ha)								
7	PL	~~*Brassica napus subsp. rapifera*~~ Turnip (BRSNA)((roots only), Cichorium intybus (CICIN) (roots only), ~~*Beta vulgaris subsp. vulgaris*~~ Beetroot(BEAVD), ~~*Brassica napus subsp. rapifera*~~ Rutabaga (BRSNA), Horseradish ~~*Armoracia rusticana*~~ (ARWLA), ~~*Apium graveolens var. rapaceum*~~ Celeriac(APUGR)	F	*Alternaria sp, Erysiphe heraclei, Sclerotinia sclerotiorum, Septoria apiicola, Botrytis cinerea, Erysiphe betae, Cercospora beticola Uromyces beticola, Alternaria brassicicola, Erysiphe cruciferarum, Turnip mosaic virus, Albugo candida, Leptosphaeria maculans, Botryotinia fuckeliana, Alternaria radicina*	Spray, medium sprayer	Spring BBCH 39-49	a)1 b)1	n/a	a) 0.8-1.0 l/ha b) 0.8-1.0 l/ha	a) 0.26-0.325 kg a.s./ha (AZX 0.16-0.2 kg a.s./ha + DIF 0.1-0.125 kg a.s/ha) b) 0.26-0.325 kg a.s./ha (AZX 0.16-0.2 kg a.s./ha + DIF 0.1-0.125 kg a.s/ha)	200-400	n/a		A	A	R	A	A	A	A
8	PL	Ornamental nursery plants, forest nursery plants, renewals, afforestation and plantations of	F	*Podosphaeras p., Gymnosporangium sp., leaf spot, Lophodermium seditiosum,*	Spray, medium sprayer	Spring the first symptoms of infection Ornamental	a)1 b)2	14	a) 1.0 l/ha b) 2.0 l/ha	a) 0.325 kg a.s./ha (AZX 0.2 kg a.s./ha + DIF 0.125 kg a.s/ha)	300-1200	n/a	Mammals-no safe – BBCH ≥40	A	A	R	A	A	A	A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
		forest trees		*Diplocarpon rosae, Colletotrichum gloeosporioides, diseases caused by soil pathogens*		nursery plants, forest nursery plants BBCH up to 39 Others BBCH > 40				b) 0.65 kg a.s./ha (AZX 0.4 kg a.s./ha + DIF 0.25 kg a.s/ha)										
9	PL	Energetic plants, *Salix viminalis (SAXVI), Wicker (1SAXG)*	F	*Podosphaeras p., Gymnosporangium sp., leaf spot, Lophodermium seditiosum, Diplocarpon rosae, Colletotrichum gloeosporioides, diseases caused by soil pathogens*	Spray, medium sprayer	Spring the first symptoms of infection BBCH>40	a)1 b)2	14	a) 0.8 l/ha b) 1.6 l/ha	a) 0.260 kg a.s./ha (AZX 0.16 kg a.s./ha + DIF 0.100 kg a.s/ha) b) 0.52 kg a.s./ha (AZX 0.32 kg a.s./ha + DIF 0.200 kg a.s/ha)	300-1200	n/a	Mammals – no safe – BBCH up to 40	A	A	R	A	A	A	A
10	PL	~~*Nicotiana tabacum*~~ *Tobacco (NIOTA)*	F	*Alternaria spp., Golovinomyces cichoracearum*	Spray, medium sprayer	Spring the first symptoms of infection BBCH≥40	a)1 b)2	14	a) 1.0 l/ha b) 2.0 l/ha	a) 0.325 kg a.s./ha (AZX 0.2 kg a.s./ha + DIF 0.125 kg a.s/ha) b) 0.65 kg a.s./ha (AZX 0.4 kg a.s./ha + DIF 0.25 kg a.s/ha)	300-1200	n/a	Birds – no safe – BBCH up to 29 Mammals – no safe – BBCH 10-39	A	A	R	A	A	A	A
Minor uses according to Article 51 (interzonal uses)																				
11																				
12																				

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

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

Explanation for column 15 – 21 “Conclusion”

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

Remarks table:

(1) Numeration necessary to allow references
(2) Use official codes/nomenclatures of EU
(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(4) F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
(5) Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named
(6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(7) Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(8) The maximum number of application possible under practical conditions of use must be provided
(9) Minimum interval (in days) between applications of the same product.
(10) For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products
(11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
(12) If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions

9.1.1 Overall conclusions

9.1.1.1 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

~~CHR/F/SCORPIO 325 SC SC pose no unacceptable risk to birds and mammals used according to the label.~~

Review Comments:

All TER values exceed the relevant triggers indicating that CHR/F/SCORPIO 325 SC does not pose an unacceptable risk to birds following applications according to recommended use pattern, except for use in tobacco BBCH 10-29.

All acute TER values exceed the relevant triggers indicating that CHR/F/SCORPIO 325 SC does not pose an unacceptable risk to mammals following applications according to recommended use pattern.

The Tier I reproductive risk assessment for mammals (voles) for **azoxystrobin** demonstrated no acceptable risk for following scenarios:

- Ornamentals and nursery – 1-2 x 200 g a.s./ha, BBCH 40-49
- Fruiting vegetables (pumpkin) - 1 x 200 g a.s./ha, BBCH 10-49
- Pulses (soybean) - 1 x 200 g a.s./ha, BBCH 40-49
- Orchards (energetic plants) – 2 x 160 g a.s./ha, BBCH 00-19
- Maize (tobacco) – 2 x 200 g a.s./ha, BBCH 10-29

The Tier I reproductive risk assessment for mammals for **difenoconazole** demonstrated no acceptable risk for following scenarios:

- Ornamentals and nursery – 1-2 x 125 g a.s./ha, BBCH 40-49
- Fruiting vegetables (pumpkin) - 1 x 125 g a.s./ha, BBCH 10-49
- Pulses (soybean) - 1 x 125 g a.s./ha, BBCH 40-49
- Orchards (energetic plants) – 2 x 100 g a.s./ha, BBCH 00-19
- Maize (tobacco) – 2 x 125 g a.s./ha, BBCH 10-29

According to results, an unacceptable chronic risk due to **combined exposure** are obtained in acording to the proposed GAP, for uses:

- Ornamentals and nursery – 2 x 325 g a.s./ha, BBCH 40-49 and BBCH ≥ 50
- Fruiting vegetables (pumpkin) - 1 x 325 g a.s./ha, BBCH 10-49
- Pulses (soybean) - 1 x 325 g a.s./ha, BBCH 40-49
- Orchards (energetic plants) – 2 x 260 g a.s./ha, BBCH 00-19 and BBCH 20-40
- Maize (tobacco) – 2 x 325 g a.s./ha, BBCH 10-29 and BBCH 30-39

Evaluation of exposing to birds and mammals through the drinking water demonstrated the acceptable risk. The risk to earthworm- and fish-eating animals from secondary poisoning is low.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

~~CHR/F/SCORPIO 325 SC SC pose no unacceptable risk to aquatic species according to the label with appropriate buffer zone.~~

Review Comments:

The risk assessment for aquatic organisms carried out by the Applicant was not accepted as the PEC/RAC calculations were based on unaccepted $PEC_{SW/SED}$ values.

Furthermore, for difenoconazole, in the revised eFate section (dRR B8) there are no sufficiently low FOCUS Step 4 $PEC_{SW/SED}$ values in case of several scenarios (including relevant for Poland D3, D4 and especially R1). Therefore, the risk assessment for difenoconazole is incomplete for all proposed uses.

No correction of the mixture toxicity was made by zRMS since, with the $PEC_{SW/SED}$ values currently available for difenoconazole, it is not possible to complete this assessment. In result, this evaluation was deleted from the report (crossed out was not possible because the assessment was inserted in the form of images).

Therefore, the risk assessment for difenoconazole needs to be completed and a new mixture toxicity assessment must be submitted.

At this stage, no safe use of the product for aquatic organisms can be demonstrated.

At the commenting stage, the Applicant submitted the appropriate $PEC_{SW/SED}$ values calculations that there considered by zRMS in updated risk assessment for difenoconazole. The updated mixture toxicity assessment for aquatic organisms carried out by the Applicant has been accepted.

The risk assessment for aquatic organisms demonstrated that for following proposed uses of CHR/F/SCORPIO 325 SC the mitigation measures are required:

I. AZOXISTROBIN

1. Potatoes BBCH 14 – for R3 scenario 10 m vfs + 5 m nsb
2. Leafy vegetables BBCH 14 – for scenarios R1, R3, R4 – 10 m vfs + 10 m nsb
3. Tobacco – for R3 scenario – 10 m vfs + 5 m nsb
4. Orchards BBCH 10 and BBCH 31 – for scenarios D3, D4, D5, R1, R3, R4 – 20 m vfs + 20 m nsb
5. Maize BBCH 14 – for scenarios R3, R4 – 10 m vfs + 10 m nsb
6. Maize BBCH 31 – for scenario R4 - 10 m vfs + 5 m nsb
7. Sunflower BBCH 14 - for scenario R4 - 10 m vfs + 10 m nsb
8. Sunflower BBCH 31 - for scenario R4 - 10 m vfs + 5 m nsb

II. DIFENOCONAZOLE

1. Winter oilseed rape BBCH 14-20 and BBCH 21-69 – for scenarios D3, D4, D5, R1, R3 – 10 m vfs + 10 m nsb
2. Winter oilseed rape BBCH 31 – for scenarios D3, D4, D5, R1, R3 – 10 m vfs + 5 m nsb
3. Spring oilseed rape BBCH 14 – for scenarios D3, D4, D5, R1 – 10 m vfs + 10 m nsb
4. Spring oilseed rape BBCH 31 – for scenarios D3, D4, D5, R1 – 10 m vfs + 5 m nsb
5. Sugar beet BBCH 39 – for scenarios D3, D4, R1, R3 - 10 m vfs + 10 m nsb
6. Sugar beet BBCH 31 – for scenarios D3, D4, R1, R3 - 10 m vfs + 5 m nsb
7. Carrots BBCH 39 – for scenarios D3, R1, R3, R4 - 10 m vfs + 10 m nsb
8. Potato BBCH 14 – for scenarios D3, D4, R1, R3 - 10 m vfs + 5 m nsb
9. Potato BBCH 31 – for scenarios D3, D4, R1, R3 - 10 m vfs + 5 m nsb
10. Leafy vegetables BBCH 14 – for scenarios D3, D4, R1, R3 – 10 m vfs + 10 m nsb and for R4 - 20 m vfs + 10 m nsb
11. Tobacco – for R3 scenario – 10 m vfs + 5 m nsb

12. Orchards BBCH 10 and BBCH 31 – for scenarios D3, D4, D5, R1, R3 – 20 m vfs + 20 m nsb + 75% drift reduction
13. Maize BBCH 14 – for scenarios D3, D4, D5, R1, R3, R4 – 10 m vfs + 10 m nsb
14. Maize BBCH 31 – for scenarios D3, D4, D5, R1, R3, R4 – 10 m vfs + 5 m nsb
15. Sunflower BBCH 14 - for scenarios D5, R1, R3, R4 - 10 m vfs + 10 m nsb
16. Sunflower BBCH 31 - for scenarios D5, R1, R3, R4 - 10 m vfs + 5 m nsb

III. MIXTURE TOXICITY

1. Winter oilseed rape BBCH 14-20 – for scenario R3 - 10 m vfs + 10 m nsb
2. Carrots BBCH 39 – for scenario R4 - 10 m vfs + 10 m nsb
3. Potato BBCH 14 – for scenarios R1, R3 - 10 m vfs + 5 m nsb
4. Potato BBCH 31 – for scenario R3 - 10 m vfs + 5 m nsb
5. Leafy vegetables BBCH 14 – for scenarios R1, R3, R4 – 10 m vfs + 10 m nsb
6. Tobacco – for R3 scenario – 10 m vfs + 5 m nsb
7. Orchards BBCH 10 and BBCH 31 – for scenarios D3, D4, D5, R1, R3, R4 – 20 m vfs + 20 m nsb + 75% drift reduction
8. Maize BBCH 14 – for scenarios R3, R4 – 10 m vfs + 10 m nsb
9. Maize BBCH 31 – for scenarios R3, R4 – 10 m vfs + 5 m nsb
10. Sunflower BBCH 14 - for scenarios R1, R4 - 10 m vfs + 10 m nsb
11. Sunflower BBCH 31 - for scenarios R3, R4 - 10 m vfs + 5 m nsb

9.1.1.3 Effects on bees (KCP 10.3.1)

CHR/F/SCORPIO 375 SC pose no unacceptable risk to bees according to the label

Review Comments:

The data requirements in accordance with Commission Regulation (EU) No 284/2013 for the chronic toxicity to adult honeybees and honeybee larvae are fulfilled.

9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)

CHR/F/SCORPIO 325 SC pose no unacceptable risk to bees according to the label

9.1.1.5 Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)

CHR/F/SCORPIO SC 325 pose no unacceptable risk to soil organisms according to the label

9.1.1.6 Effects on non-target terrestrial plants (KCP 10.6)

CHR/F/SCORPIO 325 SC pose no unacceptable risk to non-target plants ~~bees~~ according to the label

9.1.1.7 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Not relevant

9.1.2 Grouping of intended uses for risk assessment

The following table documents the grouping of the intended uses to support application of the risk envelope approach (according to SANCO/11244/2011).

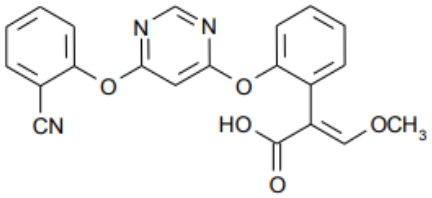
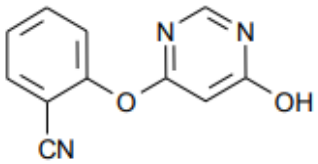
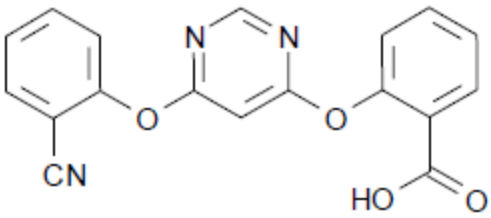
Table 9.1-2: Critical use pattern of SCORPIO 325 SC grouped according to crop, application rate, number of applications, timing criterion

Grouping			
Group	**Intended uses**	**relevant use parameters for grouping**	**relevant parameter or value for sorting**
Terrestrial vertebrates (Birds and Mammals; 9.2 and 9.3)	According to GAP	Scenarios according to EFSA Birds and Mammals Guidance (2009) Tobocco – surrogate crop – maize Energetic plants, renewals, afforestation, plantations of forest trees – surrogate crop – orchards	Crop, application rate, number of applications, timing criterion
Aquatic organisms (9.5)	According to GAP	Crops according to FOCUS surface water guidance	FOCUS modelling
Bees (9.6)	Risk envelope covering all uses	Risk assessments are based on the maximum single application rate	Maximum single application rate
Terrestrial non-target arthropods other than bees (9.7)	According to GAP	In-field and off-field risk assessments are based on the maximum application rate for each type of crops	In-field: Application rate and number of uses Off-field: Crop type (height), application rate and number of uses
Soil meso- and macrofauna / soil microorganisms (9.8 and 9.9)	Risk envelope covering all uses	Risk assessments are based on maximum PECsoil	Worst case PECsoil value
Non-target terrestrial plants (9.10)	According to GAP	Risk assessments are based on the maximum single and 2-fold application rate for each type of crops	Application rate and drift rate

9.1.3 Consideration of metabolites

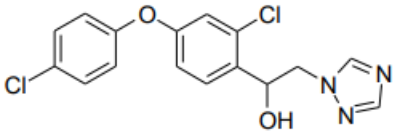
A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of CHR/F/SCORPIO 325 SC is indicated in the table.

Table 9.1-3 Metabolites of Azoxystrobine

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
R234886	389.4		Soil: 28.8% Water/Sediment: 17.7%	PECgw PECsoil PECsw
R401553	213.2		Soil: 17% Water/Sediment: 8/9%	PECgw PECsoil PECsw
R402173	333.3		Soil: 17% Water/Sediment: 2.4%	PECgw PECsoil PECsw

and azoxystrobin was found acceptable.

Table 9.1-4 Metabolites of Difenoconazole

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
CGA 71019	69		Soil: 23.4% Water/Sediment: 9.6%	PECgw PECsoil PECsw
CGA 205375	350		Soil: 9.7% (11.95%) Water/Sediment: 11.6%	PECgw PECsoil PECsw

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with difenoconazole and azoxystrobin and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents. Effects on birds of CHR/F/SCORPIO 325 SC were not evaluated as part of the EU assessment of difenoconazole and azoxystrobin.
The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process. Justifications are provided below.

Table 9.2-1: Endpoints and effect values relevant for the risk assessment for birds

Species	Substance	Exposure System	Results	Reference
Bobwhite quial	Azoxystrobin	Acute oral	LD50 > 2000 mg a.s./kg/bw	EFSA Journal 2010; 8(4):1542
Bobwhite quial	Azoxystrobin	Short-term	LC50> 1179 mg a.s./kg bw/d	EFSA Journal 2010; 8(4):1542
Bobwhite quial	Azoxystrobin	Long-term toxicity and reproduction	NOEL= 117 mg a.s/~~ka~~ kg bw/d	EFSA Journal 2010; 8(4):1542
Japanese quail.	Difenoconazole	Acute oral	LD50 > 2000 mg a.s./kg/bw	EFSA Journal 2011;9(1):1967
Mallard duck	Difenoconazole	Short-term	LC50> 349 mg a.s./kg bw/d	EFSA Journal 2011;9(1):1967
Mallard Duck	metabolite CGA131013	Dietary - 5 d Short-term	LC_{50} >1342 mg met./kg bw/day	EFSA Journal 2011;9(1):1967
Bobwhite quail	Difenoconazole	Long-term toxicity and reproduction	NOEL= 9.71 mg a.s/ka bw/d	EFSA Journal 2011;9(1):1967

9.2.1.1 Justification for new endpoints

Not required.

9.2.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).
To achieve a concise risk assessment, the risk envelope approach is applied.

9.2.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

Table 9.2-2: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of formulation in crop (use/use group)

Intended use	**oilseed rape, sugar beet, fruiting vegetables, root vegetables, pulses, sunflower**				
Active substance/product	azoxystrobin				
Application rate (g/ha)	1 x 200				
Acute / dietary toxicity (mg/kg bw)	2000 / 1179				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, and sunflower	Small omnivorous bird	158.8	1	31.76	63 / 37
Reprod. toxicity (mg/kg bw/d)	117				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, and sunflower	Small omnivorous bird	64.8	0.53	6.87	17

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-3: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of formulation in crop (use/use group)

Intended use	**Orchards (energetic plants), Ornamentals and nursery**				
Active substance/product	azoxystrobin				
Application rate (g/ha)	1 x 200				
Acute toxicity/ dietary (mg/kg bw)	2000 / 1179				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchards and ornamentals/nursery	Small omnivorous bird	46.8	1	9.36	213.7 / 126

Reprod. toxicity (mg/kg bw/d)	117				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Orchards and ornamentals/nursery	Small omnivorous bird	18.2	0.53	3.64	60.6

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2.4: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CHR/F/SCORPIO 325 SC in Sunflower

Intended use	Sunflower				
Active substance/product	azoxystrobin				
Application rate (g/ha)	2 x 200				
Acute toxicity (mg/kg bw)	2000				
TER criterion	10				
Crop scenario Growth stage	Indicator/generic focal species	SV_{ac}	MAF_{ac}	DDD_{ac} (mg/kg bw/d)	TER_A
Bulbs and onion-like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, and sunflower	Small omnivorous bird	158.8	1	31.76	62.9
Reprod. toxicity (mg/kg bw/d)	117				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Bulbs and onion-like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, and sunflower	Small omnivorous bird	64.8	0.53	12.96	17.0

Table 9.2.5: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CHR/F/SCORPIO 325 SC in Leafy vegetables (ornamental plants h<50cm)

Intended use	Leafy vegetables (ornamental plants h<50cm)				
Active substance/product	azoxystrobin				
Application rate (g/ha)	2 x 200				
Acute toxicity (mg/kg bw)	2000				
TER criterion	10				
Crop scenario Growth stage	Indicator/generic focal species	SV_{90}	MAF_{90}	DDD_{90} (mg/kg bw/d)	TER_a
Leafy vegetables	Small insectivorous bird	158.9	1.2	33.11	52.5
Reprod. toxicity (mg/kg bw/d)	117				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Leafy vegetables	Small insectivorous bird	64.8	1.4	9.63	6.72

Table 9.2-4: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CHR/F/SCORPIO 325 SC in Orchards (Ornamental nursery plants h>50cm, forest nursery plants, renewals, afforestation and plantations of forest trees, Energetic plants, Salix viminalis, Wicker)

Intended use	Orchards (Ornamental nursery plants h>50cm, forest nursery plants, renewals, afforestation and plantations of forest trees, Energetic plants, Salix viminalis, Wicker)				
Active substance/product	azoxystrobin				
Application rate (g/ha)	2 x 200				
Acute toxicity/ dietary (mg/kg bw)	2000/ 1179				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchards	Small insectivorous bird	46.8	1.2	11.23	178.1 / 105
Reprod. toxicity (mg/kg bw/d)	117				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Orchards	Small insectivorous bird	18.2	1.4 x 0.53	2.70	43.3

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.2-5: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CHR/F/SCORPIO 325 SC in maize Vineyard (surrogate crop: tobacco)

Intended use		Maize (Tobacco)			
Active substance/product		azoxystrobin			
Application rate (g/ha)		2 x 200			
Acute / dietary toxicity (mg/kg bw)		2000 / 1179			
TER criterion		10			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Maize	Small insectivorous bird	158.8	1.2	38.11	52.5 / 30.9
Reprod. toxicity (mg/kg bw/d)		117			
TER criterion		5			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Maize	Small insectivorous bird	64.8	1.4 x 0.53	9.61	12.2

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Intended use		Vineyard (Tobacco)			
Active substance/product		azoxystrobin			
Application rate (g/ha)		2 x 200			
Acute toxicity (mg/kg bw)		2000			
TER criterion		10			
Crop scenario Growth stage	Indicator/generic focal species	SV_{90}	MAF_{90}	DDD_{90} (mg/kg bw/d)	TER_a
Vineyard (Tobacco)	Small insectivorous bird	95.2	1.2	22.87	87.4
Reprod. toxicity (mg/kg bw/d)		117			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Vineyard (Tobacco)	Small insectivorous bird	38.9	1.4	5.77	20.2

Table 9.2-~~6~~: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of formulation in crop (use/use group)

Intended use	**Oilseed rape, mustard, flax, hemp**				
Active substance/product	difenoconazole				
Application rate (g/ha)	1 x 125				
Acute/ dietary toxicity (mg/kg bw)	2000 / 349				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, and sunflower	Small omnivorous bird	158.8	1	19.85	100.8 / 17.6
Reprod. toxicity (mg/kg bw/d)	9.71				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, and sunflower	Small omnivorous bird	64.8	0.53	4.29	**2.3**
Tier 1					
Oilseed rape BBCH ≥ 40	medium herbivorous/granivorous bird "pigeon" Comby to be calculated 50 % crop leaves 50 % weed seeds	0.9	-	-	162.9
Oilseed rape BBCH ≥ 40	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	2.7	-	-	54.3
Oilseed rape BBCH 10 - 19	medium herbivorous/granivorous bird "pigeon" Non-grass herbs 100% crop shoots	22.7	-	-	6.5
Oilseed rape BBCH 10 - 19	Small insectivorous bird “wagtail” ground invertebrates without interception 100% soil dwelling invertebrates	5.9	-	-	24.8

Intended use	**Oilseed rape, mustard, flax, hemp**				
Active substance/product	difenoconazole				
Application rate (g/ha)	1 x 125				
Oilseed rape BBCH 10 - 29	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	10.9	-	-	13.4
Oilseed rape BBCH 20 - 29	medium herbivorous/granivorous bird "pigeon" Comby to be calculated 50 % crop leaves 50 % weed seeds	3.5	-	-	41.9
Oilseed rape BBCH 20 - 29	Small insectivorous bird “wagtail” ground invertebrates with interception 100% soil dwelling invertebrates	2.8	-	-	52.3
Oilseed rape BBCH 30 - 39	medium herbivorous/granivorous bird "pigeon" Comby to be calculated 50 % crop leaves 50 % weed seeds	1.1	-	-	133.2
Oilseed rape BBCH 30 - 39	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	3.3	-	-	44.4
Oilseed rape early (shoots) (BBCH 10-19)	Large herbivorous bird "goose" Non-grass herbs 100% crop shoots	15.9	-	-	9.2
Oilseed rape late – late (with seeds) (BBCH 30-99)	Small insectivorous bird "dunnock) ground invertebrates with interception 100% soil dwelling invertebrates	2.7	-	-	54.3
~~Maize BBCH ≥ 20~~	~~Small insectivorous bird “wagtail” ground invertebrates with interception 50% ground arthropods, 50% foliar arthropods~~	~~4.8~~	~~-~~	~~-~~	~~30.5~~
~~Maize BBCH ≥ 40~~	~~Medium granivorous bird "gamebird" Small seeds 100% seed~~	~~0.8~~	~~-~~	~~-~~	~~183.2~~
~~Maize BBCH ≥ 40~~	~~medium herbivorous/granivorous bird "pigeon" Non-grass herbs 100% leaves~~	~~5.7~~	~~-~~	~~-~~	~~25.7~~
~~Maize BBCH ≥ 40~~	~~Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods~~	~~2.7~~	~~-~~	~~-~~	~~54.3~~

Intended use	**Oilseed rape, mustard, flax, hemp**				
Active substance/product	difenoconazole				
Application rate (g/ha)	1 x 125				
~~Maize BBCH 10 - 19~~	~~Small insectivorous bird "wagtail" ground invertebrates without interception 50% ground arthropods, 50% foliar arthropods~~	~~11.3~~	~~-~~	~~-~~	~~13.0~~
~~Maize BBCH 10 - 29~~	~~Medium granivorous bird "gamebird" Small seeds 100% seed~~	~~3.0~~	~~-~~	~~-~~	~~48.9~~
~~Maize BBCH 10 - 29~~	~~medium herbivorous/granivorous bird "pigeon" Non-grass herbs 100% leaves~~	~~22.7~~	~~-~~	~~-~~	~~6.5~~
~~Maize BBCH 10 - 29~~	~~Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods~~	~~10.9~~	~~-~~	~~-~~	~~13.4~~
~~Maize BBCH 30 - 39~~	~~Medium granivorous bird "gamebird" Small seeds 100% seed~~	~~1.5~~	~~-~~	~~-~~	~~97.7~~
~~Maize BBCH 30 - 39~~	~~medium herbivorous/granivorous bird "pigeon" Non-grass herbs 100% leaves~~	~~11.4~~	~~-~~	~~-~~	~~12.9~~
~~Maize BBCH 30 - 39~~	~~Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods~~	~~5.4~~	~~-~~	~~-~~	~~27.1~~
~~Maize Leaf development BBCH 10 to 19~~	~~Small insectivorous/worm feeding species "thrush" ground invertebrates without interception 100% soil dwelling invertebrates~~	~~5.7~~	~~-~~	~~-~~	~~25.7~~

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-7: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of formulation in crop (use/use group)

Intended use	**Sugar beet**				
Active substance/product	difenoconazole				
Application rate (g/ha)	1 x 125				
Acute/ dietary toxicity (mg/kg bw)	2000 / 349				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, and sunflower	Small omnivorous bird	158.8	1	19.85	100.8 / 17.6
Reprod. toxicity (mg/kg bw/d)	9.71				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, and sunflower	Small omnivorous bird	64.8	0.53	4.29	**2.3**
Tier 1					
Sugar beet BBCH 20 - 49	Small insectivorous bird "wagtail" ground invertebrates with interception 100% soil dwelling invertebrates	2.8	-	-	52.3
Sugar beet BBCH 20 - 49	Small insectivorous bird "wagtail" ground invertebrates with interception 50% ground arthropods 50% foliar arthropods	9.7	-	-	15.1
Sugar beet late (summer/ autumn) (BBCH 30-49)	Small granivorous bird "finch" Small seeds 100% weed seeds	11.4	-	-	12.9

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-8: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of formulation in crop (use/use group)

Intended use	**Ornamentals and nursery (cover orchards surrogate crop for energetic plants)**				
Active substance/product	difenoconazole				
Application rate (g/ha)	1 x 125				
Acute toxicity (mg/kg bw)	2000 / 349				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchards and ornamentals/nursery	Small omnivorous bird	46.8	1	5.85	341.9 / 59.7
Reprod. toxicity (mg/kg bw/d)	9.71				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Orchards and ornamentals/nursery	Small omnivorous bird	18.2	0.53	1.21	8.1

sure ratio. TER values shown in bold fall below the relevant trigger.
SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.2-9: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of formulation in crop (use/use group)

Intended use	**Fruiting vegetables**				
Active substance/product	difenoconazole				
Application rate (g/ha)	1 x 125				
Acute / dietary toxicity (mg/kg bw)	2000 / 349				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, and sunflower	Small omnivorous bird	158.8	1	19.85	100.8 / 17.6

Reprod. toxicity (mg/kg bw/d)	9.71				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, and sunflower	Small omnivorous bird	64.8	0.53	4.29	**2.3**
Tier 1					
Fruiting vegetables BBCH ≥ 20	Small insectivorous bird "wagtail" ground invertebrates with interception 50% ground arthropods, 50% foliar arthropods	9.7	-	-	15.1
Fruiting vegetables BBCH ≥ 50	Small granivorous bird "finch" Small seeds 100% weed seeds	3.4	-	-	43.1
Fruiting vegetables BBCH ≥ 50	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	3.3	-	-	44.4
Fruiting vegetables BBCH 10 - 19	Small insectivorous bird "wagtail" ground invertebrates without interception 50% ground arthropods, 50% foliar arthropods	11.3	-	-	13.0
Fruiting vegetables BBCH 10 - 49	Small granivorous bird "finch" Small seeds 100% weed seeds	11.4	-	-	12.9
Fruiting vegetables BBCH 10 - 49	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	10.9	-	-	13.4

sure ratio. TER values shown in bold fall below the relevant trigger.

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.2-10: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of formulation in crop (use/use group)

Intended use	**Root vegetables**				
Active substance/product	difenoconazole				
Application rate (g/ha)	1 x 125				
Acute/ dietary toxicity (mg/kg bw)	2000 / 349				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, and sunflower	Small omnivorous bird	158.8	1	19.85	100.8 / 17.6
Reprod. toxicity (mg/kg bw/d)	9.71				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, and sunflower	Small omnivorous bird	64.8	0.53	4.29	**2.3**
Tier 1					
Root and stem vegetables BBCH ≥ 20	Small insectivorous bird “wagtail” ground invertebrates with interception 50% ground arthropods, 50% foliar arthropods	9.7	-	-	15.1
Root and stem vegetables BBCH ≥ 40	Small granivorous bird “finch” Small seeds 100% weed seeds	3.4	-	-	43.1
Root and stem vegetables BBCH ≥ 40	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	3.3	-	-	44.4

Intended use	**Root vegetables**				
Active substance/product	difenoconazole				
Application rate (g/ha)	1 x 125				
Root and stem vegetables BBCH 10 - 19	Small insectivorous bird "wagtail" ground invertebrates without interception 50% ground arthropods, 50% foliar arthropods	11.3	-	-	13.0
Root and stem vegetables BBCH 10 - 39	Small granivorous bird "finch" Small seeds 100% weed seeds	11.4	-	-	12.9
Root and stem vegetables BBCH 10 - 39	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	10.9	-	-	13.4

sure ratio. TER values shown in bold fall below the relevant trigger.

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.2-11: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CHR/F/SCORPIO 325 SC in Sunflower

Intended use	**Sunflower**				
Active substance/product	difenoconazole				
Application rate (g/ha)	2 x 125				
Acute / dietary toxicity (mg/kg bw)	2000 / 349				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, and sunflower	Small omnivorous bird	158.8	1.0	19.85	100.8 / 17.6
Reprod. toxicity (mg/kg bw/d)	9.71				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, and sunflower	Small omnivorous bird	64.8	1.0	8.10	2.3
Tier I					
Sunflower Early (Germination/leaf develompent_ BBCH 00-19	Small insectivorous bird “wagtail” Combination (ground invertebrates without interception) 50% ground arthropods, 50% foliar arthropods	11.3	-	-	13.0
Sunflower Early (Germination/leaf develompent) BBCH 00-19	Small omnivorous bird “lark” Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	11.3 10.9	-	-	13.4
Sunflower Late (Flowering, seed ripening) BBCH 61-92	Small granivorous/insectivorous bird “bunting” Small seeds 100% crop seeds	10.0	-	-	14.7

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure

ratio. TER values shown in bold fall below the relevant trigger

Table 9.2-12: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CHR/F/SCORPIO 325 SC in maize ~~Leafy vegetables (ornamental plants h<50cm)~~

Intended use		**Maize (surrogate crop for tobacco)**			
Active substance/product		difenoconazole			
Application rate (g/ha)		2 x 125			
Acute/ dietary toxicity (mg/kg bw)		2000 / 349			
TER criterion		10			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, and sunflower	Small omnivorous bird	158.8	1.2	23.82	84 / 14.7
Reprod. toxicity (mg/kg bw/d)		9.71			
TER criterion		5			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, and sunflower	Small omnivorous bird	64.8	1.4 x 0.53	6.01	**1.6**
Tier 1					
Maize BBCH ≥ 20	Small insectivorous bird “wagtail”	4.8	1.4 x 0.53	0.45	21.6
Maize BBCH ≥ 40	Medium granivorous bird "gamebird"	0.8	1.4 x 0.53	0.074	131.2
Maize BBCH ≥ 40	medium herbivorous/granivorous bird "pigeon"	5.7	1.4 x 0.53	0.53	18.3
Maize BBCH ≥ 40	Small omnivorous bird “lark”	2.7	1.4 x 0.53	0.25	38.8
Maize BBCH 10 - 19	Small insectivorous bird “wagtail”	11.3	1.4 x 0.53	1.05	9.2
Maize BBCH 10 - 29	Medium granivorous bird "gamebird"	3.0	1.4 x 0.53	0.28	34.7

Intended use	**Maize (surrogate crop for tobacco)**				
Active substance/product	difenoconazole				
Application rate (g/ha)	2 x 125				
Maize BBCH 10 - 29	medium herbivorous/granivorous bird "pigeon"	22.7	1.4 x 0.53	2.11	**4.6**
Maize BBCH 10 - 29	Small omnivorous bird “lark”	10.9	1.4 x 0.53	1.01	9.6
Maize BBCH 30 - 39	Medium granivorous bird "gamebird"	1.5	1.4 x 0.53	0.14	69.4
Maize BBCH 30 - 39	medium herbivorous/granivorous bird "pigeon"	11.4	1.4 x 0.53	1.06	9.2
Maize BBCH 30 - 39	Small omnivorous bird “lark”	5.4	1.4 x 0.53	0.50	19.4
Maize Leaf development BBCH 10 to 19	Small insectivorous/worm feeding species “thrush”	5.7	1.4 x 0.53	0.53	18.3

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Intended use	Leafy vegetables (ornamental plants h<50cm)				
Active substance/product	difenoconazole				
Application rate (g/ha)	2 x 125				
Acute toxicity (mg/kg bw)	2000				
TER criterion	10				
Crop scenario Growth stage	Indicator/generic focal species	SV_{ac}	MAF_{ac}	DDD_{ac} (mg/kg bw/d)	TER_A
Leafy vegetables	Small insectivorous bird	158.3	1.0	19.85	100.8
Reprod. toxicity (mg/kg bw/d)	0.71				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV_{ac}	MAF_{ac} x TWA	DDD_{ac} (mg/kg bw/d)	TER_A
Leafy vegetables	Small insectivorous bird	64.8	1.0	8.01	4.6
First Tier Risk Assessment					
Leafy vegetables BBCH≥20	Small insectivorous bird "wagtail" ground invertebrates with interception 50% ground arthropods 50% foliar arthropods	9.7	1	1	10.3
Leafy vegetables BBCH≥50	Small granivorous bird "finch" Small seeds 100% seeds	7.8	1	1	27.6
Leafy vegetables BBCH≥50	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves, 25% weed seeds, 50% ground arthropods	3.3	1	1	31.7
Leafy vegetables BBCH 10-19	Small insectivorous bird "wagtail" ground invertebrates without interception 50% ground	11.3	1	1	9.3

	arthropods 50% foliar arthropods				
Leafy vegetables BBCH 10-49	Small granuvorous bird "finch" Small seeds 100% seeds	12.6	1	1	8.3
Leafy vegetables BBCH 10-49	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves, 25% weed seeds, 50% ground arthropods	10.9	1	1	9.6
Leafy vegetables BBCH 10-19	Medium herbivorous/granivorous bird "pigeon" Non-gras-herbs 100% leaves	37.0	1	1	2.8

Table 9.2-13: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CHR/F/SCORPIO 325 SC in Orchards (Ornamentals nursery plants h>50cm, forest nursery plants, renewals, afforestation and plantations of forest trees, Energetic plants, Salix viminalis, Wicker)

Intended use	**Orchards (Ornamentals nursery plants h>50cm, forest nursery plants, renewals, afforestation and plantations of forest trees, Energetic plants, Salix viminalis, Wicker)**				
Active substance/product	difenoconazole				
Application rate (g/ha)	2 x 125				
Acute / dietary toxicity (mg/kg bw)	2000 / 349				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchards	Small insectivorous bird	46.8	1.2	7.02	284.9 / 49.7
Reprod. toxicity (mg/kg bw/d)	9.71				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Orchards	Small insectivorous bird	18.2	1.4 x 0.53	1.69	5.8

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.2-14: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of CHR/F/SCORPIO 325 SC in pulses ~~Vineyard (surrogate crop: tobacco)~~

Intended use		Pulses			
Active substance/product		difenoconazole			
Application rate (g/ha)		1 x 125			
Acute / dietary toxicity (mg/kg bw)		2000 / 349			
TER criterion		10			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, and sunflower	Small insectivorous bird	158.8	1.0	19.85	100.8 / 17.6
Reprod. toxicity (mg/kg bw/d)		9.71			
TER criterion		5			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, and sunflower	Small insectivorous bird	64.8	0.53	4.29	**2.3**
Tier 1					
Pulses BBCH 10-49	Small granivorous bird"finch"	11.4	0.53	0.76	7.4
Pulses BBCH ≥ 50	Small granivorous bird"finch"	3.4	0.53	0.23	42.2
Pulses BBCH 10-49	Small omnivorous bird"lark"	10.9	0.53	0.72	13.5
Pulses BBCH ≥ 50	Small omnivorous bird"lark"	3.3	0.53	0.22	44.1
Pulses BBCH 10-19	Medium herbivorous / granivorous bird "pigeon"	22.7	0.53	1.50	6.5
Pulses BBCH 10-19	Small insectivorous bird "wagtail"	11.3	0.53	0.75	12.9
Pulses BBCH ≥ 20	Small insectivorous bird "wagtail"	9.7	0.53	0.64	15.2

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Intended use	Vineyard (surrogate crop: tobacco)				
Active substance/product	difenoconazole				
Application rate (g/ha)	2 x 125				
Acute toxicity (mg/kg bw)	2000				
TER criterion	10				
Crop scenario Growth stage	Indicator/generic focal species	SV_{50}	MAF_{50}	DDD_{50} (mg/kg bw/d)	TER_A
Vineyard	Small insectivorous bird	95.3	1.2	14.30	130.9
Reprod. toxicity (mg/kg bw/d)	0.71				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV_{50}	MAF_{50} + FWA	DDD_{50} (mg/kg bw/d)	TER_R
Vineyard	Small insectivorous bird	35.0	1.4	1.61	9.7
First Tier Risk Assessment					
Vineyard BBCH > 20	Small insectivorous species "Redstart" ground invertebrates with interception 50% ground arthropods 50% foliar arthropods	9.9	1	1	10.6
Vineyard BBCH > 40	Small granivorous bird "Finch" small seeds 100% weed seeds	3.4	1	1	30.8
Vineyard BBCH > 40	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	3.3	1	1	31.7
Vineyard BBCH 10-19	Small granivorous bird "Finch" Small seeds 100% weed seeds	6.9	1	1	15.2
Vineyard BBCH 10-19	Small insectivorous species "Redstart" ground invertebrates without interception 50% ground arthropods 50% foliar arthropods	11.5	1	1	9.1
Vineyard BBCH 10-19	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	6.5	1	1	16.1
Vineyard BBCH 20-29	Small granivorous bird "Finch" Small seeds 100% weed seeds	5.7	1	1	18.4
Vineyard BBCH 20-29	Small omnivorous bird "lark" Combination (invertebrates without interception) 25% crop leaves 25% weed seeds 50% ground arthropods	5.4	1	1	19.4
Vineyard Ripening	Frugivorous bird "Turdi/starling" Berries 100% grapes	14.4	1	1	9.2

~~Combined toxicity, using the TER value for active substances (the lowest TER)~~
~~Acute: 0.125 kg DIF /ha + 0.2 kg AZX/ha TER(mix) = 1/ ((1/63) + (1/100.8)) = 38.8~~
~~Chronic: 0.125 kg DIF /ha + 0.2 kg AZX/ha TER(mix) = 1/ ((1/17) + (1/6.5)) = **4.7**~~

~~The chronic TER_{mix} is below the trigger value of 5. However, the TER_{AZX} was taken from screening step. Thus, the lowest value of TER_{AZX} Tier 1 was included:~~
~~Chronic: 0.125 kg DIF /ha + 0.2 kg AZX/ha TER(mix) = 1/ ((1/48.6) + (1/6.5)) = 5.7~~

Review Comments:

The active substances content of CHR/F/SCORPIO 325 SC is 20% azoxystrobin and 12.5% difenoconazole, making up a total of 325 g a.s./L product. According to GAP, the maximum application rate is 1 L product/ha, therefore, an application rate of 325 g a.s./ha was considered in the assessment.

Acute risks from combined exposure

Step 1 – "tox per fraction" assessment

	Azoxystrobin	Difenoconazole	"mix"
Content in the formulation [g/L]	200	125	325
Fraction in mixture	0.6154	0.3846	1.0
LD_{50} (mg/kg bw)	1179	349	615.76
Tox per fraction	1915.88	907.40	615.76
Contribution to predicted toxicity	32.14%	67.86%	

Azoxystrobin contributes to 32.14% to mixture toxicity, while the difenoconazole have an impact on the predicted risk of 67.86%, therefore, surrogate LD_{50} need to be calculated.

Step 2 - the calculation of the predicted LD_{50} (mix)
For the calculation, the following equation was used:

$$LD_{50}(\text{mix}) = \left(\sum_i \frac{X(\text{a.s.}_i)}{LD_{50}(\text{a.s.}_i)} \right)^{-1}$$

With:

$X(\text{a.s.}_i)$ = fraction of each a.s. in the mixture
$LD_{50}(\text{a.s.}_i)$ = acute toxicity value for each a.s.

	Azoxystrobin	Difenoconazole
Content in the formulation [g/L]	200	125
Fraction in the a.s. mixture	0.6154	0.3846
LD_{50} of a.s. [mg/kg bw]	1179	349
Fraction / LD_{50}	0.00052	0.00110
Sum	0.001624	
1/ sum = predicted LD_{50} (mix)	615.76 mg mix/kg bw	

Step 3 – the acute risk assessment using surrogate LD_{50}

Screening step assessment of the acute risk for birds due to the use of CHR/F/SCORPIO 325 SC.

Intended use	All crops - one application
Active substance/product	CHR/F/SCORPIO 325 SC
Application rate (g/ha)	1 x 325

LD_{50} (mix) (mg/kg bw)	615.76				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening	Indicator species for screening	158.8	1.0	51.61	11.9

Intended use	Energetic plants, ornamentals/nursery				
Active substance/product	CHR/F/SCORPIO 325 SC				
Application rate (g/ha)	2 x 325 (14 d)				
LD_{50} (mix) (mg/kg bw)	615.76				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening	Indicator species for screening	46.8	1.2	18.25	33.7

Intended use	Tobacco				
Active substance/product	CHR/F/SCORPIO 325 SC				
Application rate (g/ha)	2 x 325 (14 d)				
LD_{50} (mix) (mg/kg bw)	615.76				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening	Indicator species for screening	158.8	1.2	61.93	9.94
Tier 1 (worst case)					
Maize BBCH 10 - 29	medium herbivorous/granivorous bird "pigeon"	55.6	1.2	21.68	28.4

According to results, no unacceptable acute risk due to combined exposure are obtained in acording to the proposed GAP.

Reproductive risks from combined exposure

Step 1 – “tox per fraction” assessment

	Azoxystrobin	Difenoconazole	“mix”
Content in the formulation [g/L]	200	125	325
Fraction in mixture	0.6154	0.3846	1.0
NOEL (mg/kg bw)	117	9.71	22.29
Tox per fraction	195.13	25.25	22.29
Contribution to predicted toxicity	11.72 %	88.28 %	

Azoxystrobin contributes to 11.72% to mixture toxicity, while the difenoconazole have an impact on the

predicted risk of 88.28%, therefore, surrogate NOEL need to be calculated.

Step 2 - the calculation of the predicted NOEL

	Azoxystrobin	Difenoconazole
Content in the formulation [g/L]	200	125
Fraction in the a.s. mixture	0.6154	0.3846
NOEL of a.s. [mg/kg bw]	117	9.71
Fraction / LD_{50}	0.0053	0.0396
Sum	0.0448	
1/ sum = predicted LD_{50} (mix)	22.29 mg mix/kg bw	

Step 3 – the chronic risk assessment using surrogate NOEL

Screening step assessment of the chronic risk for birds due to the use of CHR/F/SCORPIO 325 SC.

Intended use	All crops - one application
Active substance/product	CHR/F/SCORPIO 325 SC
Application rate (g/ha)	1 x 325
NOEL (mix) (mg/kg bw)	22.29
TER criterion	5

Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_M (mg/kg bw/d)**	**TER_{LT}**
Screening	Indicator species for screening	64.8	0.53	11.16	**2.0**
Tier 1 (worst case for crop scenario)					
Oilseed rape BBCH 10 – 19 Pulses BBCH 10-19	medium herbivorous/granivorous bird "pigeon"	22.7	0.53	3.91	5.7
Sugar beet late (summer/ autumn) (BBCH 30-49) Fruiting vegetables BBCH 10 – 49 Root and stem vegetables BBCH 10 - 39	Small granivorous bird "finch"	11.4	0.53	1.96	11.4
Sunflower Early (Germination/leaf development) BBCH 00-19	Small insectivorous bird “wagtail”	11.3	0.53	1.95	11.43

Intended use	Energetic plants, ornamentals/nursery
Active substance/product	CHR/F/SCORPIO 325 SC
Application rate (g/ha)	2 x 325 (14 d)
NOEL (mix) (mg/kg bw)	22.29
TER criterion	5

Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDDm (mg/kg bw/d)**	**TER_{LT}**
Screening	Indicator species for screening	18.2	1.4 x 0.53	4.39	5.08

Intended use	Tobacco				
Active substance/product	CHR/F/SCORPIO 325 SC				
Application rate (g/ha)	2 x 325 (14 d)				
NOEL (mix) (mg/kg bw)	22.29				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{LT}**
Screening	Indicator species for screening	64.8	1.4 x 0.53	15.63	**1.43**
Tier 1 (two worst case SVm)					
Maize BBCH 10 - 29	medium herbivorous/granivorous bird "pigeon"	22.7	1.4 x 0.53	5.47	**4.07**
Maize BBCH 30 - 39	medium herbivorous/granivorous bird "pigeon"	11.4	1.4 x 0.53	2.75	8.10

According to results, no unacceptable chronic risk due to combined exposure are obtained in acording to the proposed GAP, except for use in tobacco BBCH 10-29.

~~Conclusion~~
~~The calculated TER_{mix} value is higher than the trigger values, indicating CHR/F/SCORPIO 325 SC does not pose unacceptable acute and long term risk for birds. No further risk refinement is needed.~~

~~Based on TIER 1 assessment SCORPIO 325 SC pose unacceptable long term risk for pigeon at BBCH 10-19.~~

9.2.2.2 Higher-tier risk assessment

~~Not required.~~

The woodpigeon *Columba palumbus* is a widespread and common or abundant species in agricultural and forested landscapes, and partly also in urban areas.

Woodpigeons feed on a wide range of plant material, with seeds or green leaves dominating, depending on season. Seeds from newly sown cereal, pea or rape fields and all types of grain from stubble fields are apparently preferred when available. The summer diet is highly variable and may include up to 5% invertebrates (Christensen et al. 1996[1]). Ljunggren (1968)[2] studied adult crop contents in a rural population of woodpigeons in SW Sweden. The results are presented as percentage of food items by number are given below:

1 Christensen, K.D., Falk, K. & Petersen, B.S. 1996: Feeding Biology of Danish Farmland Birds. Working Report No. 12 1996, Danish Environmental Protection Agency.

[2] Ljunggren, L. 1968. Seasonal studies of Wood Pigeon populations. I. Body weight, feeding habits, liver and thyroid activity. Viltrevy 5: 435-504.

Time of year	Food type	% of food items
Jan – Apr	Plant leaves	52
	Cereal grain	46
	Weed seeds	2
	Rape seeds	1
	Peas	1
May – Aug	Rape seeds	28
	Cereal grain	26
	Peas	16
	Weed seeds	15
	Plant leaves	13
Sep – Nov	Cereal grain	68
	Peas	12
	Plant leaves	9
	Rape seeds	7
	Weed seeds	3

According to Appendix G of EFSA/2009/1438 ratios of daily intake rate to body weight 480g based on given diet composition was calculated:

Food category	PD (% diety)	FE (kJ/ dry g)	MC (%)`	AE (%)	FE (kJ/g fresh)	DEE (kJ)	Daily intake rate (g fresh weight/d)	FIR/bw
Rape seeds	28	21.7	9.9	0.76	4.16	-	10.03	0.02
Cereal grain	26	18.4	14.7	0.76	3.10	-	9.31	0.02
Peas	16	21.7	9.9	0.76	2.38	-	5.73	0.01
Weed seeds	15	21.7	9.9	0.76	2.23	-	5.37	0.01
Plant leaves	13	17.6	76.4	0.53	0.29	-	4.66	0.01
Total	-	-	-	-	12.15	435.25	-	-

The estimated daily exposure, i.e. the uptake of a compound via a single food item:

Table 9.2-15: Higher-tier assessment of long-term exposure for woodpigeon due to the use CHR/F/SCORPIO 325 SC

Intended use		Leafy vegetables maize							
Active substance		difenoconazole							
Application rate (g/ha)		125							
Reprod. toxicity (mg/kg bw/d)		9.71							
TER criterion		5							
Crop	**Food category, % in diet**	**FIR/bw**	**RUD**	**DF**	**MAF_m × TWA**	**Dose (kg s.a./ha)**	**DDD_m (mg/kg bw/d)**	**DDD_m (mg/kg bw/d) sum**	**TER_{LT}**
Maize BBCH 10 – 29 Leafy vegetables BBCH 10–19	Plant leaves	0.01	54.2	1	1.4	0.125	0.09	0.79	12.29
	Cereal grain	0.02	15.0	1	1.4	0.125	0.05		
	Weed seeds	0.01	28.7	1	1.4	0.125	0.05		
	Rape seeds	0.02	28.7	1	1.4	0.125	0.100		
	Peas	0.01	28.7	1	1.4	0.125	0.05		

Review Comments:

The refined reproduction risk assessment for pigeon (use in tobacco), performed by the Applicant was not accepted by the zRMS.
The pigeon is a generic focal species fixed for maize crops. According to EFSA GD (2009), if refinement is required, then it is necessary to progress to the next tier and to use a focal species. The identification of focal species involve surveying fields with the appropriate crop, its correct growth stage and at a time of the year that is relevant to the proposed use. The Applicant did not present any monitoring studies confirming that the pigeon is a focal species for maize or tobacco. Also, the literature data does not pertain to the problematic crop. Therefore, the higher tier risk assessment presented above is not accepted by zRMS.
As a result, unacceptable risk was identified for the application of CHR/F/SCORPIO 325 SC in tobacco BBCH 10-29.

9.2.2.3 Drinking water exposure

When necessary, the assessment of the risk for birds due to uptake of contaminated drinking water is conducted for a small granivorous bird with a body weight of 15.3 g (*Carduelis cannabina*) and a drinking water uptake rate of 0.46 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

Leaf scenario

Since CHR/F/SCORPIO 325 SC is not a product for spray applications / not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

With a K(f)oc of 423, azoxystrobin belongs to the group of less sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied.

For one application:

Effective application rate (g/ha)=	200		
Acute toxicity (mg/kg bw) =	2000	quotient =	0.1
Reprod. toxicity (mg/kg bw/d)=	117	quotient =	1.71

For two application:

Effective application rate (g/ha)=	400		
Acute toxicity (mg/kg bw) =	2000	quotient =	0.2
Reprod. toxicity (mg/kg bw/d)=	117	quotient =	3.42

With a K(f)oc of 3759.4, difenoconazole belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied.

For one application:

Effective application rate (g/ha)=	125		
Acute toxicity (mg/kg bw) =	2000	quotient =	0.0625
Reprod. toxicity (mg/kg bw/d)=	9.71	quotient =	12.9

For two application:

Effective application rate (g/ha)=	250		
Acute toxicity (mg/kg bw) =	2000	quotient =	0.125
Reprod. toxicity (mg/kg bw/d)=	9.71	quotient =	25.75

Review Comments:

The effective application rate should be calculated using following equations:

AR_{eff} = Application rate (g/ha) x MAF_{mean}

where

MAFm = $(1-e^{-nki}) / (1-e^{-ki})$ with $k = \ln(2)/DT_{50}$ (rate constant), n = number of applications and i = application interval [d]

As the Applicant used the cumulative dose in risk assessment, the calculations were not adjusted.

9.2.2.4 Effects of secondary poisoning

The log P_{ow} of azoxystrobin amounts to 2.5 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

The log P_{ow} of Difenoconazole amounts to 4.36 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

Risk assessment for earthworm-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous birds is assessed for a bird of 100 g body weight with a daily food consumption of 104.6 g. Bioaccumulation in earthworms is estimated based on measured/predicted concentrations in soil/porewater / is based on experimental data. To achieve a concise risk assessment, the risk envelope approach is applied.

Table 9.2-16: Assessment of the risk for earthworm-eating birds due to exposure to Difenoconazole via bioaccumulation in earthworms (secondary poisoning) for the intended use (worse case use from GAP table)

Parameter	Difenoconazole	comments
PEC_{soil} (mg/kg soil)	~~0.1637~~ ~~0.2324~~ 0.3881 (accu)	$PEC_{...}$ (the worst case-sunflower)
log P_{ow} / P_{ow}	4.36/22909	
Koc	~~3759.4~~ 2942.9	Mean (geometric – the worst case)
foc	0.02	Default
BCF_{worm}	~~3.67~~ 4.69	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.012 \times P_{ow}) / (foc \times Koc)$
PEC_{worm}	~~0.60~~ ~~1.08~~ 1.82	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	~~0.63~~ ~~1.14~~ 1.91	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	9.71	
TER_{lt}	~~15.4~~ ~~8.52~~ 5.08	

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous birds is assessed for a bird of 1000 g body weight with a daily food consumption of 159 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water / is based on the regulatory acceptable concentration for aquatic organisms as a limit value for admissible concentrations of difenoconazole in water.

Table 9.2-17: Assessment of the risk for fish-eating birds due to exposure to Difenoconazole via bioaccumulation in fish (secondary poisoning) for the intended use (worse case use from GAP table in surface water)

Parameter	Difenoconazole	comments
PEC_{sw} (twa = 21 d) (mg/L)	~~0.017099~~ ~~0.00652~~ 0.00637	~~Step 1 worst case value~~ Step 2 worst case value (pome fruit)
BCF_{fish}	330	
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	~~5.64~~ ~~2.1516~~ 2.1021	PECfish = PECwater × BCFfish
Daily dietary dose (mg/kg bw/d)	~~0.897~~ ~~0.342~~ 0.334	DDD = PECfish × 0.159
NOEL (mg/kg bw/d)	9.71	
TER_{lt}	~~10.8~~ ~~28.39~~ 29.1	

TER values shown in bold fall below the relevant trigger.

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.2.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.2.4 Overall conclusions

~~In conclusion, the acute, short term risk and long term to bird from the proposed uses of difenoconazole and azoxystrobin was found acceptable.~~

Review Comments:

The acute and chronic risks of CHR/F/SCORPIO 325 SC to birds were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with active ingredients, and maximum residues occurring on food items.

All TER values exceed the relevant triggers indicating that CHR/F/SCORPIO 325 SC does not pose an unacceptable risk to birds following applications according to recommended use pattern, except for use in tobacco BBCH 10-29.

Evaluation of exposing to birds through the drinking water demonstrated the acceptable risk. The risk to earthworm- and fish-eating animals from secondary poisoning is low.

9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with azoxystrobin. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on mammals of CHR/F/SCORPIO 325 SC were not evaluated as part of the EU assessment of azoxystrobin and difenoconazole.

Table 9.3-1: Endpoints and effect values relevant for the risk assessment for mammals

Species	Substance	Exposure System	Results	Reference
Rat	Azoxystrobin	Acute	LD50 >5000 mg/kg bw	EFSA Journal 2010; 8(4):1542
Rat	Azoxystrobin	Long term	NOEL= 32 mg a.s/kg bw/d	EFSA Journal 2010; 8(4):1542
Rat	Difenoconazole	Acute	LD50 >1453 mg/kg bw	EFSA Journal 2011;9(1):1967
Rat	Difenoconazole	Long term	NOEL= 17.3 mg a.s/kg bw/d	EFSA Journal 2011;9(1):1967

9.3.1.1 Justification for new endpoints

Not required.

9.3.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Mammals and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).
To achieve a concise risk assessment, the risk envelope approach is applied.

9.3.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

Table 9.3-2: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CHR/F/SCORPIO 325 SC

Intended use	oilseed rape, sugar beet, ~~fruiting vegetables~~, root vegetables, sunflower				
Active substance/product	Azoxystrobin				
Application rate (g/ha)	1 x 200				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Bulbs and onion like crops, cereals, oilseed rape, potatoes, root and stem vegetables, strawberries, sugar beet, and sunflower	Small herbivorous mammal	118.4	1	23.68	211.1
Reprod. toxicity (mg/kg bw/d)	32				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bulbs and onion like crops, cereals, oilseed rape, potatoes, root and stem vegetables, strawberries, sugar beet, and sunflower	Small herbivorous mammal	48.3	0.53	5.12	6.25

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-3: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CHR/F/SCORPIO 325 SC

Intended use	Ornamentals and nursery				
Active substance/product	Azoxystrobin				
Application rate (g/ha)	1 x 200				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard	Small herbivorous mammal	136.4	1	27.28	183.3
Reprod. toxicity (mg/kg bw/d)	32				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard	Small herbivorous mammal	72.3	0.53	7.66	**4.18**
Tier 1					
Ornamentals and nursery Application crop directed BBCH ≥ 50	Small omnivorous mammal "mouse" Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	3.9	-	-	77.4
Ornamentals and nursery Application crop directed BBCH 10 - 49	Small omnivorous mammal "mouse" Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	7.8	-	-	38.7
Ornamentals and nursery Application to plant – exposure to underlying ground	Small insectivorous mammal "shrew" Ground dwelling invertebrates with interception 100% ground arthropods	1.9	-	-	158.9
Ornamentals and nursery BBCH ≥ 50	Small herbivorous mammal "vole Grass + cereals 100% grass	36.1	-	-	8.4
Ornamentals and nursery BBCH 40 - 49	Small herbivorous mammal "vole Grass + cereals 100% grass	72.3	-	-	**4.2**

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Intended use	Ornamentals and nursery				
Active substance/product	Azoxystrobin				
Application rate (g/ha)	2 x 200 (14 d)				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard	Small herbivorous mammal	136.4	1.2	32.74	152.7
Reprod. toxicity (mg/kg bw/d)	32				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard	Small herbivorous mammal	72.3	1.4 x 0.53	10.73	**3.5**
Tier 1					
Ornamentals and nursery Application crop directed BBCH ≥ 50	Small omnivorous mammal “mouse”	3.9	1.4 x 0.53	0.58	55.2
Ornamentals and nursery Application crop directed BBCH 10 - 49	Small omnivorous mammal “mouse”	7.8	1.4 x 0.53	1.16	27.6
Ornamentals and nursery Application to plant – exposure to underlying ground	Small insectivorous mammal “shrew”	1.9	1.4 x 0.53	0.28	114.3
Ornamentals and nursery BBCH ≥ 50	Small herbivorous mammal "vole”	36.1	1.4 x 0.53	5.35	6.0
Ornamentals and nursery BBCH 40 - 49	Small herbivorous mammal "vole”	72.3	1.4 x 0.53	10.73	**3.5**

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-4: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CHR/F/SCORPIO 325 SC

Intended use	Fruiting vegetables				
Active substance/product	Azoxystrobin				
Application rate (g/ha)	1 x 200				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard	Small herbivorous mammal	136.4	1	27.28	183.3
Reprod. toxicity (mg/kg bw/d)	32				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard	Small herbivorous mammal	72.3	0.53	7.66	**4.18**
Tier 1					
Fruiting vegetables BBCH ≥ 20	Small insectivorous mammal “shrew” ground dwelling invertebrates with interception 100% ground arthropods	1.9	-	-	158.9
Fruiting vegetables BBCH ≥ 50	Small herbivorous mammal "vole Grass + cereals 100% grass	21.7	-	-	13.9
Fruiting vegetables BBCH ≥ 50	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	2.3	-	-	131.3
Fruiting vegetables BBCH 10 - 19	Small insectivorous mammal “shrew” ground dwelling invertebrates without interception 100% ground arthropods	4.2	-	-	71.9
Fruiting vegetables BBCH 10 - 49	Small herbivorous mammal "vole Grass + cereals 100% grass	72.3	-	-	**4.2**
Fruiting vegetables BBCH 10 - 49	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50%	7.8	-	-	38.7

	weed seeds 25% ground arthropods				
~~Fruiting vegetables Fruit stage BBCH 71-89~~	~~Frugivorous mammal "rat" Gourds 100% fruit~~	~~25.2~~	-	-	~~12.0~~

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-5: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CHR/F/SCORPIO 325 SC in pulses ~~Leafy vegetables (ornamentals plants h<50cm)~~

Intended use	Pulses				
Active substance/product	Azoxystrobin				
Application rate (g/ha)	1 x 200				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard	Small herbivorous mammal	136.4	1	27.28	183.3
Reprod. toxicity (mg/kg bw/d)	32				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard	Small herbivorous mammal	72.3	0.53	7.66	**4.18**
Tier 1					
Pulses BBCH 10-19	Small insectivorous mammal "shrew"	4.2	0.53	0.45	71.1
Pulses BBCH ≥ 20	Small insectivorous mammal "shrew"	1.9	0.53	0.20	160
Pulses BBCH 40-49	Small herbivorous mammal "vole"	72.3	0.53	7.66	**4.18**
Pulses BBCH ≥ 50	Small herbivorous mammal "vole"	21.7	0.53	2.30	13.9
Pulses BBCH 10-49	Large herbivorous mammal "lagomorph"	14.3	0.53	1.52	21.05
Pulses BBCH ≥ 50	Large herbivorous mammal "lagomorph"	4.3	0.53	0.46	69.6

Pulses BBCH 10-49	Small omnivorous mammal “mouse”	7.8	0.53	0.83	38.6
Pulses BBCH ≥ 50	Small omnivorous mammal “mouse”	2.3	0.53	0.24	133.3

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Intended use Active substance/product Application rate (g/ha)	Leafy vegetables (ornamentals-plants h<50cm) Azoxystrobin 2 x 200				
Acute toxicity (mg/kg bw) TER criterion	5000 10				
Crop scenario Growth stage	Indicator/generic focal species	SV_{ac}	MAF_{ac}	DDD_{ac} (mg/kg bw/d)	TER_A
Leafy vegetables	Small herbivorous mammal	136.4	1.2	32.74	152.7
Reprod. toxicity (mg/kg bw/d) TER criterion	4.2 5				
Crop scenario Growth stage	Indicator/generic focal species	SV_{st}	MAF_{st} x TWA	DDD_{st} (mg/kg bw/d)	TER_{lt}
Leafy vegetables	Small herbivorous mammal	72.3	1.4	10.73	2.08
Tier I					
Leafy vegetables All season	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Non-grass herbs	14.3	1	1	15.1
Leafy vegetables BBCH ≥20	Small insectivorous mammal “shrew” ground-dwelling invertebrates with interception 100% ground arthropods	4.9	1	1	43.5
Leafy vegetables BBCH ≥50	Small herbivorous mammal “vole Grass –cereals 100% grass	21.7	1	1	8.9
Leafy vegetables BBCH ≥50	Small omnivorous “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	2.3	1	1	92.9
Leafy vegetables BBCH 10-49	Small insectivorous mammal “shrew” Ground-dwelling invertebrates without interception 100%	4.2	1	1	54.3
Leafy vegetables BBCH 10-49	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	7.8	1	1	27.6
Leafy vegetables BBCH 10-49	Small herbivorous mammal “vole Grass –cereals 100% grass	72.3	1	1	8.9

Table 9.3-6: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CHR/F/SCORPIO 325 SC in Orchards ~~(ornamentals plants h<50cm)~~

Intended use	Orchards (energetic plants)				
Active substance/product	Azoxystrobin				
Application rate (g/ha)	2 x 160 (14 d)				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard	Small herbivorous mammal	136.4	1.2	26.19	190.9
Reprod. toxicity (mg/kg bw/d)	32				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard	Small herbivorous mammal	72.3	1.4 x 0.53	8.58	**3.7**
Tier 1					
Orchards BBCH < 10	Small insectivorous mammal “shrew”	1.9	1.4 x 0.53	0.23	139.1
Orchards BBCH < 10	Small herbivorous mammal “vole”	72.3	1.4 x 0.53	8.58	**3.7**
Orchards BBCH 10-19	Small herbivorous mammal “vole”	57.8	1.4 x 0.53	6.86	**4.7**
Orchards BBCH 20-40	Small herbivorous mammal “vole”	43.4	1.4 x 0.53	5.15	6.2
Orchards BBCH ≥ 40	Small herbivorous mammal “vole”	21.7	1.4 x 0.53	2.58	12.4
Orchards BBCH < 10	Large herbivorous mammal “lagomorph”	14.3	1.4 x 0.53	1.70	18.8
Orchards BBCH 10-19	Large herbivorous mammal “lagomorph”	11.5	1.4 x 0.53	1.37	23.4
Orchards BBCH 20-40	Large herbivorous mammal “lagomorph”	8.6	1.4 x 0.53	1.02	31.4
Orchards BBCH ≥ 40	Large herbivorous mammal “lagomorph”	4.3	1.4 x 0.53	0.51	62.7

Intended use	Orchards (energetic plants)				
Active substance/product	Azoxystrobin				
Application rate (g/ha)	2 x 160 (14 d)				
Orchards BBCH < 10	Small omnivorous mammal “mouse”	7.8	1.4 x 0.53	0.93	34.4
Orchards BBCH 10-19	Small omnivorous mammal “mouse”	6.2	1.4 x 0.53	0.74	43.2
Orchards BBCH 20-40	Small omnivorous mammal “mouse”	4.7	1.4 x 0.53	0.56	57.1
Orchards BBCH ≥ 40	Small omnivorous mammal “mouse”	2.3	1.4 x 0.53	0.27	118.5

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Intended use	Orchards (Ornamental nursery plants h=50cm, forest nursery plants, renewals, afforestation and plantations of forest trees, Energetic plants, Salix viminalis, Wicker)				
Active substance/product	Azoxystrobin				
Application rate (g/ha)	2 x 200				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	Indicator/generic focal species	SV_{50}	MAF_{50}	DDD_{50} (mg/kg bw/d)	TER_A
Orchards	Small herbivorous mammal	136.4	1.2	22.73	152.7
Repeod. toxicity (mg/kg bw/d)	3.2				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV_{90}	MAF_{90} x TWA	DDD_{90} (mg/kg bw/d)	TER_A
Orchards and ornamentals nursery	Small herbivorous mammal	72.2	1.4	10.73	2.98
Tier I					
Orchard BBCH<10 or not crop directed	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Non-grass herbs	14.3	1	1	15.1
Orchard BBCH<10 or not crop directed	Small herbivorous mammal “vole Grass – cereals 100% grass	72.2	1	1	3.0
Orchard BBCH<10 or not crop directed	Small insectivorous mammal “shrew” – Ground dwelling invertebrates with interception 100% ground arthropods	1.9	1	1	113.5
Orchard BBCH<10 or not crop directed	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds, 50% weed seeds, 25% ground arthropods	7.8	1	1	27.6

Table 9.3-7: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CHR/F/SCORPIO 325 SC in maize ~~Vineyard~~ (surrogate crop: tobacco)

Intended use	Maize				
Active substance/product	Azoxystrobin				
Application rate (g/ha)	2 x 200 (14 d)				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard	Small herbivorous mammal	136.4	1.2	32.74	152.7
Reprod. toxicity (mg/kg bw/d)	32				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard	Small herbivorous mammal	72.3	1.4 x 0.53	10.73	**3.5**
Tier 1					
Maize BBCH 10-19	Small insectivorous mammal "shrew"	4.2	1.4 x 0.53	0.62	51.6
Maize BBCH ≥ 20	Small insectivorous mammal "shrew"	1.9	1.4 x 0.53	0.28	114.3
Maize BBCH 10-29	Small herbivorous mammal "vole"	72.3	1.4 x 0.53	10.73	**3.5**
Maize BBCH 30-39	Small herbivorous mammal "vole"	36.1	1.4 x 0.53	5.36	6.0
Maize BBCH ≥ 40	Small herbivorous mammal "vole"	18.1	1.4 x 0.53	2.69	11.9
Maize BBCH 10-29	Small omnivorous mammal "mouse"	7.8	1.4 x 0.53	1.16	27.6
Maize BBCH 30-39	Small omnivorous mammal "mouse"	3.9	1.4 x 0.53	0.58	55.2
Maize BBCH ≥ 40	Small omnivorous mammal "mouse"	1.9	1.4 x 0.53	0.28	114.3

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Intended use Active substance/product Application rate (g/ha)	Vineyard (surrogate crop: tobacco) Azoxystrobin 2 x 200				
Acute toxicity (mg/kg bw) TER criterion	5000 10				
Crop scenario Growth stage	Indicator/generic focal species	SV_{50}	MAF_{50}	DDD_{50} (mg/kg bw/d)	TER_A
Orchards and ornamentals/nursery	Small herbivorous mammal	136.4	1.2	32.74	152.7
Repred. toxicity (mg/kg bw/d) TER criterion	4.2 5				
Crop scenario Growth stage	Indicator/generic focal species	SV_{50}	MAF_{50} x TWA	DDD_{50} (mg/kg bw/d)	TER_{LT}
Orchards and ornamentals/nursery	Small herbivorous mammal	72.3	14.46	10.73	2.08
Tier 1					
Vineyard Application crop directed BBCH 30-40	Small herbivorous mammal "vole Grass + cereals 100% grass"	21.7	1	1	8.9
Vineyard Application crop directed BBCH 30-40	Small omnivorous mammal "mouse" Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	2.3	1	1	93.8
Vineyard Application crop directed BBCH 10-19	Small herbivorous mammal "vole Grass + cereals 100% grass"	43.4	1	1	5.0
Vineyard Application crop directed BBCH 10-19	Small omnivorous mammal "mouse" Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	4.7	1	1	45.9
Vineyard Application crop directed BBCH 20-39	Small herbivorous mammal "vole Grass + cereals 100% grass"	36.1	1	1	6.0
Vineyard Application crop directed BBCH 20-39	Small omnivorous mammal "mouse" Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	3.9	1	1	55.2
Vineyard BBCH ≥ 20	Small insectivorous mammal "shrew" ground dwelling invertebrates with interception 100% ground arthropods	1.9	1	1	112.5
Vineyard BBCH ≥ 40	Large herbivorous mammal "ß-geomorph" Non-grass herbs 100% Plant matter	3.3	1	1	65.2

Vineyard BBCH 10-19	Small insectivorous mammal "shrew" ground dwelling invertebrates without interception 100% ground arthropods	4.2	1	1	51.3
Vineyard BBCH 10-19	Large herbivorous mammal "lagomorph" Non-grass herbs 100% Plant matter	6.7	1	1	32.2
Vineyard BBCH 20-39	Large herbivorous mammal "lagomorph" Non-grass herbs 100% Plant matter	5.5	1	1	39.2

Table 9.3-58: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CHR/F/SCORPIO 325 SC

Intended use	oilseed rape, sugar beet, root vegetables, sunflower				
Active substance/product	Difenoconazole				
Application rate (g/ha)	1 x 125				
Acute toxicity (mg/kg bw)	1453				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Bulbs and onion like crops, cereals, oilseed rape, potatoes, root and stem vegetables, strawberries, sugar beet, and sunflower	Small herbivorous mammal	118.4	1	14.80	98.2
Reprod. toxicity (mg/kg bw/d)	17.3				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bulbs and onion like crops, cereals, oilseed rape, potatoes, root and stem vegetables, strawberries, sugar beet, and sunflower	Small herbivorous mammal	48.3	0.53	3.20	5.41

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-69: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CHR/F/SCORPIO 325 SC

Intended use	Ornamentals and nursery				
Active substance/product	Difenoconazole				
Application rate (g/ha)	1 x 125				
Acute toxicity (mg/kg bw)	1453				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard	Small herbivorous mammal	136.4	1	17.05	85.2
Reprod. toxicity (mg/kg bw/d)	17.3				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard	Small herbivorous mammal	72.3	0.53	4.79	**3.61**
Tier 1					
Ornamentals and nursery Application crop directed BBCH ≥ 50	Small omnivorous mammal "mouse" Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	3.9	-	-	67.0
Ornamentals and nursery Application crop directed BBCH 10 - 49	Small omnivorous mammal "mouse" Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	7.8	-	-	33.5
Ornamentals and nursery Application to plant – exposure to underlying ground	Small insectivorous mammal "shrew" Ground dwelling invertebrates with interception 100% ground arthropods	1.9	-	-	137.4
Ornamentals and nursery BBCH ≥ 50	Small herbivorous mammal "vole Grass + cereals 100% grass	36.1	-	-	7.2
Ornamentals and nursery BBCH 40 - 49	Small herbivorous mammal "vole Grass + cereals 100% grass	72.3	-	-	**3.6**

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Intended use	Ornamentals and nursery				
Active substance/product	Difenoconazole				
Application rate (g/ha)	2 x 125 (14 d)				
Acute toxicity (mg/kg bw)	1453				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard	Small herbivorous mammal	136.4	1.2	20.46	71.0
Reprod. toxicity (mg/kg bw/d)	17.3				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard	Small herbivorous mammal	72.3	1.4 x 0.53	6.71	**2.6**
Tier 1					
Ornamentals and nursery Application crop directed BBCH ≥ 50	Small omnivorous mammal “mouse”	3.9	1.4 x 0.53	0.36	48.1
Ornamentals and nursery Application crop directed BBCH 10 - 49	Small omnivorous mammal “mouse”	7.8	1.4 x 0.53	0.72	24.0
Ornamentals and nursery Application to plant – exposure to underlying ground	Small insectivorous mammal “shrew”	1.9	1.4 x 0.53	0.18	96.1
Ornamentals and nursery BBCH ≥ 50	Small herbivorous mammal "vole”	36.1	1.4 x 0.53	3.35	5.2
Ornamentals and nursery BBCH 40 - 49	Small herbivorous mammal "vole”	72.3	1.4 x 0.53	6.71	**2.6**

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Table 9.3-~~710~~: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CHR/F/SCORPIO 325 SC

Intended use	Fruiting vegetables				
Active substance/product	Difenoconazole				
Application rate (g/ha)	1 x 125				
Acute toxicity (mg/kg bw)	1453				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard	Small herbivorous mammal	136.4	1	17.05	85.2
Reprod. toxicity (mg/kg bw/d)	17.3				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard	Small herbivorous mammal	72.3	0.53	4.79	**3.61**
Tier 1					
Fruiting vegetables BBCH ≥ 20	Small insectivorous mammal “shrew” ground dwelling invertebrates with interception 100% ground arthropods	1.9	-	-	137.4
Fruiting vegetables BBCH ≥ 50	Small herbivorous mammal "vole Grass + cereals 100% grass	12.0	-	-	12.0
Fruiting vegetables BBCH ≥ 50	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	113.5	-	-	113.5
Fruiting vegetables BBCH 10 - 19	Small insectivorous mammal “shrew” ground dwelling invertebrates without interception 100% ground arthropods	62.2	-	-	62.2
Fruiting vegetables BBCH 10 - 49	Small herbivorous mammal "vole Grass + cereals 100% grass	72.3	-	-	**3.6**
Fruiting vegetables BBCH 10 - 49	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50%	7.8	-	-	33.5

	weed seeds 25% ground arthropods				
~~Fruiting vegetables Fruit stage BBCH 71-89~~	~~Frugivorous mammal "rat" Gourds 100% fruit~~	~~25.2~~	-	-	~~10.4~~

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-11: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CHR/F/SCORPIO 325 SC in pulses ~~Leafy vegetables (ornamental plants h<50cm)~~

Intended use	Pulses				
Active substance/product	Difenoconazole				
Application rate (g/ha)	1 x 125				
Acute toxicity (mg/kg bw)	1453				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard	Small herbivorous mammal	136.4	1	17.05	85.2
Reprod. toxicity (mg/kg bw/d)	17.3				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard	Small herbivorous mammal	72.3	0.53	4.79	**3.6**
Tier 1					
Pulses BBCH 10-19	Small insectivorous mammal “shrew”	4.2	0.53	0.28	61.8
Pulses BBCH ≥ 20	Small insectivorous mammal “shrew”	1.9	0.53	0.13	133.1
Pulses BBCH 40-49	Small herbivorous mammal "vole”	72.3	0.53	4.79	**3.6**
Pulses BBCH ≥ 50	Small herbivorous mammal "vole”	21.7	0.53	1.44	12.0
Pulses BBCH 10-49	Large herbivorous mammal “lagomorph”	14.3	0.53	0.95	18.2
Pulses BBCH ≥ 50	Large herbivorous mammal “lagomorph”	4.3	0.53	0.28	61.8

Intended use	Pulses				
Active substance/product	Difenoconazole				
Application rate (g/ha)	1 x 125				
Pulses BBCH 10-49	Small omnivorous mammal “mouse”	7.8	0.53	0.52	33.3
Pulses BBCH ≥ 50	Small omnivorous mammal “mouse”	2.3	0.53	0.15	115.3

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Intended use	Leafy vegetables (ornamental plants h=50cm)				
Active substance/product	Difenoconazole				
Application rate (g/ha)	2 x 125				
Acute toxicity (mg/kg bw)	1453				
TER criterion	10				
Crop scenario Growth stage	Indicator/generic focal species	SV_{ao}	MAF_{ao}	DDD_{ao} (mg/kg bw/d)	TER_a
Leafy vegetables	Small herbivorous mammal	136.4	1.2	17.05	71.0
Reprod. toxicity (mg/kg bw/d)	17.3				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV_{as}	MAF_{as} x TWA	DDD_{as} (mg/kg bw/d)	TER_{as}
Leafy vegetables	Small herbivorous mammal	72.3	3.04	6.71	2.58
First Tier Risk Assessment					
Leafy vegetables All season	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Non-grass herbs	14.2	1	1	13.0
Leafy vegetables BBCH>20	Small insectivorous mammal “shrew” ground dwelling invertebrates with interception 100% ground arthropods	1.9	1	1	08.2
Leafy vegetables BBCH>50	Small herbivorous mammal “vole Grass +cereals 100% grass	21.7	1	1	91.1
Leafy vegetables BBCH>50	Small omnivorous “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	2.3	1	1	44.4
Leafy vegetables BBCH 10-19	Small insectivorous mammal “shrew” Ground dwelling invertebrates without interception 100%	4.7	1	1	73.9
Leafy vegetables BBCH 10-49	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50%	2.8	1	1	23.8

	weed seeds 75% ground arthropods				
leafy vegetables BBCH 40–49	Small herbivorous mammal ~vole Grass =cereals 100% grass	72.3	1	1	2.4

SV: shortcut value, MAF: multiple application factor, TWA: time-weighted average factor, DDD: daily dietary dose, TER: toxicity-to-exposure ratio, TER values shown in bold fall below the relevant trigger.

Table 9.3-12: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CHR/F/SCORPIO 325 SC in Orchards (Ornamental nursery plants h>50cm, forest nursery plants, renewals, afforestation and plantations of forest trees, Energetic plants, Salix viminalis, Wicker)

Intended use	Orchards (energetic plants)				
Active substance/product	Difenoconazole				
Application rate (g/ha)	2 x 100 (14 d)				
Acute toxicity (mg/kg bw)	1453				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard	Small herbivorous mammal	136.4	1.2	16.37	88.8
Reprod. toxicity (mg/kg bw/d)	17.3				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard	Small herbivorous mammal	72.3	1.4 x 0.53	5.36	**3.22**
Tier 1					
Orchards BBCH < 10	Small insectivorous mammal “shrew”	1.9	1.4 x 0.53	0.14	123.6
Orchards BBCH < 10	Small herbivorous mammal “vole”	72.3	1.4 x 0.53	5.36	**3.22**
Orchards BBCH 10-19	Small herbivorous mammal “vole”	57.8	1.4 x 0.53	4.29	**4.03**
Orchards BBCH 20-40	Small herbivorous mammal “vole”	43.4	1.4 x 0.53	3.22	5.4
Orchards BBCH ≥ 40	Small herbivorous mammal “vole”	21.7	1.4 x 0.53	1.61	10.7

Intended use	Orchards (energetic plants)				
Active substance/product	Difenoconazole				
Application rate (g/ha)	2 x 100 (14 d)				
Orchards BBCH < 10	Large herbivorous mammal “lagomorph”	14.3	1.4 x 0.53	1.06	16.3
Orchards BBCH 10-19	Large herbivorous mammal “lagomorph”	11.5	1.4 x 0.53	0.85	20.4
Orchards BBCH 20-40	Large herbivorous mammal “lagomorph”	8.6	1.4 x 0.53	0.64	27.0
Orchards BBCH ≥ 40	Large herbivorous mammal “lagomorph”	4.3	1.4 x 0.53	0.32	54.1
Orchards BBCH < 10	Small omnivorous mammal “mouse”	7.8	1.4 x 0.53	0.58	29.8
Orchards BBCH 10-19	Small omnivorous mammal “mouse”	6.2	1.4 x 0.53	0.46	37.6
Orchards BBCH 20-40	Small omnivorous mammal “mouse”	4.7	1.4 x 0.53	0.35	50.4
Orchards BBCH ≥ 40	Small omnivorous mammal “mouse”	2.3	1.4 x 0.53	0.17	101.8

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Intended use	Orchards				
Active substance/product	Difenoconazole				
Application rate (g/ha)	2 x 125				
Acute toxicity (mg/kg bw)	1453				
TER criterion	10				
Crop scenario Growth stage	Indicator/generic focal species	SV_{90}	MAF_{90}	DDD_{90} (mg/kg bw/d)	TER_A
Orchards	Small herbivorous mammal	136.4	1.2	17.05	71.0
Repeod. toxicity (mg/kg bw/d)	17.2				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV_{90}	MAF_{90} x TWA	DDD_{90} (mg/kg bw/d)	TER_A
Orchards	Small herbivorous mammal	72.3	1.4	9.04	2.58
First Tier Risk Assessment					
Orchard Application crop directed BBCH <10 or not crop directed	Large herbivorous mammal “lagomorph” Non-grass herbs 100% Non-grass herbs	14.3	1	1	13.0
Orchard Application crop directed BBCH <10 or not crop directed	Small herbivorous mammal “vole Grass +cereals 100% grass	72.3	1	1	2.6
Orchard Application crop directed BBCH <10 or not crop	Small insectivorous mammal “shrew” Ground dwelling invertebrates with interception	4.0	1	1	08.2

directed	100% ground arthropods				
Orchard Application crop directed BBCH <10 or not crop directed	Small omnivorous "mouse" Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	7.8	1	1	23.9

SV: shortcut value; MAF: multiple application factor; TWA: time weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-13: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of CHR/F/SCORPIO 325 SC in maize Vineyard (surrogate crop: tobacco)

Intended use	Maize				
Active substance/product	Difenoconazole				
Application rate (g/ha)	2 x 125 (14 d)				
Acute toxicity (mg/kg bw)	1453				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard	Small herbivorous mammal	136.4	1.2	20.46	71.0
Reprod. toxicity (mg/kg bw/d)	17.3				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard	Small herbivorous mammal	72.3	1.4 x 0.53	6.71	**2.6**
Tier 1					
Maize BBCH 10-19	Small insectivorous mammal "shrew"	4.2	1.4 x 0.53	0.39	44.4
Maize BBCH ≥ 20	Small insectivorous mammal "shrew"	1.9	1.4 x 0.53	0.18	96.1
Maize BBCH 10-29	Small herbivorous mammal "vole"	72.3	1.4 x 0.53	6.71	**2.6**
Maize BBCH 30-39	Small herbivorous mammal "vole"	36.1	1.4 x 0.53	3.35	5.2
Maize BBCH ≥ 40	Small herbivorous mammal "vole"	18.1	1.4 x 0.53	1.68	10.3

Intended use	Maize				
Active substance/product	Difenoconazole				
Application rate (g/ha)	2 x 125 (14 d)				
Maize BBCH 10-29	Small omnivorous mammal “mouse”	7.8	1.4 x 0.53	0.72	24.0
Maize BBCH 30-39	Small omnivorous mammal “mouse”	3.9	1.4 x 0.53	0.36	48.0
Maize BBCH ≥ 40	Small omnivorous mammal “mouse”	1.9	1.4 x 0.53	0.18	96.1

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger

Intended use	Vineyard (surrogate crop: tobacco)				
Active substance/product	Difenoconazole				
Application rate (g/ha)	2 x 125				
Acute toxicity (mg/kg bw)	1453				
TER criterion	10				
Crop scenario Growth stage	Indicator/generic focal species	SV_{50}	MAF_{50}	DDD_{50} (mg/kg bw/d)	TER_A
Vineyard (surrogate crop: tobacco)	Small herbivorous mammal	136.4	1.2	17.05	71.0
Reprod. toxicity (mg/kg bw/d)	17.3				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV_{90}	MAF_{90} x TWA	DDD_{90} (mg/kg bw/d)	TER_A
Vineyard (surrogate crop: tobacco)	Small herbivorous mammal	72.3	1.4	6.71	2.58
First Tier Assessment					
Vineyard Application crop directed BBCH ≥ 40	Small herbivorous mammal “vole Grass + cereals 100% grass	21.7	1	1	8.6
Vineyard Application crop directed BBCH ≥ 40	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	9.3	1	1	81.1
Vineyard Application crop directed BBCH 10-19	Small herbivorous mammal “vole Grass + cereals 100% grass”	43.4	1	1	4.3
Vineyard Application crop directed BBCH 10-19	Small omnivorous mammal “mouse” Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	4.7	1	1	39.7
Vineyard Application crop directed BBCH 20-39	Small herbivorous mammal “vole Grass + cereals 100% grass”	36.1	1	1	5.2

Vineyard Application crop directed BBCH 20-39	Small omnivorous mammal "mouse" Combination (invertebrates without interception) 25% weeds- 50% weed seeds-25% ground arthropods	5.9	-	-	47.8
Vineyard BBCH ≥ 20	Small insectivorous mammal "shrew" ground dwelling invertebrates with interception 100% ground arthropods	1.9	-	-	08.7
Vineyard BBCH ≥ 40	Large herbivorous mammal "lagomorph" Non-grass herbs 100% Plant matter	8.3	-	-	56.5
Vineyard BBCH 10-19	Small insectivorous mammal "shrew" ground dwelling invertebrates without interception 100% ground arthropods	4.2	-	-	44.4
Vineyard BBCH 10-19	Large herbivorous mammal "lagomorph" Non-grass herbs 100% Plant matter	6.7	-	-	27.8
Vineyard BBCH 20-39	Large herbivorous mammal "lagomorph" Non-grass herbs 100% Plant matter	5.5	-	-	22.9

SV: shortest value, MAF: multiple application factor, TWA: time weighted average factor, DDD: daily dietary dose, TER: toxicity to exposure ratio, TER values shown in bold fall below the relevant trigger.

Review Comments:

The active substances content of CHR/F/SCORPIO 325 SC is 20% azoxystrobin and 12.5% difenoconazole, making up a total of 325 g a.s./L product. According to GAP, the maximum application rate is 1 L product/ha, therefore, an application rate of 325 g a.s./ha was considered in the assessment. For energetic plants the application rate of 0.8 L product/ha (260 g sum a.s./ha) was evaluated.

Acute risks from combined exposure

Step 1 – "tox per fraction" assessment

	Azoxystrobin	Difenoconazole	"mix"
Content in the formulation [g/L]	200	125	325
Fraction in mixture	0.6154	0.3846	1.0
LD_{50} (mg/kg bw)	5000	1453	2578.77
Tox per fraction	8125	3777.8	2578.77
Contribution to predicted toxicity	31.74%	68.26%	

Azoxystrobin contributes to 31.74% to mixture toxicity, while the difenoconazole have an impact on the predicted risk of 68.26%, therefore, surrogate LD_{50} need to be calculated.

Step 2 - the calculation of the predicted LD_{50} (mix)
For the calculation, the following equation was used:

$$LD_{50}(\text{mix}) = \left(\sum_i \frac{X(a.s_i)}{LD_{50}(a.s_i)} \right)^{-1}$$

With:

X (a.s.$_i$) = fraction of each a.s. in the mixture
LD_{50} (a.s.$_i$) = acute toxicity value for each a.s.

	Azoxystrobin	Difenoconazole
Content in the formulation [g/L]	200	125
Fraction in the a.s. mixture	0.6154	0.3846
LD_{50} of a.s. [mg/kg bw]	5000	1453
Fraction / LD_{50}	0.00012	0.00026
Sum	0.00039	
1/ sum = predicted LD_{50} (mix)	2578.77 mg mix/kg bw	

Step 3 – the acute risk assessment using surrogate LD_{50}

Screening step assessment of the acute risk for mammals due to the use of CHR/F/SCORPIO 325 SC.

Intended use	All crops - one application
Active substance/product	CHR/F/SCORPIO 325 SC
Application rate (g/ha)	1 x 325
LD_{50} (mix) (mg/kg bw)	2578.77
TER criterion	10

Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening	Indicator species for screening	118.4	1.0	38.48	67.0
		136.4	1.0	44.33	58.2

Intended use	Ornamentals/nursery, tobacco
Active substance/product	CHR/F/SCORPIO 325 SC
Application rate (g/ha)	2 x 325 (14 d)
LD_{50} (mix) (mg/kg bw)	2578.77
TER criterion	10

Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening	Indicator species for screening	136.4	1.2	53.20	48.5

Intended use	Energetic plants
Active substance/product	CHR/F/SCORPIO 325 SC
Application rate (g/ha)	2 x 260 (14 d)
LD_{50} (mix) (mg/kg bw)	2578.77
TER criterion	10

Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening	Indicator species for screening	136.4	1.2	42.56	60.6

According to results, no unacceptable acute risk due to combined exposure are obtained in acording to the proposed GAP.

Reproductive risks from combined exposure

Step 1 – "tox per fraction" assessment

	Azoxystrobin	Difenoconazole	"mix"
Content in the formulation [g/L]	200	125	325
Fraction in mixture	0.6154	0.3846	1.0
NOEL (mg/kg bw)	32	17.3	24.12
Tox per fraction	52.00	44.98	24.12
Contribution to predicted toxicity	46.38%	53.62%	

Azoxystrobin contributes to 46.38% to mixture toxicity, while the difenoconazole have an impact on the predicted risk of 53.62%, therefore, surrogate NOEL need to be calculated.

Step 2 - the calculation of the predicted NOEL

	Azoxystrobin	Difenoconazole
Content in the formulation [g/L]	200	125
Fraction in the a.s. mixture	0.6154	0.3846
NOEL of a.s. [mg/kg bw]	32	17.3
Fraction / LD_{50}	0.01923	0.02223
Sum	0.04146	
1/ sum = predicted LD_{50} (mix)	24.12 mg mix/kg bw	

Step 3 – the chronic risk assessment using surrogate NOEL

Screening step assessment of the chronic risk for mammals due to the use of CHR/F/SCORPIO 325 SC.

Intended use	Oilseed rape, sugar beet, root vegetables, sunflower
Active substance/product	CHR/F/SCORPIO 325 SC
Application rate (g/ha)	1 x 325
NOEL (mix) (mg/kg bw)	24.12
TER criterion	5

Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_M (mg/kg bw/d)**	**TER_{LT}**
Screening	Indicator species for screening	48.3	0.53	8.32	**2.9**
Tier 1 (worst case for crop scenario)					
Oilseed rape BBCH ≥ 40 Sugar beet BBCH ≥ 40 Sunflower ≥ 40	Small herbivorous mammal "vole"	18.1	0.53	3.12	7.7
Root and stem vegetables BBCH ≥ 40	Small herbivorous mammal "vole"	21.7	0.53	3.74	6.45

Intended use	Fruiting vegetables, pulses
Active substance/product	CHR/F/SCORPIO 325 SC
Application rate (g/ha)	1 x 325
NOEL (mix) (mg/kg bw)	24.12
TER criterion	5

Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_M (mg/kg bw/d)**	**TER_{LT}**
Screening	Indicator species for screening	72.3	0.53	12.45	**1.93**
Tier 1 (two worst case SVm values for crop scenario)					
Pulses BBCH 40-49 Fruiting vegetables BBCH 10-49	Small herbivorous mammal "vole"	72.3	0.53	12.45	**1.93**
Pulses BBCH ≥ 50 Fruiting vegetables BBCH ≥ 50	Small herbivorous mammal "vole"	21.7	0.53	3.74	6.45

Intended use	Ornamentals/nursery, tobacco
Active substance/product	CHR/F/SCORPIO 325 SC
Application rate (g/ha)	2 x 325 (14 d)
NOEL (mix) (mg/kg bw)	24.12
TER criterion	5

Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{LT}**
Screening	Indicator species for screening	72.3	1.4 x 0.53	17.44	**1.4**
Tier 1 (three worst case SVm values)					
Ornamentals/nursery BBCH 40-49 Maize BBCH 10 - 29	Small herbivorous mammal "vole"	72.3	1.4 x 0.53	17.44	**1.4**
Ornamentals/nursery BBCH ≥ 50 Maize BBCH 30 - 39	Small herbivorous mammal "vole"	36.1	1.4 x 0.53	8.71	**2.8**
Maize ≥ 40	Small herbivorous mammal "vole"	18.1	1.4 x 0.53	4.36	5.5
Ornamentals/nursery BBCH 10-49	Small omnivorous mammal "mouse"	7.8	1.4 x 0.53	1.85	13.0

Intended use	Energetic plants
Active substance/product	CHR/F/SCORPIO 325 SC
Application rate (g/ha)	2 x 260 (14 d)
NOEL (mix) (mg/kg bw)	24.12
TER criterion	5

Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{LT}**
Screening	Indicator species for screening	72.3	1.4 x 0.53	13.95	**1.7**
Tier 1 (four worst case SVm values)					
Orchards BBCH < 10	Small herbivorous mammal "vole"	72.3	1.4 x 0.53	13.95	**1.7**

Orchards BBCH 10-19	Small herbivorous mammal "vole"	57.8	1.4 x 0.53	11.15	**2.2**
Orchards BBCH 20-40	Small herbivorous mammal "vole"	43.4	1.4 x 0.53	8.37	**2.9**
Orchards BBCH ≥ 40	Small herbivorous mammal "vole"	21.7	1.4 x 0.53	4.19	5.8

According to results, an unacceptable chronic risk due to **combined exposure** are obtained in acording to the proposed GAP, for uses:

- Ornamentals and nursery – 2 x 325 g a.s./ha, BBCH 40-49 and BBCH ≥ 50
- Fruiting vegetables (pumpkin) - 1 x 325 g a.s./ha, BBCH 10-49
- Pulses (soybean) - 1 x 325 g a.s./ha, BBCH 40-49
- Orchards (energetic plants) – 2 x 260 g a.s./ha, BBCH 00-19 and BBCH 20-40
- Maize (tobacco) – 2 x 325 g a.s./ha, BBCH 10-29 and BBCH 30-39

The Tier I reproductive risk assessment for mammals (voles) for **azoxystrobin** demonstrated no acceptable risk for following scenarios:

- Ornamentals and nursery – 1-2 x 200 g a.s./ha, BBCH 40-49
- Fruiting vegetables (pumpkin) - 1 x 200 g a.s./ha, BBCH 10-49
- Pulses (soybean) - 1 x 200 g a.s./ha, BBCH 40-49
- Orchards (energetic plants) – 2 x 160 g a.s./ha, BBCH 00-19
- Maize (tobacco) – 2 x 200 g a.s./ha, BBCH 10-29

The Tier I reproductive risk assessment for mammals (voles) for **difenoconazole** demonstrated no acceptable risk for following scenarios:

- Ornamentals and nursery – 1-2 x 125 g a.s./ha, BBCH 40-49
- Fruiting vegetables (pumpkin) - 1 x 125 g a.s./ha, BBCH 10-49
- Pulses (soybean) - 1 x 125 g a.s./ha, BBCH 40-49
- Orchards (energetic plants) – 2 x 100 g a.s./ha, BBCH 00-19
- Maize (tobacco) – 2 x 125 g a.s./ha, BBCH 10-29

For these scenarios a refined risk assessment is required.

9.3.2.2 Higher-tier risk assessment

~~The risk assessment showed unacceptable risk for vole due to the use of CHR/F/SCORPIO 325 SC on fruiting vegetables and ornamentals/nursery. Thus, the higher risk assessment is necessary.~~

Although voles are listed as relevant focal species, it is widely acknowledged that voles are not relevant for arable crops and orchards.

- Gurney, *et al.* (1998) reports the feeding habit of field voles (*Microus agrestis*) to be mainly rough, ungrazed grassland, including thick grass ground cover. In a two year study of small mammals on Scottish arable land and set-aside (Rodgers 19931) 159 field voles were caught, which were reported to have an almost exclusive preference for rough grassland and were completely absent from the wood and also infrequent in set-aside and crops.
- In a three year study of small mammals on an arable farm in Oxfordshire Tew (19941) failed to capture any field voles away from hedgerows around cereal fields. In the Boxworth project, field voles were occasionally caught in the fields but this was restricted to areas with dense ground cover, such as patches infested with blackgrass (Johnson *et al.*, 19921).
- No data are available from radio tracking studies for the bank vole or the field vole. Radio tracking has been tried unsuccessfully in both species (Plesner-Jensen 1993). Trapping studies have shown that although both species do not use arable fields as main habitat, they are common in hedgerows

and woods adjacent to arable fields (Pollard & Relton 1970; Jefferies et al 1973; Green 1979; Loman 1991; Johnson et al. 1992).The preference of the common vole for non-cropped areas are discussed in Jacob *et al* (2014), in which it states: "The common vole is primarily a grassland species that is well adapted to steppe habitats. Primary habitats are meadows, set-aside land, flower strips, grassy field verges and alfalfa and clover fields. It prefers to inhabit undisturbed short vegetation and can be found in grass leys in forests after clear cuts and other grassy habitats."

Furthermore, information from DEFRA's research project on "Estimating wildlife exposure to pesticides in crops: additional scenarios and data" (2009) supports the non-relevance of the vole. The aim of this work was to provide further information on use of crops by wildlife by extensive surveying and by review of public literature. The following table taken from this report shows the number of captures of small mammals in the various habitat types.

Table 9.2.2.2-1: Captures of small mammals during 11,000 trap-events in different agricultural habitats (Table 3 from Report PS2328)

	Captures per 100 trap events						
	Potatoes	**Arable hedge**	**Cereal**	**Sugar beet**	**Other non-crop**	**Orchard hedge**	**Orchard crop**
Field vole	0	0.15	0.08	0	0	1.52	1.31
Pygmy shrew	0.02	0.53	0.23	0	0.34	1.82	0.51
Common shrew	0.38	6.43	1.36	1.00	6.38	3.33	1.85
Bank vole	0.02	6.43	1.44	0	1.55	4.24	0.27
Woodmouse	0.82	8.06	7.04	0.50	2.76	7.88	2.49
Total	1.24	21.6	10.15	1.5	11.03	18.79	6.43
Trap events in this habitat	5020	2630	2570	200	580	330	2970

Although the study did not specifically include the intended crops, the results clearly show that wood mice are much more prevalent in arable crops (including potatoes, cereal and sugar beet) than voles. A follow on research project by DEFRA, on "Small mammal activity in soft fruit, cane fruit and top fruit orchards" (2012), focused only on the activity of wood mice as the key focal species. The report stated that "Although a number of species of small mammals occurred in orchards in PS2328 [DEFRA 2009], wood mice were caught in the greatest numbers and are probably at greatest risk from pesticides applied there. They are omnivorous and forage above ground, while shews and voles tend to forage beneath thatch and litter layers".

Additionally, in a study conducted in southern Moravia, Czech Republic, small mammal communities were snap trapped for six years in agricultural landscapes including vineyards (Heroldova et al., 2007) which is a comparable habitat to modern orchards. The dominant species in vineyards was also the wood mouse (*Apodemus sylvaticus*), which comprised 93% of all small mammals trapped in this habitat. The wood mouse was also regularly present in different types of vineyards in southwest Germany (Pedall et al., 2003). In contrast to the common vole, the wood mouse is a ubiquitous and euryoecious non-specialist (Tattersall et al., 1997), inhabiting a wide range of landscapes (Montgomery, 1999), and is found in arable habitats throughout the year (e.g. (Tew & Macdonald, 1994); (Loman, 1991); (Green, 1979); (Kikkawa, 1964); (Bergstedt, 1965)). This species has no specific habitat requirements, yet it tends to avoid habitats with a dense herb layer (Braun & Dieterlen, 2005). Tew et al. (2000) suggests that wood mice, due to their bouncing locomotion and granivorous habits, even favour habitats with partly bare ground over which they can easily travel and find fallen seed.

Moreover, EFSA's Bird and Mammal Guidance Document (2009) identifies the European rabbit (*Oryctolagus cuniculus*) as the representative species for large herbivorous mammals. This species is

abundant across Europe and may be associated with arable crops. Gurney *et al*. (1998) reports the feeding habitat of the rabbit to be areas of short grass; naturally occurring, dry heaths or closely grazed agricultural pastures with secure refuge nearby. The brown hare (*Lepus europaeus*) is also widespread and abundant across Europe.

Taking all of the above into consideration (high fecundity and population recuperation of the vole; primary source of food outside crops fields for the vole; necessity of population control measures since the vole is considered a crop pest when high population levels are reached; other agricultural techniques being also means of population control), voles are not considered to be a relevant focal species. Therefore, the risk assessment for small herbivorous mammals can be concluded to be acceptable (even with TER lower than the trigger value) if it is acceptable for other small omnivorous mammals (wood mouse and brown hare) which are considered as a relevant focal species.

Overall the following risk assessment focuses on the wood mouse (omnivorous) and the brown hare (herbivorous) as relevant focal species for the proposed uses.

Generic focal species	FIR/bw	RUD	App. Rate (kg a.s./ha)	MAF	Deposition factor	fTWA	DDD (mg a.s./kg bw/day)	NOEL (mg a.s./kg bw/day)	TERLT
Ornamental, forestry tree, Salix, Wicker; fruiting vegetables Application: 1 x 200 g azoxystrobin/ha									
Wood mouse Diet: 25% weeds50% weed seeds25% ground arthropods	0.27	29.2	0.200	1.0	1.0	0.53	0.84	32	38.3
Rabit (100 % plant material)	0.50	28.7	0.200	1.0	1.0	0.53	1.52	32	21.0
Ornamental, forestry tree, Salix, Wicker; fruiting vegetables Application: 2 x 125 g difenoconazole/ha									
Wood mouse Diet: 25% weeds50% weed seeds25% ground arthropods	0.27	29.2	0.125	1.0	1.0	0.53	0.52	17.3	33.1
Rabit (100 % plant material)	0.50	28.7	0.125	1.0	1.0	0.53	0.95	17.3	18.2

Combined toxicity, using the TER value for active substances (the lowest TER)
Acute: 0.125 kg DIF /ha + 0.2 kg AZX/ha TER(mix) = 1/ ((1/183.3) + (1/85.2)) = 58.2
Chronic: 0.125 kg DIF /ha + 0.2 kg AZX/ha TER(mix) = 1/ ((1/6.25) + (1/5.41)) = **2.9**

The chronic TER_{mix} is below the trigger value of 5. However, the worst case TER were taken into calculation. New calculations of TER mix for each usage is presented below:

Usage	TER_{AZX}	TER_{DIF}	TER_{mix}	Acceptable
Bulbs and onion	21.1	14.4	8.6	Yes

like crops, cereals, oilseed rape, potatoes, root and stem vegetables, strawberries, sugar beet, and sunflower (Tier 1)				
Ornamentals and nursery	21	18.2	9.75	Yes
Fruiting vegetables	12	10.4	5.57	Yes

Review Comments:

zRMS, requesting correction of the dRR, informed the Applicant that the vole could only be excluded from the risk assessment on the basis of monitoring (field) studies specific to the crop (CEU agreements). Therefore, above statement was not evaluated further.

Combined toxicity, using the TER value for active substances (the lowest TER):
Acute: 0.125 kg DIF /ha + 0.2 kg AZX/ha TER(mix) = 1/ ((1/152.7) + (1/71.0)) = 47.62
Chronic: 0.125 kg DIF /ha + 0.2 kg AZX/ha TER(mix) = 1/ ((1/2.58) + (1/2.98)) = 1.39

Review Comments:

No options to refine the chronic risk due to combined exposure or give arguments that the additivity of the active substances is unexpected were provided.

The long-term TER for mammals and application of CHR/F/SCORPIO 325 SC is below the trigger value 5. Therefore further refinement is conducted.

The dietary intake was refined. According to the study by Rinke (1991) "Percentage of volume versus number of species: Availability and intake of grasses and forbs in microtusarvalis. Folia zoologica 40 (2):143-151" voles prefer dicots instead of monocots based on the stomach content analysis. Despite the fact that monocots was more easily accessible in the surrounding areas (70%), it was shown that voles prefers dicots with the majority of voles (all seasons, sexes and ages) showing more than 80% dicot material in the stomach content. For the chronic risk assessment the diet can be set on 25% monocots and 75% dicots. These PD values were used in the refined risk assessment.

Calculations of new short cut value based on data from EFSA B&M guidance (i.e. bw and RUDs).

Indicator/generic focal species	Typ of food	FIR/bw	RUD_{mean}	PD	SV_m
Small herbivorous mammal "vole"	Monocotyledons	1.58	54.2	0.25	21.41
	Dicotyledonos	1.58	28.7	0.75	34.01
SUM				1.0	55.42

Review Comments:

zRMS, requesting a correction of dRR, informed the Applicant that the refined of the diet for the voles, in accordance with the agreements of the central zone, is possible as follows – for crops dominated by monocots (orchards, grapes, hops, cereals, meadows) 75% monocots and 25% dicots, for other crops 50/50. However, the Applicant did not follow this instruction and used a ratio of 75% dicotyledonous to 25% monocotyledonous plants for all crops. Therefore, the refined risk assessment was not accepted in its entirety.

New short cut value was used to the risk assessment:

Generic focal species	SW	App. Rate (kg a.s./ha)	MAF	Depostion factor	TWA	DDD (mg a.s./kg bw/day)	NOEL (mg a.s./kg bw/day)	TER1-F
Vineyard Application BBCH 10-19 Application: 2 x 200 g azoxystrobin/ha, interval 14d								
Small herbivorous mammal "vole Grass + cereals 100% grass	35.42	0.200	1.4	0.6	0.53	4.94	32	6.48
fruiting vegetables BBCH 10 – 49 Application: 2 x 200 g azoxystrobin/ha, interval mm 90d								
Small herbivorous mammal "vole Grass + cereals 100% grass	35.42	0.200	1.4	1	0.53	8.22	32	3.89
Orchard directed BBCH >10 or not crop directed Application: 2 x 200 g azoxystrobin/ha, interval 14d								
Small herbivorous mammal "vole Grass + cereals 100% grass	35.42	0.200	1.4	1.0	0.53	8.22	32	3.89
Leafy vegetables BBCH 40-49 Application: 2 x 200 g azoxystrobin/ha, interval 14d								
Small herbivorous mammal "vole Grass + cereals 100% grass	35.42	0.200	1.4	0.3	0.53	2.46	32	12.9
Ornamentals and nursery BBCH 40-49 Application: 1 x 200 g azoxystrobin/ha, interval 14d								

Small herbivorous mammal"vole Grass + cereals 100%-grass	55.42	0.200	1	1	0.53	3.87	12	5.15
Ornamentals and nursery-BBCH 40-49-Application 1 x 125 g difenoconazole/ha, interval 14d								
Small herbivorous mammal"vole Grass + cereals 100%-grass	55.42	0.125	1	1	0.53	3.67	17.5	4.24
fruiting vegetables-BBCH 10 – 49-Application 2 x 125 g difenoconazole/ha, interval min. 90d								
Small herbivorous mammal"vole Grass + cereals 100%-grass	55.42	0.125	1.4	1	0.53	5.14	17.5	3.36
Orchard-directed-BBCH <10 or not crop directed-Application 2 x 125 g difenoconazole/ha, interval 14d								
Small herbivorous mammal"vole Grass + cereals 100%-grass"	55.42	0.125	1.4	1.0	0.53	5.14	17.5	3.36
Leafy vegetables-BBCH 40-49-Application 2 x 125 g difenoconazole/ha, interval 14d								
Orchard-directed-BBCH <10 or not crop-directed	55.42	0.125	1.4	0.4	0.53	3.54	17.5	11.23
Vineyard-Application-BBCH 10-19-Application 2 x 200 g azoxystrobin/ha, interval 14d								
Small herbivorous mammal"vole Grass + cereals 100%-grass"	55.42	0.125	1.4	0.4	0.53	3.08	17.5	5.61

To establish a new PIR/bw factor the data form "The Impact of the Common Vole on the Vegetation of Agroecosystems" (J. Truszkowski; Acta Theriologica Vol. 27, 23: 305–345, 1982) were taken into account.

1. The average body weight of a vole from the study was 18.5 g.

2. For the purpose of the present study the amount of average daily consumption by a vole weighing 18.5 g was taken as 15.0 kcal/individual/day calculated from data contained in the paper by Sawicka-Kapusta et al. (1975).
3. In relation to the energy value of food consumed, 77.5% is assimilated. The energy value of excreted faeces is 18.7%, urine 3.8% (Drożdż, 1968).
4. The caloria value of 1 gm of dry mass of lucerne shoots Wasi taken as 4.4 kcal, rape 4.2 kcal, rye 4.1 kcal (after estimates by Sawicka-Kapusta et al., 975; Kukielska). On the basis of these data the average caloric value of the mass of upper parts of plants which form the basic food of the voles examined was taken as 4.2 kcal/g of dry mass.
The latest data about energy content show that voles eat less than 4 g/day (15.0 kcal/individual/day / 4.1 kcal = 3.66).

According to the "COMMON VOLE (*MICROTUS ARVALIS*) ECOLOGY AND MANAGEMENT: IMPLICATIONS FOR RISK ASSESSMENT OF PLANT PROTECTION PRODUCTS" Jacob, J., Manson, P., Barfknecht, R., Fredrieks, T. (2014): "*The selected habitat needs to provide food to satisfy the energy budgets for maintaining essential body functions including reproduction as well as providing shelter from predators. Food uptake is dependent on ambient temperature and can vary between 4.4 g/day/adult vole (at 27°C) and 7.8 g/day/adult vole (at 0°C) 21. For instance, twice as much alfalfa is consumed at 5°C versus 22°C (ca. 5 g versus 2.5 g)*".

Based on food uptake indicated in Jacob J., Manson P. (2014) and a bodyweight of 18.5 g (Truszyński (1982)), FIR/bw can conservatively be calculated to 0.42 (7.8 g/day/adult vole / 18.5g = 0.42).

New FIR/bw was used to the risk assessment:

Generic focal species	FIR/bw	RUD	Appl. Rate (kg a.s./ha)	MAF	Deposition factor	CTWA	DDD (mg a.s./kg bw/day)	NOEL (mg a.s./kg bw/day)	TER LT
Vineyard BBCH 10-19 Application: 2 x 200 g azoxystrobin/ha, interval 14d									
Small herbivorous mammal - Vole Grass + cereals 100% grass"	0.42	54.2	0.200	1.4	0.6	0.53	3.82	32	8.37
Fruiting vegetables BBCH 10 – 49 Application: 2 x 200 g azoxystrobin/ha, interval min. 90d									
Small herbivorous mammal - Vole Grass + cereals 100% grass BBCH BBCH 10-19	0.42	54.2	0.200	1.4	1	0.53	5.38	32	5.42
Orchard BBCH <10 or not crop directed Application: 2 x 200 g azoxystrobin/ha, interval 14d									

Small herbivorous mammal - Vole-Grass - cereals - 100% grass	0.42	54.2	0.200	1.4	1	0.53	3.38	32	3.46
Leafy vegetables BBCH 40-49 Application: 2 x 200 g azoxystrobin/ha, interval 14d									
Small herbivorous mammal - Vole-Grass - cereals - 100% grass	0.42	54.2	0.200	1.4	8.3	0.53	1.01	32	31.68
Ornamentals and nursery BBCH 40-49 Application: 1 x 200 g azoxystrobin/ha, interval 14d									
Small herbivorous mammal - Vole-Grass - cereals - 100% grass	0.42	54.2	0.200	1	1	0.53	2.41	32	13.27
Vineyard BBCH 10-19 Application 2 x 125 g difenoconazole/ha, interval 14d									
Small herbivorous mammal - Vole-Grass - cereals - 100% grass	0.42	54.2	0.125	1.4	0.8	0.53	1.27	17.3	13.62
Fruiting vegetables BBCH 10—49, Application 2 x 125 g difenoconazole/ha, interval min. 90d									
Small herbivorous mammal - Vole-Grass - cereals - 100% grass	0.42	54.2	0.125	1.4	1	0.53	2.11	17.3	8.19
Orchard BBCH <10 or not crop directed Application: 2 x 125 g difenoconazole/ha, interval 14d									
Small herbivorous mammal - Vole-Grass - cereals - 100% grass"	0.42	54.2	0.125	1.4	1	0.53	2.11	17.3	8.19

Leafy vegetables BBCH 40-49 Application: 2 x 125g azoxystrobin/ha, interval 14d									
Small herbivorous mammal - Vole Grass + cereals 100% grass"	0.42	54.2	0.125	1.4	0.3	0.53	0.63	17.3	27.46
Ornamentals and nursery BBCH 40-49 Application: 2 x 125g azoxystrobin/ha, interval 14d									
Small herbivorous mammal - Vole Grass + cereals 100% grass"	0.42	54.2	0.125	1.4	1	0.53	2.11	17.3	8.19

According to the refined risk assessment all TERlt for mammals exceed the trigger value. Therefore, CHR/F/SCORPIO 325 SC pose no unacceptable risk to and mammals used according to the label.

9.3.2.3 Drinking water exposure

When necessary, the assessment of the risk for mammals due to uptake of contaminated drinking water is conducted for a small omnivorous mammal with a body weight of 21.7 g (*Apodemus sylvaticus*) and a drinking water uptake rate of 0.24 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

With a K(f)oc of 432, azoxystrobin belongs to the group of less sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied.

Effective application rate (g/ha)	=	200		
Acute toxicity (mg/kg bw)	=	5000	quotient	= 0.04
Reprod. toxicity (mg/kg bw/d)	=	32	quotient	= 6.25

With a K(f)oc of 3759.4, difenoconazole belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied.

Effective application rate (g/ha)	=	125		
Acute toxicity (mg/kg bw)	=	1453	quotient	= 0.086
Reprod. toxicity (mg/kg bw/d)	=	17.3	quotient	= 7.2

Review Comments:

zRMS, requesting correction of the dRR, by adding the risk assessment for mammals via drinking water for two applications of the product. However, the required changes were not introduced. As an exception, zRMS performed its own calculations in this regard.

Azoxystrobin

Effective application rate (g/ha)	=	376 (200 x 1.88*)			
Acute toxicity (mg/kg bw)	=	5000	quotient	=	0.075
Reprod. toxicity (mg/kg bw/d)	=	32	quotient	=	11.75

*mean MAF(DT_{50soil} = 78 d)

Difenoconazole

Effective application rate (g/ha)	=	241.25 (125 x 1.93*)			
Acute toxicity (mg/kg bw)	=	1453	quotient	=	0.166
Reprod. toxicity (mg/kg bw/d)	=	17.3	quotient	=	13.95

*mean MAF(DT_{50soil} = 130 d)

9.3.2.4 Effects of secondary poisoning

The log P_{ow} of azoxystrobin amounts to 2.5 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.
The log P_{ow} of Difenoconazole amounts to 4.36 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

Risk assessment for earthworm-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous birds is assessed for a bird of 100 g body weight with a daily food consumption of 104.6 g. Bioaccumulation in earthworms is estimated based on measured/predicted concentrations in soil/porewater / is based on experimental data. To achieve a concise risk assessment, the risk envelope approach is applied.

Table 9.3-8: Assessment of the risk for earthworm-eating birds due to exposure to Difenoconazole via bioaccumulation in earthworms (secondary poisoning) for the intended use (worse case use from GAP table)

Parameter	Difenoconazole	comments
PEC_{soil} (mg/kg soil)	~~0.1637~~ 0.3881	~~Cereals PECaccu~~ Sunflower PECaccu
log P_{ow} / P_{ow}	4.36/22909	
Koc	~~3759.4~~ 2942.92	Mean
foc	0.02	Default
BCF_{worm}	~~3.67~~ 4.68	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.012 \times P_{ow}) / (foc \times Koc)$
PEC_{worm}	~~0.60~~ 1.82	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	~~0.63~~ ~~1.01~~ 2.33	DDD = PEC_{worm} × ~~1.05~~ 1.28
NOEL (mg/kg bw/d)	17.3	
TER_{lt}	~~27.5~~ ~~17.1~~ 7.4	

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous birds is assessed for a bird of 1000 g body weight with a daily food consumption of 159 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water / is based on the regulatory acceptable concentration for aquatic organisms as a limit value for admissible concentrations of difenoconazole in water.

Table 9.3-9: Assessment of the risk for fish-eating birds due to exposure to Difenoconazole via bioaccumulation in fish (secondary poisoning) for the intended use (worse case use from GAP table in surface water)

Parameter	Difenoconazole	comments
PEC_{sw} (twa = 21 d) (mg/L)	~~0.017099~~ ~~0.0082~~ 0.00637	~~Step 1 worst case value~~ Step 2 worst case value (pome fruit)
BCF_{fish}	330	
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	~~5.64~~ ~~2.739~~ 2.1021	PECfish = PECwater × BCFfish
Daily dietary dose (mg/kg bw/d)	~~0.897~~ ~~0.435~~ 0.298	DDD = PECfish × ~~0.159~~ 0.142
NOEL (mg/kg bw/d)	17.3	
TER_{lt}	~~19.3~~ ~~39.78~~ 58.0	

TER values shown in bold fall below the relevant trigger.

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.3.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.3.4 Overall conclusions

~~In conclusion, the acute, short term risk and long term to mammals from the proposed uses of difenoconazole and azoxystrobin was found acceptable.~~

Review Comments:

The acute and chronic risks of CHR/F/SCORPIO 325 SC to mammals were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with active ingredients, and maximum residues occurring on food items.

All acute TER values exceed the relevant triggers indicating that CHR/F/SCORPIO 325 SC does not pose an unacceptable risk to mammals following applications according to recommended use pattern.

The Tier I reproductive risk assessment for mammals (voles) for **azoxystrobin** demonstrated no acceptable risk for following scenarios:

- Ornamentals and nursery – 1-2 x 200 g a.s./ha, BBCH 40-49
- Fruiting vegetables (pumpkin) - 1 x 200 g a.s./ha, BBCH 10-49
- Pulses (soybean) - 1 x 200 g a.s./ha, BBCH 40-49
- Orchards (energetic plants) – 2 x 160 g a.s./ha, BBCH 00-19
- Maize (tobacco) – 2 x 200 g a.s./ha, BBCH 10-29

The Tier I reproductive risk assessment for mammals for **difenoconazole** demonstrated no acceptable risk for following scenarios:

- Ornamentals and nursery – 1-2 x 125 g a.s./ha, BBCH 40-49
- Fruiting vegetables (pumpkin) - 1 x 125 g a.s./ha, BBCH 10-49
- Pulses (soybean) - 1 x 125 g a.s./ha, BBCH 40-49
- Orchards (energetic plants) – 2 x 100 g a.s./ha, BBCH 00-19
- Maize (tobacco) – 2 x 125 g a.s./ha, BBCH 10-29

According to results, an unacceptable chronic risk due to **combined exposure** are obtained in acording to the proposed GAP, for uses:

- Ornamentals and nursery – 2 x 325 g a.s./ha, BBCH 40-49 and BBCH ≥ 50
- Fruiting vegetables (pumpkin) - 1 x 325 g a.s./ha, BBCH 10-49
- Pulses (soybean) - 1 x 325 g a.s./ha, BBCH 40-49
- Orchards (energetic plants) – 2 x 260 g a.s./ha, BBCH 00-19 and BBCH 20-40
- Maize (tobacco) – 2 x 325 g a.s./ha, BBCH 10-29 and BBCH 30-39

Evaluation of exposing to mammals through the drinking water demonstrated the acceptable risk. The risk to earthworm- and fish-eating animals from secondary poisoning is low.

9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

Not required.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with azoxystrobin and difenoconazole and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on aquatic organisms of CHR/F/SCORPIO 325 SC were not evaluated as part of the EU assessment of azoxystrobin and difenoconazole. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Review Comments:

This is the application for registration CHR/F/SCORPIO 325 SC (Clapton 325 SC, Scarp 325 SC), according to Article 33 of Regulation 1107/2009 based on unprotected data for compositionally comparable formulation - Scorpion 325 SC (acc. Art. 34 of Reg. 1107/2009). No new studies on aquatic organisms have been presented.

Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – azoxystrobin and relevant metabolites

Species	Substance	Exposure System	Results	Reference
Oncorhynchus mykiss	azoxystrobin	96 h, ~~s~~	96 h LC_{50} ~~EC_{50}~~ = 0.47 mg ~~a.s~~/L	EFSA Journal 2010; 8(4):1542
Lepomis macrochirus	azoxystrobin	96 h	LC_{50} = 1.1 mg/L	EFSA Journal 2010; 8(4):1542
Oncorhynchus mykiss	R234886	96 h, ~~s~~	96 h LC_{50} ~~EC_{50}~~ > 150 mg/L	EFSA Journal 2010; 8(4):1542
Oncorhynchus mykiss	R401553	96 h, s	96 h LC_{50} ~~EC_{50}~~ > 120 mg ~~a.s~~/L	EFSA Journal 2010; 8(4):1542
Oncorhynchus mykiss	R402173	96 h, s	96 h LC_{50} = 62 mg ~~a.s~~/L	EFSA Journal 2010; 8(4):1542
Pimephales promelas	azoxystrobin	33 d, chronic	NOEC = 0.147 mg ~~a.s~~/L	EFSA Journal 2010; 8(4):1542
Daphnia magna	azoxystrobin	48 h, s	48 h EC_{50} = 0.23 (mm, as) mg /L	EFSA Journal 2010; 8(4):1542
Mysidopsis bahia	azoxystrobin	96 ~~48~~ h, s	96h EC_{50} = (nom, pm) 0.055 mg/L	EFSA Journal 2010; 8(4):1542
Daphnia magna	R234886	48 h, s	48h EC_{50} > 180 mg/L	EFSA Journal 2010; 8(4):1542
Daphnia magna	R401553	48 h, s	48h EC_{50} > 120 mg/L	EFSA Journal 2010; 8(4):1542
Daphnia magna	R402173	48 h, s	48h EC_{50} > 100 mg/L	EFSA Journal 2010; 8(4):1542
Daphnia magna	azoxystrobin	21 d	21d NOEC= 0.044 mg ~~a.s~~/L	EFSA Journal 2010; 8(4):1542
Mysidopsis bahia	azoxystrobin	28 d	28 d NOEC= 0.00954 mg ~~a.s~~/L	EFSA Journal 2010; 8(4):1542
Chironomus riparius	azoxystrobin	28 d	28 d NOEC=0.8 mg/L	EFSA Journal 2010; 8(4):1542
Navicula pelliculosa	azoxystrobin	120 ~~72~~ h, s	ErC_{50} = 0.146 mg/L	EFSA Journal 2010; 8(4):1542
Selenastrum capricornutum	R234886	72 h, s	72 h EC_{50} = 47 mg/L	EFSA Journal 2010; 8(4):1542

Species	Substance	Exposure System	Results	Reference
Selenastrum capricornutum	R402173	72 h, s	72 h E_bC_{50} /ErC_{50}=67 mg/L	EFSA Journal 2010; 8(4):1542
Selenastrum capricornutum	R401553	72 h, s	72 h E_bC_{50} /ErC_{50}=120 mg/L	EFSA Journal 2010; 8(4):1542
Lemna gibba	azoxystrobin	7 d, s	Dry weight, EC_{50} >6.4mg/L Fronds, EC50=3.2 mg/L	EFSA Journal 2010; 8(4):1542
Higher-tier studies (micro- or mesocosm studies)				
The mesocosm study is considered to be a well-conducted mesocosm with an appropriate diversity and abundance of species. It should be noted that azoxystrobin was only applied once, and concentrations were only measured 21 hours after application and not throughout the course of the study. Species/groups were present in sufficient numbers to allow appropriate statistical analysis. The Notifier proposed that the no observed ecologically adverse effects concentration (NOEAEC) is 10 µg/L with assessment factor of 3.				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations

Review Comments:

To refined acute and chronic risk for aquatic invertebrates the RAC of 3.3 µg a.s/L for azoxystrobin, taken from LoEP, is proposed to be used in PEC/RAC calculations. No justification was provided to clarify why the Applicant considers that the data for the representative formulation can be used for the assessment of CHR/F/SCORPIO 325 SC. Furthermore it is also noted that RAC of 3.3 µg/L was not just derived from the mesocosm study alone but also from first tier data and the lower limit HC_5. The overall RAC determined in this manner no longer correspond to the requirements of the current guideline (EFSA Journal 2013;11(7):3290). For a risk assessment according to EFSA AGD it is also necessary to evaluate the representativeness of the mesocosm based on the $FOCUS_{sw}$ exposure profiles using the envelope curve approach. In continuation, the usage of CHR/F/SCORPIO 325 SC is completely different from the applications assessed for Annex I inclusion of azoxystrobin.

Nevertheless, zRMS accepted the RAC of 3.3 µg/L to address the risk from active substance and not the formulation. The decision was made for several reasons. Although the RAC value was determined in a manner inconsistent with current rules, it is nevertheless a value from the LoEP. An amended trigger value of 1 is used as an assessment factor has been built in to this endpoint (AF of 3). Re-assessment of such an old mesocosm would probably result in its rejection. The various "higher tier" approaches, including the mesocosm, which were ultimately incorporated into the "overall RAC" render any assessment of exposure profiles meaningless. In addition, RAC of 3.3 µg/L has been accepted by zRMS-UK in the Core Assessment for Scorpion 325 SC and in NA-PL (August 2018) for a similar range of uses.

The RAC value of 3.3 µg/L was accepted by zRMS to refine acute and chronic risk to aquatic invertebrates.

Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – difenoconazole and relevant metabolites

Species	Substance	Exposure System	Results	Reference
Oncorhynchus mykiss (rainbow trout)	Difenoconazole	96 h (flow-through)	LC_{50} = 1.1	EFSA Journal 2011;9(1):1967
Rainbow trout	difenoconazole	96 h, s	LC_{50} ~~EC_{50}~~ = 0.65 mg as/L	EFSA Journal 2011;9(1):1967
Rainbow trout	difenoconazole	34 d (flow through)	NOEC= 0.0076 mg as/ L	EFSA Journal 2011;9(1):1967
Pimephales promelas	difeconazole	F0 Generation: 178 days post-hatch F1 Generation: 90 days post-hatch	NOEC= 0.0036 mg/L	EFSA supporting publication 2014: EN-680
Daphnia magna	difenoconazole	48 h	EC_{50} = 0.77 mg/L	EFSA Journal 2011;9(1):1967
Mysidopsis bahia	difenoconazole	96 h (flow through)	EC_{50} = 0.15 (0.11 - 0.22) mg as/L	EFSA Journal 2011;9(1):1967
Daphnia magna	difenoconazole	21 d	NOEC = 0.0056 mg as/L	EFSA Journal 2011;9(1):1967
Chironomus riparius	difenoconazole	28 d	NOEC via water = 0.015 mg as/L	EFSA Journal 2011;9(1):1967
Chironomus riparius	difenoconazole	28 d (static)	NOEC via water = 0.0525 mg/kg	EFSA Journal 2011;9(1):1967
Scenedesmus subspicatus	difenoconazole	72 h	E_bC_{50} = 0.032	EFSA Journal 2011;9(1):1967
Rainbow trout	CGA 71019	96 hr	LC_{50} ~~EC_{50}~~ = 488 mg as/L	EFSA Journal 2011;9(1):1967
Rainbow trout	CGA 71019	28 d	NOEC = 3.2 mg as/L	EFSA Journal 2011;9(1):1967
Daphnia magna	CGA 71019	48 h	EC_{50} = >100 mg as/L	EFSA Journal 2011;9(1):1967
Selenastrum capricornutum	CGA 71019	96 h	Biomass: E_bC_{50} Growth rate: E_rC_{50} = 8 mg as/L	EFSA Journal 2011;9(1):1967
Rainbow trout	CGA 205375	96 h	EC_{50} = 0.74 mg as/L	EFSA Journal 2011;9(1):1967
Daphnia magna	CGA 205375	48 h	EC_{50} =1.4 mg as/L	EFSA Journal 2011;9(1):1967
Chironomus riparius	CGA 205375	28 d	NOEC 10 mg/kg dw	EFSA Journal 2011;9(1):1967
Selenastrum capricornutum	CGA 205375	72 h	Biomass: E_bC_{50} = 1.2 Growth rate: E_rC_{50} = 3.1	EFSA Journal 2011;9(1):1967
Higher-tier studies (micro- or mesocosm studies)				

Table 9.5-3: Endpoints and effect values relevant for the risk assessment for aquatic organisms – CHR/F/SCORPIO 325 SC

Species	Substance	Exposure System	Results	Reference
Fish	A13703G	96 hours	~~1.0~~ 1.7 mg/L	Registration Report, Part B, Section B: Ecotoxicological Studies, Syngenta 2013
Aquatic invertebrates (*Daphnia*)	A13703G	48 hour	~~0.63~~ 1.1 mg/L	Registration Report, Part B, Section B: Ecotoxicological Studies, Syngenta 2013
Algae *Selenastrum capricornutum* (now known as *Pseudokirchneriella subcapitata*)	A13703G	72 hours	E_rC_{50} =3.09 mg/L E_bC_{50} =0.587 mg/L NOEC = 0.23 mg/L	Registration Report, Part B, Section B: Ecotoxicological Studies, Syngenta 2013
Higher-tier studies (micro- or mesocosm studies)				
Not available				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations

Review Comments:

It should be noted that the formulation toxicity test for algae was done only for *Pseudokirchneriella subcapitata.* The RACs for both active substances have been derived using endpoints for different algal species (*Pseudokirchneriella subcapitata* for azoxystrobin and *Scenedesmus subspicatus* for difenoconazole). As both species are green algae, the comparison can be considered appropriate. Nevertheless, the most sensitive algal species for azoxystrobin was *Navicula pelliculosa.* No data are available for diatom in LoEP for difenoconazole, and therefore comparison cannot be performed. Therefore, in zRMS opinion, study no. 2033567 cannot be used for product classification and labeling purposes.

A13703G studies for fish and daphnia indicate that the product is of similar toxicity to both active substances. Therefore, additional data are not required for the risk assessment. Algae are not the most sensitive group of aquatic organisms to both active substances.

9.5.1.1 Justification for new endpoints

Not required.

9.5.2 Risk assessment

9.5.2.1 Individual substance risk assessment

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the "Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No

1107/2009", as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).
The relevant global maximum FOCUS Step 1, 2 and 3 PEC_{SW} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the table below.
To achieve a concise risk assessment, the risk envelope approach is applied.
In the following table, the ratios between predicted environmental concentrations in surface water bodies (PEC_{SW}, PEC_{SED}) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended use for each FOCUS scenario and each organism group.

Review Comments:

AZOXISTROBIN

The risk assessment for aquatic organisms carried out by the Applicant has been completely removed (crossed out), as the PEC/RAC calculations presented in the tables below were based on unaccepted $PEC_{SW/SED}$ values. In the following risk assessment, performed by zRMS, only relevant for central zone FOCUS scenarios are included (D3, D4, D5, R1, R3 and R4).

Table 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/F/SCORPIO 325 SC in winter oilseed rape (BBCH14-20)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
	45.64	**> 1**	**> 1**	**> 1**	**> 1**	**>1**	< 1	< 1	**>1**
Step 2									
N-Europe/Oct-Feb	7.70	**> 1**	< 1	**> 1**	**> 1**	<1	-	-	**>1**
Step 3									
D3/ditch	1.279	< 1	-	**> 1**	**> 1**	-	-	-	< 1
D4/pond	1.403	< 1	-	**> 1**	**> 1**	-	-	-	< 1
D4/stream	1.553	< 1	-	**> 1**	**> 1**	-	-	-	< 1
D5/pond	0.5230	< 1	-	< 1	< 1	-	-	-	< 1
D5/stream	1.182	< 1	-	**> 1**	**> 1**	-	-	-	< 1
R1/pond	0.06110	< 1	-	< 1	< 1	-	-	-	< 1
R1/stream	1.232	< 1	-	**> 1**	**> 1**	-	-	-	< 1
R3/stream	3.102	< 1	-	**> 1**	**> 1**	-	-	-	< 1

Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/F/SCORPIO 325 SC in winter oilseed rape (BBCH 21-69)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
	45.64	**> 1**	**> 1**	**> 1**	**> 1**	**>1**	< 1	< 1	**>1**
Step 2									
N-Europe/ Oct-Feb	3.47	< 1	< 1	**> 1**	**> 1**	<1	-	-	**>1**
Step 3									
D3/ditch	1.264	-	-	**> 1**	**> 1**	-	-	-	< 1
D4/pond	0.3702	-	-	< 1	< 1	-	-	-	< 1
D4/stream	0.9840	-	-	**> 1**	**> 1**	-	-	-	< 1
D5/pond	0.1352	-	-	< 1	< 1	-	-	-	< 1
D5/stream	0.8408	-	-	**> 1**	< 1	-	-	-	< 1
R1/pond	0.1294	-	-	< 1	< 1	-	-	-	< 1
R1/stream	1.238	-	-	**> 1**	**> 1**	-	-	-	< 1
R3/stream	2.095	-	-	**> 1**	**> 1**	-	-	-	< 1

Arithmetic mean:

Group		Fish acute	Fish prolonged	Invertebr. acute	Invertebr. long	Algae	Sed. dwell. prolonged	Aquatic Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula pelliculosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*
Endpoint (µg/L)		LC_{50} 0.47	NOEC 147	EC_{50} 55	NOEC 9.54	E_rC_{50}/E_yC_{50} 146	NOEC 800	EC50 3200	-
AF		100	10	100	10	10	10	10	-
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	PEC_{sw} max (µg/L)								
Step 1									
	44.460	9.460	3.024	80.836	46.604	3.045	0.556	0.139	0.042
Step 2									
N Europe	6.267	1.333	0.426	11.394	6.569	0.429	0.078	0.020	0.006
Step 3									
D3/ditch	1.272	0.271	0.087	2.313	1.333	0.087	0.016	0.004	0.385
D4/pond	2.879	0.613	0.196	5.235	3.018	0.197	0.036	0.009	0.872
D4/stream	2.986	0.635	0.203	5.429	3.130	0.205	0.037	0.009	0.905
D5/pond	1.228	0.261	0.084	2.233	1.287	0.084	0.015	0.004	0.372
D5/stream	1.268	0.270	0.086	2.305	1.329	0.087	0.016	0.004	0.384
R1/pond	0.074	0.016	0.005	0.135	0.078	0.005	0.001	0.000	0.022
R1/stream	1.246	0.265	0.085	2.265	1.306	0.085	0.016	0.004	0.378
R3/stream	3.114	0.663	0.212	5.662	3.264	0.213	0.039	0.010	0.944

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Geometric mean:

Group		Fish acute	Fish prolonged	Invertebr. acute	Invertebr. long	Algae	Sed. dwell. prolonged	Aquatic Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula pelliculosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*
Endpoint (µg/L)		LC_{50} 470	NOEC 147	EC_{50} 55	NOEC 9.54	E_rC_{50}/E_yC_{50} 146	NOEC 800	EC50 3200	-
AF		100	10	100	10	10	10	10	-
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3

Group		Fish acute	Fish prolonged	Invertebr acute	Invertebr long	Algae	Sed. dwell prolonged	Aquatic Plant	Mesocosm
FOCUS Scenario	PEC$_{sw}$ max (µg/L)								
Step 1									
	45.640	9.714	3.105	82.992	17.841	3.126	0.571	0.143	9.714
Step 2									
N-Europe	22.490	4.785	1.530	40.891	23.574	1.540	0.281	0.070	4.785
Step 3									
D3/ditch	1.272	0.271	0.087	2.313	1.222	0.087	0.016	0.004	0.385
D4/pond	3.090	0.657	0.210	5.618	3.230	0.213	0.039	0.010	0.936
D4/stream	3.147	0.670	0.214	5.722	3.299	0.216	0.039	0.010	0.954
D5/pond	1.248	0.266	0.085	2.269	1.308	0.085	0.016	0.004	0.378
D5/stream	1.448	0.308	0.099	2.633	1.518	0.099	0.018	0.005	0.439
R1/pond	0.067	0.014	0.005	0.122	0.070	0.005	0.001	0.000	0.020
R1/stream	1.270	0.271	0.087	2.320	1.338	0.087	0.016	0.004	0.387
R2/stream	3.294	0.701	0.224	5.989	3.452	0.226	0.041	0.010	0.998

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/F/SCORPIO 325 SC in winter oilseed rape (BBCH31)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
	45.64	**> 1**	**> 1**	**> 1**	**> 1**	**>1**	< 1	< 1	**>1**
Step 2									
N-Europe/ Oct-Feb	3.89	< 1	< 1	**> 1**	**> 1**	<1	-	-	**>1**
Step 3									
D3/ditch	1.264	-	-	**> 1**	**> 1**	-	-	-	< 1
D4/pond	0.3678	-	-	< 1	< 1	-	-	-	< 1
D4/stream	0.9459	-	-	**> 1**	< 1	-	-	-	< 1
D5/pond	0.1292	-	-	< 1	< 1	-	-	-	< 1
D5/stream	1.017	-	-	**> 1**	**> 1**	-	-	-	< 1
R1/pond	0.1294	-	-	< 1	< 1	-	-	-	< 1
R1/stream	1.238	-	-	**> 1**	**> 1**	-	-	-	< 1
R3/stream	2.370	-	-	**> 1**	**> 1**	-	-	-	< 1

Arithmetic mean:

Group		Fish acute	Fish prolonged	Invertebr. acute	Invertebr. long	Algae	Sed. dwell. prolonged	Aquatic Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula pelliculosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*
Endpoint (µg/L)		LC_{50} 470	NOEC 147	EC_{50} 55	NOEC 0.54	E_rC_{50}/E_bC_{50} 146	NOEC 800	EC_{50} 3200	!
AF		100	10	100	10	10	10	10	!
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	PEC $_{(plateau)}$ (µg/L)								
Step 1									
	44.45	9.459	3.024	80.829	46.600	3.045	0.556	0.139	13.472
Step 2									
N. Europe	6.267	1.333	0.426	11.394	6.569	0.429	0.078	0.020	1.899
Step 3									
D3/ditch	1.263	0.269	0.086	2.296	1.324	0.087	0.016	0.004	0.383
D4/pond	1.157	0.246	0.079	2.104	1.213	0.079	0.014	0.004	0.351
D4/stream	1.190	0.253	0.081	2.164	1.247	0.082	0.015	0.004	0.361
D5/pond	0.048	0.010	0.003	0.088	0.051	0.003	0.001	0.000	0.015
D5/stream	1.011	0.215	0.069	1.838	1.060	0.069	0.013	0.003	0.306
R1/pond	0.220	0.047	0.015	0.400	0.231	0.015	0.003	0.001	0.067
R1/stream	2.003	0.426	0.136	3.642	2.100	0.137	0.025	0.006	0.607
R3/stream	2.779	0.591	0.189	5.053	2.913	0.190	0.035	0.009	0.842

Geometric mean:

Group		Fish-acute	Fish prolonged	Inverteb. acute	Inverteb. long	Algae	Sed.-dwell. prolonged	Aquatic-Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula pelliculosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*
Endpoint (ug/L)		LC50 170	NOEC 147	EC50 55	NOEC 9.54	E_rC_{50} 146	NOEC 800	EC50 3200	1
AF		100	10	100	10	10	10	10	1
RAC (ug/L)		1.7	14.7	0.55	0.954	14.6	80	320	1
FOCUS Scenario	PEC ai-mac (ug/L)								
Step 1									
	15.641	0.741	4.105	82.093	47.841	4.124	0.571	0.143	13.830
Step 2									
N-Europe	6.434	1.268	0.437	11.693	6.741	0.430	0.080	0.020	1.949
Step 3									
D3/ditch	1.264	0.260	0.088	2.208	1.335	0.057	0.016	0.004	0.383
D4/pond	1.220	0.262	0.084	2.236	1.289	0.054	0.015	0.004	0.373
D4/stream	1.242	0.264	0.084	2.258	1.302	0.055	0.016	0.004	0.376
D5/pond	0.048	0.040	0.002	0.087	0.050	0.003	0.001	0.000	0.015
D5/stream	1.012	0.215	0.069	1.840	1.061	0.069	0.013	0.003	0.307
R1/pond	0.222	0.040	0.016	0.422	0.243	0.016	0.003	0.001	0.070
R1/stream	2.328	0.405	0.158	4.233	2.440	0.150	0.029	0.007	0.705
R3/stream	3.554	0.756	0.242	6.462	3.725	0.243	0.044	0.011	1.077
Step 4									
R3/stream	1.598	0.340	0.109	2.905	1.675	0.109	0.020	0.005	0.484

Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/F/SCORPIO 325 SC in spring oilseed rape (BBCH14)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
	45.64	**> 1**	**> 1**	**> 1**	**> 1**	**>1**	< 1	< 1	**>1**
Step 2									
N-Europe/Mar-May	3.89	< 1	< 1	**> 1**	**> 1**	<1	-	-	**>1**
Step 3									
D3/ditch	1.269	-	-	**> 1**	**> 1**	-	-	-	< 1
D4/pond	0.3753	-	-	< 1	< 1	-	-	-	< 1
D4/stream	1.049	-	-	**> 1**	**> 1**	-	-	-	< 1
D5/pond	0.1686	-	-	< 1	< 1	-	-	-	< 1
D5/stream	1.109	-	-	**> 1**	**> 1**	-	-	-	< 1
R1/pond	0.1683	-	-	< 1	< 1	-	-	-	< 1
R1/stream	1.545	-	-	**> 1**	**> 1**	-	-	-	< 1

Arithmetic mean:

Group		Fish acute	Fish prolonged	Invertebr. acute	Invertebr. long	Algae	Sed. dwell. prolonged	Aquatic-Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula pelliculosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*
Endpoint (µg/L)		LC_{50} 470	NOEC 147	EC_{50} 55	NOEC 0.54	E_rC_{50}/E_yC_{50} 146	NOEC 800	EC50 3200	!
AF		100	10	100	10	10	10	10	!
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	PEC $_{(sw)max}$ (µg/L)								
Step 1									
	44.47	9.462	3.025	80.855	46.614	3.046	0.556	0.139	13.476
Step 2									
N-Europe	13.67	2.909	0.930	24.857	14.331	0.936	0.171	0.043	4.142
Step 3									
D1/ditch	5.346	1.137	0.364	9.72	5.604	0.366	0.067	0.017	1.620
D1/stream	3.349	0.712	0.228	6.089	3.510	0.229	0.042	0.010	1.015
D3/ditch	1.267	0.270	0.086	2.304	1.328	0.087	0.016	0.004	0.384
D4/pond	1.136	0.242	0.773	2.065	1.191	0.078	0.014	0.004	0.344
D4/stream	1.172	0.249	0.080	2.131	1.228	0.080	0.015	0.004	0.355
D5/pond	0.058	0.012	0.004	0.105	0.061	0.004	0.001	0.000	0.018
D5/stream	1.006	0.214	0.068	1.829	1.054	0.069	0.013	0.003	0.305
R1/pond	0.184	0.039	0.012	0.334	0.193	0.013	0.002	0.001	0.056
R1/stream	1.963	0.418	0.133	3.569	2.058	0.134	0.025	0.006	0.595
Step 4									
D1-ditch	5.346	1.137	0.364	9.720	5.604	0.366	0.067	0.017	1.620
D1-stream	3.349	0.713	0.228	6.089	3.510	0.229	0.042	0.010	1.015

Geometric mean:

Group		Fish acute	Fish prolonged	Invertebr. acute	Invertebr. long	Algae	Sed. dwell. prolonged	Aquatic-Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula pelliculosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*

Group		Fish acute	Fish prolonged	Invertebr acute	Invertebr long	Algae	Sed. dwell, prolonged	Aquatic-Plant	Mesocosm
Endpoint (ug/L)		LC50 470	NOEC 147	EC50 55	NOEC 9.54	ErC50/E_Ca 146	NOEC 300	EC50 3200	-
AF		100	10	100	10	10	10	10	-
PAC (ug/L)		4.7	14.7	0.55	0.954	146	30	320	9.5
FOCUS Scenario	PEC al-max (ug/L)								
Step-1									
	45.64	9.711	3.105	82.982	47.841	3.126	0.571	0.143	13.930
Step-2									
N-Europe	6.42	1.368	0.437	11.693	6.741	0.440	0.080	0.020	1.949
Step-3									
D1-ditch	13.360	2.845	0.909	24.291	14.004	0.915	0.167	0.042	4.048
D1-stream	8.438	1.791	0.573	15.305	8.824	0.577	0.105	0.026	2.551
D3-ditch	1.373	0.291	0.093	2.313	1.333	0.087	0.016	0.004	0.385
D4-pond	3.000	0.637	0.204	5.618	3.239	0.212	0.039	0.010	0.936
D4-stream	3.147	0.670	0.214	5.722	3.299	0.216	0.039	0.010	0.954
D5-pond	1.248	0.266	0.085	2.269	1.308	0.085	0.016	0.004	0.378
D5-stream	1.418	0.302	0.096	2.622	1.518	0.099	0.018	0.005	0.430
R1-pond	0.067	0.014	0.005	0.122	0.070	0.005	0.001	0.000	0.020
R1-stream	1.276	0.271	0.087	2.320	1.338	0.087	0.016	0.004	0.387
Step-4 (10 m vegetative strip, 10 m no-spray buffer)									
D1-ditch	5.242	1.115	0.357	9.531	5.495	0.359	0.066	0.016	1.588
D1-stream	3.280	0.698	0.223	5.964	3.438	0.225	0.041	0.010	0.994
Step-4 (20 m vegetative strip, 20 m no-spray buffer)									
D1-ditch	5.242	1.115	0.357	9.531	5.495	0.359	0.066	0.016	1.588

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/F/SCORPIO 325 SC in spring oilseed rape (BBCH31)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
	45.64	**> 1**	**> 1**	**> 1**	**> 1**	**>1**	< 1	< 1	**>1**
Step 2									
N-Europe/Mar-May	3.89	< 1	< 1	**> 1**	**> 1**	<1	-	-	**>1**
Step 3									
D3/ditch	1.268	-	-	**> 1**	**> 1**	-	-	-	< 1
D4/pond	0.3746	-	-	< 1	< 1	-	-	-	< 1
D4/stream	1.038	-	-	**> 1**	**> 1**	-	-	-	< 1
D5/pond	0.1594	-	-	< 1	< 1	-	-	-	< 1
D5/stream	1.105	-	-	**> 1**	**> 1**	-	-	-	< 1
R1/pond	0.2417	-	-	< 1	< 1	-	-	-	< 1
R1/stream	2.629	-	-	**> 1**	**> 1**	-	-	-	< 1

Arithmetic mean:

Group		Fish acute	Fish prolonged	Invertebr. acute	Invertebr. long	Algae	Sed. dwell. prolonged	Aquatic Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula pelliculosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*
Endpoint (µg/L)		LC_{50} 470	NOEC 147	EC_{50} 55	NOEC 0.54	E_rC_{50}/E_yC_{50} 146	NOEC 800	EC50 3200	-
AF		100	10	100	10	10	10	10	-
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	PEC $_{(sw)max}$ (µg/L)								
Step 1									
	44.46	9.461	3.025	80.845	46.609	3.046	0.556	0.139	13.473
Step 2									
N-Europe	6.27	1.333	0.426	11.395	6.596	0.429	0.078	0.020	1.9
Step 3									
D1/ditch	1.871	0.398	0.127	3.402	1.961	0.128	0.023	0.006	0.567
D1/stream	1.128	0.240	0.077	2.051	1.182	0.077	0.014	0.004	0.342
D3/ditch	1.268	0.270	0.086	2.305	1.329	0.087	0.016	0.004	0.384
D4/pond	0.499	0.106	0.034	0.907	0.523	0.034	0.006	0.002	0.151
D4/stream	1.038	0.221	0.071	1.887	1.088	0.071	0.013	0.003	0.315
D5/pond	0.044	0.009	0.003	0.080	0.046	0.003	0.001	0.000	0.013
D5/stream	1.103	0.235	0.075	2.005	1.156	0.076	0.014	0.003	0.334
R1/pond	0.277	0.059	0.019	0.504	0.290	0.019	0.003	0.001	0.084
R1/stream	3.013	0.641	0.205	5.478	3.158	0.206	0.038	0.009	0.913

Geometric mean:

Group		Fish acute	Fish prolonged	Invertebr. acute	Invertebr. long	Algae	Sed. dwell. prolonged	Aquatic Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula pelliculosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}/E_yC_{50}	NOEC	EC50	-

Group		Fish acute	Fish prolonged	Invertebr. acute	Invertebr. long	Algae	Sed. dwell. prolonged	Aquatic Plant	Mesocosm
(ug/L)		470	147	55	9.54	148	800	3200	
AF		100	10	100	10	10	10	10	1
RAC (ug/L)		4.7	14.7	0.55	0.954	14.8	80	320	5.3
FOCUS Scenario	PEC max (ug/L)								
Step 1									
	45.64	9.711	3.105	82.984	47.842	3.126	0.571	0.143	13.824
Step 2									
N Europe	6.421	1.368	0.437	11.693	6.741	0.440	0.080	0.020	1.949
Step 3									
D1 dtech	5.242	1.115	0.357	9.531	5.495	0.359	0.066	0.016	1.588
D1 stream	3.280	0.698	0.223	5.964	3.438	0.225	0.041	0.010	0.994
D3 dtech	1.267	0.270	0.086	2.304	1.328	0.087	0.016	0.004	0.384
D4 pond	1.236	0.263	0.084	2.247	1.296	0.085	0.015	0.004	0.375
D4 stream	1.254	0.266	0.085	2.275	1.311	0.086	0.016	0.004	0.379
D5 pond	0.061	0.013	0.004	0.111	0.064	0.004	0.001	0.000	0.018
D5 stream	1.007	0.214	0.069	1.831	1.056	0.069	0.013	0.003	0.305
R1 pond	0.185	0.039	0.012	0.336	0.194	0.013	0.002	0.001	0.056
R1 stream	2.108	0.449	0.142	3.833	2.210	0.144	0.026	0.007	0.639

Table 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/F/SCORPIO 325 SC in sugar beet (BBCH39)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
	45.64	**> 1**	**> 1**	**> 1**	**> 1**	**>1**	< 1	< 1	**>1**
Step 2									
N-Europe/June-Sept	3.47	< 1	< 1	**> 1**	**> 1**	<1	-	-	**>1**
Step 3									
D3/ditch	1.049	-	-	**> 1**	**> 1**	-	-	-	< 1
D4/pond	0.5990	-	-	**> 1**	< 1	-	-	-	< 1
D4/stream	0.8744	-	-	**> 1**	< 1	-	-	-	< 1
R1/pond	0.1321	-	-	< 1	< 1	-	-	-	< 1
R1/stream	1.871	-	-	**> 1**	**> 1**	-	-	-	< 1
R3/stream	1.967	-	-	**> 1**	**> 1**	-	-	-	< 1

Table 9.5-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/F/SCORPIO 325 SC in sugar beet (BBCH31)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
	45.64	**> 1**	**> 1**	**> 1**	**> 1**	**>1**	< 1	< 1	**>1**
Step 2									
N-Europe/June-Sept	3.89	< 1	< 1	**> 1**	**> 1**	<1	-	-	**>1**
Step 3									
D3/ditch	1.047	-	-	**> 1**	**> 1**	-	-	-	< 1
D4/pond	0.5952	-	-	**> 1**	< 1	-	-	-	< 1
D4/stream	0.8470	-	-	**> 1**	< 1	-	-	-	< 1
R1/pond	0.3510	-	-	< 1	< 1	-	-	-	< 1
R1/stream	2.205	-	-	**> 1**	**> 1**	-	-	-	< 1
R3/stream	2.815	-	-	**> 1**	**> 1**	-	-	-	< 1

Arithmetic mean:

Group		Fish acute	Fish prolonged	Inverteb. acute	Invertebr. long	Algae	Sed. dwell. prolonged	Aquatic Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula pelliculosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*
Endpoint (µg/L)		LC_{50} 470	NOEC 147	EC_{50} 55	NOEC 9.54	E_rC_{50}/E_yC_{50} 146	NOEC 800	EC50 3200	!
AF		100	10	100	10	10	10	10	!
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	PEC a. mass (µg/L)								
Step 1									
	44.46	0.461	3.025	80.845	46.600	3.046	0.556	0.139	13.473
Step 2									
N Europe	7.91	1.683	0.538	14.385	8.294	0.542	0.099	0.099	2.397
Step 3									
D3/ditch	1.049	0.223	0.071	1.907	1.100	0.072	0.013	0.003	0.318
D4/pond	0.142	0.030	0.010	0.258	0.149	0.010	0.002	0.000	0.043
D4/stream	0.872	0.186	0.059	1.585	0.914	0.060	0.011	0.003	0.264
R1/pond	0.187	0.040	0.013	0.340	0.196	0.013	0.002	0.001	0.057
R1/stream	2.900	0.617	0.197	5.273	3.040	0.199	0.036	0.009	0.879
R3/stream	3.149	0.670	0.214	5.725	3.301	0.216	0.039	0.010	0.954

Geometric mean:

Group		Fish acute	Fish prolonged	Invertebr. acute	Invertebr. long	Algae	Sed. dwell. prolonged	Aquatic Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula pelliculosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*
Endpoint (µg/L)		LC_{50} 470	NOEC 147	EC_{50} 55	NOEC 9.54	E_rC_{50}/E_yC_{50} 146	NOEC 800	EC50 3200	!
AF		100	10	100	10	10	10	10	!
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3

Group		Fish-acute	Fish-prolonged	Inverteb.-acute	Invertebl.-long	Algae	Sed. dwell.-prolonged	Aquatic-Plant	Mesocosm
FOCUS Scenario	PEC-plasma (µg/L)								
Step-1									
	45.641	0.791	3.105	82.934	47.849	3.126	0.571	0.143	13.831
Step-2									
N-Europe	8.122	1.728	0.553	14.767	8.514	0.556	0.102	0.025	2.461
Step-3									
D3/ditch	1.049	0.223	0.071	1.907	1.100	0.072	0.013	0.003	0.318
D4/pond	0.176	0.037	0.012	0.320	0.184	0.012	0.002	0.001	0.053
D4/stream	0.572	0.186	0.050	1.585	0.914	0.060	0.011	0.003	0.264
R1/pond	0.220	0.047	0.015	0.400	0.231	0.015	0.003	0.001	0.067
R1/stream	3.523	0.750	0.240	6.405	3.693	0.241	0.044	0.011	1.068
R3/stream	3.134	0.667	0.213	5.702	3.287	0.215	0.039	0.010	0.950
Step-3 (10-m-vegetative-strip_10-m-no-spray-buffer)									
R1/stream	1.509	0.340	0.109	2.907	1.676	0.110	0.020	0.005	0.485

Table 9.5-11: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/F/SCORPIO 325 SC in carrot (BBCH39)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
	45.64	**> 1**	**> 1**	**> 1**	**> 1**	**>1**	< 1	< 1	**>1**
Step 2									
N-Europe/Oct-Feb	7.70	**> 1**	< 1	**> 1**	**> 1**	<1	-	-	**>1**
Step 3									
D3/ditch	1.267	< 1	-	**> 1**	**> 1**	-	-	-	< 1
R1/pond	0.4477	< 1	-	< 1	< 1	-	-	-	< 1
R1/stream	1.886	< 1	-	**> 1**	**> 1**	-	-	-	< 1
R3/stream	2.075	< 1	-	**> 1**	**> 1**	-	-	-	< 1
R4/stream	3.180	< 1	-	**> 1**	**> 1**	-	-	-	< 1

Arithmetic mean

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. long	Algae	Sed. dwell. prolonged	Aquatic-Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula pelliculosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*
Endpoint (µg/L)		LC_{50} 470	NOEC 147	EC_{50} 55	NOEC 0.54	E_rC_{50}/E_bC_{50} 146	NOEC 800	EC50 3200	!
AF		100	10	100	10	10	10	10	!
PAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	PEC $_{pl\ max}$ (µg/L)								
Step 1									
	44.46	9.461	3.025	80.845	46.609	3.046	0.556	0.139	13.473
Step 2									
N-Europe	7.50	1.596	0.510	13.638	7.863	0.514	0.094	0.023	2.273
Step 3									
D3/ditch	1.268	0.270	0.086	2.305	1.329	0.087	0.016	0.004	0.384
R1/pond	0.127	0.027	0.009	0.231	0.133	0.009	0.002	0.000	0.038
R1/stream	2.780	0.591	0.189	5.055	2.914	0.190	0.035	0.009	0.842
R2/stream	1.123	0.239	0.076	2.042	1.177	0.077	0.014	0.004	0.340
R2/stream	1.127	0.240	0.077	2.049	1.181	0.077	0.014	0.004	0.341
R3/stream	1.896	0.403	0.129	3.447	1.987	0.130	0.024	0.006	0.575
R4/stream	4.716	1.003	0.321	8.575	4.943	0.323	0.059	0.015	1.429
Step 4									
R4 Stream	0.161	0.034	0.011	0.293	0.169	0.011	0.002	0.001	0.049

Geometric mean

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. long	Algae	Sed.-dwell. prolonged	Aquatic-Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula pelliculosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}/E_bC_{50}	NOEC	EC50	!

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. long	Algae	Sed. dwell. prolonged	Aquatic-Plant	Mesocosm
(µg/L)		420	142	53	3.54	140	806	3200	
AF		100	10	100	10	10	10	10	1
RAC (µg/L)		4.2	14.2	0.53	0.354	14.6	80	320	3.3
FOCUS Scenario	PEC-sw max (µg/L)								
Step 1									
	45.643	9.741	3.105	82.084	47.343	3.126	0.571	0.143	13.831
Step 2									
N-Europe	7.609	1.628	0.524	13.995	8.070	0.527	0.096	0.024	2.323
Step 3									
D3-ditch	1.265	0.269	0.086	2.300	1.326	0.087	0.016	0.004	0.383
D6-ditch	1.350	0.266	0.085	2.272	1.310	0.086	0.016	0.004	0.379
R1-pond	0.605	0.129	0.041	1.100	0.634	0.043	0.008	0.002	0.183
R1stream	2.563	0.545	0.174	4.660	2.687	0.176	0.032	0.008	0.777
R2-stream	1.156	0.246	0.079	2.102	1.212	0.079	0.014	0.004	0.350
R3stream	6.889	1.466	0.469	12.525	7.221	0.475	0.086	0.022	2.088
R3stream	3.506	0.746	0.239	6.375	3.675	0.240	0.044	0.011	1.062
R4stream	1.771	1.015	0.325	8.675	5.001	0.227	0.060	0.015	1.446
Step 4 (10 m vegetative strip, 10 m no spray buffer)									
R2	3.127	0.665	0.213	5.685	3.278	0.214	0.039	0.010	0.948
R2	1.600	0.340	0.100	2.900	1.677	0.110	0.020	0.005	0.485
R4	2.168	0.461	0.147	3.942	2.273	0.148	0.027	0.007	0.657

Table 9.5-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/F/SCORPIO 325 SC in potato (BBCH14)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
	45.64	**> 1**	**> 1**	**> 1**	**> 1**	**>1**	< 1	< 1	**>1**
Step 2									
N-Europe/Mar-May	8.54	**> 1**	< 1	**> 1**	**> 1**	<1	-	-	**>1**
Step 3									
D3/ditch	1.049	< 1	-	**> 1**	**> 1**	-	-	-	< 1
D4/pond	0.5800	< 1	-	**> 1**	< 1	-	-	-	< 1
D4/stream	0.8757	< 1	-	**> 1**	< 1	-	-	-	< 1
R1/pond	0.2592	< 1	-	< 1	< 1	-	-	-	< 1
R1/stream	2.929	< 1	-	**> 1**	**> 1**	-	-	-	< 1
R3/stream	3.309	< 1	-	**> 1**	**> 1**	-	-	-	**> 1**
Step 4		10 m vegetative strip, 5 m no spray buffer							
R3/stream	1.509	-	-	**> 1**	**> 1**	-	-	-	< 1

Table 9.5-13: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/F/SCORPIO 325 SC in potato (BBCH31)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
	45.64	**> 1**	**> 1**	**> 1**	**> 1**	**>1**	< 1	< 1	**>1**
Step 2									
N-Europe/Mar-May	3.89	< 1	< 1	**> 1**	**> 1**	<1	-	-	**>1**
Step 3									
D3/ditch	1.048	-	-	**> 1**	**> 1**	-	-	-	< 1
D4/pond	0.8453	-	-	**> 1**	< 1	-	-	-	< 1
D4/stream	0.8518	-	-	**> 1**	< 1	-	-	-	< 1
R1/pond	0.3027	-	-	< 1	< 1	-	-	-	< 1
R1/stream	1.982	-	-	**> 1**	**> 1**	-	-	-	< 1
R3/stream	2.718	-	-	**> 1**	**> 1**	-	-	-	< 1

Arithmetic mean

Group		Fish acute	Fish prolonged	Invertebr. acute	Invertebr. long	Algae	Sed. dwell. prolonged	Aquatic Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula pelliculosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*
Endpoint (µg/L)		LC_{50} 170	NOEC 147	EC_{50} 55	NOEC 0.54	E_rC_{50}/E_yC_{50} 146	NOEC 800	EC50 3200	!
AF		100	10	100	10	10	10	10	!
RAC (µg/L)		1.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	PEC $_{initial}$ (µg/L)								
Step 1									
	44.46	9.461	3.025	80.845	46.609	3.046	0.556	0.139	13.473
Step 2									
N-Europe	8.32	1.771	0.566	15.135	8.725	0.570	0.104	0.026	2.521
Step 3									
D3/ditch	1.049	0.223	0.071	1.907	1.100	0.072	0.013	0.003	0.318
D4/pond	1.632	0.347	0.111	2.967	1.711	0.112	0.020	0.005	0.494
D4/stream	1.556	0.331	0.106	2.829	1.631	0.107	0.019	0.005	0.471
R1/pond	0.262	0.056	0.018	0.476	0.275	0.018	0.003	0.001	0.079
R1/stream	2.916	0.620	0.198	5.302	3.057	0.200	0.036	0.009	0.884
R2/stream	0.959	0.204	0.065	1.744	1.005	0.066	0.012	0.003	0.291
R3/stream	3.242	0.690	0.220	5.895	3.398	0.222	0.041	0.010	0.982

For the intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in all FOCUS Steps 1–4 scenarios. Therefore, no further assessment is necessary.

Geometric mean

Group		Fish acute	Fish prolonged	Invertebr. acute	Invertebr. long	Algae	Sed. dwell. prolonged	Aquatic Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula pelliculosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}/E_yC_{50}	NOEC	EC50	!

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. long	Algae	Sed. dwell. prolonged	Aquatic Plant	Mesocosm
(µg/L)		470	147	55	9.54	146	800	3200	
AF		100	10	100	10	10	10	10	1
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.2
FOCUS Scenario	PEC a,max (µg/L)								
Step 1									
	35.6412	0.711	2.105	50.084	37.842	1.126	0.571	0.142	12.334
Step 2									
N-Europe	2.5445	1.818	0.581	15.535	8.956	0.585	0.102	0.027	2.589
Step 3									
D3/dach	1.040	0.224	0.071	1.907	1.100	0.072	0.013	0.003	0.318
D4/pond	1.657	0.353	0.113	3.013	1.737	0.113	0.021	0.005	0.502
D4/stream	1.503	0.320	0.103	2.893	1.668	0.109	0.020	0.005	0.482
R1/pond	0.280	0.060	0.019	0.509	0.294	0.019	0.003	0.001	0.085
R1/stream	3.173	0.675	0.216	5.769	3.326	0.217	0.040	0.010	0.962
R2/stream	1.084	0.231	0.074	1.971	1.136	0.074	0.014	0.003	0.328
R3/stream	3.461	0.736	0.235	6.293	3.628	0.237	0.045	0.011	1.049
Step 4 (10 m vegetative strip, 10 m no spray buffer)									
R2/stream	1.570	0.334	0.107	2.871	1.653	0.108	0.020	0.005	0.478

Table 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/F/SCORPIO 325 SC in potato (BBCH31)

Arithmetic mean:

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. long	Algae	Sed. dwell. prolonged	Aquatic Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula gelliculosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}/E_yC_{50}	NOEC	EC50	-
(µg/L)		470	147	55	9.54	146	800	3200	
AF		100	10	100	10	10	10	10	1

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. long	Algae	Sed. dwell. prolonged	Aquatic Plant	Mesocosm
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	PEC a.max (µg/L)								
Step 1									
	44.47	9.462	3.025	80.855	46.614	3.046	0.556	0.139	13.476
Step 2									
N-Europe	18.31	3.896	1.246	33.291	19.193	1.254	0.229	0.057	5.548
Step 3									
D3/ditch	1.048	0.223	0.071	1.905	1.099	0.072	0.013	0.003	0.318
D4/pond	1.279	0.272	0.087	2.325	1.341	0.088	0.088	0.004	0.388
D4/stream	1.258	0.268	0.086	2.287	1.319	0.086	0.086	0.004	0.381
R1/pond	0.388	0.083	0.026	0.705	0.407	0.027	0.027	0.001	0.118
R1/stream	2.317	0.493	0.158	4.213	2.429	0.159	0.159	0.007	0.702
R2/stream	0.960	0.204	0.065	1.745	1.006	0.066	0.066	0.003	0.291
R3/stream	3.503	0.745	0.238	6.369	3.672	0.240	0.240	0.011	1.062
Step 4									
R3/stream	1.590	0.338	0.108	2.891	1.667	0.109	0.020	0.005	0.482

Geometric mean:

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. long	Algae	Sed. dwell. prolonged	Aquatic Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula pelliculosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*
Endpoint (µg/L)		LC50 470	NOEC 147	EC50 55	NOEC 9.54	EC50/EC25 146	NOEC 800	EC50 3200	-
AF		100	10	100	10	10	10	10	-
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	PEC a.max (µg/L)								

Group		Fish acute	Fish prolonged	Invertebr. acute	Invertebr. long	Algae	Sed. dwell prolonged	Aquatic-Plant	Mesocosm
Step-1									
	45.64	0.711	3.105	82.954	47.842	3.126	0.571	0.143	13.831
Step-2									
N-Europe	5.544	1.818	0.581	15.535	9.956	0.585	0.107	0.027	2.589
Step-3									
D3/ditch	1.048	0.223	0.071	1.905	1.000	0.072	0.013	0.003	0.218
D4/pond	1.364	0.290	0.093	2.480	1.320	0.093	0.017	0.004	0.413
D4/stream	1.316	0.280	0.000	2.393	1.370	0.000	0.016	0.004	0.399
D6/ditch	1.042	0.222	0.071	1.895	1.092	0.071	0.013	0.003	0.316
D6/ditch	1.042	0.222	0.071	1.895	1.092	0.071	0.013	0.003	0.316
R1/pond	0.430	0.092	0.030	0.709	0.460	0.030	0.005	0.001	0.133
R1/stream	2.781	0.592	0.189	5.056	2.915	0.190	0.035	0.009	0.843
R2/stream	1.005	0.222	0.074	1.901	1.148	0.075	0.014	0.003	0.232
R3/stream	3.833	0.816	0.261	6.969	4.018	0.263	0.048	0.012	1.162
Step-1 (10-m-vegetative-strip, 10-m-no-spray-buffer)									
R3/stream	1.730	0.370	0.118	3.162	1.823	0.119	0.022	0.005	0.527

Table 9.5-14: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/F/SCORPIO 325 SC in leafy vegetables (BBCH 14).

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
	91.28	**> 1**	**> 1**	**> 1**	**> 1**	**>1**	< 1	< 1	**>1**
Step 2									
N-Europe/Mar-May	14.32	**> 1**	< 1	**> 1**	**> 1**	<1	-	-	**>1**
Step 3									
D3/ditch	1.108	< 1	-	**> 1**	**> 1**	-	-	-	< 1
D4/pond	1.072	< 1	-	**> 1**	**> 1**	-	-	-	< 1
D4/stream	1.074	< 1	-	**> 1**	**> 1**	-	-	-	< 1
R1/pond	0.4254	< 1	-	< 1	< 1	-	-	-	< 1
R1/stream	4.942	**> 1**	-	**> 1**	**> 1**	-	-	-	**> 1**
R3/stream	3.680	< 1	-	**> 1**	**> 1**	-	-	-	**> 1**
R4/stream	6.599	**> 1**	-	**> 1**	**> 1**	-	-	-	**> 1**

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 4		10 m vegetative strip, 10 m no spray buffer							
R1/stream	2.241	< 1	-	**> 1**	**> 1**	-	-	-	< 1
R3/stream	1.869	-	-	**> 1**	**> 1**	-	-	-	< 1
R4/stream	3.001	< 1	-	**> 1**	**> 1**	-	-	-	< 1
~~**Step 4**~~		~~20 m vegetative strip, 20 m no spray buffer~~							
~~R1/stream~~	~~1.173~~	~~< 1~~	~~-~~	~~**> 1**~~	~~**> 1**~~	~~-~~	~~-~~	~~-~~	~~< 1~~
~~R3/stream~~	~~0.8711~~	~~-~~	~~-~~	~~**> 1**~~	~~**> 1**~~	~~-~~	~~-~~	~~-~~	~~< 1~~
~~R4/stream~~	~~1.573~~	~~< 1~~	~~-~~	~~**> 1**~~	~~**> 1**~~	~~-~~	~~-~~	~~-~~	~~< 1~~

Arithmetic mean

Group		Fish acute	Fish prolonged	Invertebr. acute	Invertebr. long	Algae	Sed. dwell. prolonged	Aquatic Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula pelliculosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*
Endpoint (µg/L)		LC_{50} 470	NOEC 147	EC_{50} 55	NOEC 0.54	E_rC_{50}/E_yC_{50} 146	NOEC 800	EC50 3200	!
AF		100	10	100	10	10	10	10	!
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	PEC $_{sw,max}$ (µg/L)								
Step 1									
	88.93	18.921	6.050	161.691	93.218	6.091	1.112	0.278	26.948
Step 2									
N-Europe	13.95	2.968	0.949	25.364	14.623	0.955	0.174	0.044	4.227
Step 3									
D3/ditch	1.109	0.236	0.075	2.016	1.162	0.076	0.014	0.003	0.336
D3/ditch	3.185	0.678	0.217	5.791	3.339	0.218	0.040	0.010	0.965
D4/pond	3.054	0.650	0.208	5.553	3.201	0.209	0.038	0.010	0.925
D4/stream	0.464	0.099	0.032	0.844	0.486	0.032	0.006	0.001	0.141
R1/pond	0.358	0.076	0.024	0.651	0.375	0.025	0.004	0.001	0.108
R1/pond	5.16	1.098	0.351	9.382	5.409	0.353	0.065	0.016	1.564
R1/stream	4.149	0.883	0.282	7.544	4.349	0.284	0.052	0.013	1.257
R1/stream (2nd)	1.711	0.364	0.116	3.111	1.794	0.117	0.021	0.005	0.518
R2/stream	1.762	0.375	0.120	3.204	1.847	0.121	0.022	0.006	0.534
R2/stream (2nd)	3.925	0.835	0.267	7.136	4.114	0.269	0.049	0.012	1.189
R3/stream	4.388	0.934	0.299	7.978	4.600	0.301	0.055	0.014	1.330
R3/stream (2nd)	6.646	1.414	0.452	12.084	6.966	0.455	0.083	0.021	2.014
R4/stream	5.32	1.132	0.362	9.673	5.577	0.364	0.067	0.017	1.612
R4/stream	1.109	0.236	0.075	2.016	1.162	0.076	0.014	0.003	0.336

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. long	Algae	Sed. dwell. prolonged	Aquatic Plant	Mesocosm
Step 4									
R1 stream	2.34	0.498	0.159	4.255	2.453	0.160	0.029	0.007	0.709
R1 stream	1.887	0.401	0.128	3.431	1.978	0.129	0.024	0.006	0.572
R2 stream	1.791	0.381	0.122	3.256	1.877	0.123	0.022	0.006	0.543
R3 stream	2	0.426	0.136	3.636	2.096	0.137	0.025	0.006	0.606
R4 stream	3.022	0.643	0.206	5.495	3.168	0.207	0.038	0.009	0.916
R4 stream	2.417	0.514	0.164	4.395	2.534	0.166	0.030	0.008	0.732
Geometric mean:									

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. long	Algae	Sed. dwell. prolonged	Aquatic Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula pelliculosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*
Endpoint (ug/L)		LC50 170	NOEC 147	EC50 55	NOEC 9.54	E.C50/E.C50 146	NOEC 800	EC50 3200	-
AF		100	10	100	10	10	10	10	-
PAC (ug/L)		1.7	14.7	0.55	0.954	14.6	80	320	3.2
FOCUS Scenario	PEC plateau (ug/L)								
Step 1									
	45.64	9.711	3.105	82.984	47.842	3.126	0.571	0.143	12.551
Step 2									
N Europe	7.600	1.618	0.581	15.535	8.956	0.585	0.107	0.027	2.589
Step 3									
D1/ditch	1.267	0.270	0.086	2.304	1.328	0.087	0.016	0.004	0.384
D3/ditch	1.269	0.270	0.086	2.307	1.330	0.087	0.016	0.004	0.385
D4/pond	1.679	0.357	0.114	3.053	1.760	0.115	0.021	0.005	0.509
D4/stream	1.592	0.339	0.108	2.895	1.669	0.109	0.020	0.005	0.487
R1/pond	1.240	0.264	0.084	2.255	1.300	0.085	0.016	0.004	0.376
R1/pond	0.197	0.042	0.013	0.358	0.206	0.013	0.003	0.001	0.060

Group		Fish acute	Fish prolonged	Invertebr. acute	Invertebr. long	Algae	Sed. dwell. prolonged	Aquatic Plant	Mesocosm
R1 stream	0.223	0.047	0.015	0.405	0.234	0.015	0.003	0.001	0.068
R1 stream (2nd)	0.007	0.446	0.143	3.813	2.198	0.144	0.026	0.007	0.635
R2 stream	0.503	0.533	0.170	4.551	2.624	0.171	0.031	0.008	0.758
R2 stream (2nd)	1.005	0.233	0.074	1.991	1.148	0.075	0.014	0.003	0.332
R3 stream	1.123	0.239	0.076	2.042	1.177	0.077	0.014	0.004	0.340
R3 stream (2nd)	3.658	0.778	0.249	6.651	3.834	0.251	0.046	0.011	1.108
R4 stream	3.107	0.661	0.211	5.649	3.257	0.213	0.039	0.010	0.942
R4 stream	1.459	0.310	0.099	2.653	1.529	0.100	0.018	0.005	0.442
Map 4 (10 m vegetative strip, 10 m no spray buffer)									
R1 stream	1.655	0.352	0.112	3.009	1.735	0.113	0.021	0.005	0.502
R2 stream (2nd)	1.415	0.301	0.096	2.573	1.483	0.097	0.018	0.004	0.429
R3 stream	0.664	0.141	0.045	1.207	0.696	0.045	0.008	0.002	0.201
R4 stream (2nd)	2.152	0.458	0.146	3.913	2.256	0.147	0.027	0.007	0.652

Table 9.5-15: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/F/SCORPIO 325 SC in tobacco.

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
	91.28	**> 1**	**> 1**	**> 1**	**> 1**	**>1**	< 1	< 1	**>1**
Step 2									
N-Europe/Mar-May	7.15	**> 1**	< 1	**> 1**	**> 1**	< 1	-	-	**>1**
Step 3									
R3/stream	5.682	**> 1**	-	**> 1**	**> 1**	-	-	-	**> 1**
Step 4		10 m vegetative strip, 5 m no spray buffer							
R3/stream	2.589	< 1	-	**> 1**	**> 1**	-	-	-	< 1

Arithmetic mean:

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. long	Algae	Sed. dwell. prolonged	Aquatic-Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula pelliculosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*
Endpoint (µg/L)		LC_{50} 470	NOEC 147	EC_{50} 55	NOEC 9.54	E_rC_{50}/E_yC_{50} 146	NOEC 800	EC_{50} 3200	-
AF		100	10	100	10	10	10	10	-
PAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	PEC al-max (µg/L)								
Step 1									
	88.93	18.921	6.050	161.691	93.218	6.091	1.112	0.278	26.948
Step 2									
N-Europe	14.72	3.132	1.001	26.764	15.430	1.008	0.184	0.046	4.461
Step 3									
R3/stream	2.481	0.528	0.169	4.511	2.601	0.170	0.031	0.008	0.752

Geometric mean:

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. long	Algae	Sed. dwell. prolonged	Aquatic-Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula pelliculosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*
Endpoint (µg/L)		LC_{50} 470	NOEC 147	EC_{50} 55	NOEC 9.54	E_rC_{50}/E_yC_{50} 146	NOEC 800	EC_{50} 3200	-
AF		100	10	100	10	10	10	10	-
PAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	PEC al-max (µg/L)								
Step 1									
	91.258	19.429	6.210	165.969	95.684	6.252	1.141	0.285	27.662
Step 2									
N-Europe	15.118	3.216	1.028	27.479	15.842	1.035	0.189	0.047	4.580

Group		Fish acute	Fish prolonged	Invertebr. acute	Invertebr. long	Algae	Sed. dwell. prolonged	Aquatic Plant	Mesocosm
Step 3									
D3/dach	13.37	2.845	0.910	24.400	14.015	0.916	0.167	0.042	4.052
D4/pond	1.475	0.314	0.100	2.682	1.546	0.101	0.018	0.005	0.447
D4/stream	13.51	2.874	0.919	24.564	14.161	0.925	0.169	0.047	4.094
D5/pond	1.517	0.323	0.103	2.758	1.590	0.104	0.019	0.005	0.460
D5/stream	14.32	3.047	0.974	26.036	15.010	0.981	0.179	0.045	4.339
R1/pond	1.495	0.318	0.102	2.718	1.567	0.103	0.019	0.005	0.453
R1/stream	10.72	2.281	0.729	19.491	11.237	0.734	0.134	0.034	3.248
R2/stream	14.22	3.026	0.967	25.853	14.906	0.974	0.178	0.044	4.309
R3/stream	15.17	3.228	1.032	27.592	15.901	1.039	0.190	0.047	4.597
R4/stream	10.78	2.294	0.733	19.600	11.300	0.738	0.135	0.034	3.267
Step 4 (10 m vegetative strip, 10 m no spray buffer)									
D3/dach	6.088	1.295	0.414	11.060	6.382	0.417	0.076	0.019	1.845
D4/stream	6.778	1.442	0.461	12.324	7.105	0.464	0.085	0.021	2.054
D5/stream	7.182	1.528	0.489	13.053	7.528	0.493	0.090	0.022	2.176
R1/stream	5.375	1.144	0.366	9.773	5.634	0.369	0.067	0.017	1.629
R2/stream	7.131	1.517	0.485	12.963	7.475	0.488	0.089	0.022	2.161
R3/stream	7.610	1.619	0.518	13.836	7.977	0.521	0.095	0.024	2.306
R4/stream	5.407	1.150	0.368	9.831	5.668	0.370	0.068	0.017	1.638
Step 4 (20 m vegetative strip, 20 m no spray buffer)									
D3/dach	1.576	0.335	0.107	2.865	1.652	0.108	0.020	0.005	0.478
D4/stream	1.755	0.373	0.119	3.191	1.840	0.120	0.022	0.005	0.532
D5/stream	1.859	0.396	0.126	3.380	1.949	0.127	0.023	0.006	0.563
R1/stream	1.391	0.296	0.095	2.529	1.458	0.095	0.017	0.004	0.422
R2/stream	1.846	0.393	0.126	3.356	1.935	0.126	0.023	0.006	0.559
R3/stream	1.971	0.419	0.134	3.584	2.066	0.135	0.025	0.006	0.597

Group		Fish acute	Fish prolonged	Invertebr. acute	Invertebr. long	Algae	Sed. dwell. prolonged	Aquatic Plant	Mesocosm
R4-stress	1.000	0.203	0.095	2.545	1.468	0.096	0.018	0.004	0.424

Table 9.5-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/F/SCORPIO 325 SC in pome fruit (BBCH 10).

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
	126.53	**> 1**	**> 1**	**> 1**	**> 1**	**>1**	< 1	< 1	**>1**
Step 2									
N-Europe/Mar-May	34.45	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	-	-	**>1**
Step 3									
D3/ditch	8.353	**> 1**	< 1	**> 1**	**> 1**	< 1	-	-	**> 1**
D4/pond	0.8233	< 1	< 1	**> 1**	< 1	< 1	-	-	< 1
D4/stream	8.445	**> 1**	< 1	**> 1**	**> 1**	< 1	-	-	**> 1**
D5/pond	0.9950	< 1	< 1	**> 1**	**> 1**	< 1	-	-	< 1
D5/stream	8.950	**> 1**	< 1	**> 1**	**> 1**	< 1			**> 1**
R1/pond	0.9133	< 1	< 1	**> 1**	< 1	< 1	-	-	< 1
R1/stream	6.698	**> 1**	< 1	**> 1**	**> 1**	< 1	-	-	**> 1**
R3/stream	9.483	**> 1**	< 1	**> 1**	**> 1**	< 1	-	-	**> 1**

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**								
R4/stream	6.737	**> 1**	< 1	**> 1**	**> 1**	< 1	-	-	**> 1**
Step 4		20 m vegetative strip, 20 m no spray buffer							
D3/ditch	0.9850	< 1	-	**> 1**	**> 1**	-	-	-	< 1
D4/stream	1.097	< 1	-	**> 1**	**> 1**	-	-	-	< 1
D5/stream	1.163	< 1	-	**> 1**	**> 1**	-	-	-	< 1
R1/stream	0.8696	< 1	-	**> 1**	< 1	-	-	-	< 1
R3/stream	1.232	< 1	-	**> 1**	**> 1**	-	-	-	< 1
R4/stream	0.8747	< 1	-	**> 1**	**> 1**	-	-	-	< 1

Table 9.5-17: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/F/SCORPIO 325 SC in pome fruit (BBCH 31).

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
	126.53	**> 1**	**> 1**	**> 1**	**> 1**	**>1**	< 1	< 1	**>1**
Step 2									
N-Europe/Mar-May	34.45	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	-	-	**>1**
Step 3									
D3/ditch	13.38	**> 1**	< 1	**> 1**	**> 1**	< 1	-	-	**> 1**
D4/pond	1.452	< 1	< 1	**> 1**	**> 1**	< 1	-	-	< 1
D4/stream	13.87	**> 1**	< 1	**> 1**	**> 1**	< 1	-	-	**> 1**
D5/pond	1.562	< 1	< 1	**> 1**	**> 1**	< 1	-	-	< 1
D5/stream	14.40	**> 1**	< 1	**> 1**	**> 1**	< 1	-	-	**> 1**
R1/pond	1.302	< 1	< 1	**> 1**	**> 1**	< 1	-	-	< 1
R1/stream	10.78	**> 1**	< 1	**> 1**	**> 1**	< 1	-	-	**> 1**

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**								
R3/stream	15.16	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	-	-	**> 1**
R4/stream	10.78	**> 1**	< 1	**> 1**	**> 1**	< 1	-	-	**> 1**
Step 4		20 m vegetative strip, 20 m no spray buffer							
D3/ditch	1.577	< 1	-	**> 1**	**> 1**	-	-	-	< 1
D4/stream	1.801	< 1	-	**> 1**	**> 1**	-	-	-	< 1
D5/stream	1.871	< 1	-	**> 1**	**> 1**	-	-	-	< 1
R1/stream	1.400	< 1	-	**> 1**	**> 1**	-	-	-	< 1
R3/stream	1.968	< 1	-	**> 1**	**> 1**	-	-	-	< 1
R4/stream	1.400	< 1	-	**> 1**	**> 1**	-	-	-	< 1

Arithmetic mean:

Group		fish acute	Fish prolonged	Inverteb. acute	Inverteb. long	Algae	Sed. dwell. prolonged	Aquatic Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula pellicolosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*
Endpoint (ug/L)		LC_{50} 470	NOEC 147	EC_{50} 55	NOEC 9.54	E_rC_{50}/E_bC_{50} 146	NOEC 800	EC50 3200	!
AF		100	10	100	10	10	10	10	!
fRAC (ug/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	PEC $_{gw,max}$ (ug/L)								
Step 1									
	124.18	26.421	8.448	225.782	130.168	8.505	1.552	0.388	37.630
Step 2									
N. Europe	36.77	7.823	2.501	66.855	38.543	2.518	0.460	0.115	11.142
Step 3									
D3 ditch	13.37	2.845	0.910	24.309	14.015	0.916	0.167	0.042	4.052
D4 pond	1.381	0.294	0.094	2.511	1.448	0.095	0.017	0.004	0.418
D4 stream	13.51	2.874	0.919	24.564	14.161	0.925	0.169	0.042	4.094
D5 pond	1.514	0.322	0.103	2.753	1.587	0.104	0.019	0.005	0.459
D5 stream	14.32	3.047	0.974	26.036	15.010	0.981	0.179	0.045	4.339
R1 pond	1.492	0.317	0.101	2.713	1.564	0.102	0.019	0.005	0.452
R1 stream	10.72	2.281	0.729	19.491	11.237	0.734	0.134	0.034	3.248
R2 stream	14.22	3.026	0.967	25.853	14.906	0.974	0.178	0.044	4.309
R3 stream	15.17	3.228	1.032	27.582	15.901	1.039	0.190	0.047	4.597
R4 stream	10.78	2.294	0.733	19.600	11.300	0.738	0.135	0.034	3.267
Step 4 - 10m									
D3 ditch	8.088	1.295	0.414	11.069	6.382	0.417	0.076	0.019	1.845
D4 stream	6.777	1.442	0.461	12.322	7.104	0.464	0.085	0.021	2.054
D5 stream	7.184	1.528	0.489	13.056	7.527	0.492	0.090	0.022	2.176

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. long	Algae	Sed. dwell. prolonged	Aquatic Plant	Mesocosm
R1 stream	5.375	1.144	0.366	9.773	5.634	0.368	0.067	0.017	1.629
R2 stream	7.131	1.517	0.485	12.965	7.475	0.488	0.089	0.022	2.161
R3 stream	7.609	1.619	0.518	13.835	7.976	0.521	0.095	0.024	2.306
R4 stream	5.406	1.150	0.368	9.829	5.667	0.370	0.068	0.017	1.638
Step 4 - 20m									
D3 ditch	1.576	0.335	0.107	2.865	1.652	0.108	0.020	0.005	0.478
D4 stream	1.754	0.373	0.119	3.189	1.839	0.120	0.022	0.005	0.532
D5 stream	1.859	0.396	0.126	3.380	1.949	0.127	0.023	0.006	0.563
R1 stream	1.391	0.296	0.095	2.529	1.458	0.095	0.017	0.004	0.422
R2 stream	1.846	0.393	0.126	3.356	1.935	0.126	0.023	0.006	0.559
R3 stream	1.971	0.419	0.134	3.584	2.066	0.135	0.025	0.006	0.597
R4 stream	1.399	0.298	0.095	2.544	1.466	0.096	0.017	0.004	0.424

Geometric mean:

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. long	Algae	Sed. dwell. prolonged	Aquatic Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula pelliculosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*
Endpoint (ug/L)		LC_{50} 470	NOEC 143	EC_{50} 55	NOEC 9.54	E_rC_{50}/E_bC_{50} 146	NOEC 300	EC_{50} 3200	?
AF		100	10	100	10	10	10	10	?
RAC (ug/L)		4.7	14.3	0.55	0.954	14.6	30	320	3.3
FOCUS Scenario	PEC_sw max (ug/L)								
Step 1									
	126.532	26.922	8.608	230.060	132.634	8.667	1.583	0.395	38.343
Step 2									
N. Europe	37.634	8.003	2.560	68.420	39.445	2.577	0.470	0.118	11.403

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. long	Algae	Sed. dwell. prolonged	Aquat. Plant	Mesocosm
Step 3									
D3 ditch	13.37	2.945	0.910	24.300	14.015	0.916	0.162	0.042	4.052
D4 pond	1.475	0.314	0.100	2.682	1.546	0.101	0.018	0.005	0.447
D4 stream	13.51	2.874	0.919	24.564	14.161	0.925	0.160	0.042	4.094
D5 pond	1.517	0.323	0.102	2.758	1.590	0.104	0.019	0.005	0.460
D5 stream	14.32	3.047	0.974	26.036	15.010	0.981	0.170	0.045	4.339
R1 pond	1.495	0.318	0.102	2.718	1.567	0.103	0.019	0.005	0.453
R4 stream	10.72	2.281	0.729	19.491	11.237	0.734	0.134	0.034	3.248
R2 stream	14.22	2.845	0.910	24.300	14.015	0.916	0.162	0.042	4.052
R4 stream	15.17	0.314	0.100	2.682	1.546	0.101	0.018	0.005	0.447
R4 stream	10.78	2.874	0.919	24.564	14.161	0.925	0.160	0.042	4.094
Step 4 – 10 m vegetative strip, 10 m no-spray buffer									
D3 ditch	6.088	1.295	0.414	11.060	6.382	0.417	0.076	0.019	1.845
D4 stream	6.778	1.443	0.461	12.324	7.105	0.464	0.085	0.021	2.054
D5 stream	7.182	1.528	0.489	13.058	7.528	0.493	0.090	0.022	2.176
R1 stream	5.375	1.144	0.366	9.773	5.634	0.368	0.067	0.017	1.629
R2 stream	7.131	1.517	0.485	12.965	7.475	0.489	0.089	0.022	2.161
R3 stream	7.610	1.619	0.518	13.826	7.972	0.521	0.095	0.024	2.306
R4 stream	5.407	1.150	0.368	9.834	5.668	0.370	0.068	0.017	1.638
Step 4 – (20 m vegetative strip, 20 m no-spray buffer)									
D3 ditch	1.576	0.335	0.107	2.865	1.652	0.108	0.020	0.005	0.478
D4 stream	1.755	0.373	0.119	3.191	1.840	0.120	0.022	0.005	0.532
D5 stream	1.859	0.396	0.126	3.380	1.949	0.127	0.023	0.006	0.563
R1 stream	1.391	0.296	0.095	2.529	1.458	0.095	0.017	0.004	0.422
R2 stream	1.846	0.393	0.126	3.356	1.935	0.126	0.023	0.006	0.559
R3 stream	1.971	0.419	0.134	3.583	2.066	0.135	0.025	0.006	0.597

Group		Fish acute	Fish prolonged	Inverteb. acute	Invertebr. long	Algae	Sed. dwell. prolonged	AquaG e-Plant	Mesocos m
R4 dream	1.000	0.299	0.095	2.545	1.468	0.098	0.015	0.004	0.424

Table 9.5-18: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/F/SCORPIO 325 SC in maize BBCH14.

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
	45.64	**> 1**	**> 1**	**> 1**	**> 1**	**>1**	< 1	< 1	**>1**
Step 2									
N-Europe/Mar-May	7.70	**> 1**	< 1	**> 1**	**> 1**	<1	-	-	**>1**
Step 3									
D3/ditch	1.049	< 1	-	**> 1**	**> 1**	-	-	-	< 1
D4/pond	0.5208	< 1	-	< 1	< 1	-	-	-	< 1
D4/stream	0.8992	< 1	-	**> 1**	< 1	-	-	-	< 1
D5/pond	0.4003	< 1	-	< 1	< 1	-	-	-	< 1
D5/stream	0.9419	< 1	-	**> 1**	< 1	-	-	-	< 1
R1/pond	0.1828	< 1	-	< 1	< 1	-	-	-	< 1
R1/stream	2.452	< 1	-	**> 1**	**> 1**	-	-	-	< 1
R3/stream	3.317	< 1	-	**> 1**	**> 1**	-	-	-	**> 1**

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**								
R4/stream	4.489	< 1	-	**> 1**	**> 1**	-	-	-	**> 1**
Step 4		10 m vegetative strip, 10 m no spray buffer							
R3/stream	1.496	**-**	-	**> 1**	**> 1**	-	-	-	< 1
R4/stream	2.040	**-**	-	**> 1**	**> 1**	-	-	-	< 1

Geometric mean:

Group		Fish-acute	Fish prolonged	Invertebr. acute	Invertebr. long	Algae	Sed.-dwell. prolonged	Aquatic Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula pelliculosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*
Endpoint (µg/L)		LC_{50} 170	NOEC 147	EC_{50} 55	NOEC 8.54	E_rC_{50}/E_bC_{50} 146	NOEC 800	EC_{50} 3200	-
AF		100	10	100	10	10	10	10	-
RAC (µg/L)		1.7	14.7	0.55	0.854	14.6	80	320	3.2
FOCUS Scenario	PEC max (µg/L)								
Step 1									
	45.64	0.711	3.105	82.992	47.841	3.126	0.571	0.143	13.830
Step 2									
N-Europe	7.70	1.638	0.524	14.000	8.071	0.527	0.096	0.024	2.333
Step 3									
D3/dach	1.049	0.223	0.071	1.907	1.100	0.072	0.013	0.003	0.318
D4/pond	1.503	0.320	0.102	2.733	1.575	0.103	0.019	0.005	0.455
D4/stream	1.527	0.325	0.104	2.776	1.601	0.105	0.019	0.005	0.463
D5/pond	0.043	0.009	0.003	0.078	0.045	0.003	0.001	0.000	0.013
D5/stream	0.938	0.200	0.064	1.705	0.983	0.064	0.012	0.003	0.284
D6/dach	1.051	0.224	0.071	1.911	1.102	0.072	0.013	0.003	0.318
R1/pond	0.224	0.048	0.015	0.411	0.237	0.015	0.003	0.001	0.068
R1/stream	3.126	0.665	0.213	5.684	3.277	0.214	0.039	0.010	0.947
R2/stream	1.004	0.214	0.068	1.825	1.052	0.069	0.013	0.003	0.304
R3/stream	3.662	0.779	0.249	6.658	3.839	0.251	0.046	0.011	1.110
R4/stream	4.904	1.043	0.334	8.916	5.140	0.336	0.061	0.015	1.486
Step 4 (10-m vegetative strip, 10-m no-spray buffer)									
R3/stream	1.653	0.352	0.113	3.005	1.733	0.113	0.021	0.005	0.501
R4/stream	2.220	0.474	0.152	4.053	2.336	0.153	0.028	0.007	0.675

Arithmetic mean:

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. long	Algae	Sed. dwell. prolonged	Aquatic Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula pelliculosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*
Endpoint (µg/L)		LC_{50} 470	NOEC 147	EC_{50} 55	NOEC 9.54	E_rC_{50}/E_bC_{50} 146	NOEC 800	EC_{50} 3200	I
AF		100	10	100	10	10	10	10	I
PAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	PEC $_{sl,max}$ (µg/L)								
Step 1									
	88.93	18.9213	6.0497	161.6909	93.2180	6.0911	1.1116	0.2779	26.9485
Step 2									
N-Europe	11.15	2.3723	0.7585	20.2727	11.6876	0.7637	0.1394	0.0348	3.3788
Step 3									
D3/ditch	0.910	0.1936	0.0619	1.6546	0.9539	0.0623	0.0114	0.0028	0.2758
D4/pond	3.076	0.6545	0.2093	5.5927	3.2243	0.2107	0.0385	0.0096	0.9324
D4/stream	3.088	0.6570	0.2101	5.6145	3.2369	0.2115	0.0386	0.0097	0.9358
D5/pond	0.078	0.0166	0.0053	0.1418	0.0818	0.0053	0.0010	0.0002	0.0236
D5/stream	0.883	0.1879	0.0601	1.6055	0.9256	0.0605	0.0110	0.0028	0.2676
D6/ditch	0.912	0.1940	0.0620	1.6582	0.9560	0.0625	0.0114	0.0029	0.2764
R1/pond	0.410	0.0872	0.0279	0.7455	0.4298	0.0281	0.0051	0.0013	0.1242
R1/stream	3.648	0.7762	0.2482	6.6327	3.8239	0.2499	0.0456	0.0114	1.1056
R2/stream	1.330	0.2830	0.0905	2.4182	1.3941	0.0911	0.0166	0.0042	0.4036
R3/stream	3.396	0.7226	0.2310	6.1745	3.5597	0.2326	0.0425	0.0106	1.0291
R4/stream	4.745	1.0096	0.3229	8.6273	4.9738	0.3250	0.0593	0.0148	1.4379
Step 4 (10 m vegetative strip, 10 m no spray buffer)									
R1/stream	1.527	0.3270	0.1046	2.7945	1.6111	0.1053	0.0192	0.0048	0.4658
R3/stream	1.704	0.3626	0.1159	3.0982	1.7862	0.1167	0.0213	0.0053	0.5164

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. long	Algae	Sed. dwell. prolonged	Aquatic Plant	Mesocosm
R4/stream	2_113	0.4506	0.1441	3.8509	2.2201	0.1451	0.0265	0.0066	0.6418

Table 9.5-19: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/F/SCORPIO 325 SC in maize BBCH31.

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
	45.64	**> 1**	**> 1**	**> 1**	**> 1**	**>1**	< 1	< 1	**>1**
Step 2									
N-Europe/Mar-May	5.59	**> 1**	< 1	**> 1**	**> 1**	<1	-	-	**>1**
Step 3									
D3/ditch	1.047	< 1	-	**> 1**	**> 1**	-	-	-	< 1
D4/pond	0.5924	< 1	-	**> 1**	< 1	-	-	-	< 1
D4/stream	0.9284	< 1	-	**> 1**	< 1	-	-	-	< 1
D5/pond	0.4210	< 1	-	< 1	< 1	-	-	-	< 1
D5/stream	0.9912	< 1	-	**> 1**	**> 1**	-	-	-	< 1
R1/pond	0.3823	< 1	-	< 1	< 1	-	-	-	< 1
R1/stream	2.467	< 1	-	**> 1**	**> 1**	-	-	-	< 1
R3/stream	2.646	< 1	-	**> 1**	**> 1**	-	-	-	< 1

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**								
R4/stream	4.205	< 1	-	**> 1**	**> 1**	-	-	-	**> 1**
Step 4		10 m vegetative strip, 5 m no spray buffer							
R4/stream	1.904	-	-	**> 1**	**> 1**	-	-	-	< 1

Group		Fish-acute	Fish prolonged	Inverteb. acute	Inverteb. long	Algae	Sed.-dwell. prolonged	Aquatic-Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula pelliculosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*
Endpoint (µg/L)		LC_{50} 470	NOEC 147	EC_{50} 55	NOEC 9.54	E_rC_{50}/E_bC_{50} 146	NOEC 800	EC_{50} 3200	-
AF		100	10	100	10	10	10	10	-
PAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.2
FOCUS Scenario	PEC max (µg/L)								
Step-1									
	45.64	9.711	3.105	82.992	47.841	3.126	0.571	0.143	13.930
Step-2									
N-Europe	7.70	1.638	0.524	14.000	8.071	0.527	0.096	0.024	2.333
Step-3									
D3/ditch	1.047	0.223	0.071	1.904	1.097	0.072	0.013	0.003	0.317
D4/pond	1.298	0.276	0.088	2.360	1.361	0.089	0.016	0.004	0.393
D4/stream	1.310	0.279	0.089	2.382	1.373	0.090	0.016	0.004	0.397
D5/pond	0.042	0.009	0.003	0.076	0.044	0.003	0.001	0.000	0.013
D5/stream	0.989	0.210	0.067	1.798	1.037	0.068	0.012	0.003	0.300
D6/ditch	1.042	0.222	0.071	1.895	1.092	0.071	0.013	0.002	0.316
R1/pond	0.400	0.104	0.033	0.803	0.514	0.034	0.006	0.002	0.148
R4/stream	3.046	0.648	0.207	5.538	3.193	0.209	0.038	0.010	0.925
R7/stream	1.146	0.244	0.078	2.084	1.201	0.078	0.014	0.004	0.347
R3/stream	3.178	0.676	0.216	5.778	3.331	0.218	0.040	0.010	0.963
R4/stream	4.854	1.033	0.330	8.825	5.088	0.333	0.061	0.015	1.471
Step-4 (10-m-vegetative-strip, 10-m-no-spray-buffer)									
R4/stream	2.198	0.468	0.150	3.996	2.304	0.151	0.027	0.007	0.666

Table 9.5-20: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/F/SCORPIO 325 SC in sunflower BBCH 14.

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
	45.64	**> 1**	**> 1**	**> 1**	**> 1**	**>1**	< 1	< 1	**>1**
Step 2									
N-Europe/Mar-May	7.70	**> 1**	< 1	**> 1**	**> 1**	<1	-	-	**>1**
Step 3									
D5/pond	0.2448	< 1	-	< 1	< 1	-	-	-	< 1
D5/stream	0.8970	< 1	-	**> 1**	< 1	-	-	-	< 1
R1/pond	0.2822	< 1	-	< 1	< 1	-	-	-	< 1
R1/stream	2.942	< 1	-	**> 1**	**> 1**	-	-	-	< 1
R3/stream	1.929	< 1	-	**> 1**	**> 1**	-	-	-	< 1
R4/stream	4.377	< 1	-	**> 1**	**> 1**	-	-	-	**> 1**
Step 4		10 m vegetative strip, 10 m no spray buffer							
R4/stream	1.990	**-**	-	**> 1**	**> 1**	**-**	-	**-**	< 1

Group		Fish-acute	Fish prolonged	Inverteb. acute	Inverteb. long	Algae	Sed.-dwell. prolonged	Aquatic-Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula pelliculosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*
Endpoint (µg/L)		LC_{50} 470	NOEC 147	EC_{50} 55	NOEC 9.54	E_rC_{50}/E_bC_{50} 146	NOEC 800	EC_{50} 3200	I
AF		100	10	100	10	10	10	10	I
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	5.2
FOCUS Scenario	PEC max (µg/L)								
Step-1									
	45.64	9.711	3.105	82.992	47.841	3.126	0.571	0.143	13.830
Step-2									
N-Europe	8.12	1.728	0.552	14.764	8.512	0.556	0.102	0.025	2.461
Step-3									
D5-pond	0.044	0.009	0.003	0.080	0.046	0.003	0.001	0.000	0.013
D5-stream	0.893	0.190	0.061	1.624	0.936	0.061	0.011	0.003	0.271
R1-pond	0.314	0.067	0.021	0.571	0.329	0.022	0.004	0.001	0.095
R1-stream	3.295	0.688	0.220	5.876	3.388	0.224	0.040	0.010	0.979
R3-stream	2.109	0.449	0.143	3.835	2.211	0.144	0.026	0.007	0.639
R4-stream	4.880	1.038	0.332	8.873	5.115	0.334	0.061	0.015	1.479
Step-4 (10 m vegetative strip, 10 m no-spray buffer)									
R4-stream	2.198	0.468	0.150	3.996	2.304	0.151	0.027	0.007	0.666

Table 9.5-21: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/F/SCORPIO 325 SC in sunflower BBCH 31.

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**								
Step 1									
	45.64	**> 1**	**> 1**	**> 1**	**> 1**	**>1**	< 1	< 1	**>1**
Step 2									
N-Europe/Mar-May	5.59	**> 1**	< 1	**> 1**	**> 1**	<1	-	-	**>1**
Step 3									
D5/pond	0.3636	< 1	-	< 1	< 1	-	-	-	< 1
D5/stream	0.9431	< 1	-	**> 1**	< 1	-	-	-	< 1
R1/pond	0.2000	< 1	-	< 1	< 1	-	-	-	< 1
R1/stream	2.122	< 1	-	**> 1**	**> 1**	-	-	-	< 1
R3/stream	3.012	< 1	-	**> 1**	**> 1**	-	-	-	< 1
R4/stream	3.679	< 1	-	**> 1**	**> 1**	-	-	-	**> 1**
Step 4		10 m vegetative strip, 5 m no spray buffer							
R4/stream	1.655	**-**	-	**> 1**	**> 1**	-	-	-	< 1

Group		Fish-acute	Fish prolonged	Inverteb. acute	Inverteb. long	Algae	Sed.-dwell. prolonged	Aquatic-Plant	Mesocosm
Test species		*Oncorhynchus mykiss*	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Navicula pelliculosa*	*Chironomus riparius*	*Lemna gibba*	*Mesocosm*
Endpoint (µg/L)		LC_{50} 470	NOEC 147	EC_{50} 55	NOEC 9.54	E_rC_{50}/E_bC_{50} 146	NOEC 800	EC_{50} 3200	I
AF		100	10	100	10	10	10	10	I
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	5.2
FOCUS Scenario	PEC max (µg/L)								
Step-1									
	45.64	9.711	3.105	82.992	47.841	3.126	0.571	0.143	13.830
Step-2									
N-Europe	8.12	1.728	0.552	14.764	8.512	0.556	0.102	0.025	2.461
Step-3									
D5-pond	0.042	0.009	0.003	0.076	0.044	0.003	0.001	0.000	0.013
D5-stream	0.028	0.200	0.064	1.705	0.082	0.064	0.012	0.003	0.284
R1-pond	0.281	0.060	0.019	0.511	0.295	0.019	0.004	0.001	0.085
R1-stream	3.134	0.667	0.211	5.698	3.285	0.215	0.039	0.010	0.950
R3-stream	3.823	0.813	0.260	6.951	4.007	0.262	0.048	0.012	1.158
R4-stream	4.866	1.035	0.331	8.847	5.101	0.333	0.061	0.015	1.475
Step-4 (10 m vegetative strip, 10 m no-spray buffer)									
R3-stream	1.740	0.370	0.118	3.164	1.824	0.119	0.022	0.005	0.527
R4-stream	2.198	0.468	0.150	3.996	2.304	0.151	0.027	0.007	0.666

Review Comments:

AZOXISTROBIN

The risk assessment for aquatic organisms carried out by zRMS demonstrated that for following proposed uses of CHR/F/SCORPIO 325 SC the mitigation measures are required:

1. Potatoes BBCH 14 – for R3 scenario 10 m vfs + 5 m nsb
2. Leafy vegetables BBCH 14 – for scenarios R1, R3, R4 – 10 m vfs + 10 m nsb
3. Tobacco – for R3 scenario – 10 m vfs + 5 m nsb
4. Orchards BBCH 10 and BBCH 31 – for scenarios D3, D4, D5, R1, R3, R4 – 20 m vfs + 20 m nsb
5. Maize BBCH 14 – for scenarios R3, R4 – 10 m vfs + 10 m nsb
6. Maize BBCH 31 – for scenario R4 - 10 m vfs + 5 m nsb
7. Sunflower BBCH 14 - for scenario R4 - 10 m vfs + 10 m nsb
8. Sunflower BBCH 31 - for scenario R4 - 10 m vfs + 5 m nsb

Table 9.5-22: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite R401553 for each organism group based on FOCUS Step 1 ~~Steps 1, 2 and 3~~ calculations for the use of CHR/F/SCORPIO 325 SC on different crops.

Group		**Fish acute**	**Inverteb. acute**	**Algae**
Test species		***O. mykiss***	***D. magna***	***S. capricornutum***
Endpoint (µg/L)		LC_{50} >120000	EC_{50} >120000	E_rC_{50} >120000
AF		100	100	10
RAC (µg/L)		1200	1200	12000
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**			
Winter oilseed rape, Spring oilseed rape, Sugar beet, Potatoes, Carrot, Maize, Sunflower				
Step 1				
All BBCH	2.72	< 1	< 1	< 1
Tabacco, Leafy Vegetables				
Step 1				
All BBCH	5.44	< 1	< 1	< 1
Pome Fruit				
Step 1				
All BBCH	7.10	< 1	< 1	< 1

~~Arithmetic mean:~~

~~Group~~		~~Fish acute~~	~~Inverteb. acute~~	~~Algae~~
~~Test species~~		~~*Oncorhynchus mykiss*~~	~~*Daphnia magna*~~	~~*Selenastrum capricornutum*~~

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		EC_{50} 120000	EC_{50} 120000	E_rC_{50} 120000
AF		100	100	10
PAC (µg/L)		1200	1200	12000
FOCUS Scenario	PEC $_{gl\ max}$ (µg/L)			
Winter oilseed rape (BBCH 14)				
Step 1				
	7.383	0.006	0.006	0.0006
Winter oilseed rape (BBCH 31)				
Step 1				
	7.383	0.006	0.006	0.0006
Spring oilseed rape BBCH 14				
Step 1				
	7.383	0.006	0.006	0.0006
Spring oilseed rape BBCH 31				
Step 1				
	7.383	0.006	0.006	0.0006
Sugar beet				
Step 1				
	7.383	0.006	0.006	0.0006
Carrot				
Step 1				
	7.383	0.006	0.006	0.0006
Potato BBCH 14				
Step 1				
	7.383	0.006	0.006	0.0006

Group		Fish acute	Inverteb. acute	Algae
Potato BBCH 31				
Step 1				
	7.383	0.006	0.006	0.0006
Leafy vegetables				
Step 1				
	14.77	0.012	0.012	0.0012
Tobacco				
Step 1				
	14.77	0.012	0.012	0.0012
Pome fruit				
Step 1				
	16.42	0.013	0.013	0.001

Geometric mean:

Group		Fish acute	Inverteb. acute	Algae
Test species		*Oncorhynchus mykiss*	*Daphnia magna*	*Selenastrum capricornutum*
Endpoint (µg/L)		EC50 120000	EC50 120000	EC50 120000
AF		100	100	10
RAC (µg/L)		1200	1200	12000
FOCUS Scenario	PEC µ-ass (µg/L)			
Winter-oilseed rape (BBCH 14)				
Step 1				
	7.75	0.01	0.01	0.00

Group		Fish acute	Invertebr. acute	Algae
Winter oilseed rape (BBCH 31)				
Step 1				
	7.75	0.01	0.01	0.00
Spring oilseed rape BBCH 14				
Step 1				
	7.75	0.01	0.01	0.00
Spring oilseed rape BBCH 31				
Step 1				
	7.75	0.01	0.01	0.00
Sugar beet				
Step 1				
	7.75	0.01	0.01	0.00
Carrot				
Step 1				
	7.75	0.01	0.01	0.00
Potato BBCH 14				
Step 1				
	7.75	0.01	0.01	0.00
Potato BBCH 31				
Step 1				
	7.75	0.01	0.01	0.00
Leafy vegetables				
Step 1				
	15.500	0.012	0.012	0.001

Group		Fish acute	Invertebr. acute	Algae
Tobacco				
Step 1				
	15.500	0.013	0.013	0.001
Pome-fruit				
Step 1				
	17.170	0.014	0.014	0.001
Maize-BBCH-14				
Step 1				
	7.750	0.006	0.006	0.001
Maize-BBCH-31				
Step 1				
	7.750	0.006	0.006	0.001
Sunflower-BBCH-14				
Step 1				
	7.750	0.006	0.006	0.001
Sunflower-BBCH-31				
Step 1				
	7.750	0.006	0.006	0.001

Table 9.5-23: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite R402173 for each organism group based on FOCUS Step 1 ~~Steps 1, 2 and 3~~ calculations for the use of CHR/F/SCORPIO 325 SC on different crops.

Group		**Fish acute**	**Inverteb. acute**	**Algae**
Test species		***O. mykiss***	***D. magna***	***S. capricornutum***
Endpoint		LC_{50}	EC_{50}	E_rC_{50}
(µg/L)		62000	>100000	67000
AF		100	100	10
RAC (µg/L)		620	1000	6700
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**			
Winter oilseed rape, Spring oilseed rape, Sugar beet, Potatoes, Carrot, Maize, Sunflower				
Step 1				
All BBCH	1.32	< 1	< 1	< 1
Tabacco, Leafy Vegetables				
Step 1				
All BBCH	2.63	< 1	< 1	< 1
Pome Fruit				
Step 1				
All BBCH	3.33	< 1	< 1	< 1

~~Arithmetic mean:~~

~~Group~~		~~Fish acute~~	~~Inverteb. acute~~	~~Algae~~
~~Test species~~		~~*Oncorhynchus mykiss*~~	~~*Daphnia magna*~~	~~*Selenastrum capricornutum*~~
~~Endpoint (µg/L)~~		~~EC_{50} 62000~~	~~EC_{50} 100000~~	~~EC_{50} 67000~~
~~AF~~		~~100~~	~~100~~	~~10~~
~~RAC (µg/L)~~		~~620~~	~~1000~~	~~6700~~
~~FOCUS Scenario~~	~~PEC $_{gl\text{-}max}$ (µg/L)~~			
~~Winter oilseed rape (BBCH 14)~~				
~~Step 1~~				
	~~10.38~~	~~59.730~~	~~0.010~~	~~0.001~~

Group		Fish acute	Inverteb. acute	Algae
Winter oilseed rape (BBCH 31)				
Step 1				
	10.38	59.730	0.010	0.001
Spring oilseed rape BBCH 14				
Step 1				
	10.38	59.730	0.010	0.001
Spring oilseed rape BBCH 31				
Step 1				
	10.38	59.730	0.010	0.001
Sugar beet				
Step 1				
	10.38	59.730	0.010	0.001
Carrot				
Step 1				
	10.38	59.730	0.010	0.001
Potato BBCH 14				
Step 1				
	10.38	59.730	0.010	0.001
Potato BBCH 31				
Step 1				
	10.38	59.730	0.010	0.001
Leafy vegetables				
Step 1				
	20.76	0.033	0.021	0.003

Group		Fish acute	Inverteb. acute	Algae
Tobacco				
Step 1				
	20.76	0.033	0.021	0.003
Pome fruit				
Step 1				
	21.45	0.035	0.021	0.003

Geometric mean:

Group		Fish acute	Inverteb. acute	Algae
Test species		*Oncorhynchus mykiss*	*Daphnia magna*	*Selenastrum capricornutum*
Endpoint (µg/L)		EC_{50} >2000	EC_{50} 100000	EC_{50} 67000
AF		100	100	10
RAC (µg/L)		620	1000	6700
FOCUS Scenario	PEC global (µg/L)			
Winter-oilseed-rape-BBCH-1-9				
Step 1				
	0.760	0.016	0.010	0.001
Winter-oilseed-rape-BBCH-31				
Step 1				
	0.760	0.016	0.010	0.001
Spring-oilseed-rape-BBCH-14				
Step 1				
	0.760	0.016	0.010	0.001

Group		Fish acute	Invertebr. acute	Algae
Spring oilseed rape BBCH 31				
Step 1				
	0.760	0.016	0.010	0.001
Sugar beet				
Step 1				
	0.760	0.016	0.010	0.001
Carrot				
Step 1				
	0.760	0.016	0.010	0.001
Potato BBCH 14				
Step 1				
	0.760	0.016	0.010	0.001
Potato BBCH 34				
Step 1				
	0.760	0.016	0.010	0.001
Leafy vegetables				
Step 1				
	19.520	0.032	0.020	0.003
Tobacco				
Step 1				
	19.520	0.032	0.020	0.003
Pome fruit				
Step 1				
	39.520	0.032	0.020	0.003
Maize BBCH 14				

Group		Fish acute	Inverteb. acute	Algae
Step 1				
	9.76	0.016	0.010	0.001
Maize BBCH 31				
Step 1				
	9.76	0.016	0.010	0.001
Sunflower BBCH 14				
Step 1				
	9.76	0.016	0.010	0.001

Sunflower BBCH 31				
Step 1				
	9.76	0.016	0.010	0.001

Table 9.5-24: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite R234886 for each organism group based on FOCUS Step 1 ~~Steps 1, 2 and 3~~ calculations for the use of CHR/F/SCORPIO 325 SC on different crops.

Group		**Fish acute**	**Inverteb. acute**	**Algae**
Test species		***O. mykiss***	***D. magna***	***S. capricornutum***
Endpoint		LC_{50}	EC_{50}	EC_{50}
(µg/L)		>150000	>180000	47000
AF		100	100	10
RAC (µg/L)		1500	1800	4700
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**			
Winter oilseed rape, Spring oilseed rape, Sugar beet, Potatoes, Carrot, Maize, Sunflower				
Step 1				
All BBCH	11.40	< 1	< 1	< 1
Tabacco, Leafy Vegetables				
Step 1				
All BBCH	22.79	< 1	< 1	< 1
Pome Fruit				
Step 1				
All BBCH	28.81	< 1	< 1	< 1

Arithmetic mean:

Group		fish acute	Inverteb. acute	Algae
Test species		*Oncorhynchus mykiss*	*Daphnia magna*	*Selenastrum capricornutum*
Endpoint (µg/L)		EC_{50} 150000	EC_{50} 180000	E_rC_{50} 47000
AF		100	100	10
RAC (µg/L)		1500	1800	4700
FOCUS Scenario	PEC act max (µg/L)			
Winter oilseed rape (BBCH 14)				
Step 1				
	22.04	0.015	0.012	0.005
Winter oilseed rape (BBCH 31)				
Step 1				
	22.04	0.015	0.012	0.005
Spring oilseed rape BBCH 14				
Step 1				
	22.04	0.015	0.012	0.005
Spring oilseed rape BBCH 31				
Step 1				
	22.04	0.015	0.012	0.005
Sugar beet				
Step 1				
	22.04	0.015	0.012	0.005
Carrot				
Step 1				
	22.04	0.015	0.012	0.005

Group		Fish acute	Inverteb. acute	Algae
Potato BBCH 14				
Step 1				
	22.04	0.015	0.012	0.005
Potato BBCH 31				
Step 1				
	22.04	0.015	0.012	0.005
Leafy vegetables				
Step 1				
	44.07	0.029	0.024	0.009
Tobacco				
Step 1				
	44.07	0.029	0.024	0.009
Pome fruit				
Step 1				
	80.10	0.033	0.028	0.011

Geometric mean:

Group		Fish acute	Inverteb. acute	Algae
Test species		*Oncorhynchus mykiss*	*Daphnia magna*	*Selenastrum capricornutum*
Endpoint (µg/L)		EC50 150000	EC50 180000	E.C.50 47000
AF		100	100	10
PAC (µg/L)		1500	1800	4700
FOCUS Scenario	PEC gl-eas (µg/L)			

Group		Fish acute	Invertebr. acute	Algae
Winter-oilseed-rape-BBCH-14				
Step-1				
	11.400	0.008	0.006	0.002
Winter-oilseed-rape-BBCH-34				
Step-1				
	11.400	0.008	0.006	0.002
Spring-oilseed-rape-BBCH-14				
Step-1				
	11.44	0.008	0.006	0.002
Spring-oilseed-rape-BBCH-34				
Step-1				
	11.44	0.008	0.006	0.002
Sugar-beet				
Step-1				
	11.44	0.008	0.006	0.002
Carrot				
Step-1				
	11.44	0.008	0.006	0.002
Potato-BBCH-14				
Step-1				
	11.44	0.008	0.006	0.002
Potato-BBCH-34				
Step-1				
	11.44	0.008	0.006	0.002

Group		Fish acute	Invertebr. acute	Algae
Leafy vegetables				
Step 1				
	92.810	0.015	0.013	0.005
Tobacco				
Step 1				
	92.810	0.015	0.013	0.005
Pome-fruit				
Step 1				
	23.630	0.016	0.013	0.005
Maize BBCH 14				
Step 1				
	11.41	0.03	0.01	0.00
Maize BBCH 31				
Step 1				
	11.41	0.03	0.01	0.00
Sunflower BBCH 14				
Step 1				
	11.41	0.03	0.01	0.00
Sunflower BBCH 31				
Step 1				
	11.41	0.03	0.01	0.00

Review Comments:

DIFENOCONAZOLE

zRMS, requesting a correction of dRR, informed the Applicant that in the risk assessment for aquatic organisms for difenoconazole, the NOEC of 3.6 µg/L for fish from FFLC should be taken into account. This is in accordance with EFSA supporting publication 2014:EN-680. It is also the lowest RAC for difenoconazole.

The risk assessment for aquatic organisms carried out by the Applicant has been completely removed, as the PEC/RAC calculations presented in the tables below were based on unaccepted $PEC_{SW/SED}$ values. Although the applicant's PEC/RAC calculations used corrected endpoint for fish, the revised eFate section (dRR B8) does not include sufficiently low FOCUS Step 4 PEC_{SW} values in case of several scenarios (especially R1 – for all crops).

Furthermore, requesting a correction of dRR, zRMS indicated that in the assessment for aquatic organisms for difenoconazole, the *Ch. riparius* NOEC of 52.5 µg/kg sediment should be considered. The Applicant did not incorporate the required modifications. No FOCUS Step 4 PEC_{SED} values are provided in Section B8.

Therefore, the risk assessment for difenoconazole is incomplete. At the commenting stage, the Applicant has the opportunity to supplement this report with the appropriate PEC/RAC calculations for difenoconazole.

At the commenting stage, the Applicant submitted the appropriate $PEC_{SW/SED}$ values calculations that there considered by zRMS in updated risk assessment for difenoconazole.

In the following risk assessment, performed by zRMS, only relevant for central zone FOCUS Step 3-4 scenarios are included (D3, D4, D5, R1, R3 and R4).

Table 9.5-25: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Steps 1, 2 and 3 - 4 calculations for the use of CHR/F/SCORPIO 325 SC in winter oilseed rape (BBCH14-20)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 1									
	9.61	< 1	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	255.34	**> 1**
Step 2									
N-Europe	1.56	-	**> 1**	**> 1**	**> 1**	< 1	< 1	43.28	**> 1**
Step 3									
D3/ditch	0.7904	-	**> 1**	< 1	**> 1**	-	-	0.8935	< 1
D4/pond	0.02707	-	< 1	< 1	< 1	-	-	0.3482	< 1
D4/stream	0.6806	-	**> 1**	< 1	**> 1**	-	-	0.1483	< 1
D5/pond	0.02713	-	< 1	< 1	< 1	-	-	0.2989	< 1
D5/stream	0.7343	-	**> 1**	< 1	**> 1**	-	-	0.1029	< 1
R1/pond	0.04714	-	< 1	< 1	< 1	-	-	0.9628	< 1
R1/stream	0.5202	-	**> 1**	< 1	< 1	-	-	0.8472	< 1

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
R3/stream	0.7276	-	**> 1**	< 1	**> 1**	-	-	3.393	< 1
Step 4		10 m vegetative strip, 10 m no spray buffer							
D3/ditch	0.1133	-	< 1	-	< 1	-	-	-	-
D4/stream	0.1317	-	< 1	-	< 1	-	-	-	-
D5/stream	0.1421	-	< 1	-	< 1	-	-	-	-
R1/stream	0.1067	-	< 1	-	-	-	-	-	-
R3/stream	0.1408	-	< 1	-	< 1	-	-	-	-

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010). and no effects were seen at the highest test concentration

Review Comments:

The report Section 8 does not include the FOCUS Step 4 PEC_{SW} values for the R1 stream scenario. Therefore, the risk assessment for difenoconazole for the above usage remains incomplete. At the commenting stage, the Applicant has the opportunity to supplement this report with the appropriate PEC/RAC calculations for difenoconazole.

At the commenting stage, the Applicant submitted the appropriate PEC_{SW} values calculations that there considered by zRMS in updated risk assessment for difenoconazole.

Table 9.5-26: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Steps 1, 2, 3 and 4 calculations for the use of CHR/F/SCORPIO 325 SC in winter oilseed rape (BBCH21-69)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 1									
	9.61	< 1	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	255.34	**> 1**
Step 2									
N-Europe	1.15	-	**> 1**	< 1	**> 1**	< 1	< 1	18.96	**> 1**
Step 3									
D3/ditch	0.7851	-	**> 1**	-	**> 1**	-	-	0.4501	< 1
D4/pond	0.02705	-	< 1	-	< 1	-	-	0.2738	< 1
D4/stream	0.6109	-	**> 1**	-	**> 1**	-	-	0.02609	< 1
D5/pond	0.02715	-	< 1	-	< 1	-	-	0.2676	< 1
D5/stream	0.5097	-	**> 1**	-	< 1	-	-	0.006953	< 1
R1/pond	0.03223	-	< 1	-	< 1	-	-	0.5665	< 1
R1/stream	0.5173	-	**> 1**	-	< 1	-	-	1.439	< 1
R3/stream	0.7334	-	**> 1**	-	**> 1**	-	-	4.374	< 1

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 4		10 m vegetative strip, 10 m no spray buffer							
D3/ditch	0.1125	-	< 1	-	< 1	-	-	-	-
D4/stream	0.1183	-	< 1	-	< 1	-	-	-	-
D5/stream	0.09865	-	< 1	-	-	-	-	-	-
R1/stream	0.1001	-	< 1	-	-	-	-	-	-
R3/stream	0.1420	-	< 1	-	< 1	-	-	-	-

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010). and no effects were seen at the highest test concentration

Review Comments:

The report Section 8 does not include the FOCUS Step 4 PEC_{SW} values for the D5 stream and R1 stream scenarios. Therefore, the risk assessment for difenoconazole for the above usage remains incomplete. At the commenting stage, the Applicant has the opportunity to supplement this report with the appropriate PEC/RAC calculations for difenoconazole.

At the commenting stage, the Applicant submitted the appropriate PEC_{SW} values calculations that there considered by zRMS in updated risk assessment for difenoconazole.

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Fathead minnow*	*Mysidopsis bahia*	*Daphnia magna*	*Chironomus riparius*	*Scenedesmus subspicatus*
Endpoint (µg/L)		EC_{50} 650	NOEC 7.6	EC_{50} 150	NOEC 5.6	NOEC 15	EbC_{50} 32
AF		100	10	100	10	10	10
RAC (µg/L)		6.5	0.76	1.5	0.56	1.5	3.2
FOCUS Scenario	PEC $_{gl-max}$ (µg/L)						
Step 1							
	8.08	1.243	10.632	5.387	14.429	5.387	2.525
Step 2							
	2.303	0.354	3.030	1.535	4.113	1.535	0.720
Step 3							
D3 ditch	0.789	0.121	1.038	0.526	1.409	0.526	0.247
D4 pond	0.027	0.004	0.036	0.018	0.048	0.018	0.008
D4 stream	0.679	0.104	0.893	0.453	1.213	0.453	0.212
D5 pond	0.027	0.004	0.036	0.018	0.048	0.018	0.008
D5 stream	0.733	0.113	0.964	0.489	1.309	0.489	0.229
R1 stream	0.519	0.080	0.683	0.346	0.927	0.346	0.162
R3 stream	0.726	0.112	0.955	0.484	1.296	0.484	0.227
Step 4							
D3 ditch	0.113	0.017	1.487	0.075	0.202	0.075	0.035
D4 stream	0.131	0.020	1.724	0.087	0.234	0.087	0.041
D5 stream	0.142	0.022	1.868	0.095	0.254	0.095	0.044
R3 stream	0.141	0.022	1.855	0.094	0.252	0.094	0.044

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Fathead minnow*	*Mysidopsis bahia*	*Daphnia magna*	*Chironomus riparius*	*Scenedesmus subspicatus*
Endpoint (µg/L)		EC_{50} 650	NOEC 7.6	EC_{50} 150	NOEC 5.6	NOEC 52.5	EbC_{50} 32
AF		100	10	100	10	10	10
RAC (µg/L)		6.5	0.76	1.5	0.56	5.25	3.2

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
FOCUS Scenario	PEC ini. max (µg/L)						
Step 1							
	9.61	1.478	26.694	6.407	17.161	1.830	3.003
Step 2							
	1.31	0.202	3.639	0.873	2.339	0.250	0.409
Step 3							
D2 ditch	0.810	0.125	2.250	0.540	1.446	0.154	0.253
D2 stream	0.712	0.110	1.978	0.475	1.271	0.136	0.222
D3 ditch	0.790	0.122	2.194	0.527	1.411	0.150	0.247
D4 pond	0.022	0.004	0.078	0.018	0.048	0.005	0.009
D4 stream	0.681	0.105	1.893	0.454	1.216	0.130	0.213
D5 pond	0.022	0.004	0.078	0.018	0.048	0.005	0.009
D5 stream	0.734	0.113	2.039	0.489	1.311	0.140	0.229
R1 pond	0.048	0.007	0.133	0.032	0.086	0.009	0.015
R1 stream	0.520	0.080	1.444	0.347	0.929	0.099	0.163
R3 stream	0.728	0.112	2.022	0.485	1.300	0.139	0.228
Step 4 (10 m vegetative 10 m no spray buffer)							
D2 Ditch	0.198	0.030	0.550	0.132	0.354	0.038	0.062
D2 Stream	0.140	0.022	0.390	0.092	0.250	0.027	0.043
D3 Ditch	0.113	0.017	0.314	0.075	0.202	0.022	0.035
D4 Stream	0.132	0.020	0.367	0.088	0.236	0.025	0.041
D5 Stream	0.142	0.022	0.394	0.095	0.254	0.027	0.044
R1 Stream	0.103	0.016	0.284	0.069	0.184	0.020	0.032
R3 Stream	0.141	0.022	0.393	0.094	0.252	0.027	0.044

Table 9.5-27: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Steps 1, 2 and 3- 4 calculations for the use of CHR/F/SCORPIO 325 SC in winter oilseed rape (BBCH31)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 1									
	9.61	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	255.34	**> 1**
Step 2									
N-Europe	1.15	< 1	**> 1**	< 1	**> 1**	< 1	< 1	21.39	**> 1**
Step 3									
D3/ditch	0.7851	-	**> 1**	-	**> 1**	-	-	0.4501	< 1
D4/pond	0.02704	-	< 1	-	< 1	-	-	0.2646	< 1
D4/stream	0.5870	-	**> 1**	-	**> 1**	-	-	0.02002	< 1
D5/pond	0.02714	-	< 1	-	< 1	-	-	0.2742	< 1
D5/stream	0.6267	-	**> 1**	-	**> 1**	-	-	0.01831	< 1
R1/pond	0.03121	-	< 1	-	< 1	-	-	0.5562	< 1
R1/stream	0.5173	-	**> 1**	-	< 1	-	-	1.504	< 1
R3/stream	0.7273	-	**> 1**	-	**> 1**	-	-	0.1949	< 1

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 4		10 m vegetative strip, 5 m no spray buffer							
D3/ditch	0.2125	-	< 1	-	< 1	-	-	-	-
D4/stream	0.2143	-	< 1	-	< 1	-	-	-	-
D5/stream	0.2288	-	< 1	-	< 1	-	-	-	-
R1/stream	0.1888	-	< 1	-	-	-	-	-	-
R3/stream	0.2655	-	< 1	-	< 1	-	-	-	-

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010). and no effects were seen at the highest test concentration

Review Comments:

The report Section 8 does not include the FOCUS Step 4 PEC_{SW} values for the R1 stream scenario. Therefore, the risk assessment for difenoconazole for the above usage remains incomplete. At the commenting stage, the Applicant has the opportunity to supplement this report with the appropriate PEC/RAC calculations for difenoconazole.

At the commenting stage, the Applicant submitted the appropriate PEC_{SW} values calculations that there considered by zRMS in updated risk assessment for difenoconazole.

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Fathead minnow*	*Mysidopsis bahia*	*Daphnia magna*	*Chironomus riparius*	*Scenedesmus subspicatus*
Endpoint (µg/L)		EC_{50} 650	NOEC 7.6	EC_{50} 150	NOEC 5.6	NOEC 15	EbC_{50} 32
AF		100	10	100	10	10	10
RAC (µg/L)		6.5	0.76	1.5	0.56	1.5	3.2
FOCUS Scenario	PEC $_{gl-max}$ (µg/L)						
Step 1							
	8.08	1.243	10.632	5.387	14.429	5.387	2.525
Step 2							
	1.15	0.177	1.513	0.767	2.054	0.767	0.359
Step 3							
D3 ditch	0.784	0.121	1.032	0.523	1.400	0.523	0.245
D4 pond	0.027	0.004	0.036	0.018	0.048	0.018	0.008
D4 stream	0.586	0.090	0.771	0.391	1.046	0.391	0.183
D5 pond	0.027	0.004	0.036	0.018	0.048	0.018	0.008
D5 stream	0.626	0.096	0.824	0.417	1.118	0.417	0.196
R1 pond	0.041	0.006	0.054	0.027	0.073	0.027	0.013
R1 stream	0.516	0.079	0.679	0.344	0.921	0.344	0.161
R3 stream	0.726	0.112	0.955	0.484	1.296	0.484	0.227
Step 4							
D3 ditch	0.112	0.017	1.939	0.075	0.200	0.075	0.035
D4 pond	0.017	0.003	0.295	0.011	0.030	0.011	0.005
D4 stream	0.113	0.017	1.957	0.075	0.202	0.075	0.035
D5 stream	0.121	0.019	2.095	0.081	0.216	0.081	0.038
R3 stream	0.141	0.022	2.441	0.094	0.252	0.094	0.044

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Fathead minnow*	*Mysidopsis bahia*	*Daphnia magna*	*Chironomus riparius*	*Scenedesmus subspicatus*
Endpoint		EC_{50}	NOEC	EC_{50}	NOEC	NOEC	EbC_{50}

Group		Fish-acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell prolonged	Algae
ug/L)		850	1.6	150	5.6	52.5	32
AF		100	10	100	10	10	10
RAC ug/L)		8.5	0.16	1.5	0.56	5.25	3.2
FOCUS Scenario	PEC ai-max (µg/L)						
Step 1							
	0.610	4.478	96.694	5.467	17.464	3.650	3.069
Step 2							
	1.310	0.203	2.630	0.373	0.330	0.250	0.409
Step 3							
D2 ditch	0.810	0.125	2.250	0.540	1.446	0.154	0.253
D2 stream	0.712	0.110	1.978	0.475	1.271	0.136	0.223
D3 ditch	0.785	0.121	2.181	0.523	1.402	0.150	0.245
D4 pond	0.027	0.004	0.075	0.018	0.048	0.005	0.008
D4 stream	0.587	0.090	1.631	0.391	1.048	0.112	0.183
D5 pond	0.027	0.004	0.075	0.018	0.049	0.005	0.009
D5 stream	0.627	0.096	1.742	0.418	1.120	0.119	0.196
R1 pond	0.033	0.005	0.092	0.022	0.059	0.006	0.010
R1 stream	0.517	0.080	1.436	0.345	0.923	0.098	0.162
R3 stream	0.727	0.112	2.019	0.485	1.298	0.138	0.227
Step 4 (10 m vegetative, 10 m no spray buffer)							
D2 Ditch	0.209	0.032	0.581	0.139	0.373	0.040	0.065
D2 Stream	0.140	0.022	0.389	0.093	0.250	0.027	0.044
D3 Ditch	0.113	0.017	0.314	0.075	0.202	0.022	0.035
D4 Pond	0.017	0.003	0.047	0.011	0.030	0.003	0.005
D4 Stream	0.114	0.018	0.317	0.076	0.204	0.022	0.036
D5 Stream	0.121	0.019	0.336	0.081	0.216	0.023	0.038
R3 Stream	0.141	0.022	0.393	0.094	0.253	0.027	0.044

Table 9.5-28: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Steps 1, 2 and 3- 4 calculations for the use of CHR/F/SCORPIO 325 SC in spring oilseed rape (BBCH14)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 1									
	9.61	< 1	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	255.34	**> 1**
Step 2									
N-Europe	1.15	-	**> 1**	< 1	**> 1**	< 1	< 1	21.39	**> 1**
Step 3									
D3/ditch	0.7874	-	**> 1**	-	**> 1**	-	-	0.5825	< 1
D4/pond	0.02706	-	< 1	-	< 1	-	-	0.2552	< 1
D4/stream	0.6448	-	**> 1**	-	**> 1**	-	-	0.04616	< 1
D5/pond	0.02714	-	< 1	-	< 1	-	-	0.2711	< 1
D5/stream	0.6246	-	**> 1**	-	**> 1**	-	-	0.01797	< 1
R1/pond	0.04047	-	< 1	-	< 1	-	-	1.222	< 1
R1/stream	0.5182	-	**> 1**	-	< 1	-	-	2.229	< 1

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 4		10 m vegetative strip, 10 m no spray buffer							
D3/ditch	0.1128	-	< 1	-	< 1	-	-	-	-
D4/stream	0.1248	-	< 1	-	< 1	-	-	-	-
D5/stream	0.1209	-	< 1	-	< 1	-	-	-	-
R1/stream	0.1094	-	< 1	-	-	-	-	-	-

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010). and no effects were seen at the highest test concentration

Review Comments:

The report Section 8 does not include the FOCUS Step 4 PEC_{SW} values for the R1 stream scenario. Therefore, the risk assessment for difenoconazole for the above usage remains incomplete. At the commenting stage, the Applicant has the opportunity to supplement this report with the appropriate PEC/RAC calculations for difenoconazole.

At the commenting stage, the Applicant submitted the appropriate PEC_{SW} values calculations that there considered by zRMS in updated risk assessment for difenoconazole.

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Fathead minnow*	*Mysidopsis bahia*	*Daphnia magna*	*Chironomus riparius*	*Scenedesmus subspicatus*
Endpoint (µg/L)		EC_{50} 650	NOEC 7.6	EC_{50} 150	NOEC 5.6	NOEC 15	EbC_{50} 32
AF		100	10	100	10	10	10
RAC (µg/L)		6.5	0.76	1.5	0.56	1.5	3.2
FOCUS Scenario	PEC $_{gl-max}$ (µg/L)						
Step 1							
	8.08	1.243	10.632	5.387	14.429	5.387	2.525
Step 2							
	2.3	0.354	3.026	1.533	4.107	1.533	0.719
Step 3							
D1 ditch	0.795	0.122	1.046	0.530	1.420	0.530	0.248
D1 stream	0.695	0.107	0.914	0.463	1.241	0.463	0.217
D3 ditch	0.786	0.121	1.034	0.524	1.403	0.524	0.246
D4 pond	0.027	0.004	0.036	0.018	0.048	0.018	0.008
D4 stream	0.644	0.099	0.847	0.429	1.149	0.429	0.201
D5 stream	0.623	0.096	0.820	0.416	1.113	0.416	0.195
R1 pond	0.044	0.007	0.058	0.029	0.078	0.029	0.014
R1 stream	0.517	0.080	0.680	0.345	0.923	0.345	0.162
Step 4							
D1 ditch	0.114	0.018	0.150	0.076	0.204	0.076	0.036
D1 stream	0.135	0.021	0.178	0.090	0.241	0.090	0.042
D3 ditch	0.113	0.017	0.149	0.075	0.202	0.075	0.035
D4 stream	0.125	0.019	0.164	0.083	0.223	0.083	0.039
D5 stream	0.121	0.019	0.159	0.081	0.216	0.081	0.038

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Fathead minnow*	*Mysidopsis bahia*	*Daphnia magna*	*Chironomus riparius*	*Scenedesmus subspicatus*
Endpoint (µg/L)		EC_{50} 650	NOEC 7.6	EC_{50} 150	NOEC 5.6	NOEC 52.5	EbC_{50} 32

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
AF		100	10	100	10	10	10
PAC (µg/L)		6.5	0.36	1.5	0.56	5.25	3.2
FOCUS Scenario	PEC a-max (µg/L)						
Step 1							
	0.61	1.478	26.694	6.407	17.161	1.830	3.002
Step 2							
	1.31	0.202	3.639	0.873	2.339	0.250	0.409
Step 3							
D1 ditch	0.797	0.123	2.214	0.531	1.423	0.152	0.249
D1 stream	0.697	0.107	1.936	0.465	1.245	0.133	0.218
D2 ditch	0.787	0.121	2.186	0.525	1.405	0.150	0.246
D4 pond	0.027	0.004	0.075	0.018	0.048	0.005	0.009
D4 stream	0.645	0.099	1.793	0.430	1.152	0.123	0.202
D5 pond	0.027	0.004	0.075	0.018	0.048	0.005	0.009
D5 stream	0.625	0.096	1.736	0.417	1.116	0.119	0.195
R1 pond	0.053	0.008	0.142	0.034	0.091	0.010	0.016
R1 stream	0.519	0.080	1.430	0.345	0.925	0.099	0.162
Step 4 (10 m vegetative, 10 m no spray buffer)							
D1 Ditch	0.114	0.018	0.317	0.076	0.204	0.022	0.036
D1 Stream	0.135	0.021	0.375	0.090	0.241	0.026	0.043
D5 Ditch	0.113	0.017	0.314	0.075	0.202	0.022	0.035
D4 Stream	0.125	0.019	0.347	0.083	0.223	0.024	0.039
D5 Stream	0.121	0.019	0.336	0.081	0.216	0.023	0.038
R1 Stream	0.128	0.020	0.356	0.085	0.229	0.024	0.040

Table 9.5-29: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Steps 1, 2 and 3 - 4 calculations for the use of CHR/F/SCORPIO 325 SC in spring oilseed rape (BBCH31)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 1									
	9.61	< 1	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	255.34	**> 1**
Step 2									
N-Europe	1.15	-	**> 1**	< 1	**> 1**	< 1	< 1	21.39	**> 1**
Step 3									
D3/ditch	0.7882	-	**> 1**	-	**> 1**	-	-	0.6496	< 1
D4/pond	0.02706	-	< 1	-	< 1	-	-	0.2552	< 1
D4/stream	0.6448	-	**> 1**	-	**> 1**	-	-	0.04616	< 1
D5/pond	0.02713	-	< 1	-	< 1	-	-	0.2698	< 1
D5/stream	0.6852	-	**> 1**	-	**> 1**	-	-	0.04341	< 1
R1/pond	0.04340	-	< 1	-	< 1	-	-	0.04294	< 1
R1/stream	0.5171	-	**> 1**	-	< 1	-	-	2.992	< 1

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 4		10 m vegetative strip, 5 m no spray buffer							
D3/ditch	0.2133	-	< 1	-	< 1	-	-	-	-
D4/stream	0.2354	-	< 1	-	< 1	-	-	-	-
D5/stream	0.2501	-	< 1	-	< 1	-	-	-	-
R1/stream	0.1888	-	< 1	-	-	-	-	-	-

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010). and no effects were seen at the highest test concentration

Review Comments:

The report Section 8 does not include the FOCUS Step 4 PEC_{SW} values for the R1 stream scenario. Therefore, the risk assessment for difenoconazole for the above usage remains incomplete. At the commenting stage, the Applicant has the opportunity to supplement this report with the appropriate PEC/RAC calculations for difenoconazole.

At the commenting stage, the Applicant submitted the appropriate PEC_{SW} values calculations that there considered by zRMS in updated risk assessment for difenoconazole.

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Fathead minnow*	*Mysidopsis bahia*	*Daphnia magna*	*Chironomus riparius*	*Scenedesmus subspicatus*
Endpoint (µg/L)		EC_{50} 650	NOEC 7.6	EC_{50} 150	NOEC 5.6	NOEC 15	EbC_{50} 32
AF		100	10	100	10	10	10
RAC (µg/L)		6.5	0.76	1.5	0.56	1.5	3.2
FOCUS Scenario	PEC gl-max (µg/L)						
Step 1							
	8.08	1.243	10.632	5.387	14.429	5.387	2.525
Step 2							
	1.15	0.177	1.513	0.767	2.054	0.767	0.359
Step 3							
D1 ditch	0.795	0.122	1.046	0.530	1.420	0.530	0.248
D1 stream	0.695	0.107	0.914	0.463	1.241	0.463	0.217
D3 ditch	0.787	0.121	1.036	0.524	1.405	0.524	0.246
D4 pond	0.027	0.004	0.036	0.018	0.048	0.018	0.008
D4 stream	0.644	0.099	0.847	0.429	1.149	0.429	0.201
D5 pond	0.027	0.004	0.036	0.018	0.048	0.018	0.008
D5 stream	0.684	0.105	0.900	0.456	1.221	0.456	0.214
R1 pond	0.049	0.008	0.064	0.033	0.088	0.033	0.015
R1 stream	0.516	0.079	0.679	0.344	0.921	0.344	0.161
Step 4							
D1 ditch	0.114	0.018	0.150	0.076	0.204	0.076	0.036
D1 stream	0.135	0.021	0.178	0.090	0.241	0.090	0.042
D3 ditch	0.113	0.017	0.149	0.075	0.202	0.075	0.035
D4 stream	0.125	0.019	0.164	0.083	0.223	0.083	0.039
D5 stream	0.132	0.020	0.174	0.088	0.236	0.088	0.041

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Fathead minnow*	*Mysidopsis bahia*	*Daphnia magna*	*Chironomus riparius*	*Scenedesmus subspicatus*

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Endpoint (µg/L)		EC_{50} 650	NOEC 3.4	EC_{50} 150	NOEC 5.6	NOEC 52.5	EbC_{50} 32
AF		100	10	100	10	10	10
PAC (µg/L)		6.5	0.36	1.5	0.56	5.25	3.2
FOCUS Scenario	PEC plateau (µg/L)						
Step 1							
	9.61	1.478	26.694	6.407	17.161	1.830	3.003
Step 2							
	1.31	0.202	3.639	0.873	2.339	0.250	0.409
Step 3							
D1 ditch	0.797	0.123	2.214	0.531	1.423	0.152	0.249
D1 stream	0.607	0.107	1.936	0.465	1.245	0.133	0.218
D3 ditch	0.788	0.121	2.190	0.525	1.407	0.150	0.246
D4 pond	0.022	0.004	0.075	0.018	0.048	0.005	0.008
D4 stream	0.645	0.099	1.792	0.430	1.152	0.123	0.202
D5 pond	0.022	0.004	0.075	0.018	0.048	0.005	0.008
D5 stream	0.685	0.105	1.903	0.457	1.223	0.130	0.214
R1 pond	0.047	0.007	0.133	0.031	0.084	0.009	0.015
R4 stream	0.517	0.080	1.436	0.345	0.923	0.098	0.162
Step 4 (10 m vegetative, 10 m no spray buffer)							
D1 Ditch	0.114	0.018	0.317	0.076	0.204	0.022	0.036
D1 Stream	0.135	0.021	0.375	0.090	0.241	0.026	0.043
D3 Ditch	0.113	0.017	0.314	0.075	0.202	0.022	0.035
D4 Stream	0.125	0.019	0.347	0.083	0.223	0.024	0.039
D5 Stream	0.133	0.020	0.369	0.089	0.238	0.025	0.042
R1 Stream	0.109	0.017	0.303	0.073	0.195	0.021	0.033

Table 9.5-30: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Steps 1, 2 and 3 - 4 calculations for the use of CHR/F/SCORPIO 325 SC in sugar beet (BBCH39)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 1									
	9.61	< 1	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	255.34	**> 1**
Step 2									
N-Europe	1.15	-	**> 1**	< 1	**> 1**	< 1	< 1	18.96	**> 1**
Step 3									
D3/ditch	0.6506	-	**> 1**	-	**> 1**	-	-	0.4385	< 1
D4/pond	0.02616	-	< 1	-	< 1	-	-	0.2465	< 1
D4/stream	0.5210	-	**> 1**	-	< 1	-	-	0.04199	< 1
R1/pond	0.04395	-	< 1	-	< 1	-	-	1.180	< 1
R1/stream	0.4511	-	**> 1**	-	< 1	-	-	2.788	< 1
R3/stream	0.6345	-	**> 1**	-	**> 1**	-	-	2.409	< 1

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 4		10 m vegetative strip, 10 m no spray buffer							
D3/ditch	0.1127	-	< 1	-	< 1	-	-	-	-
D4/stream	0.1169	-	< 1	-	-	-	-	-	-
R1/stream	0.1069	-	< 1	-	-	-	-	-	-
R3/stream	0.1416	-	< 1	-	< 1	-	-	-	-

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010). and no effects were seen at the highest test concentration

Review Comments:

The report Section 8 does not include the FOCUS Step 4 PEC_{SW} values for the D4 stream and R1 stream scenarios. Therefore, the risk assessment for difenoconazole for the above usage remains incomplete. At the commenting stage, the Applicant has the opportunity to supplement this report with the appropriate PEC/RAC calculations for difenoconazole.

At the commenting stage, the Applicant submitted the appropriate PEC_{SW} values calculations that there considered by zRMS in updated risk assessment for difenoconazole.

Table 9.5-31: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Steps 1, 2, 3 and 4 calculations for the use of CHR/F/SCORPIO 325 SC in sugar beet (BBCH31)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 1									
	9.61	< 1	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	255.34	**> 1**
Step 2									
N-Europe	1.15	-	**> 1**	< 1	**> 1**	< 1	< 1	21.39	**> 1**
Step 3									
D3/ditch	0.6506	-	**> 1**	-	**> 1**	-	-	0.4385	< 1
D4/pond	0.02616	-	< 1	-	< 1	-	-	0.5237	< 1
D4/stream	0.5237	-	**> 1**	-	< 1	-	-	0.03608	< 1
R1/pond	0.07267	-	< 1	-	< 1	-	-	0.07161	< 1
R1/stream	0.4515	-	**> 1**	-	< 1	-	-	0.1917	< 1
R3/stream	0.6366	-	**> 1**	-	**> 1**	-	-	0.02151	< 1

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 4		10 m vegetative strip, 5 m no spray buffer							
D3/ditch	0.2129	-	< 1	-	< 1	-	-	-	-
D4/stream	0.2204	-	< 1	-	-	-	-	-	-
R1/stream	0.1900	-	< 1	-	-	-	-	-	-
R3/stream	0.2679	-	< 1	-	< 1	-	-	-	-

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010). and no effects were seen at the highest test concentration

Review Comments:

The report Section 8 does not include the FOCUS Step 4 PEC_{SW} values for the D4 stream and R1 stream scenarios. Therefore, the risk assessment for difenoconazole for the above usage remains incomplete. At the commenting stage, the Applicant has the opportunity to supplement this report with the appropriate PEC/RAC calculations for difenoconazole.

At the commenting stage, the Applicant submitted the appropriate PEC_{SW} values calculations that there considered by zRMS in updated risk assessment for difenoconazole.

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Fathead minnow*	*Mysidopsis bahia*	*Daphnia magna*	*Chironomus riparius*	*Scenedesmus subspicatus*
Endpoint (µg/L)		EC_{50} 650	NOEC 7.6	EC_{50} 150	NOEC 5.6	NOEC 15	EbC_{50} 32
AF		100	10	100	10	10	10
RAC (µg/L)		6.5	0.76	1.5	0.56	1.5	3.2
FOCUS Scenario	PEC $_{gl\ max}$ (µg/L)						
Step 1							
	8.08	1.243	10.632	5.387	14.429	5.387	2.525
Step 2							
	1.35	0.208	1.776	0.900	2.411	0.900	0.422
Step 3							
D3 ditch	0.65	0.100	0.855	0.433	1.161	0.433	0.203
D4 pond	0.026	0.004	0.034	0.017	0.046	0.017	0.008
D4 stream	0.541	0.083	0.712	0.361	0.966	0.361	0.169
R1 pond	0.082	0.013	0.108	0.055	0.146	0.055	0.026
R1 stream	0.447	0.069	0.588	0.298	0.798	0.298	0.140
R3 stream	0.635	0.098	0.836	0.423	1.134	0.423	0.198
Step 4							
D3 ditch	0.113	0.017	0.149	0.075	0.202	0.075	0.035
D4 stream	0.121	0.019	0.159	0.081	0.216	0.081	0.038
R3 stream	0.142	0.022	0.187	0.095	0.254	0.095	0.044

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Fathead minnow*	*Mysidopsis bahia*	*Daphnia magna*	*Chironomus riparius*	*Scenedesmus subspicatus*
Endpoint (µg/L)		EC_{50} 650	NOEC 7.6	EC_{50} 150	NOEC 5.6	NOEC 52.5	EbC_{50} 32
AF		100	10	100	10	10	10
RAC (µg/L)		6.5	0.76	1.5	0.56	5.25	3.2

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
FOCUS Scenario	PEC at max (µg/L)						
Step 1							
	0.61	1.478	26.694	6.407	17.161	1.830	3.002
Step 2							
	1.64	0.252	1.556	1.003	2.020	0.312	0.513
Step 3							
D3 ditch	0.652	0.018	0.317	0.076	0.204	0.022	0.036
D4 pond	0.026	0.021	0.375	0.090	0.241	0.026	0.042
D4 stream	0.542	0.017	0.314	0.075	0.202	0.022	0.035
R1 pond	0.066	0.019	0.343	0.083	0.223	0.024	0.039
D1 stream	0.445	0.020	0.360	0.080	0.238	0.025	0.042
R4 stream	0.632	0.017	0.303	0.073	0.195	0.021	0.034
Step 4 (10 m vegetative 10 m no spray buffer)							
D3 Ditch	0.113	0.017	0.314	0.075	0.202	0.022	0.035
D1 Stream	0.121	0.019	0.336	0.081	0.216	0.023	0.038
R4 Stream	0.100	0.015	0.275	0.067	0.179	0.019	0.031
D2 Stream	0.142	0.022	0.394	0.095	0.254	0.027	0.044

Table 9.5-32: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Steps 1, 2 and 3 - 4 calculations for the use of CHR/F/SCORPIO 325 SC in carrot (BBCH39).

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 1									
	9.61	< 1	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	255.34	**> 1**
Step 2									
N-Europe	1.56	-	**> 1**	< 1	**> 1**	< 1	< 1	43.28	**> 1**
Step 3									
D3/ditch	0.7872	-	**> 1**	-	**> 1**	-	-	0.5760	< 1
R1/pond	0.07223	-	< 1	-	< 1	-	-	1.725	< 1
R1/stream	0.5178	-	**> 1**	-	< 1	-	-	5.412	**> 1**
R3/stream	0.7334	-	**> 1**	-	**> 1**	-	-	1.850	< 1
R4/stream	0.5167	-	**> 1**	-	< 1			4.438	< 1

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 4		10 m vegetative strip, 10 m no spray buffer							
D3/ditch	0.1128	-	< 1	-	< 1	-	-	-	-
R1/stream	0.1055	-	< 1	-	-	-	-	0.8910	< 1
R3/stream	0.1420	-	< 1	-	< 1	-	-	-	-
R4/stream	0.1618	-	< 1	-	-	-	-	-	-

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010). and no effects were seen at the highest test concentration

Review Comments:

The report Section 8 does not include the FOCUS Step 4 PEC_{SW} values for the R1 stream, R4 stream scenarios and PEC_{SED} for R1 stream. Therefore, the risk assessment for difenoconazole for the above usage remains incomplete. At the commenting stage, the Applicant has the opportunity to supplement this report with the appropriate PEC/RAC calculations for difenoconazole.

At the commenting stage, the Applicant submitted the appropriate $PEC_{SW/SED}$ values calculations that there considered by zRMS in updated risk assessment for difenoconazole.

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Fathead minnow*	*Mysidopsis bahia*	*Daphnia magna*	*Chironomus riparius*	*Scenedesmus subspicatus*
Endpoint (µg/L)		EC_{50} 650	NOEC 7.6	EC_{50} 150	NOEC 5.6	NOEC 15	EbC_{50} 32
AF		100	10	100	10	10	10
RAC (µg/L)		6.5	0.76	1.5	0.56	1.5	3.2
FOCUS Scenario	PEC gl-max (µg/L)						
Step 1							
	8.08	1.243	10.632	5.387	14.429	5.387	2.525
Step 2							
	1.29	0.198	1.697	0.860	2.304	0.860	0.403
Step 3							
D3 ditch	0.786	0.121	1.034	0.524	1.404	0.524	0.246
R1 pond	0.082	0.013	0.108	0.055	0.146	0.055	0.026
R1 stream	0.51	0.078	0.671	0.340	0.911	0.340	0.159
R2 stream	0.697	0.107	0.917	0.465	1.245	0.465	0.218
R2 stream	0.696	0.107	0.916	0.464	1.243	0.464	0.218
R3 stream	0.732	0.113	0.963	0.488	1.307	0.488	0.229
R4 stream	0.516	0.079	0.679	0.344	0.921	0.344	0.161
Step 4							
D3 ditch	0.113	0.113	0.149	1.487	0.075	0.202	0.075
R2 stream	0.135	0.135	0.178	1.776	0.090	0.241	0.090
R2 stream 2nd	0.135	0.135	0.178	1.776	0.090	0.241	0.090
R3 stream	0.142	0.142	0.187	1.868	0.095	0.254	0.095

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Fathead minnow*	*Mysidopsis bahia*	*Daphnia magna*	*Chironomus riparius*	*Scenedesmus subspicatus*
Endpoint (µg/L)		EC_{50} 650	NOEC 7.6	EC_{50} 150	NOEC 5.6	NOEC 52.5	EbC_{50} 32
AF		100	10	100	10	10	10
RAC (µg/L)		6.5	0.76	1.5	0.56	5.25	3.2

Group		Fish-acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell prolonged	Algae
FOCUS Scenario	PEC max (µg/L)						
Step 1							
	0.61	1.478	26.694	6.407	17.163	1.830	3.003
Step 2							
	1.58	0.257	4.550	1.093	2.920	0.312	0.513
Step 3							
D3 ditch	0.787	0.121	2.186	0.525	1.405	0.150	0.246
D6 ditch	0.777	0.120	2.158	0.518	1.388	0.148	0.243
R1 pond	0.075	0.012	0.209	0.050	0.134	0.014	0.023
R1 stream	0.515	0.080	1.439	0.345	0.925	0.099	0.162
R2 stream	0.687	0.106	1.908	0.458	1.227	0.131	0.215
R2 stream (2nd)	0.698	0.107	1.939	0.465	1.246	0.133	0.218
R3 stream	0.733	0.112	2.036	0.480	1.309	0.140	0.229
R4 stream	0.517	0.080	1.434	0.345	0.923	0.098	0.162
Step 4 (10 m vegetative 10 m no spray buffer)							
D3 Ditch	0.112	0.017	0.314	0.075	0.202	0.022	0.035
D6 Ditch	0.111	0.017	0.309	0.074	0.198	0.021	0.035
R1 Stream	0.106	0.016	0.294	0.071	0.189	0.020	0.033
R2 Stream	0.132	0.020	0.369	0.089	0.238	0.025	0.042
R2 Stream (2nd)	0.135	0.021	0.375	0.090	0.241	0.026	0.042
R3 stream	0.142	0.022	0.394	0.095	0.254	0.027	0.044
R4 stream	0.102	0.025	0.450	0.108	0.289	0.031	0.051

Table 9.5-33: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Steps 1, 2 and 3 - 4 calculations for the use of CHR/F/SCORPIO 325 SC in potato BBCH 14.

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 1									
	9.61	< 1	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	255.34	**> 1**
Step 2									
N-Europe	1.73	-	**> 1**	**> 1**	**> 1**	< 1	< 1	48.15	**> 1**
Step 3									
D3/ditch	0.6516	-	**> 1**	< 1	**> 1**	-	-	0.5121	< 1
D4/pond	0.02616	-	< 1	< 1	< 1	-	-	0.2556	< 1
D4/stream	0.5407	-	**> 1**	< 1	< 1	-	-	0.05787	< 1
R1/pond	0.04768	-	< 1	< 1	< 1	-	-	1.437	< 1
R1/stream	0.4426	-	**> 1**	< 1	< 1	-	-	2.871	< 1
R3/stream	0.6354	-	**> 1**	< 1	**> 1**	-	-	2.026	< 1

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 4		10 m vegetative strip, 5 m no spray buffer							
D3/ditch	0.2132	-	< 1	-	< 1	-	-	-	-
D4/stream	0.2276	-	< 1	-	-	-	-	-	-
R1/stream	0.1862	-	< 1	-	-	-	-	-	-
R3/stream	0.2674	-	< 1	-	< 1	-	-	-	-
~~Step 4~~		~~10 m vegetative strip, 10 m no spray buffer~~							
~~D3/ditch~~	~~0.1129~~	~~-~~	~~< 1~~	~~-~~	~~< 1~~	~~-~~	~~-~~	~~-~~	~~-~~
~~D4/stream~~	~~?~~	~~-~~	~~?~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~
~~R1/stream~~	~~?~~	~~-~~	~~?~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~
~~R3/stream~~	~~0.1418~~	~~-~~	~~< 1~~	~~-~~	~~< 1~~	~~-~~	~~-~~	~~-~~	~~-~~

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010). and no effects were seen at the highest test concentration

Review Comments:

The report Section 8 does not include the FOCUS Step 4 PEC_{SW} values for the D4 stream and R1 stream scenarios. Therefore, the risk assessment for difenoconazole for the above usage remains incomplete. At the commenting stage, the Applicant has the opportunity to supplement this report with the appropriate PEC/RAC calculations for difenoconazole.

At the commenting stage, the Applicant submitted the appropriate PEC_{SW} values calculations that there considered by zRMS in updated risk assessment for difenoconazole.

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Fathead minnow*	*Mysidopsis bahia*	*Daphnia magna*	*Chironomus riparius*	*Scenedesmus subspicatus*
Endpoint (µg/L)		EC_{50} 650	NOEC 7.6	EC_{50} 150	NOEC 5.6	NOEC 15	EbC_{50} 32
AF		100	10	100	10	10	10
RAC (µg/L)		6.5	0.76	1.5	0.56	1.5	3.2
FOCUS Scenario	PEC gl-max (µg/L)						
Step 1							
	8.08	1.243	10.632	5.387	14.429	5.387	2.525
Step 2							
	3.15	0.485	4.145	2.100	5.625	2.100	0.984
Step 3							
D3 ditch	0.650	0.100	0.855	0.434	1.161	0.434	0.203
D4 pond	0.026	0.004	0.034	0.017	0.047	0.017	0.008
D4 stream	0.540	0.083	0.711	0.360	0.964	0.360	0.169
R1 pond	0.049	0.007	0.064	0.032	0.087	0.032	0.015
R1 stream	0.442	0.068	0.582	0.294	0.789	0.294	0.138
R2 stream	0.595	0.092	0.783	0.397	1.062	0.397	0.186
R3 stream	0.634	0.098	0.834	0.423	1.132	0.423	0.198
Step 4							
D3 ditch	0.113	0.017	0.149	0.075	0.202	0.075	0.035
R2 stream	0.133	0.020	0.175	0.089	0.238	0.089	0.042
R3 stream	0.141	0.022	0.186	0.094	0.252	0.094	0.044

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Fathead minnow*	*Mysidopsis bahia*	*Daphnia magna*	*Chironomus riparius*	*Scenedesmus subspicatus*
Endpoint (µg/L)		EC_{50} 650	NOEC 3.6	EC_{50} 150	NOEC 5.6	NOEC 52.5	EbC_{50} 32
AF		100	10	100	10	10	10
RAC (µg/L)		6.5	0.36	1.5	0.56	5.25	3.2

Group		Fish-acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
FOCUS Scenario	PEC$_{sw,max}$ (µg/L)						
Step 1							
	9.610	1.478	26.604	8.407	17.161	1.830	3.003
Step 2							
	1.720	0.266	4.806	1.153	3.089	0.330	0.543
Step 3							
D3 ditch	0.651	0.100	1.805	0.434	1.163	0.124	0.203
D4 pond	0.026	0.004	0.072	0.017	0.046	0.005	0.008
D5 stream	0.471	0.073	1.308	0.314	0.841	0.090	0.147
D6 ditch	0.647	0.100	1.797	0.431	1.155	0.123	0.202
D6 ditch	0.647	0.100	1.797	0.431	1.155	0.123	0.202
R1 pond	0.070	0.011	0.194	0.047	0.125	0.013	0.022
R1 stream	0.452	0.070	1.256	0.301	0.807	0.086	0.141
R2 stream	0.596	0.092	1.656	0.397	1.064	0.114	0.186
R2 stream	0.635	0.098	1.764	0.423	1.134	0.121	0.198
Step 4 (10 m vegetative, 10 m no-spray buffer)							
D3 Ditch	0.112	0.017	0.314	0.075	0.202	0.022	0.035
D4 Stream	0.105	0.016	0.293	0.070	0.188	0.020	0.033
D6 Ditch	0.112	0.017	0.311	0.075	0.200	0.021	0.035
D6 Ditch	0.161	0.025	0.447	0.107	0.288	0.031	0.050
R1 Stream	0.107	0.016	0.297	0.071	0.191	0.020	0.033
R2 Stream	0.133	0.020	0.369	0.089	0.238	0.025	0.042
R2 Stream	0.142	0.022	0.394	0.095	0.254	0.027	0.044

Table 9.5-34: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Steps 1, 2 and 3 - 4 calculations for the use of CHR/F/SCORPIO 325 SC in potato BBCH 31.

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 1									
	9.61	< 1	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	255.34	**> 1**
Step 2									
N-Europe	1.15	-	**> 1**	**> 1**	**> 1**	< 1	< 1	31.12	**> 1**
Step 3									
D3/ditch	0.6510	-	**> 1**	< 1	**> 1**	-	-	0.4607	< 1
D4/pond	0.02614	-	< 1	< 1	< 1	-	-	0.2627	< 1
D4/stream	0.4706	-	**> 1**	< 1	< 1	-	-	0.04813	< 1
R1/pond	0.06833	-	< 1	< 1	< 1	-	-	1.591	< 1
R1/stream	0.4515	-	**> 1**	< 1	< 1	-	-	5.008	< 1
R3/stream	0.6345	-	**> 1**	< 1	**> 1**	-	-	2.494	< 1
Step 4		10 m vegetative strip, 5 m no spray buffer							
D3/ditch	0.2130	-	< 1	-	< 1	-	-	-	-

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
D4/stream	0.1980	-	< 1	-	-	-	-	-	-
R1/stream	0.1900	-	< 1	-	-	-	-	-	-
R3/stream	0.2670	-	< 1	-	< 1	-	-	-	-

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010). and no effects were seen at the highest test concentration

Review Comments:

The report Section 8 does not include the FOCUS Step 4 PEC_{SW} values for the D4 stream scenario. Therefore, the risk assessment for difenoconazole for the above usage remains incomplete. At the commenting stage, the Applicant has the opportunity to supplement this report with the appropriate PEC/RAC calculations for difenoconazole.

At the commenting stage, the Applicant submitted the appropriate PEC_{SW} values calculations that there considered by zRMS in updated risk assessment for difenoconazole.

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Rainbow trout*	*Mysidopsis bahia*	*Daphnia magna*	*Chironomus riparius*	*Scenedesmus subspicatus*
Endpoint (µg/L)		EC_{50} 650	NOEC 7.6	EC_{50} 150	NOEC 5.6	NOEC 15	EbC_{50} 32
AF		100	10	100	10	10	10
RAC (µg/L)		6.5	0.76	1.5	0.56	1.5	3.2
FOCUS Scenario	PEC gl-max (µg/L)						
Step 1							
	8.08	1.243	10.632	5.387	14.429	5.387	2.525
Step 2							
	1.42	0.218	1.868	0.947	2.536	0.947	0.444
Step 3							
D3 ditch	0.650	0.100	0.855	0.433	1.160	0.433	0.203
D4 pond	0.026	0.004	0.034	0.017	0.047	0.017	0.008
D4 stream	0.470	0.072	0.618	0.313	0.839	0.313	0.147
R1 pond	0.070	0.011	0.092	0.047	0.125	0.047	0.022
R1 stream	0.451	0.069	0.593	0.300	0.805	0.300	0.141
R2 stream	0.595	0.092	0.783	0.397	1.062	0.397	0.186
R3 stream	0.633	0.097	0.833	0.422	1.131	0.422	0.198
Step 4							
D3 ditch	0.113	0.017	0.149	0.075	0.202	0.075	0.035
R1 stream	0.108	0.017	0.142	0.072	0.193	0.072	0.034
R2 stream	0.133	0.020	0.175	0.089	0.238	0.089	0.042
R3 stream	0.223	0.034	0.293	0.149	0.398	0.149	0.070

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Fathead minnow*	*Mysidopsis bahia*	*Daphnia magna*	*Chironomus riparius*	*Scenedesmus subspicatus*
Endpoint (µg/L)		EC_{50} 650	NOEC 3.0	EC_{50} 150	NOEC 5.6	NOEC 52.5	EbC_{50} 32
AF		100	10	100	10	10	10

Group		Fish-acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell, prolonged	Algae
RAC (µg/L)		6.5	0.36	1.5	0.56	5.25	3.2
FOCUS Scenario	PEC$_{pl,max}$ (µg/L)						
Step 1							
	9.610	1.478	26.694	6.407	17.161	1.830	3.003
Step 2							
	1.730	0.266	4.806	1.153	3.089	0.330	0.541
Step 3							
D3 ditch	0.651	0.100	1.808	0.434	1.163	0.124	0.203
D4 pond	0.026	0.004	0.072	0.017	0.046	0.005	0.008
D4 stream	0.471	0.072	1.308	0.314	0.841	0.090	0.147
D6 ditch	0.647	0.100	1.797	0.431	1.155	0.123	0.202
D6 ditch	0.640	0.099	1.778	0.427	1.143	0.122	0.200
R1 pond	0.070	0.011	0.194	0.047	0.125	0.013	0.022
R1 stream	0.452	0.070	1.256	0.301	0.807	0.086	0.141
R2 stream	0.596	0.092	1.656	0.397	1.064	0.114	0.186
R3 stream	0.635	0.100	1.808	0.434	1.163	0.124	0.203
Step 4 (10 m vegetative, 10 m no-spray buffer)							
D3 Ditch	0.113	0.017	0.314	0.075	0.202	0.022	0.035
D4 Stream	0.105	0.016	0.292	0.070	0.188	0.020	0.033
D6 Ditch	0.112	0.017	0.311	0.075	0.200	0.021	0.035
D6 Ditch	0.161	0.025	0.447	0.107	0.288	0.031	0.050
R1 Stream	0.107	0.016	0.297	0.071	0.191	0.020	0.033
R2 Stream	0.133	0.020	0.369	0.089	0.238	0.025	0.042
R3 Stream	0.142	0.022	0.394	0.095	0.254	0.027	0.044

Table 9.5-35: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Steps 1, 2 and 3 - 4 calculations for the use of CHR/F/SCORPIO 325 SC in leafy vegetables (BBCH14).

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 1									
	19.22	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	510.69	**> 1**
Step 2									
N-Europe	2.95	< 1	**> 1**	**> 1**	**> 1**	< 1	**> 1**	82.18	**> 1**
Step 3									
D3/ditch	0.6892	-	**> 1**	< 1	**> 1**	-	< 1	0.8065	< 1
D4/pond	0.03655	-	< 1	< 1	< 1	-	< 1	0.4904	< 1
D4/stream	0.5436	-	**> 1**	< 1	< 1	-	< 1	0.1325	< 1
R1/pond	0.2037	-	< 1	< 1	< 1	-	< 1	4.588	< 1
R1/stream	0.6084	-	**> 1**	< 1	**> 1**	-	< 1	19.81	**> 1**
R3/stream	0.6306	-	**> 1**	< 1	**> 1**	-	< 1	17.68	**> 1**
R4/stream	0.9462	-	**> 1**	< 1	**> 1**	-	< 1	4.814	< 1

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 4		10 m vegetative strip, 10 m no spray buffer							
D3/ditch	0.09275	-	< 1	-	< 1	-	-	-	-
D4/stream	0.1252	-	< 1	-	-	-	-	-	-
R1/stream	0.2123	-	< 1	-	< 1	-	-	1.805	< 1
R3/stream	0.2497	-	< 1	-	< 1	-	-	2.893	< 1
R4/stream	0.4300		**> 1**	-	< 1	-	-	-	-
Step 4		20 m vegetative strip, 10 m no spray buffer							
R4/stream	0.1719		< 1	-	-	-	-	-	-

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010). and no effects were seen at the highest test concentration

Review Comments:

The report Section 8 does not include the FOCUS Step 4 PEC_{SW} values for the D4 stream scenario and PEC_{SED} for R1 stream, R3 stream. The unacceptable risk for R4 stream scenario was identified, when 10 m vfs and 10 m nsb from surface water bodies are applied. Therefore, the risk assessment for difenoconazole for the above usage remains incomplete. At the commenting stage, the Applicant has the opportunity to supplement this report with the appropriate PEC/RAC calculations for difenoconazole.

At the commenting stage, the Applicant submitted the appropriate $PEC_{SW/SED}$ values calculations that there considered by zRMS in updated risk assessment for difenoconazole.

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Fathead minnow*	*Mysidopsis bahia*	*Daphnia magna*	*Chironomus riparius*	*Scenedesmus subspicatus*
Endpoint (µg/L)		EC_{50} 650	NOEC 7.6	EC_{50} 150	NOEC 5.6	NOEC 15	EbC_{50} 32
AF		100	10	100	10	10	10
RAC (µg/L)		6.5	0.76	1.5	0.56	1.5	3.2
FOCUS Scenario	PEC gl-max (µg/L)						
Step 1							
	16.16	2.486	21.263	10.773	28.857	10.773	5.050
Step 2							
	2.42	0.372	3.184	1.613	4.321	1.613	0.756
Step 3							
D3 ditch	0.786	0.121	1.034	0.524	1.404	0.524	0.246
D3 ditch 2nd	0.782	0.120	1.029	0.522	1.397	0.522	0.245
D4 pond	0.027	0.004	0.036	0.018	0.048	0.018	0.008
D4 stream	0.616	0.095	0.811	0.411	1.100	0.411	0.192
R1 pond 1st	0.769	0.013	1.012	0.055	0.148	0.055	0.026
R1 pond 2nd	0.083	0.017	0.109	0.073	0.197	0.073	0.034
R1 stream 1st	0.11	0.080	0.145	0.345	0.924	0.345	0.162
R1 stream 2nd	0.518	0.080	0.682	0.346	0.928	0.346	0.162
R2 stream 1st	0.52	0.105	0.684	0.456	1.222	0.456	0.214
R2 stream 2nd	0.685	0.107	0.901	0.464	1.244	0.464	0.218
R3 stream	0.697	0.112	0.917	0.487	1.304	0.487	0.228
R4 stream 1st	0.73	0.080	0.961	0.345	0.923	0.345	0.162
R4 stream 2nd	0.517	0.079	0.680	0.343	0.919	0.343	0.161
Step 4							
D3 ditch	0.113	0.017	0.149	0.075	0.202	0.075	0.035

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
D3 ditch 2nd	0.112	0.017	0.147	0.075	0.200	0.075	0.035
D4 stream	0.119	0.018	0.157	0.079	0.213	0.079	0.037
R2 stream 1st	0.132	0.020	0.174	0.088	0.236	0.088	0.041
R2 stream 2nd	0.135	0.021	0.178	0.090	0.241	0.090	0.042
R3 stream	0.141	0.022	0.186	0.094	0.252	0.094	0.044
R3 stream	0.141	0.022	0.186	0.094	0.252	0.094	0.044

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Fathead minnow*	*Mysidopsis bahia*	*Daphnia magna*	*Chironomus riparius*	*Scenedesmus subspicatus*
Endpoint (µg/L)		EC_{50} 650	NOEC 3.6	EC_{50} 350	NOEC 3.6	NOEC 52.5	ErC_{50} 32
AF		100	10	100	10	10	10
RAC (µg/L)		6.5	0.36	3.5	0.36	5.25	3.2
FOCUS Scenario	PEC_{sw} max (µg/L)						
Step 1							
	10.330	1.959	53.389	12.813	34.321	3.661	6.006
Step 2							
	2.950	0.454	8.104	1.967	5.268	0.562	0.922
Step 3							
D3 ditch	0.689	0.104	1.814	0.459	1.230	0.131	0.215
D3 ditch (2nd)	1.269	0.195	3.525	0.846	2.266	0.242	0.397
D4 pond	0.037	0.006	0.103	0.025	0.066	0.007	0.012
D4 stream	0.544	0.084	1.514	0.363	0.971	0.104	0.170
D6 ditch	0.677	0.104	1.881	0.451	1.209	0.129	0.212
R1 pond (1st)	0.202	0.031	0.564	0.135	0.362	0.039	0.062
R1 pond (2nd)	0.225	0.035	0.625	0.150	0.402	0.043	0.070
R1 stream (1st)	0.549	0.084	1.525	0.366	0.980	0.105	0.172
R1 stream (2nd)	0.462	0.072	1.287	0.311	0.834	0.089	0.146

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
R2 stream (1st)	0.580	0.091	1.634	0.293	1.052	0.112	0.184
R2 stream (2nd)	0.603	0.093	1.675	0.302	1.077	0.115	0.188
R2 stream	0.631	0.097	1.753	0.321	1.129	0.120	0.197
R2 stream (2nd)	0.636	0.098	1.767	0.324	1.136	0.121	0.199
R4 stream (1st)	0.773	0.119	2.147	0.515	1.380	0.147	0.242
R4 stream (2nd)	0.724	0.111	2.011	0.483	1.293	0.138	0.226
Step 4 (10 m vegetative, 10 m no spray buffer)							
D3 Ditch	0.093	0.014	0.258	0.062	0.166	0.018	0.029
D3 Ditch (2nd)	0.093	0.014	0.258	0.062	0.166	0.018	0.029
D4 Stream	0.125	0.019	0.347	0.082	0.223	0.024	0.039
D6 Ditch	0.450	0.069	1.250	0.300	0.804	0.086	0.141
R1 Stream	0.249	0.038	0.692	0.166	0.445	0.047	0.078
R1 Stream (2nd)	0.213	0.033	0.589	0.141	0.379	0.040	0.066
R2 Stream	0.108	0.017	0.300	0.072	0.193	0.021	0.034
R2 Stream (2nd)	0.110	0.017	0.306	0.073	0.196	0.021	0.034
R3 Stream	0.220	0.034	0.611	0.147	0.393	0.042	0.069
R3 Stream (2nd)	0.198	0.030	0.550	0.132	0.354	0.038	0.062
R4 Stream	0.351	0.054	0.975	0.234	0.627	0.067	0.110
R4 Stream (2nd)	0.329	0.051	0.914	0.219	0.588	0.063	0.103
Step 4 (20 m vegetative strip, 20 m no spray buffer)							
D6 Ditch	0.450	0.069	1.250	0.300	0.804	0.086	0.141

Table 9.5-36: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Steps 1, 2 and 3 - 4 calculations for the use of CHR/F/SCORPIO 325 SC in tobacco.

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 1									
	19.22	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	510.69	**> 1**
Step 2									
N-Europe	1.51	< 1	**> 1**	**> 1**	**> 1**	< 1	**> 1**	39.97	**> 1**
Step 3									
R3/stream	0.5035	-	**> 1**	< 1	< 1	-	< 1	11.43	**> 1**
Step 4		10 m vegetative strip, 5 m no spray buffer							
R3/stream	0.2241	-	< 1	-	-	-	-	1.961	< 1

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010). and no effects were seen at the highest test concentration

Review Comments:

The report Section 8 does not include the FOCUS Step 4 $PEC_{SW/SED}$ values for the R3 stream scenario. The unacceptable risk for R3 stream scenario was identified based on FOCUS Step 1-3 PEC/RAC calculations. Therefore, the risk assessment for difenoconazole for the above usage remains incomplete. At the commenting stage, the Applicant has the opportunity to supplement this report with the appropriate PEC/RAC calculations for difenoconazole.

At the commenting stage, the Applicant submitted the appropriate $PEC_{SW/SED}$ values calculations that there considered by zRMS in updated risk assessment for difenoconazole.

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Fathead minnow*	*Mysidopsis bahia*	*Daphnia magna*	*Chironomus riparius*	*Scenedesmus subspicatus*
Endpoint (µg/L)		EC_{50} 650	NOEC 7.6	EC_{50} 150	NOEC 5.6	NOEC 15	EbC_{50} 32
AF		100	10	100	10	10	10
RAC (µg/L)		6.5	0.76	1.5	0.56	1.5	3.2
FOCUS Scenario	PEC gl-max (µg/L)						
Step 1							
	16.16	2.486	21.263	10.773	28.857	10.773	5.050
Step 2							
	2.55	0.392	3.355	1.700	4.554	1.700	0.797
Step 3							
R3 stream	0.503	0.077	0.662	0.335	0.898	0.335	0.157

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Fathead minnow*	*Mysidopsis bahia*	*Daphnia magna*	*Chironomus riparius*	*Scenedesmus subspicatus*
Endpoint (µg/L)		EC_{50} 650	NOEC 3.6	EC_{50} 150	NOEC 5.6	NOEC 32.5	EbC_{50} 22
AF		100	10	100	10	10	10
RAC (µg/L)		6.5	0.36	1.5	0.56	3.25	2.2
FOCUS Scenario	PEC gl-max (µg/L)						
Step 1							
	19.220	2.957	53.389	12.813	34.334	3.661	6.006
Step 2							
	3.110	0.478	8.639	2.073	5.554	0.592	0.972
Step 3							
D3 ditch	8.229	1.291	23.136	5.553	14.877	1.586	2.603
D4 pond	0.763	0.117	2.110	0.500	1.363	0.145	0.238
D4 stream	8.411	1.294	23.364	5.607	15.020	1.602	2.628
D5 pond	0.872	0.134	2.422	0.581	1.557	0.166	0.272

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
D5 stream	8.913	1.371	24.758	5.042	15.916	1.609	2.785
R1 pond	0.860	0.132	2.389	0.573	1.536	0.164	0.269
R1 stream	3.669	1.024	18.525	4.446	11.909	1.270	2.084
R2 stream	8.850	1.362	24.583	5.900	15.804	1.686	2.766
R3 stream	9.430	1.452	26.210	6.203	16.855	1.703	2.950
R4 stream	6.709	1.032	18.636	4.473	11.950	1.273	2.097
Step 4 (10 m vegetative, 10 m no spray buffer)							
D3 ditch	3.701	0.583	10.534	2.527	6.770	0.722	1.185
D4 pond	0.482	0.074	1.343	0.322	0.863	0.092	0.151
D4 stream	4.216	0.649	11.714	2.814	7.529	0.803	1.318
D5 pond	0.554	0.085	1.538	0.369	0.989	0.105	0.173
D5 stream	4.468	0.687	12.411	2.979	7.979	0.851	1.396
R1 pond	0.546	0.084	1.518	0.364	0.976	0.104	0.171
R1 stream	3.343	0.514	9.286	2.229	5.970	0.637	1.045
R2 stream	4.427	0.682	12.325	2.958	7.923	0.845	1.387
R3 stream	4.732	0.728	13.144	3.155	8.450	0.901	1.479
R4 stream	3.363	0.517	9.342	2.242	6.005	0.641	1.051
Step 4 (20 m vegetative strip, 20 m no spray buffer)							
D3 ditch	0.981	0.151	2.724	0.654	1.751	0.187	0.306
D4 pond	0.144	0.022	0.399	0.096	0.257	0.027	0.045
D4 stream	1.090	0.168	3.028	0.727	1.946	0.208	0.341
D5 stream	1.156	0.178	3.211	0.771	2.064	0.220	0.361
D5 pond	0.166	0.025	0.460	0.110	0.296	0.032	0.052
R1 stream	0.865	0.133	2.402	0.576	1.544	0.165	0.270
R1 pond	0.163	0.025	0.454	0.109	0.292	0.031	0.051
R2 stream	1.147	0.176	3.186	0.765	2.048	0.218	0.358
R3 stream	1.224	0.188	3.400	0.816	2.186	0.233	0.383
R4 stream	0.870	0.134	2.416	0.580	1.553	0.166	0.272
Step 4 (30 m vegetative strip, 20 m no spray buffer)							
D3 ditch	0.327	0.052	0.935	0.224	0.601	0.064	0.105
D4 stream	0.375	0.058	1.040	0.250	0.669	0.071	0.117
D5 stream	0.397	0.061	1.103	0.265	0.709	0.076	0.124
R1 stream	0.297	0.046	0.825	0.198	0.530	0.057	0.093
R2 stream	0.394	0.061	1.094	0.263	0.704	0.075	0.123
R3 stream	0.420	0.065	1.168	0.280	0.751	0.080	0.131
R4 stream	0.299	0.046	0.830	0.199	0.533	0.057	0.093

Table 9.5-37: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Steps 1, 2 and 3 - 4 calculations for the use of CHR/F/SCORPIO 325 SC in pome fruit (BBCH 10).

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 1									
	41.26	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	642.08	**> 1**
Step 2									
N-Europe	13.49	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	180.15	**> 1**
Step 3									
D3/ditch	8.329	< 1	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	9.568	**> 1**
D4/pond	0.7510	< 1	**> 1**	< 1	**> 1**	< 1	< 1	8.133	**> 1**
D4/stream	8.411	< 1	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	0.7918	< 1
D5/pond	0.8661	< 1	**> 1**	< 1	**> 1**	< 1	< 1	8.594	**> 1**
D5/stream	8.913	< 1	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	0.7644	< 1
R1/pond	0.8537	< 1	**> 1**	< 1	**> 1**	< 1	< 1	7.797	**> 1**
R1/stream	6.669	< 1	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	1.117	< 1
R3/stream	9.439	< 1	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	3.525	< 1

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
R4/stream	6.709	< 1	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	1.648	< 1
Step 4		20 m vegetative strip, 20 m no spray buffer							
D3/ditch	0.9805	-	**> 1**	< 1	**> 1**	< 1	< 1	1.219	< 1
D4/pond	0.1417	-	< 1	-	< 1	-	-	1.691	< 1
D4/stream	1.090	-	**> 1**	< 1	**> 1**	< 1	< 1	-	-
D5/pond	0.1647	-	< 1	-	< 1	-	-	1.785	< 1
D5/stream	1.156	-	**> 1**	< 1	**> 1**	< 1	< 1	-	-
R1/pond	0.1623	-	< 1	-	< 1	-	-	1.627	< 1
R1/stream	0.8646	-	**> 1**	< 1	**> 1**	< 1	< 1	-	-
R3/stream	1.224	-	**> 1**	< 1	**> 1**	< 1	< 1	-	-
R4/stream	0.8697	-	**> 1**	< 1	**> 1**	< 1	< 1	-	-
Step 4		20 m vegetative strip, 20 m no spray buffer, 50% nozzle reduction							
D3/ditch	0.4897	-	**> 1**	-	< 1	-	-	~~?~~	~~?~~
D4/pond	-	-	< 1	-	< 1	-	-	~~?~~	~~?~~
D4/stream	0.5447	-	**> 1**	-	< 1	-	-	-	-

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
~~D5/pond~~	-	-	-	-	-	-	-	?	?
D5/stream	0.5772	-	**> 1**	-	**> 1**	-	-	-	-
~~R1/pond~~	-	-	-	-	-	-	-	?	?
R1/stream	0.4319	-	**> 1**	-	< 1	-	-	-	-
R3/stream	0.6113	-	**> 1**	-	**> 1**	-	-	-	-
R4/stream	0.4344	-	**> 1**	-	< 1	-	-	-	-
Step 4		20 m vegetative strip, 20 m no spray buffer, 75% nozzle reduction							
D3/ditch	0.2448	-	< 1	-	-	-	-	-	-
~~D4/pond~~	-	-	-	-	-	-	-	?	?
D4/stream	0.2721	-	< 1	-	-	-	-	-	-
~~D5/pond~~	-	-	-	-	-	-	-	?	?
D5/stream	0.2884	-	< 1	-	-	-	-	-	-
~~R1/pond~~	-	-	-	-	-	-	-	?	?
R1/stream	0.2158	-	< 1	-	-	-	-	-	-
R3/stream	0.3055	-	< 1	-	< 1	-	-	-	-

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
R4/stream	0.2170	-	< 1	-	-	-	-	-	-

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010). and no effects were seen at the highest test concentration

Review Comments:

The report Section 8 does not include the FOCUS Step 4 PEC_{SW} values for the D3 ditch, D4 stream, R1 stream, R4 stream scenarios and PEC_{SED} for D3 ditch, D4 pond, D5 pond, R1 pond. Therefore, the risk assessment for difenoconazole for the above usage remains incomplete. At the commenting stage, the Applicant has the opportunity to supplement this report with the appropriate PEC/RAC calculations for difenoconazole.

At the commenting stage, the Applicant submitted the appropriate PEC_{SWSED} values calculations that there considered by zRMS in updated risk assessment for difenoconazole.

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Fathead minnow*	*Mysidopsis bahia*	*Daphnia magna*	*Chironomus riparius*	*Scenedesmus subspicatus*
Endpoint (µg/L)		EC_{50} 650	NOEC 7.6	EC_{50} 150	NOEC 5.6	NOEC 15	EbC_{50} 32
AF		100	10	100	10	10	10
RAC (µg/L)		6.5	0.76	1.5	0.56	1.5	3.2
FOCUS Scenario	PEC $_{gl-max}$ (µg/L)						
Step 1							
	38.19	5.875	50.250	25.460	68.196	25.460	11.934
Step 2							
	13.01	2.002	17.118	8.673	23.232	8.673	4.066
Step 3							
D3 ditch	6.653	1.024	8.754	4.435	11.880	4.435	2.079
D4 pond	0.599	0.092	0.788	0.399	1.070	0.399	0.187
D4 stream	6.719	1.034	8.841	4.479	11.998	4.479	2.100
D5 pond	0.688	0.106	0.905	0.459	1.229	0.459	0.215
D5 stream	7.120	1.095	9.368	4.747	12.714	4.747	2.225
R1 pond	0.679	0.104	0.893	0.453	1.213	0.453	0.212
R1 stream	5.327	0.820	7.009	3.551	9.513	3.551	1.665
R2 stream	7.069	1.088	9.301	4.713	12.623	4.713	2.209
R3 stream	7.540	1.160	9.921	5.027	13.464	5.027	2.356
R4 stream	5.359	0.824	7.051	3.573	9.570	3.573	1.675
Step 4 – 10 m vegetative strip, 10 m no spray buffer							
D3 ditch	3.028	0.466	3.984	2.019	5.407	2.019	0.946
D4 pond	0.38	0.058	0.500	0.253	0.679	0.253	0.119
D4 stream	3.368	0.518	4.432	2.245	6.014	2.245	1.053
D5 pond	0.437	0.067	0.575	0.291	0.780	0.291	0.137
D5 stream	3.569	0.549	4.696	2.379	6.373	2.379	1.115
R1 pond	0.432	0.066	0.568	0.288	0.771	0.288	0.135
R1 stream	2.67	0.411	3.513	1.780	4.768	1.780	0.834
R2 stream	3.543	0.545	4.662	2.362	6.327	2.362	1.107
R3 stream	3.779	0.581	4.972	2.519	6.748	2.519	1.181
R4 stream	2.686	0.413	3.534	1.791	4.796	1.791	0.839

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Step 4 – 10 m vegetative strip, 20 m no spray buffer							
D3 ditch	0.782	0.120	1.029	0.521	1.396	0.521	0.244
D4 pond	0.113	0.017	0.149	0.075	0.202	0.075	0.035
D4 stream	0.871	0.134	1.146	0.581	1.555	0.581	0.272
D5 stream	0.923	0.142	1.214	0.615	1.648	0.615	0.288
R1 stream	0.69	0.106	0.908	0.460	1.232	0.460	0.216
R2 stream	0.916	0.141	1.205	0.611	1.636	0.611	0.286
R3 stream	0.977	0.150	1.286	0.651	1.745	0.651	0.305
R4 stream	0.694	0.107	0.913	0.463	1.239	0.463	0.217
Step 4 – 30 m vegetative strip, 20 m (VFS)							
D3 ditch	0.269	0.041	0.354	0.179	0.480	0.179	0.084
D4 pond	0.049	0.008	0.064	0.033	0.088	0.033	0.015
D4 stream	0.299	0.046	0.393	0.199	0.534	0.199	0.093
D5 stream	0.317	0.049	0.417	0.211	0.566	0.211	0.099
R1 stream	0.237	0.036	0.312	0.158	0.423	0.158	0.074
R2 stream	0.314	0.048	0.413	0.209	0.561	0.209	0.098
R3 stream	0.335	0.052	0.441	0.223	0.598	0.223	0.105
R4 stream	0.238	0.037	0.313	0.159	0.425	0.159	0.074

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Fathead minnow*	*Mysidopsis bahia*	*Daphnia magna*	*Chironomus riparius*	*Scenedesmus subspicatus*
Endpoint (µg/L)		EC50 6.50	NOEC 1.6	EC50 150	NOEC 5.6	NOEC 52.5	ErC50 32
AF		100	10	100	10	10	10
RAC (µg/L)		6.5	0.16	1.5	0.56	5.25	3.2
FOCUS Scenario	PEC$_{gw,max}$ (µg/L)						
Step 1							
	41.260	6.348	144.611	27.507	73.670	7.859	12.894
Step 2							
	13.400	2.075	37.473	8.993	24.080	2.570	4.216
Step 3							
D3 ditch	8.329	1.281	23.134	5.553	14.873	1.586	2.603

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
D4 pond	0.763	0.117	2.119	0.509	1.263	0.145	0.239
D4 stream	3.411	1.204	22.364	5.607	15.020	1.602	2.628
D5 pond	0.872	0.134	2.422	0.584	1.557	0.166	0.273
D5 stream	3.913	1.271	24.758	5.943	15.916	1.603	2.785
R1 pond	0.860	0.122	2.280	0.573	1.536	0.163	0.269
R1 stream	6.669	1.036	18.525	3.446	11.909	1.270	2.084
R2 stream	5.850	1.262	24.533	5.900	15.304	1.636	2.766
R3 stream	3.439	1.457	26.219	6.293	16.855	1.798	2.950
R4 stream	6.709	1.032	18.636	3.473	11.930	1.279	2.097
Step 4 (10 m vegetative, 10 m no spray buffer)							
D3 ditch	3.791	0.585	10.534	2.527	6.770	0.727	1.185
D4 pond	0.4834	0.074	1.343	0.322	0.863	0.092	0.151
D4 stream	4.216	0.649	11.714	2.814	7.529	0.803	1.318
D5 pond	0.5536	0.085	1.538	0.369	0.989	0.105	0.173
D5 stream	4.468	0.687	12.414	2.950	7.970	0.851	1.396
R1 pond	0.5463	0.084	1.518	0.364	0.976	0.104	0.171
R1 stream	3.343	0.514	9.286	2.229	5.970	0.637	1.045
R2 stream	4.437	0.682	12.325	2.958	7.923	0.845	1.387
R3 stream	4.732	0.728	13.144	3.154	8.450	0.901	1.479
R4 stream	3.362	0.517	9.342	2.242	6.005	0.641	1.051
Step 4 (20 m vegetative strip, 20 m no spray buffer)							
D3 ditch	-0.9305	0.151	2.724	0.654	1.751	0.187	0.306
D4 pond	0.1439	0.022	0.399	0.096	0.257	0.027	0.045
D4 stream	1.090	0.168	3.028	0.727	1.946	0.208	0.341
D5 stream	1.156	0.178	3.211	0.771	2.064	0.220	0.361
D5 pond	0.1657	0.025	0.460	0.110	0.296	0.032	0.052
R1 stream	0.8646	0.133	2.402	0.576	1.544	0.165	0.270
R1 pond	0.1634	0.025	0.454	0.109	0.292	0.031	0.051
R2 stream	1.147	0.176	3.186	0.765	2.048	0.218	0.358
R3 stream	1.224	0.188	3.400	0.816	2.186	0.233	0.383
R4 stream	0.8697	0.134	2.416	0.580	1.553	0.166	0.272
Step 4 (30 m vegetative strip, 20 m no spray buffer)							
D3 ditch	0.337	0.052	0.935	0.224	0.601	0.064	0.105
D4 stream	0.375	0.058	1.040	0.250	0.669	0.071	0.117
D5 stream	0.397	0.061	1.103	0.264	0.709	0.076	0.124
R1 stream	0.297	0.046	0.825	0.198	0.530	0.057	0.093
R2 stream	0.394	0.061	1.094	0.263	0.704	0.075	0.123

Group		Fish-acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
R3 stream	0.420	0.065	1.168	0.280	0.754	0.050	0.131
R4 stream	0.299	0.046	0.820	0.199	0.533	0.057	0.093

Table 9.5-38: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Steps 1, 2, 3 and 4 calculations for the use of CHR/F/SCORPIO 325 SC in pome fruit (BBCH 31).

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 1									
	41.26	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	642.08	**> 1**
Step 2									
N-Europe	13.49	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	180.15	**> 1**
Step 3									
D3/ditch	8.337	< 1	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	6.941	**> 1**
D4/pond	0.8436	< 1	**> 1**	< 1	**> 1**	< 1	< 1	8.110	**> 1**
D4/stream	8.635	< 1	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	1.496	< 1
D5/pond	0.8403	< 1	**> 1**	< 1	**> 1**	< 1	< 1	8.490	**> 1**
D5/stream	8.963	< 1	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	0.9603	< 1
R1/pond	0.7498	< 1	**> 1**	< 1	**> 1**	< 1	< 1	7.439	**> 1**
R1/stream	6.710	< 1	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	1.341	< 1
R3/stream	9.438	< 1	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	2.814	< 1

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
R4/stream	6.709	< 1	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	2.021	< 1
Step 4		20 m vegetative strip, 20 m no spray buffer							
D3/ditch	0.9815	-	**> 1**	< 1	**> 1**	< 1	< 1	1.325	< 1
D4/pond	0.1600	-	< 1	-	< 1	-	-	1.685	< 1
D4/stream	1.119	-	**> 1**	< 1	**> 1**	< 1	< 1	-	-
D5/pond	0.1593	-	< 1	-	< 1	-	-	1.766	< 1
D5/stream	1.162	-	**> 1**	< 1	**> 1**	< 1	< 1	-	-
R1/pond	0.1417	-	< 1	-	< 1	-	-	1.552	< 1
R1/stream	0.8699	-	**> 1**	< 1	**> 1**	< 1	< 1	-	-
R3/stream	1.224	-	**> 1**	< 1	**> 1**	< 1	< 1	-	-
R4/stream	0.8697	-	**> 1**	< 1	**> 1**	< 1	< 1	-	-
Step 4		20 m vegetative strip, 20 m no spray buffer, 50% nozzle reduction							
D3/ditch	0.4902	-	**> 1**	-	< 1	-	-	-	-
~~D4/pond~~	-	-	-	-	-	-	-	~~?~~	~~?~~
D4/stream	0.5592	-	**> 1**	-	< 1	-	-	-	-

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
~~D5/pond~~	-	-	-	-	-	-	-	?	?
D5/stream	0.5805	-	**> 1**	-	**> 1**	-	-	-	-
~~R1/pond~~	-	-	-	-	-	-	-	?	?
R1/stream	0.4345	-	**> 1**	-	< 1	-	-	-	-
R3/stream	0.6112	-	**> 1**	-	**> 1**	-	-	-	-
R4/stream	0.4344	-	**> 1**	-	< 1	-	-	-	-
Step 4		20 m vegetative strip, 20 m no spray buffer, 75% nozzle reduction							
D3/ditch	0.2451	-	< 1	-	-	-	-	?	?
~~D4/pond~~	-	-	-	-	-	-	-	?	?
D4/stream	0.2794	-	< 1	-	-	-	-	-	-
~~D5/pond~~	-	-	-	-	-	-	-	?	?
D5/stream	0.2900	-	< 1	-	-	-	-	-	-
~~R1/pond~~	-	-	-	-	-	-	-	?	?
R1/stream	0.2171	-	< 1	-	-	-	-	-	-
R3/stream	0.3054	-	< 1	-	< 1	-	-	-	-

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
R4/stream	0.2170	-	< 1	-	-	-	-	-	-

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010). and no effects were seen at the highest test concentration

Review Comments:

The report Section 8 does not include the FOCUS Step 4 PEC_{SW} values for the D3 ditch, D4 stream, R1 stream, R4 stream scenarios and PEC_{SED} for D3 ditch, D4 pond, D5 pond R1 pond. Therefore, the risk assessment for difenoconazole for the above usage remains incomplete. At the commenting stage, the Applicant has the opportunity to supplement this report with the appropriate PEC/RAC calculations for difenoconazole.

At the commenting stage, the Applicant submitted the appropriate $PEC_{SW/SED}$ values calculations that there considered by zRMS in updated risk assessment for difenoconazole.

Table 9.5-39: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/F/SCORPIO 325 SC in maize BBCH14.

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 1									
	9.61	< 1	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	255.34	**> 1**
Step 2									
N-Europe	1.56	-	**> 1**	**> 1**	**> 1**	< 1	**> 1**	43.28	**> 1**
Step 3									
D3/ditch	0.6517	-	**> 1**	< 1	**> 1**	-	< 1	0.5169	< 1
D4/pond	0.02617	-	< 1	< 1	< 1	-	< 1	0.2456	< 1
D4/stream	0.5576	-	**> 1**	< 1	< 1	-	< 1	0.03847	< 1
D5/pond	0.02626	-	< 1	< 1	< 1	-	< 1	0.2537	< 1
D5/stream	0.5820	-	**> 1**	< 1	**> 1**	-	< 1	0.02924	< 1
R1/pond	0.05228	-	< 1	< 1	< 1	-	< 1	1.372	< 1
R1/stream	0.4511	-	**> 1**	< 1	< 1	-	< 1	3.512	< 1

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
R3/stream	0.6335	-	**> 1**	< 1	**> 1**	-	< 1	3.105	< 1
R4/stream	0.4498	-	**> 1**	< 1	< 1	-	< 1	2.984	< 1
Step 4		10 m vegetative strip, 10 m no spray buffer							
D3/ditch	0.1129	-	< 1	-	< 1	-	-	-	-
D4/stream	0.1244	-	< 1	-	-	-	-	-	-
D5/stream	0.1299	-	< 1	-	< 1	-	-	-	-
R1/stream	0.1081	-	< 1	-	-	-	-	-	-
R3/stream	0.1414	-	< 1	-	< 1	-	-	-	-
R4/stream	0.1963	-	< 1	-	-	-	-	-	-

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010). and no effects were seen at the highest test concentration

Review Comments:

The report Section 8 does not include the FOCUS Step 4 PEC_{SW} values for the D4 stream, R1 stream, R4 stream scenario. Therefore, the risk assessment for difenoconazole for the above usage remains incomplete. At the commenting stage, the Applicant has the opportunity to supplement this report with the appropriate PEC/RAC calculations for difenoconazole.

At the commenting stage, the Applicant submitted the appropriate PEC_{SW} values calculations that there considered by zRMS in updated risk assessment for difenoconazole.

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Fathead minnow*	*Mysidopsis bahia*	*Daphnia magna*	*Chironomus riparius*	*Scenedesmus subspicatus*
Endpoint (µg/L)		EC_{50} 650	NOEC 3.6	EC_{50} 150	NOEC 5.6	NOEC 82.5	ErC_{50} 22
AF		100	10	100	10	10	10
RAC (µg/L)		6.5	0.36	1.5	0.56	8.25	2.2
FOCUS Scenario	PEC_{sw} max (µg/L)						
Step 1							
	9.620	1.480	26.722	6.413	17.179	1.833	3.006
Step 2							
	1.560	0.240	4.333	1.040	2.786	0.297	0.488
Step 3							
D3 ditch	0.652	0.100	1.811	0.435	1.164	0.124	0.204
D4 pond	0.026	0.004	0.072	0.017	0.046	0.005	0.008
D4 stream	0.558	0.080	1.550	0.373	0.996	0.106	0.174
D5 pond	0.026	0.004	0.072	0.017	0.046	0.005	0.008
D5 stream	0.582	0.000	1.617	0.388	1.039	0.111	0.182
D6 ditch	0.653	0.100	1.814	0.435	1.166	0.124	0.204
R1 pond	0.055	0.008	0.153	0.037	0.098	0.010	0.017
R1 stream	0.451	0.069	1.253	0.301	0.805	0.086	0.141
R2 stream	0.604	0.093	1.678	0.403	1.079	0.115	0.189
R3 stream	0.624	0.098	1.761	0.423	1.132	0.121	0.198
R4 stream	0.450	0.069	1.250	0.300	0.804	0.086	0.141
Step 4 (10 m vegetative, 10 m no-spray buffer)							
D3 ditch	0.113	0.017	0.314	0.075	0.202	0.022	0.035
D4 stream	0.124	0.019	0.344	0.083	0.221	0.024	0.039
D5 stream	0.130	0.020	0.361	0.087	0.232	0.025	0.041
D6 ditch	0.113	0.017	0.314	0.075	0.202	0.022	0.035
R1 stream	0.108	0.017	0.300	0.072	0.193	0.021	0.034
R2 stream	0.135	0.021	0.375	0.090	0.241	0.026	0.042
R3 stream	0.141	0.022	0.392	0.094	0.252	0.027	0.044
R4 stream	0.196	0.030	0.544	0.131	0.350	0.037	0.061

Table 9.5-40: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/F/SCORPIO 325 SC in maize BBCH31.

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 1									
	9.61	< 1	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	255.34	**> 1**
Step 2									
N-Europe	1.15	-	**> 1**	< 1	**> 1**	< 1	< 1	31.12	**> 1**
Step 3									
D3/ditch	0.6504	-	**> 1**	-	**> 1**	-	-	0.4248	< 1
D4/pond	0.02617	-	< 1	-	< 1	-	-	0.2429	< 1
D4/stream	0.5764	-	**> 1**	-	**> 1**	-	-	0.06760	< 1
D5/pond	0.02626	-	< 1	-	< 1	-	-	0.02578	< 1
D5/stream	0.6144	-	**> 1**	-	**> 1**	-	-	0.06898	< 1
R1/pond	0.07982	-	< 1	-	< 1	-	-	1.882	< 1
R1/stream	0.4515	-	**> 1**	-	< 1	-	-	5.933	< 1
R3/stream	0.6366	-	**> 1**	-	**> 1**	-	-	5.679	< 1

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
R4/stream	0.4402	-	**> 1**	-	< 1	-	-	3.447	< 1
Step 4		10 m vegetative strip, 5 m no spray buffer							
D3/ditch	0.2128	-	< 1	-	< 1	-	-	-	-
D4/stream	0.2426	-	< 1	-	< 1	-	-	-	-
D5/stream	0.2586	-	< 1	-	< 1	-	-	-	-
R1/stream	0.1900	-	< 1	-	-	-	-	-	-
R3/stream	0.2679	-	< 1	-	< 1	-	-	-	-
R4/stream	0.1853	-	< 1	-	-	-	-	-	-

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010). and no effects were seen at the highest test concentration

Review Comments:

The report Section 8 does not include the FOCUS Step 4 PEC_{SW} values for the R1 stream and R4 stream scenarios. Therefore, the risk assessment for difenoconazole for the above usage remains incomplete. At the commenting stage, the Applicant has the opportunity to supplement this report with the appropriate PEC/RAC calculations for difenoconazole.

At the commenting stage, the Applicant submitted the appropriate PEC_{SW} values calculations that there considered by zRMS in updated risk assessment for difenoconazole.

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Fathead minnow*	*Mysidopsis bahia*	*Daphnia magna*	*Chironomus riparius*	*Scenedesmus subspicatus*
Endpoint (µg/L)		EC_{50} 650	NOEC 3.6	EC_{50} 150	NOEC 5.6	NOEC 32.5	ErC_{50} 22
AF		100	10	100	10	10	10
RAC (µg/L)		6.5	0.36	1.5	0.56	3.25	2.2
FOCUS Scenario	PEC_{sw} max (µg/L)						
Step 1							
	9.61	1.480	26.722	6.413	17.179	1.533	3.006
Step 2							
	1.56	0.240	4.333	1.040	2.786	0.249	0.488
Step 3							
D3 ditch	0.650	0.100	1.806	0.433	1.161	0.124	0.203
D4 pond	0.026	0.004	0.072	0.017	0.046	0.005	0.008
D4 stream	0.576	0.089	1.600	0.384	1.029	0.110	0.180
D5 pond	0.026	0.004	0.072	0.017	0.046	0.005	0.008
D5 stream	0.614	0.094	1.706	0.409	1.096	0.117	0.192
D6 ditch	0.648	0.100	1.800	0.432	1.157	0.123	0.203
R1 pond	0.082	0.013	0.228	0.055	0.146	0.016	0.026
R1 stream	0.452	0.070	1.256	0.301	0.807	0.086	0.141
R2 stream	0.605	0.093	1.681	0.403	1.080	0.115	0.189
R3 stream	0.627	0.098	1.760	0.423	1.128	0.121	0.199
R4 stream	0.440	0.100	1.806	0.433	1.161	0.124	0.203
Step 4 (10 m vegetative, 10 m no-spray buffer)							
D3 ditch	0.113	0.017	0.314	0.075	0.202	0.022	0.035
D4 pond	0.120	0.020	0.358	0.086	0.230	0.025	0.040
D5 stream	0.137	0.021	0.381	0.091	0.245	0.026	0.043
D6 ditch	0.112	0.017	0.311	0.075	0.200	0.021	0.035
R1 stream	0.124	0.019	0.344	0.083	0.221	0.024	0.039
R2 stream	0.135	0.021	0.375	0.090	0.241	0.026	0.042
R3 stream	0.142	0.022	0.394	0.095	0.254	0.027	0.044
R4 stream	0.179	0.028	0.497	0.119	0.320	0.034	0.056

Table 9.5-41: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/F/SCORPIO 325 SC in sunflower BBCH14.

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 1									
	9.61	< 1	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	255.34	**> 1**
Step 2									
N-Europe	1.64	-	**> 1**	**> 1**	**> 1**	< 1	**> 1**	45.71	**> 1**
Step 3									
D5/pond	0.02624	-	< 1	< 1	< 1	-	< 1	0.2519	< 1
D5/stream	0.5543	-	**> 1**	< 1	< 1	-	< 1	0.01845	< 1
R1/pond	0.0511	-	< 1	< 1	< 1	-	< 1	1.557	< 1
R1/stream	0.4420	-	**> 1**	< 1	< 1	-	< 1	3.715	< 1
R3/stream	0.6349	-	**> 1**	< 1	**> 1**	-	< 1	2.283	< 1
R4/stream	0.4507	-	**> 1**	< 1	< 1	-	< 1	2.897	< 1
Step 4		10 m vegetative strip, 10 m no spray buffer							
D5/stream	0.1237	-	< 1	-	-	-	-	-	-

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
R1/stream	0.1237	-	< 1	-	-	-	-	-	-
R3/stream	0.1417	-	< 1	-	< 1	-	-	-	-
R4/stream	0.1950	-	< 1	-	-	-	-	-	-

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010). and no effects were seen at the highest test concentration

Review Comments:

The report Section 8 does not include the FOCUS Step 4 PEC_{SW} values for the D 5 stream, R1 stream and R4 stream scenarios. Therefore, the risk assessment for difenoconazole for the above usage remains incomplete. At the commenting stage, the Applicant has the opportunity to supplement this report with the appropriate PEC/RAC calculations for difenoconazole.

At the commenting stage, the Applicant submitted the appropriate PEC_{SW} values calculations that there considered by zRMS in updated risk assessment for difenoconazole.

Group		Fish-acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed.-dwelli prolonged	Algae
Test species		*Rainbow trout*	*Fathead minnow*	*Mysidopsis bahia*	*Daphnia magna*	*Chironomus riparius*	*Scenedesmus subspicatus*
Endpoint (µg/L)		EC50 650	NOEC 3.6	EC50 150	NOEC 5.6	NOEC 52.5	ErC50 32
AF		100	10	100	10	10	10
PAC (µg/L)		6.5	0.36	1.5	0.56	5.25	3.2
FOCUS Scenario	PEC-soil max (µg/L)						
Step 1							
	0.61	1.450	36.733	6.414	17.170	1.833	3.006
Step 2							
	1.64	0.752	4.556	1.003	2.929	0.313	0.513
Step 3							
DS pond	0.026	0.004	0.072	0.017	0.046	0.005	0.008
DS stream	0.554	0.085	1.539	0.360	0.980	0.106	0.173
R1 pond	0.056	0.009	0.156	0.037	0.100	0.011	0.018
R1 stream	0.442	0.068	1.228	0.295	0.780	0.084	0.138
R3 stream	0.635	0.098	1.764	0.424	1.134	0.121	0.198
R4 stream	0.451	0.069	1.253	0.301	0.805	0.086	0.141
Step 4 (10 m vegetative, 10 m no spray buffer)							
DS stream	0.124	0.019	0.344	0.083	0.221	0.024	0.039
R1 stream	0.123	0.019	0.342	0.082	0.220	0.023	0.038
R4 stream	0.105	0.030	0.542	0.130	0.348	0.037	0.061

Table 9.5-42: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CHR/F/SCORPIO 325 SC in sunflower BBCH31.

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 1									
	9.61	< 1	**> 1**	**> 1**	**> 1**	**> 1**	**> 1**	255.34	**> 1**
Step 2									
N-Europe	1.15	-	**> 1**	< 1	**> 1**	< 1	< 1	31.12	**> 1**
Step 3									
D5/pond	0.02626	-	< 1	-	< 1	-	-	0.2535	< 1
D5/stream	0.5828	-	**> 1**	-	**> 1**	-	-	0.03771	< 1
R1/pond	0.04887	-	< 1	-	< 1	-	-	1.460	< 1
R1/stream	0.4509	-	**> 1**	-	< 1	-	-	4.634	< 1
R3/stream	0.6332	-	**> 1**	-	**> 1**	-	-	3.557	< 1
R4/stream	0.4415	-	**> 1**	-	< 1	-	-	3.489	< 1
Step 4		10 m vegetative strip, 5 m no spray buffer							
D5/stream	0.2453	-	< 1	-	< 1	-	-	-	-

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
R1/stream	0.1897	-	< 1	-	-	-	-	-	-
R3/stream	0.2665	-	< 1	-	< 1	-	-	-	-
R4/stream	0.1858	-	< 1	-	-	-	-	-	-

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010). and no effects were seen at the highest test concentration

Review Comments:

The report Section 8 does not include the FOCUS Step 4 PEC_{SW} values for the R1 stream and R4 stream scenarios. Therefore, the risk assessment for difenoconazole for the above usage remains incomplete. At the commenting stage, the Applicant has the opportunity to supplement this report with the appropriate PEC/RAC calculations for difenoconazole.

At the commenting stage, the Applicant submitted the appropriate PEC_{SW} values calculations that there considered by zRMS in updated risk assessment for difenoconazole.

Group		Fish acute	Fish prolonged	Aquatic invertebrate acute	Aquatic invertebrate prolonged	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Fathead minnow*	*Mysidopsis bahia*	*Daphnia magna*	*Chironomus riparius*	*Scenedesmus subspicatus*
Endpoint (µg/L)		EC_{50} 650	NOEC 3.6	EC_{50} 150	NOEC 5.6	NOEC 52.5	ErC_{50} 32
AF		100	10	100	10	10	10
RAC (µg/L)		6.5	0.36	1.5	0.56	5.25	3.2
FOCUS Scenario	PEC_{sw} max (µg/L)						
Step 1							
	9.61	1.480	26.722	6.413	17.170	1.833	3.006
Step 2							
	1.64	0.252	4.556	1.093	2.929	0.312	0.513
Step 3							
DS pond	0.026	0.004	0.072	0.017	0.046	0.005	0.008
DS stream	0.582	0.090	1.619	0.390	1.041	0.111	0.182
R1 pond	0.053	0.008	0.147	0.035	0.095	0.010	0.017
R1 stream	0.451	0.069	1.253	0.301	0.805	0.086	0.141
R3 stream	0.633	0.097	1.758	0.422	1.130	0.121	0.198
R4 stream	0.442	0.068	1.228	0.295	0.789	0.084	0.138
Step 4 (10 m vegetative, 10 m no spray buffer)							
DS stream	0.130	0.020	0.361	0.087	0.232	0.025	0.041
R1 stream	0.101	0.016	0.281	0.067	0.180	0.019	0.032
R3 stream	0.141	0.022	0.392	0.094	0.252	0.027	0.044
R4 stream	0.160	0.026	0.469	0.113	0.302	0.032	0.053

Review Comments:

DIFENOCONAZOLE

The risk assessment for aquatic organisms carried out by zRMS demonstrated that for following proposed uses of CHR/F/SCORPIO 325 SC the mitigation measures are required:

1. Winter oilseed rape BBCH 14-20 and BBCH 21-69 – for scenarios D3, D4, D5, R1, R3 – 10 m vfs + 10 m nsb
2. Winter oilseed rape BBCH 31 – for scenarios D3, D4, D5, R1, R3 – 10 m vfs + 5 m nsb
3. Spring oilseed rape BBCH 14 – for scenarios D3, D4, D5, R1 – 10 m vfs + 10 m nsb
4. Spring oilseed rape BBCH 31 – for scenarios D3, D4, D5, R1 – 10 m vfs + 5 m nsb
5. Sugar beet BBCH 39 – for scenarios D3, D4, R1, R3 - 10 m vfs + 10 m nsb
6. Sugar beet BBCH 31 – for scenarios D3, D4, R1, R3 - 10 m vfs + 5 m nsb
7. Carrots BBCH 39 – for scenarios D3, R1, R3, R4 - 10 m vfs + 10 m nsb
8. Potato BBCH 14 – for scenarios D3, D4, R1, R3 - 10 m vfs + 5 m nsb
9. Potato BBCH 31 – for scenarios D3, D4, R1, R3 - 10 m vfs + 5 m nsb
10. Leafy vegetables BBCH 14 – for scenarios D3, D4, R1, R3 – 10 m vfs + 10 m nsb and for R4 - 20 m vfs + 10 m nsb
11. Tobacco – for R3 scenario – 10 m vfs + 5 m nsb
12. Orchards BBCH 10 and BBCH 31 – for scenarios D3, D4, D5, R1, R3 – 20 m vfs + 20 m nsb + 75% drift reduction
13. Maize BBCH 14 – for scenarios D3, D4, D5, R1, R3, R4 – 10 m vfs + 10 m nsb
14. Maize BBCH 31 – for scenarios D3, D4, D5, R1, R3, R4 – 10 m vfs + 5 m nsb
15. Sunflower BBCH 14 - for scenarios D5, R1, R3, R4 - 10 m vfs + 10 m nsb
16. Sunflower BBCH 31 - for scenarios D5, R1, R3, R4 - 10 m vfs + 5 m nsb

Table 9.5-43: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 71019 ~~(slow phase as worst case scenario)~~ (1,2-4 – triazole) for each organism group based on FOCUS Step 1 ~~Steps 1, 2 and 3~~ calculations for the use of CHR/F/SCORPIO 325 SC in crops.**

Group		Fish acute	Fish chronic	Inverteb. acute	Algae
Test species		***O. mykiss***	***O. mykiss***	***D. magna***	***S. capricornutum***
Endpoint		LC_{50}	NOEC	EC_{50}	E_rC_{50}
(µg/L)		498000	3200	100000	>31000
AF		100	10	100	10
RAC (µg/L)		4980	320	1000	>3100
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**				
Winter oilseed rape, Spring oilseed rape, Sugar beet, Potatoes, Carrot, Maize, Sunflower					
Step 1					
All BBCH	2.12	< 1	< 1	< 1	< 1
Tabacco, Leafy Vegetables					
Step 1					
All BBCH	4.25	< 1	< 1	< 1	< 1
Pome Fruit					
Step 1					
All BBCH	4.60	< 1	< 1	< 1	< 1

~~Group~~		~~Fish acute~~	~~Fish prolonged~~	~~Aquatic invertebrate~~	~~Algae~~
~~Test species~~		~~*Rainbow trout*~~	~~*Rainbow trout*~~	~~*Daphnia magna*~~	~~*Selenastrum capricornutum*~~
~~Endpoint~~		~~LC_{50}~~	~~EC_{50}~~	~~EC_{50}~~	~~E_rC_{50}~~
~~(µg/L)~~		~~498000~~	~~3200~~	~~100000~~	~~8000~~
~~AF~~		~~100~~	~~1000~~	~~100~~	~~10~~
~~RAC (µg/L)~~		~~4980~~	~~3.2~~	~~1000~~	~~800~~
~~FOCUS Scenario~~	~~PEC $_{gl\text{-}max}$ (µg/L)~~				
~~Winter oilseed rape (BBCH 14)~~					
~~Step 1~~					
	~~2.11~~	~~0.000~~	~~0.659~~	~~0.002~~	~~0.003~~

Group		Fish acute	Fish prolonged	Aquatic invertebrate	Algae
Winter oilseed rape (BBCH 31)					
Step 1					
	2.11	0.000	0.659	0.002	0.003
Spring oilseed (BBCH 14)					
Step 1					
	2.11	0.000	0.659	0.002	0.003
Spring oilseed (BBCH 31)					
Step 1					
	2.11	0.000	0.659	0.002	0.003
Sugar beet					
Step 1					
	2.11	0.000	0.659	0.002	0.003
Carrot					
Step 1					
	2.11	0.000	0.659	0.002	0.003
Potato (BBCH 14)					
Step 1					
	2.11	0.000	0.659	0.002	0.003
Potato (BBCH 31)					
Step 1					
	2.11	0.000	0.659	0.002	0.003
Leafy vegetables					
Step 1					
	4.22	0.001	1.319	0.004	0.005

Group		Fish acute	Fish prolonged	Aquatic invertebrate	Algae
Tobacco					
Step 1					
	4.22	0.001	1.319	0.004	0.005
Pome fruit					
Step 1					
	4.57	0.001	1.428	0.005	0.006

Group		Fish acute	Fish prolonged	Aquatic invertebrate	Algae
Test species		*Rainbow trout*	*Rainbow trout*	*Daphnia magna*	*Selenastrum capricornutum*
Endpoint (µg/L)		LC_{50} 498000	EC_{50} 3200	EC_{50} 100000	E_rC_{50} 8000
AF		100	1000	100	10
RAC (µg/L)		4980	3.2	1000	800
FOCUS Scenario	PEC $_{gl-max}$ (µg/L)				
Winter oilseed rape (BBCH 14)					
Step 1					
	2.123	0.000	0.066	0.002	0.003
Winter oilseed rape (BBCH 31)					
Step 1					
	2.123	0.000	0.066	0.002	0.003
Spring oilseed (BBCH 14)					
Step 1					
	2.123	0.000	0.066	0.002	0.003

Group		Fish acute	Fish prolonged	Aquatic invertebrate	Algae
Spring oilseed (BBCH 31)					
Step 1					
	2.123	0.000	0.066	0.002	0.003
Sugar beet					
Step 1					
	2.123	0.000	0.066	0.002	0.003
Carrot					
Step 1					
	2.123	0.000	0.066	0.002	0.003
Potato (BBCH 14)					
Step 1					
	2.123	0.000	0.066	0.002	0.003
Potato (BBCH 31)					
Step 1					
	2.123	0.000	0.066	0.002	0.003
Leafy vegetables					
Step 1					
	4.246	0.001	0.133	0.004	0.005
Tobacco					
Step 1					
	4.246	0.001	0.133	0.004	0.005
Pome fruit					
Step 1					
	4.605	0.001	0.144	0.005	0.006

Group		Fish acute	Fish prolonged	Aquatic invertebrate	Algae
Maize BBCH 14					
Step 1					
	2.123	0.000	0.066	0.002	0.003
Maize BBCH 31					
Step 1					
	2.123	0.000	0.066	0.002	0.003
Sunflower BBCH 14					
Step 1					
	2.123	0.000	0.066	0.002	0.003
Sunflower BBCH 31					
Step 1					
	2.123	0.000	0.066	0.002	0.003

Group		Fish acute	Fish prolonged	Aquatic invertebrate	Algae
Test species		*Rainbow trout*	*Rainbow trout*	*Daphnia magna*	*Selenastrum capricornutum*
Endpoint		LC_{50}	EC_{50}	EC_{50}	E_rC_{50}
(µg/L)		498000	3200	100000	8000
AF		100	1000	100	10
RAC (µg/L)		4980	3.2	1000	800
FOCUS Scenario	PEC act max (µg/L)				
Winter oilseed rape (BBCH 14)					
Step 1					
	4.25	0.0009	1.3281	0.0043	0.0053
Step 2					
	0.28	0.0001	0.1188	0.0004	0.0005

Group		Fish acute	Fish prolonged	Aquatic invertebrate	Algae
Spring oilseed					
Step 1					
	4.25	0.0009	1.3281	0.0043	0.0053
Step 2					
	0.38	0.0001	0.1188	0.0004	0.0005
Sugar beet					
Step 1					
	2.12	0.0004	0.6625	0.0021	0.0027
Carrot					
Step 1					
	2.12	0.0004	0.6625	0.0021	0.0027
Potato					
Step 1					
	4.25	0.0009	1.3281	0.0043	0.0053
Step 2					
	0.52	0.0001	0.1625	0.0005	0.0007
Leafy vegetables					
Step 1					
	4.25	0.0009	1.3281	0.0043	0.0053
Step 2					
	0.60	0.0001	0.1875	0.0006	0.0008
Tobacco					
Step 1					
	4.25	0.0009	1.3281	0.0043	0.0053
Step 2					
	0.64	0.0001	0.2000	0.0006	0.0008
Pome fruit					
Step 1					
	3.68	0.0007	1.1500	0.0037	0.0046

Group		Fish acute	Fish prolonged	Aquatic invertebrate	Algae
Step 2					
	0.74	0.0001	0.2313	0.0007	0.0009
Maize					
Step 1					
	4.25	0.0009	1.3281	0.0043	0.0053
Step 2					
	0.42	0.0001	0.1469	0.0005	0.0006
Sunflower					
Step 1					
	4.25	0.0009	1.3281	0.0043	0.0053
Step 2					
	0.49	0.0001	0.1531	0.0005	0.0006

Table 9.5-44: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 205375 for each organism group based on FOCUS Step 1 Steps 1, 2 and 3 calculations for the use of CHR/F/SCORPIO 325 SC in crops.**

Group		**Fish acute**	**Inverteb. acute**	**Algae**	**Sed. dwell. Prolonged**		**Sed. dwell. prolonged**
Test species		***O. mykiss***	***D. magna***	***S. capricornutum***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	EC_{50}	E_rC_{50}	NOEC		NOEC
(µg/L)		740	1400	3100	400		10000
AF		100	100	10	10		10
RAC (µg/L)		7.4	14	310	40		1000
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**					**PEC $_{gl\text{-}max}$ (µg/kg)**	
Winter oilseed rape, Spring oilseed rape, Sugar beet, Potatoes, Carrot, Maize, Sunflower							
Step 1							
All BBCH	1.80	< 1	< 1	< 1	< 1	45.37	< 1
Tabacco, Leafy Vegetables							
Step 1							
All BBCH	3.59	< 1	< 1	< 1	< 1	90.74	< 1
Pome Fruit							
Step 1							
All BBCH	5.80	< 1	< 1	< 1	< 1	103.61	< 1

Group		Fish acute	Aquatic invertebrate	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Daphnia magna*	*Chironomus riparius*	*Selenastrum capricornutum*
Endpoint (µg/L)		EC_{50} 740	EC_{50} 1400	NOEC 10000	E_rC_{50} 1200
AF		100	100	10	10
RAC (µg/L)		7.4	14	1000	120
FOCUS Scenario	PEC gl-max (µg/L)				
Winter oilseed rape BBCH14					
Step 1					
	1.65	0.223	0.118	0.002	0.014
Winter oilseed rape BBCH 31					
Step 1					
	1.65	0.223	0.118	0.002	0.014
Spring oilseed rape BBCH 14					
Step 1					
	1.65	0.223	0.118	0.002	0.014
Spring oilseed rape BBCH 31					
Step 1					
	1.65	0.223	0.118	0.002	0.014
Sugar beet					
Step 1					
	1.65	0.223	0.118	0.002	0.014
Carrot					
Step 1					
	1.65	0.223	0.118	0.002	0.014

Group		Fish acute	Aquatic invertebrate	Sed. dwell. prolonged	Algae
Potato BBCH 14					
Step 1					
	1.65	0.223	0.118	0.002	0.014
Potato BBCH 31					
Step 1					
	1.65	0.223	0.118	0.002	0.014
Leafy vegetables					
Step 1					
	3.31	0.447	0.236	0.003	0.028
Tobbaco					
Step 1					
	3.31	0.447	0.236	0.003	0.028
Pome fruit					
Step 1					
	5.51	0.745	0.394	0.006	0.046

Group		Fish acute	Aquatic invertebrate	Sed. dwell. prolonged	Algae
Test species		*Rainbow trout*	*Daphnia magna*	*Chironomus riparius*	*Selenastrum capricornutum*
Endpoint (µg/L)		EC50 740	EC50 1400	NOEC 10000	EC50 1200
AF		100	100	10	10
RAC (µg/L)		7.4	14	1000	120
FOCUS Scenario	PEC el max (µg/L)				
Winter oilseed rape BBCH14					
Step 1					
	2.701	0.365	0.193	0.003	0.023

Group		Fish acute	Aquatic invertebrate	Sed. dwell. prolonged	Algae
Winter oilseed rape BBCH 31					
Step 3					
	2.701	0.365	0.193	0.003	0.023
Spring oilseed rape BBCH 14					
Step 3					
	2.701	0.365	0.193	0.003	0.023
Spring oilseed rape BBCH 31					
Step 3					
	2.701	0.365	0.193	0.003	0.023
Sugar beet					
Step 3					
	2.701	0.365	0.193	0.003	0.023
Carrot					
Step 3	2.701	0.365	0.193	0.003	0.023
Potato BBCH 14					
Step 3					
	2.701	0.365	0.193	0.003	0.023
Potato BBCH 31					
Step 3					
	2.701	0.365	0.193	0.003	0.023
Leafy vegetables					
Step 3					
	5.400	0.730	0.386	0.005	0.045

Group		Fish acute	Aquatic Invertebrate	Sed. dwell, prolonged	Algae
Tobbacco					
Step 1					
	5.400	0.720	0.336	0.005	0.045
Pome-fruit					
Step 1					
	2.230	0.077	0.516	0.007	0.060
Maize–BBCH 14					
Step 1					
	2.700	0.365	0.193	0.003	0.023
Maize–BBCH 31					
Step 1					
	2.700	0.365	0.193	0.002	0.023
Sunflower–BBCH 14					
Step 1					
	2.700	0.365	0.193	0.003	0.023
Sunflower–BBCH 31					
Step 1					
	2.700	0.365	0.193	0.002	0.023

Review Comments:

MIXTURE TOXICITY

The risk assessment for aquatic organisms carried out by the Applicant has been completely removed (crossed out was not possible because the assessment was inserted in the form of images from EXCEL), as the PEC/RAC calculations were based on unaccepted $PEC_{SW/SED}$ values.

Furthermore, for difenoconazole, in the revised eFate section (dRR B8) there are no sufficiently low FOCUS Step 4 $PEC_{SW/SED}$ values in case of several scenarios (including relevant for Poland D3, D4 and especially R1). Therefore, the risk assessment for difenoconazole is incomplete for all proposed uses.

No correction of the mixture toxicity was made by zRMS since, with the $PEC_{SW/SED}$ values currently available for difenoconazole, it is not possible to complete this assessment.

Therefore, the new mixture toxicity assessment need to be provided (in a format suitable for possible amendment). At the commenting stage, the Applicant has the opportunity to supplement this report with the appropriate PEC/RAC calculations for formulation.

~~**Decision scheme for mixture toxcitiy risk assessment for CHR/F/SCORPIO 325 SC for crops** (Winter oilseed rape, sugar beet, spring oilseed rape, Sinapis alba, Papver somniferum, Glycine max, Healinathus annus, Cucurbita pepo, Linum usitatissium, Cannabis satica, Brassica napus subsp. rapifera, Cichorium intybus, Beta vulgaris subsp. vulgaris, Brassica napus subsp. rapifera, Armoracia rusticana, Apim graveolens var. rapaceum, Ornamental nursery plants, forest nursery plants, renewals, afforestation and plantations of forest trees, Energetic plants, Salix viminalis, Wicker, Nicotiana tabacum)~~

~~Decision scheme for mixture toxicity risk assessment for CHR/F/SCORPIO 325 SC for crops~~

~~Measured toxicity data for the formulation and the a.s. are available for fish, daphnia and algae. For azoxystrobin the most rigoristic endpoints was from mesocosm study. The assessment factor is equal 1~~

Review Comments:

The following PEC/RAC calculations for azoxystrobin submitted by the Applicant are not necessary and were not requested by the zRMS. For this reason, they have been crossed out.

The following PEC/RAC calculations for difenoconazole submitted by the Applicant are not necessary, as the correct FOCUS Step 4 $PEC_{SW/SED}$ values have already been used by zRMS in the tables above, which were prepared in the previous version of the report.

To complete the documentation with the missing information, the applicant provides the required details below.

Table 9.5-45: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in winter oilseed rape (BBCH14-20)

Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Aquatic plants	Higher Tier information
Test species		*O. mykiss*	*P. promelas*	*M. bahia*	*M. bahia*	*N. pelliculosa*	*C. riparius*	*L. gibba*	Mesocosm Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	$PEC_{gl\text{-}max}$ (µg/L)								
Step 4		10 m vegetative strip, 10 m no spray buffer							
D3/ditch	0.1838	0.0391	0.0125	0.3342	0.1927	0.0126	0.0023	0.0006	0.0557
D4/stream	1.553	0.3304	0.1056	2.8236	1.6279	0.1064	0.0194	0.0049	0.4706
D5/stream	1.077	0.2291	0.0733	1.9582	1.1289	0.0738	0.0135	0.0034	0.3264
R1/stream	0.5404	0.1150	0.0368	0.9825	0.5665	0.0370	0.0068	0.0017	0.1638
R3/stream	1.412	0.3004	0.0961	2.5673	1.4801	0.0967	0.0177	0.0044	0.4279

Table 9.5-46: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in winter oilseed rape (BBCH 21-69)

Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Aquatic plants	Higher Tier information
Test species		*O. mykiss*	*P. promelas*	*M. bahia*	*M. bahia*	*N. pelliculosa*	*C. riparius*	*L. gibba*	Mesocosm Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	$PEC_{gl\text{-}max}$ (µg/L)								
Step 4		10 m vegetative strip, 10 m no spray buffer							
D3/ditch	0.1816	0.0386	0.0124	0.3302	0.1904	0.0124	0.0023	0.0006	0.0550
D4/stream	0.4112	0.0875	0.0280	0.7476	0.4310	0.0282	0.0051	0.0013	0.1246
D5/stream	0.1791	0.0381	0.0122	0.3256	0.1877	0.0123	0.0022	0.0006	0.0543
R1/stream	0.5615	0.1195	0.0382	1.0209	0.5886	0.0385	0.0070	0.0018	0.1702
R3/stream	0.9253	0.1969	0.0629	1.6824	0.9699	0.0634	0.0116	0.0029	0.2804

Table 9.5-47: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in winter oilseed rape (BBCH31)

Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Aquatic plants	Higher Tier information
Test species		*O. mykiss*	*P. promelas*	*M. bahia*	*M. bahia*	*N. pellieculosa*	*C. riparius*	*L. gibba*	Mesocosm Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	$PEC_{gl\ max}$ (µg/L)								
Step 4		10 m vegetative strip, 5 m no spray buffer							
D3/ditch	0.3426	0.0729	0.0233	0.6229	0.3591	0.0235	0.0043	0.0011	0.1038
D4/stream	0.4159	0.0885	0.0283	0.7562	0.4360	0.0285	0.0052	0.0013	0.1260
D5/stream	0.3764	0.0801	0.0256	0.6844	0.3945	0.0258	0.0047	0.0012	0.1141
R1/stream	0.5615	0.1195	0.0382	1.0209	0.5886	0.0385	0.0070	0.0018	0.1702
R3/stream	1.065	0.2266	0.0724	1.9364	1.1164	0.0729	0.0133	0.0033	0.3227

Table 9.5-48: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in spring oilseed rape (BBCH14)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**$PEC_{gl\text{-}max}$ (µg/L)**								
Step 4		10 m vegetative strip, 10 m no spray buffer							
D3/ditch	0.1823	0.0388	0.0124	0.3315	0.1911	0.0125	0.0023	0.0006	0.0552
D4/stream	0.4394	0.0935	0.0299	0.7989	0.4606	0.0301	0.0055	0.0014	0.1332
D5/stream	0.2530	0.0538	0.0172	0.4600	0.2652	0.0173	0.0032	0.0008	0.0767
R1/stream	0.7025	0.1495	0.0478	1.2773	0.7364	0.0481	0.0088	0.0022	0.2129

Table 9.5-49: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in spring oilseed rape (BBCH31)

Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Aquatic plants	Higher Tier information
Test species		*O. mykiss*	*P. promelas*	*M. bahia*	*M. bahia*	*N. pelliculosa*	*C. riparius*	*L. gibba*	Mesocosm Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	$PEC_{gl\text{-}max}$ (µg/L)								
Step 4		10 m vegetative strip, 5 m no spray buffer							
D3/ditch	0.3439	0.0732	0.0234	0.6253	0.3605	0.0236	0.0043	0.0011	0.1042
D4/stream	0.4385	0.0933	0.0298	0.7973	0.4596	0.0300	0.0055	0.0014	0.1329
D5/stream	0.4052	0.0862	0.0276	0.7367	0.4247	0.0278	0.0051	0.0013	0.1228
R1/stream	1.194	0.2540	0.0812	2.1709	1.2516	0.0818	0.0149	0.0037	0.3618

Table 9.5-50: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in sugar beet (BBCH39)

Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Aquatic plants	Higher Tier information
Test species		*O. mykiss*	*P. promelas*	*M. bahia*	*M. bahia*	*N. pelliculosa*	*C. riparius*	*L. gibba*	Mesocosm Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	$PEC_{gl\text{-}max}$ (µg/L)								
Step 4		10 m vegetative strip, 10 m no spray buffer							
D3/ditch	0.1822	0.0388	0.0124	0.3313	0.1910	0.0125	0.0023	0.0006	0.0552
D4/stream	0.6845	0.1456	0.0466	1.2445	0.7175	0.0469	0.0086	0.0021	0.2074
R1/stream	0.8493	0.1807	0.0578	1.5442	0.8903	0.0582	0.0106	0.0027	0.2574
R3/stream	0.8963	0.1907	0.0610	1.6296	0.9395	0.0614	0.0112	0.0028	0.2716

Table 9.5-51: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in sugar beet (BBCH31)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**PEC$_{gl\ max}$ (µg/L)**								
Step 4		10 m vegetative strip, 5 m no spray buffer							
D3/ditch	0.3432	0.0730	0.0233	0.6240	0.3597	0.0235	0.0043	0.0011	0.1040
D4/stream	0.6300	0.1340	0.0429	1.1455	0.6604	0.0432	0.0079	0.0020	0.1909
R1/stream	1.005	0.2138	0.0684	1.8273	1.0535	0.0688	0.0126	0.0031	0.3045
R3/stream	1.277	0.2717	0.0869	2.3218	1.3386	0.0875	0.0160	0.0040	0.3870

Table 9.5-52: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in carrot (BBCH39)

Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Aquatic plants	Higher Tier information
Test species		*O. mykiss*	*P. promelas*	*M. bahia*	*M. bahia*	*N. pelliculosa*	*C. riparius*	*L. gibba*	Mesocosm Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	$PEC_{gl\text{-}max}$ (µg/L)								
Step 4		10 m vegetative strip, 10 m no spray buffer							
D3/ditch	0.1821	0.0387	0.0124	0.3311	0.1909	0.0125	0.0023	0.0006	0.0552
D4/stream	0.8588	0.1827	0.0584	1.5615	0.9002	0.0588	0.0107	0.0027	0.2602
R1/stream	0.9470	0.2015	0.0644	1.7218	0.9927	0.0649	0.0118	0.0030	0.2870
R3/stream	1.445	0.3074	0.0983	2.6273	1.5147	0.0990	0.0181	0.0045	0.4379

Table 9.5-53: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in potato (BBCH14)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**$PEC_{gl\text{-}max}$ (µg/L)**								
Step 4		10 m vegetative strip, 5 m no spray buffer							
D3/ditch	0.3437	0.0731	0.0234	0.6249	0.3603	0.0235	0.0043	0.0011	0.1042
D4/stream	0.5815	0.1237	0.0396	1.0573	0.6095	0.0398	0.0073	0.0018	0.1762
R1/stream	1.326	0.2821	0.0902	2.4109	1.3899	0.0908	0.0166	0.0041	0.4018

Table 9.5-54: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in potato (BBCH31)

Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Aquatic plants	Higher Tier information
Test species		*O. mykiss*	*P. promelas*	*M. bahia*	*M. bahia*	*N. pelliculosa*	*C. riparius*	*L. gibba*	Mesocosm Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	$PEC_{gl\text{-}max}$ (µg/L)								
Step 4		10 m vegetative strip, 5 m no spray buffer							
D3/ditch	0.3434	0.0731	0.0234	0.6244	0.3600	0.0235	0.0043	0.0011	0.1041
D4/stream	0.8518	0.1812	0.0579	1.5487	0.8929	0.0583	0.0106	0.0027	0.2581
R1/stream	0.9022	0.1920	0.0614	1.6404	0.9457	0.0618	0.0113	0.0028	0.2734
R3/stream	1.234	0.2626	0.0839	2.2436	1.2935	0.0845	0.0154	0.0039	0.3739

Table 9.5-55: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in leafy vegetables (BBCH 14).

Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Aquatic plants	Higher Tier information
Test species		*O. mykiss*	*P. promelas*	*M. bahia*	*M. bahia*	*N. pelliculosa*	*C. riparius*	*L. gibba*	Mesocosm Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	PEC_{gl-max} (µg/L)								
Step 4		10 m vegetative strip, 10 m no spray buffer							
D3/ditch	0.1494	0.0318	0.0102	0.2716	0.1566	0.0102	0.0019	0.0005	0.0453
D4/stream	1.075	0.2287	0.0731	1.9545	1.1268	0.0736	0.0134	0.0034	0.3258
R1/stream	2.241	0.4768	0.1524	4.0745	2.3491	0.1535	0.0280	0.0070	0.6791
R3/stream	1.869	0.3977	0.1271	3.3982	1.9591	0.1280	0.0234	0.0058	0.5664
R4/stream	3.001	0.6385	0.2041	5.4564	3.1457	0.2055	0.0375	0.0094	0.9094
Step 4		20 m vegetative strip, 10 m no spray buffer							
R4/stream	1.573	0.3347	0.1070	2.8600	1.6488	0.1077	0.0197	0.0049	0.4767

Table 9.5-56: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in tobacco.

Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Aquatic plants	Higher Tier information
Test species		*O. mykiss*	*P. promelas*	*M. bahia*	*M. bahia*	*N. pelliculosa*	*C. riparius*	*L. gibba*	Mesocosm Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	$PEC_{gl\text{-}max}$ (µg/L)								
Step 4		10 m vegetative, 5 m no spray buffer							
R3/stream	2.589	0.5509	0.1761	4.7073	2.7138	0.1773	0.0324	0.0081	0.7845

Table 9.5-57: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in pome fruit (BBCH 10).

Group		**Fish acute**	**Fish prolonged**	**Inverteb. Acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**	**Aquatic plants**	**Higher Tier information**
Test species		***O. mykiss***	***P. promelas***	***M. bahia***	***M. bahia***	***N. pelliculosa***	***C. riparius***	***L. gibba***	**Mesocosm** Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	**PEC$_{gl-max}$ (µg/L)**								
Step 4		20 m vegetative strip, 20 m no spray buffer, 75% nozzle reduction							
D3/ditch	0.2463	0.0524	0.0168	0.4478	0.2582	0.0169	0.0031	0.0008	0.0746
D4/stream	0.2740	0.0583	0.0186	0.4982	0.2872	0.0188	0.0034	0.0009	0.0830
D5/stream	0.2911	0.0619	0.0198	0.5293	0.3051	0.0199	0.0036	0.0009	0.0882
R1/stream	0.2173	0.0462	0.0148	0.3951	0.2278	0.0149	0.0027	0.0007	0.0658
R3/stream	0.3524	0.0750	0.0240	0.6407	0.3694	0.0241	0.0044	0.0011	0.1068
R4/stream	0.2342	0.0498	0.0159	0.4258	0.2455	0.0160	0.0029	0.0007	0.0710

Table 9.5-58: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in pome fruit (BBCH 31).

Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Aquatic plants	Higher Tier information
Test species		*O. mykiss*	*P. promelas*	*M. bahia*	*M. bahia*	*N. pelliculosa*	*C. riparius*	*L. gibba*	Mesocosm Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	$PEC_{gl\ max}$ (µg/L)								
Step 4		20 m vegetative strip, 20 m no spray buffer, 75% nozzle reduction							
D3/ditch	0.3942	0.0839	0.0268	0.7167	0.4132	0.0270	0.0049	0.0012	0.1195
D4/pond	0.4211	0.0896	0.0286	0.7656	0.4414	0.0288	0.0053	0.0013	0.1276
D4/stream	0.5203	0.1107	0.0354	0.9460	0.5454	0.0356	0.0065	0.0016	0.1577
D5/pond	0.2388	0.0508	0.0162	0.4342	0.2503	0.0164	0.0030	0.0007	0.0724
D5/stream	0.4688	0.0997	0.0319	0.8524	0.4914	0.0321	0.0059	0.0015	0.1421
R1/pond	0.06290	0.0134	0.0043	0.1144	0.0659	0.0043	0.0008	0.0002	0.0191
R1/stream	0.5392	0.1147	0.0367	0.9804	0.5652	0.0369	0.0067	0.0017	0.1634
R3/stream	0.4919	0.1047	0.0335	0.8944	0.5156	0.0337	0.0061	0.0015	0.1491
R4/stream	0.7445	0.1584	0.0506	1.3536	0.7804	0.0510	0.0093	0.0023	0.2256

Table 9.5-59: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in maize BBCH14.

Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Aquatic plants	Higher Tier information
Test species		*O. mykiss*	*P. promelas*	*M. bahia*	*M. bahia*	*N. pelliculosa*	*C. riparius*	*L. gibba*	Mesocosm Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	$PEC_{gl\ max}$ (µg/L)								
Step 4		10 m vegetative strip, 10 m no spray buffer							
D4/stream	0.5887	0.1253	0.0400	1.0704	0.6171	0.0403	0.0074	0.0018	0.1784
D5/stream	0.5464	0.1163	0.0372	0.9935	0.5727	0.0374	0.0068	0.0017	0.1656
R1/stream	1.114	0.2370	0.0758	2.0255	1.1677	0.0763	0.0139	0.0035	0.3376
R3/stream	1.496	0.3183	0.1018	2.7200	1.5681	0.1025	0.0187	0.0047	0.4533

Table 9.5-60: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in maize BBCH31.

Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Aquatic plants	Higher Tier information
Test species		*O. mykiss*	*P. promelas*	*M. bahia*	*M. bahia*	*N. pelliculosa*	*C. riparius*	*L. gibba*	Mesocosm Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	$PEC_{gl\ max}$ (µg/L)								
Step 4		10 m vegetative strip, 5 m no spray buffer							
D3/ditch	0.3431	0.0730	0.0233	0.6238	0.3596	0.0235	0.0043	0.0011	0.1040
D4/stream	0.6541	0.1392	0.0445	1.1893	0.6856	0.0448	0.0082	0.0020	0.1982
D5/stream	0.5655	0.1203	0.0385	1.0282	0.5928	0.0387	0.0071	0.0018	0.1714
R1/stream	1.123	0.2389	0.0764	2.0418	1.1771	0.0769	0.0140	0.0035	0.3403
R3/stream	1.208	0.2570	0.0822	2.1964	1.2662	0.0827	0.0151	0.0038	0.3661

Table 9.5-61: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in sunflower BBCH 14.

Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Aquatic plants	Higher Tier information
Test species		*O. mykiss*	*P. promelas*	*M. bahia*	*M. bahia*	*N. pelliculosa*	*C. riparius*	*L. gibba*	Mesocosm Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	$PEC_{gl\ max}$ (µg/L)								
Step 4		10 m vegetative strip, 10 m no spray buffer							
D5/stream	0.3654	0.0777	0.0249	0.6644	0.3830	0.0250	0.0046	0.0011	0.1107
R1/stream	1.332	0.2834	0.0906	2.4218	1.3962	0.0912	0.0167	0.0042	0.4036
R3/stream	0.8447	0.1797	0.0575	1.5358	0.8854	0.0579	0.0106	0.0026	0.2560

Table 9.5-62: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in sunflower BBCH 31.

Group		Fish acute	Fish prolonged	Inverteb. Acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged	Aquatic plants	Higher Tier information
Test species		*O. mykiss*	*P. promelas*	*M. bahia*	*M. bahia*	*N. pelliculosa*	*C. riparius*	*L. gibba*	Mesocosm Invertebrates Acute and chronic
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	ErC_{50}	NOEC	EC_{50}	NOAEC
(µg/L)		470	147	55	9.54	146	800	3200	10
AF		100	10	100	10	10	10	10	3
RAC (µg/L)		4.7	14.7	0.55	0.954	14.6	80	320	3.3
FOCUS Scenario	$PEC_{gl\ max}$ (µg/L)								
Step 4		10 m vegetative strip, 5 m no spray buffer							
D5/stream	0.4859	0.1034	0.0331	0.8835	0.5093	0.0333	0.0061	0.0015	0.1472
R1/stream	0.9651	0.2053	0.0657	1.7547	1.0116	0.0661	0.0121	0.0030	0.2925
R3/stream	1.371	0.2917	0.0933	2.4927	1.4371	0.0939	0.0171	0.0043	0.4155

Table 9.5-63: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in winter oilseed rape (BBCH14-20)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**$PEC_{gl\ max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 4		10 m vegetative strip, 10 m no spray buffer							
R1/stream	0.1067	0.0097	0.2964	0.0711	0.1905	0.0333	0.0711	0.0003	0.0001

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010), and no effects were seen at the highest test concentration

Table 9.5-64: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in winter oilseed rape (BBCH21-69)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**$PEC_{gl\ max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 4		10 m vegetative strip, 10 m no spray buffer							
D5/stream	0.09865	0.0090	0.2740	0.0658	0.1762	0.0308	0.0658	0.0003	0.0001
R1/stream	0.1001	0.0091	0.2781	0.0667	0.1788	0.0313	0.0667	0.0003	0.0001

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. October 2010), and no effects were seen at the highest test concentration

Table 9.5-65: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in winter oilseed rape (BBCH31)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**$PEC_{gl\ max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 4		10 m vegetative strip, 5 m no spray buffer							
R1/stream	0.1888	0.0172	0.5244	0.1259	0.3371	0.0590	0.1259	0.0006	0.0001

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010), and no effects were seen at the highest test concentration

Table 9.5-66: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in spring oilseed rape (BBCH14)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**$PEC_{gl\ max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 4		10 m vegetative strip, 10 m no spray buffer							
R1/stream	0.1094	0.0099	0.3039	0.0729	0.1954	0.0342	0.0729	0.0003	0.0001

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010), and no effects were seen at the highest test concentration

Table 9.5-67: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in spring oilseed rape (BBCH31)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged		Sed. dwell. prolonged
Test species		*S. gairdneri*	*Pimephales promelas*	*M. bahia*	*D. magna*	*S. subspicatus*	*C. riparius*		*C. riparius*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	$PEC_{gl\ max}$ (µg/L)							PEC_{SED} (µg/kg)	
Step 4		10 m vegetative strip, 5 m no spray buffer							
R1/stream	0.1888	0.0172	0.5244	0.1259	0.3371	0.0590	0.1259	0.5266	0.1003

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010). and no effects were seen at the highest test concentration

Table 9.5-68: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in sugar beet (BBCH39)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**$PEC_{gl\ max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 4		10 m vegetative strip, 10 m no spray buffer							
D3/ditch	0.1127	0.0102	0.3131	0.0751	0.2013	0.0352	0.0751	0.0773	0.0147
D4/stream	0.1169	0.0106	0.3247	0.0779	0.2088	0.0365	0.0779	0.0340	0.0065
R1/stream	0.1069	0.0097	0.2969	0.0713	0.1909	0.0334	0.0713	0.9423	0.1795
R3/stream	0.1416	0.0129	0.3933	0.0944	0.2529	0.0443	0.0944	0.4723	0.0900

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010), and no effects were seen at the highest test concentration

Table 9.5-69: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in sugar beet (BBCH31)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**$PEC_{gl\ max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 4		10 m vegetative strip, 5 m no spray buffer							
D4/stream	0.2204	0.0200	0.6122	0.1469	0.3936	0.0689	0.1469	0.0346	0.0066
R1/stream	0.19	0.0173	0.5278	0.1267	0.3393	0.0594	0.1267	0.9475	0.1805

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. October 2010), and no effects were seen at the highest test concentration

Table 9.5-70: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in carrot (BBCH39).

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**$PEC_{gl\ max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 4		10 m vegetative strip, 10 m no spray buffer							
R1/stream	0.1055	0.0096	0.2931	0.0703	0.1884	0.0330	0.0703	0.8910	0.1697
R4/stream	0.1618	0.0147	0.4494	0.1079	0.2889	0.0506	0.1079	0.9040	0.1722

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. October 2010), and no effects were seen at the highest test concentration

Table 9.5-71: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in potato BBCH 14.

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**$PEC_{gl\ max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 4		10 m vegetative strip, 5 m no spray buffer							
D3/ditch	0.2132	0.0194	0.5922	0.1421	0.3807	0.0666	0.1421	0.1698	0.0323
D4/stream	0.2276	0.0207	0.6322	0.1517	0.4064	0.0711	0.1517	0.0561	0.0107
R1/stream	0.1862	0.0169	0.5172	0.1241	0.3325	0.0582	0.1241	0.5250	0.1000
R3/stream	0.2674	0.0243	0.7428	0.1783	0.4775	0.0836	0.1783	0.4233	0.0806

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010), and no effects were seen at the highest test concentration

Table 9.5-72: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in potato BBCH 31.

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged		Sed. dwell. prolonged
Test species		*S. gairdneri*	*Pimephales promelas*	*M. bahia*	*D. magna*	*S. subspicatus*	*C. riparius*		*C. riparius*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	$PEC_{gl\ max}$ (µg/L)							PEC_{SED} (µg/kg)	
Step 4		10 m vegetative strip, 5 m no spray buffer							
D4/stream	0.1980	0.0180	0.5500	0.1320	0.3536	0.0619	0.1320	0.0472	0.0090

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010), and no effects were seen at the highest test concentration

Table 9.5-73: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in leafy vegetables (BBCH14).

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged		Sed. dwell. prolonged
Test species		*S. gairdneri*	*Pimephales promelas*	*M. bahia*	*D. magna*	*S. subspicatus*	*C. riparius*		*C. riparius*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	$PEC_{gl\ max}$ (µg/L)							PEC_{SED} (µg/kg)	
Step 4		10 m vegetative strip, 10 m no spray buffer							
D4/stream	0.1252	0.0114	0.3478	0.0835	0.2236	0.0391	0.0835	0.1279	0.0244
R1/stream	0.2757	0.0251	0.7658	0.1838	0.4923	0.0862	0.1838	3.246	0.6183
R3/stream	0.2497	0.0227	0.6936	0.1665	0.4459	0.0780	0.1665	2.893	0.5510
R4/stream	0.4300	0.0391	1.1944	0.2867	0.7679	0.1344	0.2867	1.173	0.2234
Step 4		20 m vegetative strip, 10 m no spray buffer							
R4/stream	0.1719	0.0156	0.4775	0.1146	0.3070	0.0537	0.1146	0.4117	0.0784

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9, 0ctober 2010), and no effects were seen at the highest test concentration

Table 9.5-74: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in tobacco.

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged		Sed. dwell. prolonged
Test species		*S. gairdneri*	*Pimephales promelas*	*M. bahia*	*D. magna*	*S. subspicatus*	*C. riparius*		*C. riparius*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	$PEC_{gl\ max}$ (µg/L)							PEC_{SED} (µg/kg)	
Step4		10 m vegetative strip, 5 m no spray buffer							
R3/stream	0.2241	0.0204	0.6225	0.1494	0.4002	0.0700	0.1494	1.955	0.3724

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010), and no effects were seen at the highest test concentration

Table 9.5-75: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in pome fruit (BBCH 10).

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged		Sed. dwell. prolonged
Test species		*S. gairdneri*	*Pimephales promelas*	*M. bahia*	*D. magna*	*S. subspicatus*	*C. riparius*		*C. riparius*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	$PEC_{gl\ max}$ (µg/L)							PEC_{SED} (µg/kg)	
R4/stream	6.709	0.6099	18.6361	4.4727	11.9804	2.0966	4.4727	1.648	0.3139
Step 4		20 m vegetative strip, 20 m no spray buffer							
D3/ditch	0.9805	0.0891	2.7236	0.6537	1.7509	0.3064	0.6537	0.7983	0.1521
D4/pond	0.1417	0.0129	0.3936	0.0945	0.2530	0.0443	0.0945	1.691	0.3221
D5/pond	0.1647	0.0150	0.4575	0.1098	0.2941	0.0515	0.1098	1.785	0.3400
R1/pond	0.1623	0.0148	0.4508	0.1082	0.2898	0.0507	0.1082	1.627	0.3099
Step 4		20 m vegetative strip, 20 m no spray buffer, 50% nozzle reduction							
D3/ditch	0.4897	0.0445	1.3603	0.3265	0.8745	0.1530	0.3265	0.6234	0.1187
D4/pond	0.07034	0.0064	0.1954	0.0469	0.1256	0.0220	0.0469	0.8736	0.1664
D5/pond	0.08208	0.0075	0.2280	0.0547	0.1466	0.0257	0.0547	0.9229	0.1758
R1/pond	0.08085	0.0074	0.2246	0.0539	0.1444	0.0253	0.0539	0.8457	0.1611
Step 4		20 m vegetative strip, 20 m no spray buffer, 75% nozzle reduction							
D3/ditch	0.2448	0.0223	0.6800	0.1632	0.4371	0.0765	0.1632	0.3188	0.0607
D4/pond	0.0348	0.0032	0.0967	0.0232	0.0621	0.0109	0.0232	0.4497	0.0857
D4/stream	0.2721	0.0247	0.7558	0.1814	0.4859	0.0850	0.1814	0.02684	0.0051

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged		Sed. dwell. prolonged
Test species		*S. gairdneri*	*Pimephales promelas*	*M. bahia*	*D. magna*	*S. subspicatus*	*C. riparius*		*C. riparius*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	$PEC_{gl\ max}$ (µg/L)							PEC_{SED} (µg/kg)	
D5/pond	0.04081	0.0037	0.1134	0.0272	0.0729	0.0128	0.0272	0.4761	0.0907
R1/pond	0.04016	0.0037	0.1116	0.0268	0.0717	0.0126	0.0268	0.4402	0.0838
R1/stream	0.2158	0.0196	0.5994	0.1439	0.3854	0.0674	0.1439	0.08115	0.0155
R4/stream	0.217	0.0197	0.6028	0.1447	0.3875	0.0678	0.1447	0.2270	0.0432

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010), and no effects were seen at the highest test concentration

Table 9.5-76: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in pome fruit (BBCH 31).

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**$PEC_{gl\ max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 4		20 m vegetative strip, 20 m no spray buffer							
D3/ditch	0.9815	0.0892	2.7264	0.6543	1.7527	0.3067	0.6543	1.325	0.2524
D4/pond	0.1600	0.0145	0.4444	0.1067	0.2857	0.0500	0.1067	1.685	0.3210
D5/pond	0.1593	0.0145	0.4425	0.1062	0.2845	0.0498	0.1062	1.766	0.3364
R1/pond	0.1417	0.0129	0.3936	0.0945	0.2530	0.0443	0.0945	1.552	0.2956
Step 4		20 m vegetative strip, 20 m no spray buffer, 50% nozzle reduction							
D3/ditch	0.4902	0.0446	1.3617	0.3268	0.8754	0.1532	0.3268	0.6782	0.1292
D4/pond	0.0796	0.0072	0.2211	0.0531	0.1421	0.0249	0.0531	0.8706	0.1658
D5/pond	0.07050	0.0064	0.1958	0.0470	0.1259	0.0220	0.0470	0.9138	0.1741
R1/pond	0.07929	0.0072	0.2203	0.0529	0.1416	0.0248	0.0529	0.8067	0.1537
Step 4		20 m vegetative strip, 20 m no spray buffer, 75% nozzle reduction							
D3/ditch	0.2451	0.0223	0.6808	0.1634	0.4377	0.0766	0.1634	0.347	0.0661
D4/pond	0.03953	0.0036	0.1098	0.0264	0.0706	0.0124	0.0264	0.4482	0.0854
D4/stream	0.2794	0.0254	0.7761	0.1863	0.4989	0.0873	0.1863	0.05179	0.0099
D5/pond	0.03938	0.0036	0.1094	0.0263	0.0703	0.0123	0.0263	0.4721	0.0899

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**$PEC_{gl\ max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
R1/pond	0.03504	0.0032	0.0973	0.0234	0.0626	0.0110	0.0234	0.4195	0.0799
R1/stream	0.2171	0.0197	0.6031	0.1447	0.3877	0.0678	0.1447	0.08815	0.0168
R4/stream	0.217	0.0197	0.6028	0.1447	0.3875	0.0678	0.1447	0.2551	0.0486

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. October 2010), and no effects were seen at the highest test concentration

Table 9.5-77: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in maize BBCH14.

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged		Sed. dwell. prolonged
Test species		*S. gairdneri*	*Pimephales promelas*	*M. bahia*	*D. magna*	*S. subspicatus*	*C. riparius*		*C. riparius*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	$PEC_{gl\ max}$ (µg/L)							PEC_{SED} (µg/kg)	
Step 4		10 m vegetative strip, 10 m no spray buffer							
D4/stream	0.1244	0.0113	0.3456	0.0829	0.2221	0.0389	0.0829	0.02701	0.0051
R1/stream	0.1081	0.0098	0.3003	0.0721	0.1930	0.0338	0.0721	0.6122	0.1166
R4/stream	0.1963	0.0178	0.5453	0.1309	0.3505	0.0613	0.1309	0.6993	0.1332

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. October 2010), and no effects were seen at the highest test concentration

Table 9.5-78: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in maize BBCH31.

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**$PEC_{gl\ max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 4		10 m vegetative strip, 5 m no spray buffer							
R1/stream	0.1900	0.0173	0.5278	0.1267	0.3393	0.0594	0.1267	1.018	0.1939
R4/stream	0.1853	0.0168	0.5147	0.1235	0.3309	0.0579	0.1235	0.7713	0.1469

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. October 2010), and no effects were seen at the highest test concentration

Table 9.5-79: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in sunflower BBCH14.

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**		**Sed. dwell. prolonged**
Test species		***S. gairdneri***	***Pimephales promelas***	***M. bahia***	***D. magna***	***S. subspicatus***	***C. riparius***		***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	**$PEC_{gl,max}$ (µg/L)**							**PEC_{SED} (µg/kg)**	
Step 4		10 m vegetative strip, 10 m no spray buffer							
D5/stream	0.1237	0.0112	0.3436	0.0825	0.2209	0.0387	0.0825	0.004384	0.0008
R1/stream	0.1234	0.0112	0.3428	0.0823	0.2204	0.0386	0.0823	0.6551	0.1248
R4/stream	0.195	0.0177	0.5417	0.1300	0.3482	0.0609	0.1300	0.677	0.1290

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. October 2010), and no effects were seen at the highest test concentration

Table 9.5-42: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for difenoconazole for each organism group based on FOCUS Step 4 calculations for the use of CHR/F/SCORPIO 325 SC in sunflower BBCH31.

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged		Sed. dwell. prolonged
Test species		*S. gairdneri*	*Pimephales promelas*	*M. bahia*	*D. magna*	*S. subspicatus*	*C. riparius*		*C. riparius*
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_bC_{50}	NOEC		NOEC*
(µg/L)		1100	3.6	150	5.6	32	15		52.5
AF		100	10	100	10	10	10		10
RAC (µg/L)		11	0.36	1.5	0.56	3.2	1.5		5.25*
FOCUS Scenario	$PEC_{gl,max}$ (µg/L)							PEC_{SED} (µg/kg)	
Step 4		10 m vegetative strip, 5 m no spray buffer							
R1/stream	0.1897	0.0172	0.5269	0.1265	0.3388	0.0593	0.1265	0.7841	0.1494
R4/stream	0.1858	0.0169	0.5161	0.1239	0.3318	0.0581	0.1239	0.7363	0.1402

*it should be noted that the NOEC value was based on very conservative estimate of the concentration in the sediment (see Addendum B.9. 0ctober 2010), and no effects were seen at the highest test concentration

9.5.2.2 Mixture toxicity risk assessment

The evaluation of the mixture toxicity risks for aquatic (and sediment-dwelling) organisms was performed in accordance with the "Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009", as provided by the Commission Services (SANTE-2015-00080, 15. January 2015) and in EFSA Journal 2013;11(7):3290 (Aquatic Guidance Document, abbreviated as EFSA, 2013). The whole mixture assessment is based on the model of concentration addition (CA) and particularly the decision scheme as provided by EFSA (2013, section 10.3.11) was applied. The calculations were performed with the tool "AGD_AquaMix".[3] To keep the assessment concise the focus of this section of this registration report is on the parts of the assessment leading to the most critical results. It does not cover each calculation step for each organism group. Further documentation of the full results is given in the attached mixture risk calculation file.

As part of the risk assessment for product Clapton 325 SC, calculations were carried out for two crop groups: Pome fruits and Winter oilseed rape, representing two worst-case scenarios. The predicted environmental concentration values were selected for the same growth stage in the case of both crop groups (BBCH 31).

~~Organisms from the Algae group were not considered in the assessment due to the absence of a common species available for both active substances. Since no identical test species was available for both substances within the Algae group, including different species for each would have introduced variability and potentially biased the comparative analysis. Therefore, the assessment focused only on groups where a fair and consistent comparison was possible.~~

As both *Pseudokirchneriella subcapitata* and *Scenedesmus subspicatus* belong to the group of green algae, the comparison of their respective endpoints is considered appropriate and provides a reliable basis for the evaluation of aquatic organisms. The endpoint E_bC_{50} was selected from the available algal studies to ensure consistency across the dataset and maintain comparability with other trophic levels. Moreover, the use of E_bC_{50}, which reflects inhibition of biomass growth, is considered a conservative approach, as E_bC_{50} values are generally lower than E_rC_{50} values. Therefore, its application represents a worst-case scenario and strengthens the precautionary basis of the aquatic risk assessment.

Organisms from the Algae group were not considered in the assessment due to the absence of a common species available for both active substances. Since no identical test species was available for both substances within the Algae group, including different species for each would have introduced variability and potentially biased the comparative analysis. Therefore, the assessment focused only on groups where a fair and consistent comparison was possible.

Organisms from the Macrophytes group were not considered in the assessment due to the absence of product-specific studies for this group. As no studies on the product were conducted for organisms within the Macrophytes group, it is not possible to compare the results with those available at the European level. Including this group without comparable data would undermine the reliability of the assessment.

Review Comments:

The evaluation submitted by the applicant was not accepted by zRMS. The assessment below was carried out assuming incorrect active substances contents, i.e., 125 g/L azoxystrobin and 200 g/L difenoconazole. Whereas CHR/F/SCORPIO 325 SC contains 200 g/L azoxystrobin and 125 g/L difenoconazole (MDR, Table 9.5.2.2-2). It is also necessary to correct the endpoints for both active substances used in the risk assessment for the mixture.

[3] Sometimes also termed "Aquatic MixTox Tool". The current version can be found on the EFSA Knowledge Junction platform, DOI: 10.5281/zenodo.4593675 (Aquatic Mixture Toxicity Tool and additional Information | Zenodo)

9.5.2.2.1 Risk assessment of mixture toxicity based on Pome Fruit

Table 9.5.2.2-1: Summary of assessment steps considered for the mixture risk assessment

Steps	Conclusion on the Steps	
	Fish	Invertebrates
Screening 1: ETR trigger (optional Step)	-	-
Screening 2: Driver (optional Step)	-	-
Step 1: data available?	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.
Step 2: apparent synergism or antagonism?	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is <0.2. Thus, antagonism is indicated, go to Step 9.
Step 3: mixture similar or not?	Mixture similar every scenario. All scenarios can be assessed via product test, go to Step 4.	Different assessment factor or additional data available, go to Step 8.
Step 4: ETRmix assessment (ECxPPP)	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	

Step 5: driver available?		
Step 6: driver assessment	-	-
Step 7: synergism assessment (few data)	-	-
Step 8a: ETRmix assessment	-	-
Step 8b: RQmix assessment	-	Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).
Step 9: antagonism assessment	-	Measured mixture toxicity not plausible: go to Step 8
Step 10: synergism assessment	-	-

Overview of the assessment steps: Table 9.5.2.2-1 gives a summary of the decisions made for each organism group during the mixture risk assessment with respect to the decision scheme as provided by EFSA (2013, section 10.3.11). A discussion of all details of every decision is not intended in this section of this registration report. Further in-depth justification and explanation for the decisions made are documented in the attached mixture risk calculation file. However, at least data for some important steps are documented in this section of this registration report, beginning with the check for (and potentially assessment of) synergistic or antagonistic effects (Step 2 and Steps 7, 9 and 10) as well as the ETR_{mix} or RQ_{mix} calculation results for the assessed FOCUS Scenarios (Steps 4 and 8a/b).

Step 2: MDR calculation to check for synergistic or antagonistic effects

Table 9.5.2.2-2: Calculated mixture toxicity and MDR for each group of organisms (see sections 10.3.3 and 10.3.4 of EFSA (2013) for more details)

Species	Active substance	Concentration (C_i) in formulation (g a.s./L)	P_i	ECx_i (mg a.s./L)	ECx_{mix-CA} (mg sum a.s. /L)	ECx_{PPP} (mg sum a.s./L)	MDR[2]
Fish, acute toxicity[1]							
species sp.	Azoxystrobin	125	0.38	0.47	0.57	0.496227771	1.14
	Difenoconazole	200	0.62	0.65			
Invertebrates, acute toxicity[1]							
species sp.	Azoxystrobin	125	0.38	0.01	0.02	0.321088558	0.07
	Difenoconazole	200	0.62	0.15			

[1] For a possible inclusion of chronic toxicity please refer to the FAQ document distributed alongside the aquatic mixture toxicity calculation tool "AGD_AquaMix".

[2] MDR = 0.2 – 5 → Go to Step 3 (concentration addition (CA) approximately holds for the calculated mixture);

MDR > 5 → Go to Step 10 (the calculated mixture is more toxic than CA, i.e. synergistic);

MDR < 0.2 → Go to Step 9 (the calculated mixture is less toxic than CA, i.e. antagonistic)

Step 3 Comparison of mixture composition of PPP and PEC_{mix}

According to Step 3 it has to be checked whether the mixture composition in the formulation is similar to the mixture composition at PEC_{mix} (which is the sum of PEC_i of individual active substances). Therefore, the "ECx_{mix-CA} (a.s. in PPP) / ECx_{mix-CA} (a.s. in PEC_{mix})" ratios were calculated.

In case the ratio is in the range of 0.8–1.2 (mixture similar), the risk assessment can be based on the ECx_{PPP} (Step 4).

In case the ratio is outside the range of 0.8–1.2 (i.e. mixture not similar), the endpoint ECx_{mix-CA} normalized to the mixture composition at PEC_{mix} (reported as "ECx_{mix-CA} (a.s. in PEC_{mix})" in EFSA, 2013, and the following parts of this report) has to be used to calculate the risk (Step 5 or Step 8, respectively).

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if product or calculated endpoint data (according to Step 3) have to be used. Further in-depth justification and explanation are documented in the attached mixture risk calculation file.

Step 5: Driver detection

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if a driver of risk is available according to Step 5. Further in-depth justification and explanation are documented in the attached mixture risk calculation file. Further information for the availability of a driver for the risk assessment of particular FOCUS Scenarios is given in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) and

Table 9.5.2.2-4 (FOCUS Step 4) below.

Step 4 and Step 8a: Mixture risk assessment based on measured and calculated mixture toxicity

Decisions taken when using the scheme as provided by EFSA (2013, section 10.3.11) lead to several assessment steps, which give a conclusion on the risk of a mixture or provide additional information important for the assessment. In the tables below the conclusions of different steps of the mixture risk assessment are summarized for the FOCUS Scenarios of concern. Information is reported on:

a) Step 2 and associated steps, in which the question is answered if concentration addition can be assumed (i.e. a standard mixture toxicity risk assessment is appropriate) or if an antagonism/synergism is possible (more detailed information on Step 2 is given above). This is important to derive if further, specific considerations have to be made in the risk assessment. Associated steps are Step 7, Step 9 and Step 10.
b) Step 5, in which the question is answered if there is a driver of risk and if so, which of the substance can be classified as driver (more detailed information on Step 5 is given the attached mixture risk calculation file). This is reported as additional information in case an assessment based on a driver would also be possible; for comparative reasons the table always lists the results from the mixture risk assessment according to Step 4 and/or Step 8. For an assessment based on a particular a.s. (the driver) please be referred to the individual a.s. risk assessment.
c) Step 4 with the assessment results for cases where product data are usable (according to Step 3) and the risk assessment can be carried out based on the measured toxicity.
d) Step 8 (a/b) with the assessment results for cases where product data are not usable (according to Step 3) and the risk assessment has to be based on calculated mixture toxicity.

The respective assessment conclusions are presented in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) or

Table 9.5.2.2-4 (FOCUS Step 4). The assessment is based either on the exposure-toxicity ratio (ETR_{mix}) or the risk quotient (RQ_{mix}); the ETR_{mix} and RQ_{mix} are compared to respective trigger values: 1/10 or 1/100 for the ETR_{mix} (depending on the species assessed) and 1 for RQ_{mix}. Values below the trigger indicating a high risk are marked in **bold**. For the sake of a concise assessment the results below are limited to the organism groups most at risk. Further in-depth justification and explanation for other organism groups are documented in the attached mixture risk calculation file.

Table 9.5.2.2-3: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for fish, for FOCUS Step 1 – 3 for application of Clapron 325 SC in Pome fruit

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	no driver	0.34	Go to Step 4
Step 2				
N-Europe		no driver	0.10	Go to Step 4
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.04	Go to Step 4
D4/ pond		no driver	0.00	Go to Step 4
D4/ stream		no driver	0.05	Go to Step 4
D5/ pond		no driver	0.00	Go to Step 4
D5/ stream		no driver	0.05	Go to Step 4
D6/ ditch		Scenario D6 are not relevant for Central Zone		
R1/ pond		no driver	0.00	Go to Step 4
R1/ stream		no driver	0.04	Go to Step 4
R2/ stream		Scenario R2 are not relevant for Central Zone		
R3/ stream		no driver	0.05	Go to Step 4
R4/ stream		no driver	0.04	Go to Step 4

Table 9.5.2.2-4: Summary of the mixture toxicity risk assessment (related to Step 4) for fish based on FOCUS Step 4 calculations for application of Clapton 325 SC in Pome fruit

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch									
50%										
75%										0.00
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream									
50%										
75%										0.00
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream									
50%										
75%										0.00
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream									
50%										
75%										0.00
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream									
50%										
75%										0.00
90%										
None	R4 stream									
50%										
75%										0.00

90%										

Table 9.5.2.2-5: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for invertebrates, for FOCUS Step 1 – 3 for application of Clapron 325 SC in Pome fruit

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	ETR_{mix-CA} (Step 8a)	RQ_{mix} (Step 8b)
Step 1	not applicable	Azoxystrobin	Go to Step 4	**65.47**
Step 2				
N-Europe		Azoxystrobin	Go to Step 4	**19.33**
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		Azoxystrobin	Go to Step 4	**9.57**
D4/ pond		Azoxystrobin	Go to Step 4	1.00
D4/ stream		Azoxystrobin	Go to Step 4	**9.92**
D5/ pond		Azoxystrobin	Go to Step 4	**1.03**
D5/ stream		Azoxystrobin	Go to Step 4	**10.30**
D6/ ditch		Scenario D6 are not relevant for Central Zone		
R1/ pond		Azoxystrobin	Go to Step 4	0.89
R1/ stream		Azoxystrobin	Go to Step 4	**7.71**
R2/ stream		Scenario R2 are not relevant for Central Zone		
R3/ stream		Azoxystrobin	Go to Step 4	**10.84**
R4/ stream		Azoxystrobin	Go to Step 4	**7.71**

Table 9.5.2.2-6: Summary of the mixture toxicity risk assessment (related to Step 4) for invertebrates based on FOCUS Step 4 calculations for application of Clapton 325 SC in Pome fruit

FOCUS Step 4	Scenario	RQmix								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch									
50%										
75%										0.28
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream									
50%										
75%										0.34
90%										
None	D5 Pond									
50%										
75%										0.10
90%										
None	D5 stream									
50%										
75%										0.33
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream									
50%										
75%										0.31
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								

None	**R3 stream**									
50%										
75%										0.35
90%										
None	**R4 stream**									
50%										
75%										0.37
90%										

9.5.2.2.2 Risk assessment of mixture toxicity based on Winter Oilseed Rape

Table 9.5.2.2.7: Summary of assessment steps considered for the mixture risk assessment

Steps	Conclusion on the Steps	
	Fish	Invertebrates
Screening 1: ETR trigger (optional Step)	Not relevant	Not relevant
Screening 2: Driver (optional Step)	Not relevant	Not relevant
Step 1: data available?	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.
Step 2: apparent synergism or antagonism?	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is <0.2. Thus, antagonism is indicated, go to Step 9.
Step 3: mixture similar or not?	Mixture similar every scenario. All scenarios can be assessed via product test, go to Step 4.	Different assessment factor or additional data available, go to Step 8.
Step 4: ETRmix assessment (ECxPPP)	Acceptable risk have been found in all scenarios in FOCUS step 1-3.	Not relevant

Step 5: driver available?	There is no driver for fish in all scenarios. Go to Step 8.	There is no driver for invertebrates in all scenarios. Go to Step 8.
Step 6: driver assessment	Not relevant	Not relevant
Step 7: synergism assessment (few data)	Not relevant	Not relevant
Step 8a: ETRmix assessment	Not relevant	Not relevant
Step 8b: RQmix assessment	Not relevant	Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).
Step 9: antagonism assessment	Not relevant	Measured mixture toxicity not plausible: go to Step 8
Step 10: synergism assessment	Not relevant	Not relevant

Overview of the assessment steps: Table 9.5.2.2-1 gives a summary of the decisions made for each organism group during the mixture risk assessment with respect to the decision scheme as provided by EFSA (2013, section 10.3.11). A discussion of all details of every decision is not intended in this section of this registration report. Further in-depth justification and explanation for the decisions made are documented in the attached mixture risk calculation file. However, at least data for some important steps are documented in this section of this registration report, beginning with the check for (and potentially assessment of) synergistic or antagonistic effects (Step 2 and Steps 7, 9 and 10) as well as the ETR_{mix} or RQ_{mix} calculation results for the assessed FOCUS Scenarios (Steps 4 and 8a/b).

Step 2: MDR calculation to check for synergistic or antagonistic effects

Table 9.5.2.2-8: Calculated mixture toxicity and MDR for each group of organisms (see sections 10.3.3 and 10.3.4 of EFSA (2013) for more details)

Species	Active substance	Concentration (C_i) in formulation (g a.s./L)	P_i	ECx_i (mg a.s./L)	$ECx_{mix,CA}$ (mg sum a.s. /L)	ECx_{ppp} (mg sum a.s./L)	MDR[2]
Fish, acute toxicity[1]							
species sp.	Azoxystrobin	125	0.38	0.47	0.57	0.496227771	1.14
-	Difenoconazole	200	0.62	0.65			
Invertebrates, acute toxicity[1]							
species sp.	Azoxystrobin	125	0.38	0.01	0.02	0.321088558	0.07
-	Difenoconazole	200	0.62	0.15			

[1] For a possible inclusion of chronic toxicity please refer to the FAQ document distributed alongside the aquatic mixture toxicity calculation tool "AGD_AquaMix".

[2] MDR = 0.2 – 5 → Go to Step 3 (concentration addition (CA) approximately holds for the calculated mixture);

MDR > 5 → Go to Step 10 (the calculated mixture is more toxic than CA, i.e. synergistic);

MDR < 0.2 → Go to Step 9 (the calculated mixture is less toxic than CA, i.e. antagonistic)

Step 3 Comparison of mixture composition of PPP and PEC_{mix}

According to Step 3 it has to be checked whether the mixture composition in the formulation is similar to the mixture composition at PEC_{mix} (which is the sum of PEC_i of individual active substances). Therefore, the "$ECx_{mix,CA}$ (a.s. in PPP) / $ECx_{mix,CA}$ (a.s. in PEC_{mix})" ratios were calculated.

In case the ratio is in the range of 0.8–1.2 (mixture similar), the risk assessment can be based on the ECx_{ppp} (Step 4).

In case the ratio is outside the range of 0.8–1.2 (i.e. mixture not similar), the endpoint $ECx_{mix,CA}$ normalized to the mixture composition at PEC_{mix} (reported as "$ECx_{mix,CA}$ (a.s. in PEC_{mix})" in EFSA, 2013, and the following parts of this report) has to be used to calculate the risk (Step 5 or Step 8, respectively).

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if product or calculated endpoint data (according to Step 3) have to be used. Further in-depth justification and explanation are documented in the attached mixture risk calculation file.

~~**Step 5:** Driver detection~~

~~The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if a driver of risk is available according to Step 5. Further in-depth justification and explanation are documented in the attached mixture risk calculation file. Further information for the availability of a driver for the risk assessment of particular FOCUS Scenarios is given in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) and~~

~~Table 9.5.2.2-4 (FOCUS Step 4) below.~~

~~**Step 4 and Step 8a:** Mixture risk assessment based on measured and calculated mixture toxicity~~

~~Decisions taken when using the scheme as provided by EFSA (2013, section 10.3.11) lead to several assessment steps, which give a conclusion on the risk of a mixture or provide additional information important for the assessment. In the tables below the conclusions of different steps of the mixture risk assessment are summarized for the FOCUS Scenarios of concern. Information is reported on:~~

- ~~e) Step 2 and associated steps, in which the question is answered if concentration addition can be assumed (i.e. a standard mixture toxicity risk assessment is appropriate) or if an antagonism/synergism is possible (more detailed information on Step 2 is given above). This is important to derive if further, specific considerations have to be made in the risk assessment. Associated steps are Step 7, Step 9 and Step 10.~~
- ~~f) Step 5, in which the question is answered if there is a driver of risk and if so, which of the substance can be classified as driver (more detailed information on Step 5 is given the attached mixture risk calculation file). This is reported as additional information in case an assessment based on a driver would also be possible; for comparative reasons the table always lists the results from the mixture risk assessment according to Step 4 and/or Step 8. For an assessment based on a particular a.s. (the driver) please be referred to the individual a.s. risk assessment.~~
- ~~g) Step 4 with the assessment results for cases where product data are usable (according to Step 3) and the risk assessment can be carried out based on the measured toxicity.~~
- ~~h) Step 8 (a/b) with the assessment results for cases where product data are not usable (according to Step 3) and the risk assessment has to be based on calculated mixture toxicity.~~

~~The respective assessment conclusions are presented in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 3) or~~

~~Table 9.5.2.2-4 (FOCUS Step 4). The assessment is based either on the exposure-toxicity ratio (ETR_{mix}) or the risk quotient (RQ_{mix}); the ETR_{mix} and RQ_{mix} are compared to respective trigger values: 1/10 or 1/100 for the ETR_{mix} (depending on the species assessed) and 1 for RQ_{mix}. Values below the trigger indicating a high risk are marked in **bold**. For the sake of a concise assessment the results below are limited to the organism groups most at risk. Further in-depth justification and explanation for other organism groups are documented in the attached mixture risk calculation file.~~

Table 9.5.2.2-9: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for invertebrates, for FOCUS Step 1 – 3 for application of Clapron 325 SC in Winter oilseed rape

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix\ PPP}$ (Step 4)	$ETR_{mix\ CA}$ (Step 8a)
Step 1		no driver	0.11	Go to Step 4
Step 2				
N Europe		no driver	0.01	Go to Step 4
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch	not applicable	no driver	0.00	Go to Step 4
D4/ pond		Azoxystrobin	0.00	Go to Step 4
D4/ stream		no driver	0.00	Go to Step 4
D5/ pond		no driver	0.00	Go to Step 4
D5/ stream		no driver	0.00	Go to Step 4
D6/ ditch		Scenario D6 are not relevant for Central Zone		
R1/ pond		no driver	0.00	Go to Step 4
R1/ stream		no driver	0.00	Go to Step 4
R2/ stream		Scenario R2 are not relevant for Central Zone		
R3/ stream		no driver	0.00	Go to Step 4
R4/ stream		no driver	0.00	Go to Step 4

Table 9.5.2.2-10: Summary of the mixture toxicity risk assessment (related to Step 4) for fish based on FOCUS Step 4 calculations for application of Clapton 325 SC in Winter oilseed rape

FOCUS Step 4	Scenario	$ETR_{mix,CA}$								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch	-	-	-	-	-	-	0.00	-	-
50%	-	-	-	-	-	-	-	-	-	-
75%	-	-	-	-	-	-	-	-	-	
90%	-	-	-	-	-	-	-	-	-	-
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream	-	-	-	-	-	-	0.00	-	-
50%	-	-	-	-	-	-	-	-	-	-
75%	-	-	-	-	-	-	-	-	-	-
90%	-	-	-	-	-	-	-	-	-	-
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream	-	-	-	-	-	-	0.00	-	-
50%	-	-	-	-	-	-	-	-	-	
75%	-	-	-	-	-	-	-	-	-	
90%	-	-	-	-	-	-	-	-	-	-
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream	-	-	-	-	-	-	0.00	-	-
50%	-	-	-	-	-	-	-	-	-	-

75%	-	-	-	-	-	-	-	-	-	
90%	-	-	-	-	-	-	-	-	-	-
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream	-	-	-	-	-	-	0.00	-	-
50%	-	-	-	-	-	-	-	-	-	
75%	-	-	-	-	-	-	-	-	-	
90%	-	-	-	-	-	-	-	-	-	

Table 9.5.2.2-11: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for invertebrates, for FOCUS Step 1 – 3 for application of Clapron 325 SC in Winter oilseed rape

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	RQ_{mix} (Step 8b)
Step 1	not applicable	Azoxystrobin	20.10
Step 2			
N Europe		Azoxystrobin	1.93
Step 3			
D1/ ditch		Scenarios are not relevant for Central Zone	
D1/ stream			
D2/ ditch		Scenarios are not relevant for Central Zone	
D2/ stream			
D3/ ditch		Azoxystrobin	0.90
D4/ pond		Azoxystrobin	0.13
D4/ stream		Azoxystrobin	0.68
D5/ pond		Azoxystrobin	0.06
D5/ stream		Azoxystrobin	0.72
D6/ ditch		Scenario D6 are not relevant for Central Zone	
R1/ pond		Azoxystrobin	0.06
R1/ stream		Azoxystrobin	0.72

R2/ stream		Scenario R2 are not relevant for Central Zone	
R3/ stream		Azoxystrobin	1.20

Table 9.5.2.2-12: Summary of the mixture toxicity risk assessment (related to Step 4) for invertebrates based on FOCUS Step 4 calculations for application of Clapton 325 SC in Winter oilseed rape

FOCUS Step 4	Scenario	RQmix								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch	The risk was considered acceptable at Step 3								
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream	The risk was considered acceptable at Step 3								
None	D5 Pond	The risk was considered acceptable at Step 3								
None	D5 stream	The risk was considered acceptable at Step 3								
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream	The risk was considered acceptable at Step 3								
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream	-	-	-	-	-	-	0.50	-	-
50%	-	-	-	-	-	-	-	-	-	-
75%	-	-	-	-	-	-	-	-	-	
90%	-	-	-	-	-	-	-	-	-	

Review Comments:

The following mixture toxicity assessment for aquatic organisms carried out by the Applicant has been accepted. Only the summary tables have been changed by zRMS. This is due to the different way of presenting the results of the risk analysis in the applied calculator compared to the PEC/RAC calculations carried out for active substances and their metabolites. These tables only include relevant for central zone FOCUS scenarios are included (D3, D4, D5, R1, R3 and R4).

9.5.2.2.3 Risk assessment of mixture toxicity based on Pome Fruit (BBCH 31)

Table 9.5.2.2.3-13: Summary of assessment steps considered for the mixture risk assessment

Steps	Conclusion on the Steps		
	Fish	Invertebrates	Algae
Screening 1: ETR trigger (optional Step)	-	-	-
Screening 2: Driver (optional Step)	-	-	-
Step 1: data available?	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.
Step 2: apparent synergism or antagonism?	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.
Step 3: mixture similar or not?	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.
Step 4: ETRmix assessment (ECxPPP)	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).
Step 5: driver available?	There is no driver for fish in all scenarios. Go to Step 8.	There is no driver for invertebrates in all scenarios. Go to Step 8.	There is no driver for algae in all scenarios. Go to Step 8.
Step 6: driver assessment	-	-	-

Step 7: synergism assessment (few data)	-	-	-
Step 8a: ETRmix assessment	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**
Step 8b: RQmix assessment	~~**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**~~ -	~~**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**~~ -	~~**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**~~ -
Step 9: antagonism assessment	-	-	-
Step 10: synergism assessment	-	-	-

Overview of the assessment steps: Table 9.5.2.2-1 gives a summary of the decisions made for each organism group during the mixture risk assessment with respect to the decision scheme as provided by EFSA (2013, section 10.3.11). A discussion of all details of every decision is not intended in this section of this registration report. Further in-depth justification and explanation for the decisions made are documented in the attached mixture risk calculation file. However, at least data for some important steps are documented in this section of this registration report, beginning with the check for (and potentially assessment of) synergistic or antagonistic effects (Step 2 and Steps 7, 9 and 10) as well as the ETR_{mix} or RQ_{mix} calculation results for the assessed FOCUS Scenarios (Steps 4 and 8a/b).

Step 2: MDR calculation to check for synergistic or antagonistic effects

Table 9.5.2.2.3-14: Calculated mixture toxicity and MDR for each group of organisms (see sections 10.3.3 and 10.3.4 of EFSA (2013) for more details)

Species	Substance	Concentration (Ci) in formulation (g a.s./L)	Pi	ECxi (mg a.s./L)	ECxmix-CA (mg sum a.s. /L)	ECxPPP (mg sum a.s. /L)	MDR
Fish, acute toxicity 1							
Oncorhynchus mykiss	Azoxystrobin	200	0.62	0.47	0.603	0.496227771	1.21
Oncorhynchus mykiss	Difenoconazole	125	0.38	1.1			
Invertebrates, acute toxicity 1							
Daphnia	Azoxystrobin	200	0.62	0.23	0.315	0.321088558	0.98
Daphnia	Difenoconazole	125	0.38	0.77			
Algae							
Selenastrum capricornutum (green algae)	Azoxystrobin	200	0.62	0.36	0.072	0.17134453	0.43
Scenedesmus subspicatus (green alage)	Difenoconazole	125	0.38	0.032			

[1] For a possible inclusion of chronic toxicity please refer to the FAQ document distributed alongside the aquatic mixture toxicity calculation tool "AGD_AquaMix".

[2] MDR = 0.2 – 5 → Go to Step 3 (concentration addition (CA) approximately holds for the calculated mixture);

MDR > 5 → Go to Step 10 (the calculated mixture is more toxic than CA, i.e. synergistic);

MDR < 0.2 → Go to Step 9 (the calculated mixture is less toxic than CA, i.e. antagonistic)

The density of the liquid formulation of SCORPIO 3250 SC, equal to 1.1134 g/ml, was used in the performed calculations.

Step 3 Comparison of mixture composition of PPP and PEC_{mix}

According to Step 3 it has to be checked whether the mixture composition in the formulation is similar to the mixture composition at PEC_{mix} (which is the sum of PEC_i of individual active substances). Therefore,

the "ECx_{mix-CA} (a.s. in PPP) / ECx_{mix-CA} (a.s. in PEC_{mix})" ratios were calculated.

In case the ratio is in the range of 0.8–1.2 (mixture similar), the risk assessment can be based on the ECx_{PPP} (Step 4).

In case the ratio is outside the range of 0.8–1.2 (i.e. mixture not similar), the endpoint ECx_{mix-CA} normalized to the mixture composition at PEC_{mix} (reported as "ECx_{mix-CA} (a.s. in PEC_{mix})" in EFSA, 2013, and the following parts of this report) has to be used to calculate the risk (Step 5 or Step 8, respectively).

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if product or calculated endpoint data (according to Step 3) have to be used. Further in-depth justification and explanation are documented in the attached mixture risk calculation file.

Step 5: Driver detection

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if a driver of risk is available according to Step 5. Further in-depth justification and explanation are documented in the attached mixture risk calculation file. Further information for the availability of a driver for the risk assessment of particular FOCUS Scenarios is given in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) and

Table 9.5.2.2-4 (FOCUS Step 4) below.

Step 4 and Step 8a: Mixture risk assessment based on measured and calculated mixture toxicity

Decisions taken when using the scheme as provided by EFSA (2013, section 10.3.11) lead to several assessment steps, which give a conclusion on the risk of a mixture or provide additional information important for the assessment. In the tables below the conclusions of different steps of the mixture risk assessment are summarized for the FOCUS Scenarios of concern. Information is reported on:

i) Step 2 and associated steps, in which the question is answered if concentration addition can be assumed (i.e. a standard mixture toxicity risk assessment is appropriate) or if an antagonism/synergism is possible (more detailed information on Step 2 is given above). This is important to derive if further, specific considerations have to be made in the risk assessment. Associated steps are Step 7, Step 9 and Step 10.
j) Step 5, in which the question is answered if there is a driver of risk and if so, which of the substance can be classified as driver (more detailed information on Step 5 is given the attached mixture risk calculation file). This is reported as additional information in case an assessment based on a driver would also be possible; for comparative reasons the table always lists the results from the mixture risk assessment according to Step 4 and/or Step 8. For an assessment based on a particular a.s. (the driver) please be referred to the individual a.s. risk assessment.
k) Step 4 with the assessment results for cases where product data are usable (according to Step 3) and the risk assessment can be carried out based on the measured toxicity.
l) Step 8 (a/b) with the assessment results for cases where product data are not usable (according to Step 3) and the risk assessment has to be based on calculated mixture toxicity.

The intermediate results of the mixture toxicity risk assessment are presented below for the respective FOCUS steps.

Table 9.5.2.2.3-15: Results of the mixture toxicity risk assessment (related to Step 8a) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in Pome Fruit (BBCH 31).

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	Go to Step 4	Go to Step 4	~~1.64~~ 1.641
Step 2			
N-Europe	Go to Step 4	Go to Step 4	~~0.52~~ 0.517
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
D4/ pond	Go to Step 4	Go to Step 4	Go to Step 4
D4/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D5/ pond	Go to Step 4	Go to Step 4	Go to Step 4
D5/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	Go to Step 4	Go to Step 4	Go to Step 4
R1/ stream	Go to Step 4	Go to Step 4	Go to Step 4
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	Go to Step 4	Go to Step 4	Go to Step 4
R4/ stream	Go to Step 4	Go to Step 4	Go to Step 4
Step 4	20 m vegetative strip, 20 m no spray buffer and 75% nozzle reduction		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
D4/ pond	~~0.00~~ 0.001	~~0.00~~ 0.002	~~0.00~~ 0.002
D4/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D5/ pond	Go to Step 4	~~0.00~~ 0.001	~~0.00~~ 0.002
D5/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	Go to Step 4	Go to Step 4	Go to Step 4
R1/ stream	Go to Step 4	Go to Step 4	~~0.01~~ 0.008
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	Go to Step 4	Go to Step 4	Go to Step 4
R4/ stream	Go to Step 4	Go to Step 4	~~0.01~~ 0.009

Table 9.5.2.2.3-4: Results of the mixture toxicity risk assessment (related to Step 4) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in pome fruit (BBCH 31).

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	~~0.34~~ 0.338	~~0.52~~ 0.523	Go to Step 5/8
Step 2			
N-Europe	~~0.01~~ 0.097	~~0.15~~ 0.149	Go to Step 5/8
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	~~0.04~~ 0.044	~~0.07~~ 0.068	~~0.13~~ 0.127
D4/ pond	~~0.00~~ 0.005	~~0.01~~ 0.007	~~0.01~~ 0.013
D4/ stream	~~0.05~~ 0.045	~~0.07~~ 0.070	~~0.13~~ 0.131
D5/ pond	~~0.00~~ 0.005	~~0.01~~ 0.007	~~0.01~~ 0.014
D5/ stream	~~0.05~~ 0.047	~~0.07~~ 0.073	~~0.14~~ 0.136
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	~~0.00~~ 0.004	~~0.00~~ 0.006	~~0.00~~ 0.012
R1/ stream	~~0.04~~ 0.035	~~0.05~~ 0.054	~~0.04~~ 0.102
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	~~0.05~~ 0.0050	~~0.05~~ 0.077	~~0.05~~ 0.144
R4/ stream	~~0.04~~ 0.035	~~0.04~~ 0.054	~~0.04~~ 0.102
Step 4	20 m vegetative strip, 20 m no spray buffer and 75% nozzle reduction		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	~~0.00~~ 0.001	~~0.00~~ 0.002	~~0.00~~ 0.004
D4/ pond	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
D4/ stream	~~0.00~~ 0.002	~~0.00~~ 0.002	~~0.00~~ 0.005
D5/ pond	~~0.00~~ 0.001	Go to Step 5/8	Go to Step 5/8
D5/ stream	~~0.00~~ 0.002	~~0.00~~ 0.002	~~0.00~~ 0.004
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	~~0.00~~ 0.000	~~0.00~~ 0.000	~~0.00~~ 0.001

R1/ stream	~~0.00~~ 0.002	~~0.00~~ 0.002	Go to Step 5/8
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	~~0.00~~ 0.002	~~0.00~~ 0.002	~~0.00~~ 0.005
R4/ stream	~~0.00~~ 0.002	~~0.00~~ 0.003	Go to Step 5/8

The respective assessment conclusions are presented in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) or

Table 9.5.2.2-4 (FOCUS Step 4). The assessment is based either on the exposure-toxicity ratio (ETR_{mix}) or the risk quotient (RQ_{mix}); the ETR_{mix} and RQ_{mix} are compared to respective trigger values: 1/10 or 1/100 for the ETR_{mix} (depending on the species assessed) and 1 for RQ_{mix}. Values below the trigger indicating a high risk are marked in **bold**. For the sake of a concise assessment the results below are limited to the organism groups most at risk. Further in-depth justification and explanation for other organism groups are documented in the attached mixture risk calculation file.

Table 9.5.2.2.3-5: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for fish, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Pome fruit (BBCH 31).

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	no driver	~~**0.34**~~ **0.338**	Go to Step 4
Step 2				
N-Europe		no driver	~~**0.10**~~ **0.097**	Go to Step 4
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	~~**0.04**~~ **0.044**	Go to Step 4
D4/ pond		no driver	~~0.00~~ 0.005	Go to Step 4
D4/ stream		no driver	~~**0.05**~~ **0.045**	Go to Step 4
D5/ pond		no driver	~~0.00~~ 0.005	Go to Step 4
D5/ stream		no driver	~~**0.05**~~ **0.047**	Go to Step 4
D6/ ditch		Scenario is not relevant for Central Zone		
R1/ pond		no driver	~~0.00~~ 0.004	Go to Step 4

R1/ stream		no driver	~~**0.04**~~ **0.035**	Go to Step 4
R2/ stream		Scenario is not relevant for Central Zone		
R3/ stream		no driver	~~**0.05**~~ **0.050**	Go to Step 4
R4/ stream		no driver	~~**0.04**~~ **0.035**	Go to Step 4

Table 9.5.2.2.3-6: Summary of the mixture toxicity risk assessment (related to Step 4) for fish based on FOCUS Step 4 calculations for application of Clapton 325 SC in Pome fruit (BBCH 31).

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch									
50%										
75%										0.001
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream									
50%										
75%										0.001
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream									
50%										
75%										0.002
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream									
50%										
75%										0.001
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream									
50%										
75%										0.002
90%										
None	R4 stream									
50%										

75%										0.000
90%										

Table 9.5.2.2.3-7: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for invertebrates, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Pome fruit (BBCH 31).

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	~~0.52~~ 0.523	Go to Step 4
Step 2				
N-Europe		no driver	~~0.15~~ 0.149	Go to Step 4
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	~~0.07~~ 0.068	Go to Step 4
D4/ pond		no driver	~~0.01~~ 0.007	Go to Step 4
D4/ stream		no driver	~~0.07~~ 0.070	Go to Step 4
D5/ pond		no driver	~~0.01~~ 0.007	Go to Step 4
D5/ stream		no driver	~~0.07~~ 0.073	Go to Step 4
D6/ ditch		Scenario D6 are not relevant for Central Zone		
R1/ pond		no driver	~~0.01~~ 0.006	Go to Step 4
R1/ stream		no driver	~~0.05~~	Go to Step 4

			0.054	
R2/ stream		Scenario R2 are not relevant for Central Zone		
R3/ stream		no driver	~~0.08~~ 0.077	Go to Step 4
R4/ stream		no driver	~~0.05~~ 0.054	Go to Step 4

Table 9.5.2.2.3-8: Summary of the mixture toxicity risk assessment (related to Step 4) for invertebrates based on FOCUS Step 4 calculations for application of Clapton 325 SC in Pome fruit (BBCH 31).

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch									
50%										
75%										0.002
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream									
50%										
75%										0.002
90%										
None	D5 Pond									
50%										
75%										0.002
90%										
None	D5 stream									
50%										
75%										0.001
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream									
50%										
75%										0.002
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								

None	R3 stream									
50%										
75%										0.002
90%										
None	R4 stream									
50%										
75%										0.003
90%										

Table 9.5.2.2.3-9: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for algae, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Pome fruit (BBCH 31).

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	no driver	Go to Step 5/8	1.64 1.641
Step 2				
N-Europe		no driver	Go to Step 5/8	0.52 0.517
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	~~0.13~~ 0.127	Go to Step 4
D4/ pond		no driver	~~0.01~~ 0.013	Go to Step 4
D4/ stream		no driver	~~0.13~~ 0.131	Go to Step 4
D5/ pond		no driver	~~0.01~~ 0.014	Go to Step 4

D5/ stream		no driver	~~0.14~~ 0.136	Go to Step 4
D6/ ditch		Scenario D6 are not relevant for Central Zone		
R1/ pond		no driver	~~0.01~~ 0.012	Go to Step 4
R1/ stream		no driver	~~0.10~~ 0.102	Go to Step 4
R2/ stream		Scenario R2 are not relevant for Central Zone		
R3/ stream		no driver	~~0.14~~ 0.144	Go to Step 4
R4/ stream		no driver	~~0.10~~ 0.102	Go to Step 4

Table 9.5.2.2.3-10: Summary of the mixture toxicity risk assessment (related to Step 4) for algae based on FOCUS Step 4 calculations for application of Clapton 325 SC in Pome fruit (BBCH 31).

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch									
50%										
75%										0.004
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream									
50%										
75%										0.005
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream									

50%										
75%										0.004
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream									
50%										
75%										0.008
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream									
50%										
75%										0.005
90%										
None	R4 stream									
50%										
75%										0.009
90%										

Review Comments:

The risk assessment for pome fruit BBCH 31 carried out by the Applicant has been completely removed (crossed out), as the PEC/RAC calculations presented in the table below were based on incorrect $PEC_{SW/SED}$ values. In the following risk assessment, performed by zRMS, only relevant for central zone FOCUS scenarios are included (D3, D4, D5, R1, R3 and R4).

Table 9.5.2.2.3-161: Summary of mixture toxicity assessment for SCORPIO 325 SC for aquatic organisms for the use according to the GAP table for Pome Fruit (BBCH 31)

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50}	E_rC_{50}	E_bC_{50}
AF		100	100	10
RAC_{mix} (µg/L)		496.227	321.088	171.345
FOCUS scenerio	PEC_{max} (µg/L)			
Step 1	55.25	0.1113	0.1721	0.3224
Step 2				
N-Europe	9.26	0.0187	0.0288	0.0540
Step 3				
D3 / Ditch	2.05	0.0041	0.0064	0.0120
D6 / Ditch	2.03	0.0041	0.0063	0.0118
R1 / Pond	0.52	0.0010	0.0016	0.0030
R1 / Stream	2.40	0.0048	0.0075	0.0140
R2 / Stream	1.79	0.0036	0.0056	0.0105
R3 / Stream	2.81	0.0057	0.0087	0.0164

R4 / Stream	3.70	0.0074	0.0115	0.0216
Step 4				
D3 / Ditch	0.29	0.0006	0.0009	0.0017
R1 / Stream	0.96	0.0019	0.0030	0.0056
R2 / Stream	-	0.0000	0.0000	0.0000
R3 / Stream	1.09	0.0022	0.0034	0.0064
R4 / Stream	1.61	0.0032	0.0050	0.0094

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50} 496.227	E_rC_{50} 321.088	E_bC_{50} 171.345
AF		100	100	10
RAC_{mix} (µg/L)		4.962	3.211	17.135
FOCUS scenerio	**PEC_{max} (µg/L)**			
Step 1	167.8	>1	>1	>1
Step 2				
N-Europe	47.94	>1	>1	>1
Step 3				
D3 / Ditch	21.72	>1	>1	>1
D4 / Pond	2.30	<1	<1	<1
D4 / Stream	22.5	>1	>1	>1
D5 / Pond	2.40	<1	<1	<1
D5 / Stream	23.36	>1	>1	>1
R1 / Pond	2.052	<1	<1	<1
R1 / Stream	19.74	>1	>1	>1
R3 / Stream	24.60	>1	>1	>1
R4 / Stream	17.49	>1	>1	>1
Step 4	**20 vegetative strip + 20 no spray buffer + 75% nozzle reduction**			
D3 / Ditch	0.64	<1	<1	<1
D4 / Stream	0.60	<1	<1	<1
D5 / Stream	0.76	<1	<1	<1
R1 / Stream	0.76	<1	<1	<1
R3 / Stream	0.80	<1	<1	<1
R4 / Stream	0.96	<1	<1	<1

9.5.2.2.4 Risk assessment of mixture toxicity based on Winter Oilseed Rape (BBCH 31)

Table 9.5.2.2.4-17: Summary of assessment steps considered for the mixture risk assessment

Steps	Conclusion on the Steps		
	Fish	Invertebrates	Algae
Screening 1: ETR trigger (optional Step)	-	-	-
Screening 2: Driver (optional Step)	-	-	-
Step 1: data available?	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.
Step 2: apparent synergism or antagonism?	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.
Step 3: mixture similar or not?	Mixture similar every scenario. All scenarios can be assessed via product test, go to Step 4.	Mixture similar every scenario. All scenarios can be assessed via product test, go to Step 4.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.
Step 4: ETRmix assessment (ECxPPP)	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).

Step 5: driver available?	**There is a driver for fish in some scenarios. Go either to Step 6 or 8.**	**There is a driver for invertebrates in some scenarios. Go either to Step 6 or 8.**	**There is no driver for algae in all scenarios. Go to Step 8.**
Step 6: driver assessment	-	-	-
Step 7: synergism assessment (few data)	-	-	-
Step 8a: ETRmix assessment	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**
Step 8b: RQmix assessment	~~Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).~~ -	~~Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).~~ -	~~Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).~~ -
Step 9: antagonism assessment	-	-	-
Step 10: synergism assessment	-	-	-

Overview of the assessment steps: Table 9.5.2.2-1 gives a summary of the decisions made for each organism group during the mixture risk assessment with respect to the decision scheme as provided by EFSA (2013, section 10.3.11). A discussion of all details of every decision is not intended in this section of this registration report. Further in-depth justification and explanation for the decisions made are documented in the attached mixture risk calculation file. However, at least data for some important steps are documented in this section of this registration report, beginning with the check for (and potentially assessment of) synergistic or antagonistic effects (Step 2 and Steps 7, 9 and 10) as well as the ETR_{mix} or RQ_{mix} calculation results for the assessed FOCUS Scenarios (Steps 4 and 8a/b).

Step 2: MDR calculation to check for synergistic or antagonistic effects

Table 9.5.2.2.4-18: Calculated mixture toxicity and MDR for each group of organisms (see sections 10.3.3 and 10.3.4 of EFSA (2013) for more details)

Species	Substance	Concentration (Ci) in formulation (g a.s./L)	Pi	ECxi (mg a.s./L)	ECxmix-CA (mg sum a.s. /L)	ECxPPP (mg sum a.s. /L)	MDR
Fish, acute toxicity 1							
Oncorhynchus mykiss	Azoxystrobin	200	0.62	0.47	0.603	0.496227771	1.21
Oncorhynchus mykiss	Difenoconazole	125	0.38	1.1			
Invertebrates, acute toxicity 1							
Daphnia	Azoxystrobin	200	0.62	0.23	0.315	0.321088558	0.98
Daphnia	Difenoconazole	125	0.38	0.77			
Algae							
Selenastrum capricornutum (green algae)	Azoxystrobin	200	0.62	0.36	0.073	0.17134453	0.43
Scenedesmus subspicatus (green alage)	Difenoconazole	125	0.38	0.032			

[1] For a possible inclusion of chronic toxicity please refer to the FAQ document distributed alongside the aquatic mixture toxicity calculation tool "AGD_AquaMix".

[2] MDR = 0.2 – 5 → Go to Step 3 (concentration addition (CA) approximately holds for the calculated mixture);

MDR > 5 → Go to Step 10 (the calculated mixture is more toxic than CA, i.e. synergistic);

MDR < 0.2 → Go to Step 9 (the calculated mixture is less toxic than CA, i.e. antagonistic)

The density of the liquid formulation of SCORPIO 3250 SC, equal to 1.1134 g/ml, was used in the performed calculations.

Step 3 Comparison of mixture composition of PPP and PEC_{mix}

According to Step 3 it has to be checked whether the mixture composition in the formulation is similar to the mixture composition at PEC_{mix} (which is the sum of PEC_i of individual active substances). Therefore,

the "$ECx_{mix\text{-}CA}$ (a.s. in PPP) / $ECx_{mix\text{-}CA}$ (a.s. in PEC_{mix})" ratios were calculated.

In case the ratio is in the range of 0.8–1.2 (mixture similar), the risk assessment can be based on the ECx_{PPP} (Step 4).

In case the ratio is outside the range of 0.8–1.2 (i.e. mixture not similar), the endpoint $ECx_{mix\text{-}CA}$ normalized to the mixture composition at PEC_{mix} (reported as "$ECx_{mix\text{-}CA}$ (a.s. in PEC_{mix})" in EFSA, 2013, and the following parts of this report) has to be used to calculate the risk (Step 5 or Step 8, respectively).

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if product or calculated endpoint data (according to Step 3) have to be used. Further in-depth justification and explanation are documented in the attached mixture risk calculation file.

Step 5: Driver detection

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if a driver of risk is available according to Step 5. Further in-depth justification and explanation are documented in the attached mixture risk calculation file. Further information for the availability of a driver for the risk assessment of particular FOCUS Scenarios is given in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) and

Table 9.5.2.2-4 (FOCUS Step 4) below.

Step 4 and Step 8a: Mixture risk assessment based on measured and calculated mixture toxicity

Decisions taken when using the scheme as provided by EFSA (2013, section 10.3.11) lead to several assessment steps, which give a conclusion on the risk of a mixture or provide additional information important for the assessment. In the tables below the conclusions of different steps of the mixture risk assessment are summarized for the FOCUS Scenarios of concern. Information is reported on:

m) Step 2 and associated steps, in which the question is answered if concentration addition can be assumed (i.e. a standard mixture toxicity risk assessment is appropriate) or if an antagonism/synergism is possible (more detailed information on Step 2 is given above). This is important to derive if further, specific considerations have to be made in the risk assessment. Associated steps are Step 7, Step 9 and Step 10.
n) Step 5, in which the question is answered if there is a driver of risk and if so, which of the substance can be classified as driver (more detailed information on Step 5 is given the attached mixture risk calculation file). This is reported as additional information in case an assessment based on a driver would also be possible; for comparative reasons the table always lists the results from the mixture risk assessment according to Step 4 and/or Step 8. For an assessment based on a particular a.s. (the driver) please be referred to the individual a.s. risk assessment.
o) Step 4 with the assessment results for cases where product data are usable (according to Step 3) and the risk assessment can be carried out based on the measured toxicity.
p) Step 8 (a/b) with the assessment results for cases where product data are not usable (according to Step 3) and the risk assessment has to be based on calculated mixture toxicity.

The intermediate results of the mixture toxicity risk assessment are presented below for the respective FOCUS steps.

Table 9.5.2.2.4-19: Results of the mixture toxicity risk assessment (related to Step 8a) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in Winter Oilseed rape.

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	~~10.58~~ 10.584	~~21.09~~ 21.092	~~4.27~~ 4.271
Step 2			
N-Europe	~~0.93~~ 0.932	~~1.84~~ 1.841	~~0.47~~ 0.467
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	~~0.34~~ 0.340	~~0.65~~ 0.652	~~0.28~~ 0.280
D4/ pond	~~0.08~~ 0.081	~~0.16~~ 0.163	~~0.02~~ 0.019
D4/ stream	~~0.25~~ 0.255	~~0.49~~ 0.487	~~0.21~~ 0.210
D5/ pond	~~0.03~~ 0.030	~~0.06~~ 0.060	~~0.01~~ 0.012
D5/ stream	~~0.27~~ 0.273	~~0.52~~ 0.524	~~0.22~~ 0.224
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	~~0.03~~ 0.030	~~0.06~~ 0.060	~~0.01~~ 0.013
R1/ stream	~~0.31~~ 0.310	~~0.61~~ 0.605	~~0.20~~ 0.196
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	~~0.57~~ 0.570	~~1.12~~ 1.125	~~0.29~~ 0.293
Step 4	10 m vegetative strip, 5 m no spray buffer and no nozzle reduction		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	~~0.09~~ 0.092	~~0.18~~ 0.177	~~0.08~~ 0.076
D4/ pond	The risk was considered acceptable at Step 3		
D4/ stream	~~0.11~~ 0.108	~~0.21~~ 0.209	~~0.08~~ 0.079
D5/ pond	The risk was considered acceptable at Step 3		
D5/ stream	~~0.10~~ 0.101	~~0.19~~ 0.193	~~0.08~~ 0.082
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	The risk was considered acceptable at Step 3		
R1/ stream	~~0.14~~ 0.137	~~0.27~~ 0.269	~~0.07~~ 0.075
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	~~0.25~~ 0.251	~~0.50~~ 0.498	~~0.11~~ 0.113

Table 9.5.2.2.4-4: Results of the mixture toxicity risk assessment (related to Step 4) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in Winter Oilseed rape.

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	0.11 0.111	Go to Step 5/8	Go to Step 5/8
Step 2			
N-Europe	0.01 0.010	0.02 0.016	Go to Step 5/8
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	~~0.00~~ 0.004	~~0.01~~ 0.006	Go to Step 5/8
D4/ pond	Go to Step 5/8	Go to Step 5/8	~~0.01~~ 0.012
D4/ stream	~~0.00~~ 0.003	~~0.00~~ 0.005	Go to Step 5/8
D5/ pond	~~0.00~~ 0.000	Go to Step 5/8	~~0.01~~ 0.009
D5/ stream	~~0.00~~ 0.003	~~0.01~~ 0.005	Go to Step 5/8
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	~~0.00~~ 0.000	~~0.00~~ 0.001	Go to Step 5/8
R1/ stream	~~0.00~~ 0.004	~~0.01~~ 0.005	~~0.01~~ 0.010
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	~~0.01~~ 0.006	~~0.01~~ 0.010	Go to Step 5/8
Step 4	**10 m vegetative strip, 5 m no spray buffer and no nozzle reduction**		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	~~0.00~~ 0.001	~~0.00~~ 0.002	~~0.00~~ 0.003
D4/ pond	The risk was considered acceptable at Step 3		
D4/ stream	~~0.00~~ 0.001	~~0.00~~ 0.002	~~0.00~~ 0.004
D5/ pond	The risk was considered acceptable at Step 3		
D5/ stream	~~0.00~~ 0.001	~~0.00~~ 0.002	~~0.00~~ 0.004
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	The risk was considered acceptable at Step 3		
R1/ stream	~~0.00~~ 0.002	~~0.00~~ 0.002	Go to Step 5/8
R2/ stream	Scenario is not relevant for Central Zone		

R3/ stream	~~0.00~~ 0.003	~~0.00~~ 0.004	Go to Step 5/8

The respective assessment conclusions are presented in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) or

Table 9.5.2.2-4 (FOCUS Step 4). The assessment is based either on the exposure-toxicity ratio (ETR_{mix}) or the risk quotient (RQ_{mix}); the ETR_{mix} and RQ_{mix} are compared to respective trigger values: 1/10 or 1/100 for the ETR_{mix} (depending on the species assessed) and 1 for RQ_{mix}. Values below the trigger indicating a high risk are marked in **bold**. For the sake of a concise assessment the results below are limited to the organism groups most at risk. Further in-depth justification and explanation for other organism groups are documented in the attached mixture risk calculation file.

Table 9.5.2.2.4-5: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for fish, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Winter oilseed rape

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	~~0.11~~ 0.111	Go to Step 4
Step 2				
N-Europe		no driver	~~0.01~~ 0.010	Go to Step 4
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	~~0.00~~ 0.004	Go to Step 4
D4/ pond		Azoxystrobin	Go to Step 5/8	~~0.00~~ 0.001
D4/ stream		no driver	~~0.00~~ 0.003	Go to Step 4
D5/ pond		Azoxystrobin	~~0.00~~ 0.000	Go to Step 4
D5/ stream		no driver	~~0.00~~ 0.003	Go to Step 4
D6/ ditch		Scenario D6 are not relevant for Central Zone		
R1/ pond		Azoxystrobin	~~0.00~~ 0.000	Go to Step 4
R1/ stream		no driver	~~0.00~~ 0.004	Go to Step 4
R2/ stream		Scenario R2 are not relevant for Central Zone		
R3/ stream		no driver	~~0.01~~ 0.006	Go to Step 4

Table 9.5.2.2.4-6: Summary of the mixture toxicity risk assessment (related to Step 4) for fish based on FOCUS Step 4 calculations for application of Clapton 325 SC in Winter oilseed rape

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch						~~0.00~~ 0.001			
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream						~~0.00~~ 0.001			
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream						~~0.00~~ 0.001			
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream						~~0.00~~ 0.002			
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream						~~0.00~~ 0.003			
50%										
75%										
90%										

Table 9.5.2.2.4-7: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for invertebrates, for FOCUS Step 1 – 3 for application of Clapton 325 SC Winter oilseed rape

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	Go to Step 5/8	~~0.21~~ 0.211
Step 2				
N-Europe		Azoxystrobin	~~0.02~~ 0.016	Go to Step 4
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	~~0.01~~ 0.006	Go to Step 4
D4/ pond		Azoxystrobin	Go to Step 5/8	~~0.00~~ 0.002
D4/ stream		no driver	~~0.00~~ 0.005	Go to Step 4
D5/ pond		Azoxystrobin	Go to Step 5/8	~~0.00~~ 0.001
D5/ stream		no driver	~~0.01~~ 0.005	Go to Step 4
D6/ ditch		Scenario D6 are not relevant for Central Zone		
R1/ pond		Azoxystrobin	0.001	Go to Step 4
R1/ stream		no driver	0.005	Go to Step 4
R2/ stream		Scenario R2 are not relevant for Central Zone		
R3/ stream		Azoxystrobin	~~0.01~~ 0.010	Go to Step 4

Table 9.5.2.2.4-8: Summary of the mixture toxicity risk assessment (related to Step 4) for invertebrates based on FOCUS Step 4 calculations for application of Clapton 325 SC in Winter oilseed rape

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch						~~0.00~~ 0.002			
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream						~~0.00~~ 0.002			
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream						~~0.00~~ 0.002			
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream						~~0.00~~ 0.002			
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream						~~0.00~~ 0.004			
50%										
75%										
90%										

Table 9.5.2.2.4-9: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for algae, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Winter oilseed rape

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	no driver	Go to Step 5/8	~~0.43~~ 0.427
Step 2				
N-Europe		no driver	Go to Step 5/8	~~0.05~~ 0.047
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	~~0.01~~ 0.012	Go to Step 4
D4/ pond		no driver	Go to Step 5/8	~~0.00~~ 0.002
D4/ stream		no driver	~~0.01~~ 0.009	Go to Step 4
D5/ pond		no driver	Go to Step 5/8	~~0.00~~ 0.001
D5/ stream		no driver	~~0.01~~ 0.010	Go to Step 4
D6/ ditch		Scenario D6 are not relevant for Central Zone		
R1/ pond		no driver	Go to Step 5/8	~~0.00~~ 0.001
R1/ stream		no driver	~~0.01~~ 0.010	Go to Step 4
R2/ stream		Scenario R2 are not relevant for Central Zone		
R3/ stream		no driver	Go to Step 5/8	~~0.03~~ 0.029

Table 9.5.2.2.4-10: Summary of the mixture toxicity risk assessment (related to Step 4) for algae based on FOCUS Step 4 calculations for application of Clapton 325 SC in Winter oilseed rape

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch						~~0.00~~ 0.004			
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream						~~0.00~~ 0.004			
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream						~~0.00~~ 0.004			
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream						~~0.01~~ 0.007			
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream						~~0.01~~ 0.011			
50%										
75%										
90%										

Table 9.5.2.2.3-201: Summary of mixture toxicity assessment for SCORPIO 325 SC for aquatic organisms for the use according to the GAP table for Winter Oilseed rape (BBCH 31)

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50}	E_rC_{50}	E_bC_{50}
AF		100	100	10
RAC_{mix} (µg/L)		496.227	321.088	171.345
FOCUS scenerio	PEC_{max} (µg/L)			
Step 1	55.25	0.1113	0.1721	0.3224
Step 2				
N-Europe	5.04	0.0102	0.0157	0.0294
Step 3				
D3 / Ditch	2.05	0.0041	0.0064	0.0120
D4 / Pond	0.39	0.0008	0.0012	0.0023
D4 / Stream	1.53	0.0031	0.0048	0.0089
D5 / Pond	0.16	0.0003	0.0005	0.0009
D5 / Stream	1.64	0.0033	0.0051	0.0096
R1 / Pond	0.16	0.0003	0.0005	0.0009
R1 / Stream	1.76	0.0035	0.0055	0.0102
R3 / Stream	3.10	0.0062	0.0096	0.0181
Step 4				
D3 / Ditch	0.56	0.0011	0.0017	0.0032
D4 / Stream	0.61	0.0012	0.0019	0.0035
R1 / Stream	0.75	0.0015	0.0023	0.0044
R3 / Stream	1.33	0.0027	0.0041	0.0078

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50} 496.227	E_rC_{50} 321.088	E_bC_{50} 171.345
AF		100	100	10
RAC_{mix} (µg/L)		4.962	3.211	17.135
FOCUS scenerio	**PEC_{max} (µg/L)**			
Step 1	55.25	>1	>1	>1
Step 2				
N-Europe	5.04	>1	>1	<1
Step 3				
D3 / Ditch	2.05	<1	<1	-
D4 / Pond	0.39	<1	<1	-
D4 / Stream	1.53	<1	<1	-
D5 / Pond	0.16	<1	<1	-
D5 / Stream	1.64	<1	<1	-
R1 / Pond	0.16	<1	<1	-
R1 / Stream	1.76	<1	<1	-
R3 / Stream	3.10	<1	<1	-

9.5.2.2.5 Risk assessment of mixture toxicity based on Winter Oilseed Rape (BBCH 14 – 20)

Table 9.5.2.2.4-21: Summary of assessment steps considered for the mixture risk assessment

Steps	Conclusion on the Steps		
	Fish	Invertebrates	Algae
Screening 1: ETR trigger (optional Step)	-	-	-
Screening 2: Driver (optional Step)	-	-	-
Step 1: data available?	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.
Step 2: apparent synergism or antagonism?	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.
Step 3: mixture similar or not?	Mixture similar every scenario. All scenarios can be assessed via product test, go to Step 4.	Mixture similar every scenario. All scenarios can be assessed via product test, go to Step 4.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.
Step 4: ETRmix assessment (ECxPPP)	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).
Step 5: driver available?	There is a driver for fish in some scenarios. Go either to Step 6 or 8.	There is a driver for invertebrates in some scenarios. Go either to Step 6 or 8.	There is no driver for algae in all scenarios. Go to Step 8.

Step 6: driver assessment	-	-	-
Step 7: synergism assessment (few data)	-	-	-
Step 8a: ETRmix assessment	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**
Step 8b: RQmix assessment	-	-	-
Step 9: antagonism assessment	-	-	-
Step 10: synergism assessment	-	-	-

Overview of the assessment steps: Table 9.5.2.2-1 gives a summary of the decisions made for each organism group during the mixture risk assessment with respect to the decision scheme as provided by EFSA (2013, section 10.3.11). A discussion of all details of every decision is not intended in this section of this registration report. Further in-depth justification and explanation for the decisions made are documented in the attached mixture risk calculation file. However, at least data for some important steps are documented in this section of this registration report, beginning with the check for (and potentially assessment of) synergistic or antagonistic effects (Step 2 and Steps 7, 9 and 10) as well as the ETR_{mix} or RQ_{mix} calculation results for the assessed FOCUS Scenarios (Steps 4 and 8 a/b).

Step 2: MDR calculation to check for synergistic or antagonistic effects

Table 9.5.2.2.4-22: Calculated mixture toxicity and MDR for each group of organisms (see sections 10.3.3 and 10.3.4 of EFSA (2013) for more details)

Species	Substance	Concentration (Ci) in formulation (g a.s./L)	Pi	ECxi (mg a.s./L)	ECxmix-CA (mg sum a.s. /L)	ECxPPP (mg sum a.s. /L)	MDR
Fish, acute toxicity 1							
Oncorhynchus mykiss	Azoxystrobin	200	0.62	0.47	0.603	0.496227771	1.21
Oncorhynchus mykiss	Difenoconazole	125	0.38	1.1			
Invertebrates, acute toxicity 1							
Daphnia	Azoxystrobin	200	0.62	0.23	0.315	0.321088558	0.98
Daphnia	Difenoconazole	125	0.38	0.77			
Algae							
Selenastrum capricornutum (green algae)	Azoxystrobin	200	0.62	0.36	0.072	0.17134453	0.43
Scenedesmus subspicatus (green alage)	Difenoconazole	125	0.38	0.032			

[1] For a possible inclusion of chronic toxicity please refer to the FAQ document distributed alongside the aquatic mixture toxicity calculation tool "AGD_AquaMix".

[2] MDR = 0.2 – 5 → Go to Step 3 (concentration addition (CA) approximately holds for the calculated mixture);

MDR > 5 → Go to Step 10 (the calculated mixture is more toxic than CA, i.e. synergistic);

MDR < 0.2 → Go to Step 9 (the calculated mixture is less toxic than CA, i.e. antagonistic)

The density of the liquid formulation of SCORPIO 3250 SC, equal to 1.1134 g/ml, was used in the performed calculations.

Step 3 Comparison of mixture composition of PPP and PEC_{mix}

According to Step 3 it has to be checked whether the mixture composition in the formulation is similar to the mixture composition at PEC_{mix} (which is the sum of PEC_i of individual active substances). Therefore,

the "$ECx_{mix\text{-}CA}$ (a.s. in PPP) / $ECx_{mix\text{-}CA}$ (a.s. in PEC_{mix})" ratios were calculated.

In case the ratio is in the range of 0.8–1.2 (mixture similar), the risk assessment can be based on the ECx_{PPP} (Step 4).

In case the ratio is outside the range of 0.8–1.2 (i.e. mixture not similar), the endpoint $ECx_{mix\text{-}CA}$ normalized to the mixture composition at PEC_{mix} (reported as "$ECx_{mix\text{-}CA}$ (a.s. in PEC_{mix})" in EFSA, 2013, and the following parts of this report) has to be used to calculate the risk (Step 5 or Step 8, respectively).

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if product or calculated endpoint data (according to Step 3) have to be used. Further in-depth justification and explanation are documented in the attached mixture risk calculation file.

Step 5: Driver detection

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if a driver of risk is available according to Step 5. Further in-depth justification and explanation are documented in the attached mixture risk calculation file. Further information for the availability of a driver for the risk assessment of particular FOCUS Scenarios is given in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) and

Table 9.5.2.2-4 (FOCUS Step 4) below.

Step 4 and Step 8a: Mixture risk assessment based on measured and calculated mixture toxicity

Decisions taken when using the scheme as provided by EFSA (2013, section 10.3.11) lead to several assessment steps, which give a conclusion on the risk of a mixture or provide additional information important for the assessment. In the tables below the conclusions of different steps of the mixture risk assessment are summarized for the FOCUS Scenarios of concern. Information is reported on:

q) Step 2 and associated steps, in which the question is answered if concentration addition can be assumed (i.e. a standard mixture toxicity risk assessment is appropriate) or if an antagonism/synergism is possible (more detailed information on Step 2 is given above). This is important to derive if further, specific considerations have to be made in the risk assessment. Associated steps are Step 7, Step 9 and Step 10.
r) Step 5, in which the question is answered if there is a driver of risk and if so, which of the substance can be classified as driver (more detailed information on Step 5 is given the attached mixture risk calculation file). This is reported as additional information in case an assessment based on a driver would also be possible; for comparative reasons the table always lists the results from the mixture risk assessment according to Step 4 and/or Step 8. For an assessment based on a particular a.s. (the driver) please be referred to the individual a.s. risk assessment.
s) Step 4 with the assessment results for cases where product data are usable (according to Step 3) and the risk assessment can be carried out based on the measured toxicity.
t) Step 8 (a/b) with the assessment results for cases where product data are not usable (according to Step 3) and the risk assessment has to be based on calculated mixture toxicity.

The intermediate results of the mixture toxicity risk assessment are presented below for the respective FOCUS steps.

Table 9.5.2.2.4-23: Results of the mixture toxicity risk assessment (related to Step 8a) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in Winter Oilseed rape (BBCH 14-20).

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	Go to Step 4	0.211	0.427
Step 2			
N-Europe	Go to Step 4	0.036	0.070
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	0.027	0.054	0.059
D2/ stream	0.017	0.034	0.044
D3/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
D4/ pond	0.003	0.006	0.005
D4/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D5/ pond	0.001	0.002	0.002
D5/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	Go to Step 4	Go to Step 4	Go to Step 4
R1/ stream	Go to Step 4	Go to Step 4	Go to Step 4
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	Go to Step 4	Go to Step 4	0.031
Step 4	10 m vegetative strip, 10 m no spray buffer and no nozzle reduction		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	The risk was considered acceptable at Step 3		
D2/ stream			
D3/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
D4/ pond	The risk was considered acceptable at Step 3		
D4/ stream	0.003	0.007	0.008
D5/ pond	The risk was considered acceptable at Step 3		
D5/ stream	Go to Step 4	0.005	0.007
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	The risk was considered acceptable at Step 3		
R1/ stream	Go to Step 4	0.002	0.005
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	0.003	0.006	0.008

Table 9.5.2.2.4-4: Results of the mixture toxicity risk assessment (related to Step 4) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in Winter Oilseed rape (BBCH 14-20).

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	0.111	Go to Step 5/8	Go to Step 5/8
Step 2			
N-Europe	0.019	Go to Step 5/8	Go to Step 5/8
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
D2/ stream	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
D3/ ditch	0.004	Go to Step 5/8	Go to Step 5/8
D4/ pond	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
D4/ stream	0.005	0.006	0.012
D5/ pond	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
D5/ stream	0.004	0.007	0.013
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	0.000	0.000	0.001
R1/ stream	0.004	0.005	0.010
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	0.008	0.012	Go to Step 5/8
Step 4	10 m vegetative strip, 5 m no spray buffer and no nozzle reduction		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	0.001	0.001	0.002
D4/ pond	The risk was considered acceptable at Step 3		
D4/ stream	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
D5/ pond	The risk was considered acceptable at Step 3		
D5/ stream	0.002	Go to Step 5/8	Go to Step 5/8
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	The risk was considered acceptable at Step 3		
R1/ stream	0.001	Go to Step 5/8	Go to Step 5/8
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8

The respective assessment conclusions are presented in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) or

Table 9.5.2.2-4 (FOCUS Step 4). The assessment is based either on the exposure-toxicity ratio (ETR_{mix}) or the risk quotient (RQ_{mix}); the ETR_{mix} and RQ_{mix} are compared to respective trigger values: 1/10 or 1/100 for the ETR_{mix} (depending on the species assessed) and 1 for RQ_{mix}. For the sake of a concise assessment the results below are limited to the organism groups most at risk. Further in-depth justification and explanation for other organism groups are documented in the attached mixture risk calculation file.

Table 9.5.2.2.4-5: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for fish, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Winter oilseed rape (BBCH 14-20)

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	0.111	Go to Step 4
Step 2				
N-Europe		Azoxystrobin	0.019	Go to Step 4
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Azoxystrobin	Go to Step 5/8	0.027
D2/ stream		Azoxystrobin	Go to Step 5/8	0.017
D3/ ditch		no driver	0.004	Go to Step 4
D4/ pond		Azoxystrobin	Go to Step 5/8	0.003
D4/ stream		no driver	0.005	Go to Step 4
D5/ pond		Azoxystrobin	Go to Step 5/8	0.001
D5/ stream		no driver	0.004	Go to Step 4
D6/ ditch		Scenario D6 are not relevant for Central Zone		
R1/ pond		no driver	0.000	Go to Step 4
R1/ stream		no driver	0.004	Go to Step 4
R2/ stream		Scenario R2 are not relevant for Central Zone		
R3/ stream		Azoxystrobin	0.008	Go to Step 4

Table 9.5.2.2.4-6: Summary of the mixture toxicity risk assessment (related to Step 4) for fish based on FOCUS Step 4 calculations for application of Clapton 325 SC in Winter oilseed rape (BBCH 14-20)

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.001		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.003		
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream							0.002		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.001		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.003		
50%										
75%										
90%										

Table 9.5.2.2.4-7: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for invertebrates, for FOCUS Step 1 – 3 for application of Clapton 325 SC Winter oilseed rape (BBCH 14-20)

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	Go to Step 5/8	0.211
Step 2				
N-Europe		Azoxystrobin	Go to Step 5/8	0.036
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Azoxystrobin	Go to Step 5/8	0.054
D2/ stream		Azoxystrobin	Go to Step 5/8	0.034
D3/ ditch		no driver	0.006	Go to Step 4
D4/ pond		Azoxystrobin	Go to Step 5/8	0.006
D4/ stream		no driver	0.07	Go to Step 4
D5/ pond		Azoxystrobin	Go to Step 5/8	0.002
D5/ stream		no driver	0.006	Go to Step 4
D6/ ditch		Scenario D6 are not relevant for Central Zone		
R1/ pond		no driver	0.000	Go to Step 4
R1/ stream		no driver	0.005	Go to Step 4
R2/ stream		Scenario R2 are not relevant for Central Zone		
R3/ stream		Azoxystrobin	0.012	Go to Step 4

Table 9.5.2.2.4-8: Summary of the mixture toxicity risk assessment (related to Step 4) for invertebrates based on FOCUS Step 4 calculations for application of Clapton 325 SC in Winter oilseed rape (BBCH 14-20)

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.001		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.007		
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream							0.005		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.002		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.006		
50%										
75%										
90%										

Table 9.5.2.2.4-9: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for algae, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Winter oilseed rape (BBCH 14-20)

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	no driver	Go to Step 5/8	0.427
Step 2				
N-Europe		no driver	Go to Step 5/8	0.070
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		no driver	Go to Step 5/8	0.059
D2/ stream		no driver	Go to Step 5/8	0.044
D3/ ditch		no driver	0.012	Go to Step 4
D4/ pond		no driver	Go to Step 5/8	0.005
D4/ stream		no driver	0.013	Go to Step 4
D5/ pond		no driver	Go to Step 5/8	0.002
D5/ stream		no driver	0.011	Go to Step 4
D6/ ditch		Scenario D6 are not relevant for Central Zone		
R1/ pond		no driver	0.001	Go to Step 4
R1/ stream		no driver	0.010	Go to Step 4
R2/ stream		Scenario R2 are not relevant for Central Zone		
R3/ stream		no driver	Go to Step 5/8	0.031

Table 9.5.2.2.4-10: Summary of the mixture toxicity risk assessment (related to Step 4) for algae based on FOCUS Step 4 calculations for application of Clapton 325 SC in Winter oilseed rape (BBCH 14-20)

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.002		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.008		
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream							0.007		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.005		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.008		
50%										
75%										
90%										

Table 9.5.2.2.3-241: Summary of mixture toxicity assessment for SCORPIO 325 SC for aquatic organisms for the use according to the GAP table for Winter oilseed rape (BBCH 14-20)

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50}	E_rC_{50}	E_bC_{50}
AF		100	100	10
RAC_{mix} (µg/L)		496.227	321.088	171.345
FOCUS scenerio	**PEC_{max} (µg/L)**			
Step 1	55.2500	0.1113	0.1721	0.3224
Step 2		-		
N-Europe	9.2600	0.0187	0.0288	0.0540
Step 3		-		
D2 / Ditch	12.9642	0.0261	0.0404	0.0757
D2 / Stream	8.3693	0.0169	0.0261	0.0488
D3 / Ditch	2.0694	0.0042	0.0064	0.0121
D4 / Pond	1.4301	0.0029	0.0045	0.0083
D4 / Stream	2.2336	0.0045	0.0070	0.0130
D5 / Pond	0.5501	0.0011	0.0017	0.0032
D5 / Stream	1.9163	0.0039	0.0060	0.0112
R1 / Pond	0.1082	0.0002	0.0003	0.0006
R1 / Stream	1.7522	0.0035	0.0055	0.0102
R3 / Stream	3.8296	0.0077	0.0119	0.0224
Step 4		-		
D3 / Ditch	0.2917	0.0006	0.0009	0.0017
D4 / Stream	1.6847	0.0034	0.0052	0.0098
D5 / Stream	1.2191	0.0025	0.0038	0.0071
R1 / Stream	0.6471	0.0013	0.0020	0.0038
R3 / Stream	1.5528	0.0031	0.0048	0.0091

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50} 496.227	E_rC_{50} 321.088	E_bC_{50} 171.345
AF		100	100	10
RAC_{mix} (µg/L)		4.962	3.211	17.135
FOCUS scenerio	**PEC_{max} (µg/L)**			
Step 1	55.2500	>1	>1	>1
Step 2				
N-Europe	9.2600	>1	>1	<1
Step 3				
D3 / Ditch	2.0694	<1	<1	-
D4 / Pond	1.4301	<1	<1	-
D4 / Stream	2.2336	<1	<1	-
D5 / Pond	0.5501	<1	<1	-
D5 / Stream	1.9163	<1	<1	-
R1 / Pond	0.1082	<1	<1	-
R1 / Stream	1.7522	<1	<1	-
R3 / Stream	3.8296	<1	>1	-
Step 4	**10 m vegetative strip + 10 m no spray buffer**			
R3 / Stream	1.5528	-	<1	-

9.5.2.2.6 Risk assessment of mixture toxicity based on Winter Oilseed Rape (BBCH 21 – 69)

Table 9.5.2.2.3-25: Summary of assessment steps considered for the mixture risk assessment

Steps	Conclusion on the Steps		
	Fish	Invertebrates	Algae
Screening 1: ETR trigger (optional Step)	-	-	-
Screening 2: Driver (optional Step)	-	-	-
Step 1: data available?	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.
Step 2: apparent synergism or antagonism?	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.
Step 3: mixture similar or not?	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.
Step 4: ETRmix assessment (ECxPPP)	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).
Step 5: driver available?	There is no driver for fish in all scenarios. Go to Step 8.	There is no driver for invertebrates in all scenarios. Go to Step 8.	There is no driver for algae in all scenarios. Go to Step 8.
Step 6: driver assessment	-	-	-

Step 7: synergism assessment (few data)	-	-	-
Step 8a: ETRmix assessment	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**
Step 8b: RQmix assessment	-	-	-
Step 9: antagonism assessment	-	-	-
Step 10: synergism assessment	-	-	-

Overview of the assessment steps: Table 9.5.2.2-1 gives a summary of the decisions made for each organism group during the mixture risk assessment with respect to the decision scheme as provided by EFSA (2013, section 10.3.11). A discussion of all details of every decision is not intended in this section of this registration report. Further in-depth justification and explanation for the decisions made are documented in the attached mixture risk calculation file. However, at least data for some important steps are documented in this section of this registration report, beginning with the check for (and potentially assessment of) synergistic or antagonistic effects (Step 2 and Steps 7, 9 and 10) as well as the ETR_{mix} or RQ_{mix} calculation results for the assessed FOCUS Scenarios (Steps 4 and 8a/b).

Step 2: MDR calculation to check for synergistic or antagonistic effects

Table 9.5.2.2.3-26: Calculated mixture toxicity and MDR for each group of organisms (see sections 10.3.3 and 10.3.4 of EFSA (2013) for more details)

Species	Substance	Concentration (Ci) in formulation (g a.s./L)	Pi	ECxi (mg a.s./L)	ECxmix-CA (mg sum a.s. /L)	ECxPPP (mg sum a.s. /L)	MDR
Fish, acute toxicity 1							
Oncorhynchus mykiss	Azoxystrobin	200	0.62	0.47	0.603	0.496227771	1.21
Oncorhynchus mykiss	Difenoconazole	125	0.38	1.1			
Invertebrates, acute toxicity 1							
Daphnia	Azoxystrobin	200	0.62	0.23	0.315	0.321088558	0.98
Daphnia	Difenoconazole	125	0.38	0.77			
Algae							
Selenastrum capricornutum (green algae)	Azoxystrobin	200	0.62	0.36	0.073	0.17134453	0.43
Scenedesmus subspicatus (green alage)	Difenoconazole	125	0.38	0.032			

[1] For a possible inclusion of chronic toxicity please refer to the FAQ document distributed alongside the aquatic mixture toxicity calculation tool "AGD_AquaMix".

[2] MDR = 0.2 – 5 → Go to Step 3 (concentration addition (CA) approximately holds for the calculated mixture);

MDR > 5 → Go to Step 10 (the calculated mixture is more toxic than CA, i.e. synergistic);

MDR < 0.2 → Go to Step 9 (the calculated mixture is less toxic than CA, i.e. antagonistic)

The density of the liquid formulation of SCORPIO 3250 SC, equal to 1.1134 g/ml, was used in the performed calculations.

Step 3 Comparison of mixture composition of PPP and PEC_{mix}

According to Step 3 it has to be checked whether the mixture composition in the formulation is similar to the mixture composition at PEC_{mix} (which is the sum of PEC_i of individual active substances). Therefore, the "$ECx_{mix\text{-}CA}$ (a.s. in PPP) / $ECx_{mix\text{-}CA}$ (a.s. in PEC_{mix})" ratios were calculated.

In case the ratio is in the range of 0.8–1.2 (mixture similar), the risk assessment can be based on the ECx_{PPP} (Step 4).

In case the ratio is outside the range of 0.8–1.2 (i.e. mixture not similar), the endpoint $ECx_{mix\text{-}CA}$ normalized to the mixture composition at PEC_{mix} (reported as "$ECx_{mix\text{-}CA}$ (a.s. in PEC_{mix})" in EFSA, 2013, and the following parts of this report) has to be used to calculate the risk (Step 5 or Step 8, respectively).

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if product or calculated endpoint data (according to Step 3) have to be used. Further in-depth justification and explanation are documented in the attached mixture risk calculation file.

Step 5: Driver detection

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if a driver of risk is available according to Step 5. Further in-depth justification and explanation are documented in the attached mixture risk calculation file. Further information for the availability of a driver for the risk assessment of particular FOCUS Scenarios is given in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) and

Table 9.5.2.2-4 (FOCUS Step 4) below.

Step 4 and Step 8a: Mixture risk assessment based on measured and calculated mixture toxicity

Decisions taken when using the scheme as provided by EFSA (2013, section 10.3.11) lead to several assessment steps, which give a conclusion on the risk of a mixture or provide additional information important for the assessment. In the tables below the conclusions of different steps of the mixture risk assessment are summarized for the FOCUS Scenarios of concern. Information is reported on:

u) Step 2 and associated steps, in which the question is answered if concentration addition can be assumed (i.e. a standard mixture toxicity risk assessment is appropriate) or if an antagonism/synergism is possible (more detailed information on Step 2 is given above). This is important to derive if further, specific considerations have to be made in the risk assessment. Associated steps are Step 7, Step 9 and Step 10.
v) Step 5, in which the question is answered if there is a driver of risk and if so, which of the substance can be classified as driver (more detailed information on Step 5 is given the attached mixture risk calculation file). This is reported as additional information in case an assessment based on a driver would also be possible; for comparative reasons the table always lists the results from the mixture risk assessment according to Step 4 and/or Step 8. For an assessment based on a particular a.s. (the driver) please be referred to the individual a.s. risk assessment.
w) Step 4 with the assessment results for cases where product data are usable (according to Step 3) and the risk assessment can be carried out based on the measured toxicity.
x) Step 8 (a/b) with the assessment results for cases where product data are not usable (according to Step 3) and the risk assessment has to be based on calculated mixture toxicity.

The intermediate results of the mixture toxicity risk assessment are presented below for the respective FOCUS steps.

Table 9.5.2.2.3-27: Results of the mixture toxicity risk assessment (related to Step 8a) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in Winter Oilseed Rape (BBCH 21-69).

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	Go to Step 4	0.211	0.427
Step 2			
N-Europe	Go to Step 4	Go to Step 4	0.046
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Go to Step 4	0.023	0.039
D2/ stream	Go to Step 4	Go to Step 4	0.031
D3/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
D4/ pond	0.001	0.002	0.002
D4/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D5/ pond	Go to Step 4	0.001	0.001
D5/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	Go to Step 4	Go to Step 4	0.001
R1/ stream	Go to Step 4	Go to Step 4	Go to Step 4
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	Go to Step 4	Go to Step 4	0.029
Step 4	10 m vegetative strip, 10 m no spray buffer and no nozzle reduction		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
D4/ pond	The risk was considered acceptable at Step 3		
D4/ stream	Go to Step 4	Go to Step 4	0.005
D5/ pond	Go to Step 4	Go to Step 4	Go to Step 4
D5/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	Go to Step 4	Go to Step 4	Go to Step 4
R1/ stream	Go to Step 4	0.003	0.005
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	Go to Step 4	0.004	0.007

Table 9.5.2.2.3-4: Results of the mixture toxicity risk assessment (related to Step 4) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in Winter oilseed rape (BBCH 21-69).

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	0.111	Go to Step 5/8	Go to Step 5/8
Step 2			
N-Europe	0.009	0.014	Go to Step 5/8
Step 3			
D1/ ditch D1/ stream	Scenarios are not relevant for Central Zone		
D2/ ditch	0.012	Go to Step 5/8	Go to Step 5/8
D2/ stream	0.008	0.012	Go to Step 5/8
D3/ ditch	0.004	0.006	0.012
D4/ pond	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
D4/ stream	0.003	0.005	0.009
D5/ pond	0.000	Go to Step 5/8	Go to Step 5/8
D5/ stream	0.003	0.004	0.008
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	0.000	0.001	Go to Step 5/8
R1/ stream	0.004	0.005	0.010
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	0.006	0.009	Go to Step 5/8
Step 4	**10 m vegetative strip, 10 m no spray buffer and no nozzle reduction**		
D1/ ditch D1/ stream	Scenarios are not relevant for Central Zone		
D2/ ditch D2/ stream	Scenarios are not relevant for Central Zone		
D3/ ditch	0.001	0.001	0.002
D4/ stream	0.001	0.002	Go to Step 5/8
D5/ stream	0.001	0.001	0.002
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ stream	0.001	Go to Step 5/8	Go to Step 5/8
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	0.002	Go to Step 5/8	Go to Step 5/8

The respective assessment conclusions are presented in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) or

Table 9.5.2.2-4 (FOCUS Step 4). The assessment is based either on the exposure-toxicity ratio (ETR_{mix}) or the risk quotient (RQ_{mix}); the ETR_{mix} and RQ_{mix} are compared to respective trigger values: 1/10 or 1/100 for the ETR_{mix} (depending on the species assessed) and 1 for RQ_{mix}. For the sake of a concise assessment the results below are limited to the organism groups most at risk. Further in-depth justification and explanation for other organism groups are documented in the attached mixture risk calculation file.

Table 9.5.2.2.3-5: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for fish, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Winter Oilseed rape (BBCH 21-69)

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	0.111	Go to Step 4
Step 2				
N-Europe		no driver	0.009	Go to Step 4
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Azoxystrobin	0.012	Go to Step 4
D2/ stream		Azoxystrobin	0.008	Go to Step 4
D3/ ditch		no driver	0.004	Go to Step 4
D4/ pond		Azoxystrobin	Go to Step 5/8	0.001
D4/ stream		no driver	0.003	Go to Step 4
D5/ pond		Azoxystrobin	0.000	Go to Step 4
D5/ stream		no driver	0.003	Go to Step 4
D6/ ditch		Scenario is not relevant for Central Zone		
R1/ pond		Azoxystrobin	0.000	Go to Step 4
R1/ stream		no driver	0.004	Go to Step 4
R2/ stream		Scenario is not relevant for Central Zone		
R3/ stream		no driver	0.006	Go to Step 4

Table 9.5.2.2.3-6: Summary of the mixture toxicity risk assessment (related to Step 4) for fish based on FOCUS Step 4 calculations for application of Clapton 325 SC in Winter Oilseed rape (BBCH 21-69)

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.00 1		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.001		
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream							0.001		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.001		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.002		
50%										
75%										
90%										

Table 9.5.2.2.3-7: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for invertebrates, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Winter Oilseed rape (BBCH 21-69)

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	Go to Step 5/8	0.211
Step 2				
N-Europe		Azoxystrobin	0.014	Go to Step 4
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Azoxystrobin	Go to Step 5/8	0.023
D2/ stream		Azoxystrobin	0.012	Go to Step 4
D3/ ditch		no driver	0.006	Go to Step 4
D4/ pond		Azoxystrobin	Go to Step 5/8	0.002
D4/ stream		no driver	0.005	Go to Step 4
D5/ pond		Azoxystrobin	Go to Step 5/8	0.001
D5/ stream		no driver	0.004	Go to Step 4
D6/ ditch		Scenario D6 are not relevant for Central Zone		
R1/ pond		Azoxystrobin	0.001	Go to Step 4
R1/ stream		no driver	0.005	Go to Step 4
R2/ stream		Scenario R2 are not relevant for Central Zone		
R3/ stream		Azoxystrobin	0.009	Go to Step 4

Table 9.5.2.2.3-8: Summary of the mixture toxicity risk assessment (related to Step 4) for invertebrates based on FOCUS Step 4 calculations for application of Clapton 325 SC in Winter Oilseed rape (BBCH 21-69)

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.001		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.002		
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream							0.001		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.003		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.004		
50%										
75%										
90%										

Table 9.5.2.2.3-9: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for algae, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Winter Oilseed rape (BBCH 21-69)

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	no driver	Go to Step 5/8	0.427
Step 2				
N-Europe		no driver	Go to Step 5/8	0.046
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		no driver	Go to Step 5/8	0.039
D2/ stream		no driver	Go to Step 5/8	0.031
D3/ ditch		no driver	0.012	Go to Step 4
D4/ pond		no driver	Go to Step 5/8	0.002
D4/ stream		no driver	0.009	Go to Step 4
D5/ pond		no driver	Go to Step 5/8	0.001
D5/ stream		no driver	0.008	Go to Step 4
D6/ ditch		Scenario D6 are not relevant for Central Zone		
R1/ pond		no driver	Go to Step 5/8	0.001
R1/ stream		no driver	0.010	Go to Step 4
R2/ stream		Scenario R2 are not relevant for Central Zone		
R3/ stream		no driver	Go to Step 5/8	0.029

Table 9.5.2.2.3-10: Summary of the mixture toxicity risk assessment (related to Step 4) for algae based on FOCUS Step 4 calculations for application of Clapton 325 SC in Winter Oilseed rape (BBCH 21-69)

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.002		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.005		
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream							0.002		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.005		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.007		
50%										
75%										
90%										

Table 9.5.2.2.3-281: Summary of mixture toxicity assessment for SCORPIO 325 SC for aquatic organisms for the use according to the GAP table for Winter Oilseed rape (BBCH 21-69)

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50}	E_rC_{50}	E_bC_{50}
AF		100	100	10
RAC_{mix} (µg/L)		496.227	321.088	171.345
FOCUS scenerio	**PEC_{max} (µg/L)**			
Step 1	55.2500	0.1113	0.1721	0.3224
Step 2				
N-Europe	4.6200	0.0093	0.0144	0.0270
Step 3				
D2 / Ditch	5.9057	0.0119	0.0184	0.0345
D2 / Stream	3.9050	0.0079	0.0122	0.0228
D3 / Ditch	2.0491	0.0041	0.0064	0.0120
D4 / Pond	0.3973	0.0008	0.0012	0.0023
D4 / Stream	1.5949	0.0032	0.0050	0.0093
D5 / Pond	0.1624	0.0003	0.0005	0.0009
D5 / Stream	1.3505	0.0027	0.0042	0.0079
R1 / Pond	0.1616	0.0003	0.0005	0.0009
R1 / Stream	1.7553	0.0035	0.0055	0.0102
R3 / Stream	2.8284	0.0057	0.0088	0.0165
Step 4				
D3 / Ditch	0.2941	0.0006	0.0009	0.0017
D4 / Stream	0.5295	0.0011	0.0016	0.0031
D5 / Stream	0.2778	0.0006	0.0009	0.0016
R1 / Stream	0.6616	0.0013	0.0021	0.0039
R3 / Stream	1.0673	0.0022	0.0033	0.0062

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50} 496.227	E_rC_{50} 321.088	E_bC_{50} 171.345
AF		100	100	10
RAC_{mix} (µg/L)		4.962	3.211	17.135
FOCUS scenerio	**PEC_{max} (µg/L)**			
Step 1	55.2500	>1	>1	>1
Step 2				
N-Europe	4.6200	>1	>1	<1
Step 3				
D3 / Ditch	2.0491	<1	<1	-
D4 / Pond	0.3973	<1	<1	-
D4 / Stream	1.5949	<1	<1	-
D5 / Pond	0.1624	<1	<1	-
D5 / Stream	1.3505	<1	<1	-
R1 / Pond	0.1616	<1	<1	-
R1 / Stream	1.7553	<1	<1	-
R3 / Stream	2.8284	<1	<1	-

9.5.2.2.7 Risk assessment of mixture toxicity based on Carrot

Table 9.5.2.2.3-29: Summary of assessment steps considered for the mixture risk assessment

Steps	Conclusion on the Steps		
	Fish	Invertebrates	Algae
Screening 1: ETR trigger (optional Step)	-	-	-
Screening 2: Driver (optional Step)	-	-	-
Step 1: data available?	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.
Step 2: apparent synergism or antagonism?	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.
Step 3: mixture similar or not?	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.
Step 4: ETRmix assessment (ECxPPP)	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).
Step 5: driver available?	There is no driver for fish in all scenarios. Go to Step 8.	There is no driver for invertebrates in all scenarios. Go to Step 8.	There is no driver for algae in all scenarios. Go to Step 8.
Step 6: driver assessment	-	-	-

Step 7: synergism assessment (few data)	-	-	-
Step 8a: ETRmix assessment	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**
Step 8b: RQmix assessment	-	-	-
Step 9: antagonism assessment	-	-	-
Step 10: synergism assessment	-	-	-

Overview of the assessment steps: Table 9.5.2.2-1 gives a summary of the decisions made for each organism group during the mixture risk assessment with respect to the decision scheme as provided by EFSA (2013, section 10.3.11). A discussion of all details of every decision is not intended in this section of this registration report. Further in-depth justification and explanation for the decisions made are documented in the attached mixture risk calculation file. However, at least data for some important steps are documented in this section of this registration report, beginning with the check for (and potentially assessment of) synergistic or antagonistic effects (Step 2 and Steps 7, 9 and 10) as well as the ETR_{mix} or RQ_{mix} calculation results for the assessed FOCUS Scenarios (Steps 4 and 8a/b).

Step 2: MDR calculation to check for synergistic or antagonistic effects

Table 9.5.2.2.3-30: Calculated mixture toxicity and MDR for each group of organisms (see sections 10.3.3 and 10.3.4 of EFSA (2013) for more details)

Species	Substance	Concentration (Ci) in formulation (g a.s./L)	Pi	ECxi (mg a.s./L)	ECxmix-CA (mg sum a.s. /L)	ECxPPP (mg sum a.s. /L)	MDR
Fish, acute toxicity 1							
Oncorhynchus mykiss	Azoxystrobin	200	0.62	0.47	0.603	0.496227771	1.21
Oncorhynchus mykiss	Difenoconazole	125	0.38	1.1			
Invertebrates, acute toxicity 1							
Daphnia	Azoxystrobin	200	0.62	0.23	0.315	0.321088558	0.98
Daphnia	Difenoconazole	125	0.38	0.77			
Algae							
Selenastrum capricornutum (green algae)	Azoxystrobin	200	0.62	0.36	0.072	0.17134453	0.43
Scenedesmus subspicatus (green alage)	Difenoconazole	125	0.38	0.032			

[1] For a possible inclusion of chronic toxicity please refer to the FAQ document distributed alongside the aquatic mixture toxicity calculation tool "AGD_AquaMix".

[2] MDR = 0.2 – 5 → Go to Step 3 (concentration addition (CA) approximately holds for the calculated mixture);

MDR > 5 → Go to Step 10 (the calculated mixture is more toxic than CA, i.e. synergistic);

MDR < 0.2 → Go to Step 9 (the calculated mixture is less toxic than CA, i.e. antagonistic)

The density of the liquid formulation of SCORPIO 3250 SC, equal to 1.1134 g/ml, was used in the performed calculations.

Step 3 Comparison of mixture composition of PPP and PEC_{mix}

According to Step 3 it has to be checked whether the mixture composition in the formulation is similar to the mixture composition at PEC_{mix} (which is the sum of PEC_i of individual active substances). Therefore,

the "ECx_{mix-CA} (a.s. in PPP) / ECx_{mix-CA} (a.s. in PEC_{mix})" ratios were calculated.

In case the ratio is in the range of 0.8–1.2 (mixture similar), the risk assessment can be based on the ECx_{PPP} (Step 4).

In case the ratio is outside the range of 0.8–1.2 (i.e. mixture not similar), the endpoint ECx_{mix-CA} normalized to the mixture composition at PEC_{mix} (reported as "ECx_{mix-CA} (a.s. in PEC_{mix})" in EFSA, 2013, and the following parts of this report) has to be used to calculate the risk (Step 5 or Step 8, respectively).

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if product or calculated endpoint data (according to Step 3) have to be used. Further in-depth justification and explanation are documented in the attached mixture risk calculation file.

Step 5: Driver detection

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if a driver of risk is available according to Step 5. Further in-depth justification and explanation are documented in the attached mixture risk calculation file. Further information for the availability of a driver for the risk assessment of particular FOCUS Scenarios is given in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) and

Table 9.5.2.2-4 (FOCUS Step 4) below.

Step 4 and Step 8a: Mixture risk assessment based on measured and calculated mixture toxicity

Decisions taken when using the scheme as provided by EFSA (2013, section 10.3.11) lead to several assessment steps, which give a conclusion on the risk of a mixture or provide additional information important for the assessment. In the tables below the conclusions of different steps of the mixture risk assessment are summarized for the FOCUS Scenarios of concern. Information is reported on:

y) Step 2 and associated steps, in which the question is answered if concentration addition can be assumed (i.e. a standard mixture toxicity risk assessment is appropriate) or if an antagonism/synergism is possible (more detailed information on Step 2 is given above). This is important to derive if further, specific considerations have to be made in the risk assessment. Associated steps are Step 7, Step 9 and Step 10.

z) Step 5, in which the question is answered if there is a driver of risk and if so, which of the substance can be classified as driver (more detailed information on Step 5 is given the attached mixture risk calculation file). This is reported as additional information in case an assessment based on a driver would also be possible; for comparative reasons the table always lists the results from the mixture risk assessment according to Step 4 and/or Step 8. For an assessment based on a particular a.s. (the driver) please be referred to the individual a.s. risk assessment.

aa) Step 4 with the assessment results for cases where product data are usable (according to Step 3) and the risk assessment can be carried out based on the measured toxicity.

bb) Step 8 (a/b) with the assessment results for cases where product data are not usable (according to Step 3) and the risk assessment has to be based on calculated mixture toxicity.

The intermediate results of the mixture toxicity risk assessment are presented below for the respective FOCUS steps.

Table 9.5.2.2.3-31: Results of the mixture toxicity risk assessment (related to Step 8a) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in carrot.

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	Go to Step 4	0.211	0.427
Step 2			
N-Europe	Go to Step 4	0.036	0.070
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
D6/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
R1/ pond	Go to Step 4	0.002	0.004
R1/ stream	Go to Step 4	Go to Step 4	0.021
R2/ stream	Go to Step 4	Go to Step 4	0.029
R3/ stream	Go to Step 4	Go to Step 4	0.025
R4/ stream	Go to Step 4	0.014	Go to Step 4
Step 4	10 m vegetative strip, 10 m no spray buffer and no nozzle reduction		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	Go to Step 4	Go to Step 4	Go to Step 4
R1/ stream	0.002	0.004	0.006
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	Go to Step 4	0.004	0.007
R4/ stream	0.003	0.006	0.009

Table 9.5.2.2.3-4: Results of the mixture toxicity risk assessment (related to Step 4) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in carrot.

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	0.111	Go to Step 5/8	Go to Step 5/8
Step 2			
N-Europe	0.019	Go to Step 5/8	Go to Step 5/8
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	0.004	0.006	0.012
D6/ ditch	0.004	0.006	0.012
R1/ pond	0.001	Go to Step 5/8	Go to Step 5/8
R1/ stream	0.005	0.007	Go to Step 5/8
R2/ stream	0.004	0.006	0.010
R3/ stream	0.006	0.009	Go to Step 5/8
R4/ stream	0.007	Go to Step 5/8	Go to Step 5/8
Step 4	10 m vegetative strip, 10 m no spray buffer and no nozzle reduction		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	0.001	0.001	0.002
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	The risk was considered acceptable at Step 3		
R1/ stream	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	0.002	Go to Step 5/8	Go to Step 5/8
R4/ stream	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8

The respective assessment conclusions are presented in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) or

Table 9.5.2.2-4 (FOCUS Step 4). The assessment is based either on the exposure-toxicity ratio (ETR_{mix}) or the risk quotient (RQ_{mix}); the ETR_{mix} and RQ_{mix} are compared to respective trigger values: 1/10 or 1/100 for the ETR_{mix} (depending on the species assessed) and 1 for RQ_{mix}. For the sake of a concise assessment the results below are limited to the organism groups most at risk. Further in-depth justification and explanation for other organism groups are documented in the attached mixture risk calculation file.

Table 9.5.2.2.3-5: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for fish, for FOCUS Step 1 – 3 for application of Clapton 325 SC in carrot

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	0.111	Go to Step 4
Step 2				
N-Europe		Azoxystrobin	0.019	Go to Step 4
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.004	Go to Step 4
D6/ stream		no driver	0.004	Go to Step 4
R1/ pond		Azoxystrobin	0.001	Go to Step 4
R1/ stream		no driver	0.005	Go to Step 4
R2/ stream		no driver	0.004	Go to Step 4
R3/ stream		no driver	0.006	Go to Step 4
R4/ stream		Azoxystrobin	0.007	Go to Step 4

Table 9.5.2.2.3-6: Summary of the mixture toxicity risk assessment (related to Step 4) for fish based on FOCUS Step 4 calculations for application of Clapton 325 SC in carrot

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.001		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.002		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.002		
50%										
75%										
90%										
None	R4 stream							0.003		
50%										
75%										
90%										

Table 9.5.2.2.3-7: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for invertebrates, for FOCUS Step 1 – 3 for application of Clapton 325 SC in carrot

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	Go to Step 5/8	0.211
Step 2				
N-Europe		Azoxystrobin	Go to Step 5/8	0.036
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.006	Go to Step 4
D6/ stream		no driver	0.006	Go to Step 4
R1/ pond		Azoxystrobin	Go to Step 5/8	0.002
R1/ stream		Azoxystrobin	0.007	Go to Step 4
R2/ stream		no driver	0.006	Go to Step 4
R3/ stream		Azoxystrobin	0.009	Go to Step 4
R4/ stream		Azoxystrobin	Go to Step 5/8	0.014

Table 9.5.2.2.3-8: Summary of the mixture toxicity risk assessment (related to Step 4) for invertebrates based on FOCUS Step 4 calculations for application of Clapton 325 SC in carrot

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.001		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.004		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.004		
50%										
75%										
90%										
None	R4 stream							0.006		
50%										
75%										
90%										

Table 9.5.2.2.3-9: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for algae, for FOCUS Step 1 – 3 for application of Clapton 325 SC in carrot

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	no driver	Go to Step 5/8	0.427
Step 2				
N-Europe		no driver	Go to Step 5/8	0.070
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.012	Go to Step 4
D6/ stream		no driver	0.012	Go to Step 4
R1/ pond		no driver	Go to Step 5/8	0.004
R1/ stream		no driver	Go to Step 5/8	0.021
R2/ stream		no driver	0.010	Go to Step 4
R3/ stream		no driver	Go to Step 5/8	0.029
R4/ stream		no driver	Go to Step 5/8	0.025

Table 9.5.2.2.3-10: Summary of the mixture toxicity risk assessment (related to Step 4) for algae based on FOCUS Step 4 calculations for application of Clapton 325 SC in carrot

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.002		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.006		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.007		
50%										
75%										
90%										
None	R4 stream							0.009		
50%										
75%										
90%										

Table 9.5.2.2.3-321: Summary of mixture toxicity assessment for SCORPIO 325 SC for aquatic organisms for the use according to the GAP table for Carrot

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50}	E_rC_{50}	E_bC_{50}
AF		100	100	10
RAC_{mix} (µg/L)		496.227	321.088	171.345
FOCUS scenerio	PEC_{max} (µg/L)			
Step 1	55.2500	0.1113	0.1721	0.3224
Step 2		-		
N-Europe	9.2600	0.0187	0.0288	0.0540
Step 3		-		
D3 / Ditch	2.0542	0.0041	0.0064	0.0120
D6 / Ditch	2.0290	0.0041	0.0063	0.0118
R1 / Pond	0.5199	0.0010	0.0016	0.0030
R1 / Stream	2.4038	0.0048	0.0075	0.0140
R2 / Stream	1.7931	0.0036	0.0056	0.0105
R3 / Stream	2.8084	0.0057	0.0087	0.0164
R4 / Stream	3.6967	0.0074	0.0115	0.0216
Step 4		-		
D3 / Ditch	0.2949	0.0006	0.0009	0.0017
R1 / Stream	0.9643	0.0019	0.0030	0.0056
R3 / Stream	1.0890	0.0022	0.0034	0.0064
R4 / Stream	1.6068	0.0032	0.0050	0.0094

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50} 496.227	E_rC_{50} 321.088	E_bC_{50} 171.345
AF		100	100	10
RAC_{mix} (µg/L)		4.962	3.211	17.135
FOCUS scenerio	**PEC_{max} (µg/L)**			
Step 1	55.2500	>1	>1	>1
Step 2				
N-Europe	9.2600	>1	>1	<1
Step 3				
D3 / Ditch	2.0542	<1	<1	-
R1 / Pond	0.5199	<1	<1	-
R1 / Stream	2.4038	<1	<1	-
R3 / Stream	2.8084	<1	<1	-
R4 / Stream	3.6967	<1	>1	-
Step 4	**10 m vegetative strip + 10 m no spray buffer**			
R4 / Stream	1.6068	-	<1	-

9.5.2.2.8 Risk assessment of mixture toxicity based on Leafy vegetables

Table 9.5.2.2.3-33: Summary of assessment steps considered for the mixture risk assessment

Steps	Conclusion on the Steps		
	Fish	Invertebrates	Algae
Screening 1: ETR trigger (optional Step)	-	-	-
Screening 2: Driver (optional Step)	-	-	-
Step 1: data available?	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.
Step 2: apparent synergism or antagonism?	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.
Step 3: mixture similar or not?	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.
Step 4: ETRmix assessment (ECxPPP)	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).
Step 5: driver available?	There is no driver for fish in all scenarios. Go to Step 8.	There is no driver for invertebrates in all scenarios. Go to Step 8.	There is no driver for algae in all scenarios. Go to Step 8.
Step 6: driver assessment	-	-	-

Step 7: synergism assessment (few data)	-	-	-
Step 8a: ETRmix assessment	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**
Step 8b: RQmix assessment	-	-	-
Step 9: antagonism assessment	-	-	-
Step 10: synergism assessment	-	-	-

Overview of the assessment steps: Table 9.5.2.2-1 gives a summary of the decisions made for each organism group during the mixture risk assessment with respect to the decision scheme as provided by EFSA (2013, section 10.3.11). A discussion of all details of every decision is not intended in this section of this registration report. Further in-depth justification and explanation for the decisions made are documented in the attached mixture risk calculation file. However, at least data for some important steps are documented in this section of this registration report, beginning with the check for (and potentially assessment of) synergistic or antagonistic effects (Step 2 and Steps 7, 9 and 10) as well as the ETR_{mix} or RQ_{mix} calculation results for the assessed FOCUS Scenarios (Steps 4 and 8a/b).

Step 2: MDR calculation to check for synergistic or antagonistic effects

Table 9.5.2.2.3-34: Calculated mixture toxicity and MDR for each group of organisms (see sections 10.3.3 and 10.3.4 of EFSA (2013) for more details)

Species	Substance	Concentration (Ci) in formulation (g a.s./L)	Pi	ECxi (mg a.s./L)	ECxmix-CA (mg sum a.s. /L)	ECxPPP (mg sum a.s. /L)	MDR
Fish, acute toxicity 1							
Oncorhynchus mykiss	Azoxystrobin	200	0.62	0.47	0.603	0.496227771	1.21
Oncorhynchus mykiss	Difenoconazole	125	0.38	1.1			
Invertebrates, acute toxicity 1							
Daphnia	Azoxystrobin	200	0.62	0.23	0.315	0.321088558	0.98
Daphnia	Difenoconazole	125	0.38	0.77			
Algae							
Selenastrum capricornutum (green algae)	Azoxystrobin	200	0.62	0.36	0.073	0.17134453	0.43
Scenedesmus subspicatus (green alage)	Difenoconazole	125	0.38	0.032			

[1] For a possible inclusion of chronic toxicity please refer to the FAQ document distributed alongside the aquatic mixture toxicity calculation tool "AGD_AquaMix".

[2] MDR = 0.2 – 5 → Go to Step 3 (concentration addition (CA) approximately holds for the calculated mixture);

MDR > 5 → Go to Step 10 (the calculated mixture is more toxic than CA, i.e. synergistic);

MDR < 0.2 → Go to Step 9 (the calculated mixture is less toxic than CA, i.e. antagonistic)

The density of the liquid formulation of SCORPIO 3250 SC, equal to 1.1134 g/ml, was used in the performed calculations.

Step 3 Comparison of mixture composition of PPP and PEC_{mix}

According to Step 3 it has to be checked whether the mixture composition in the formulation is similar to the mixture composition at PEC_{mix} (which is the sum of PEC_i of individual active substances). Therefore, the "$ECx_{mix\text{-}CA}$ (a.s. in PPP) / $ECx_{mix\text{-}CA}$ (a.s. in PEC_{mix})" ratios were calculated.

In case the ratio is in the range of 0.8–1.2 (mixture similar), the risk assessment can be based on the ECx_{PPP} (Step 4).

In case the ratio is outside the range of 0.8–1.2 (i.e. mixture not similar), the endpoint $ECx_{mix\text{-}CA}$ normalized to the mixture composition at PEC_{mix} (reported as "$ECx_{mix\text{-}CA}$ (a.s. in PEC_{mix})" in EFSA, 2013, and the following parts of this report) has to be used to calculate the risk (Step 5 or Step 8, respectively).

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if product or calculated endpoint data (according to Step 3) have to be used. Further in-depth justification and explanation are documented in the attached mixture risk calculation file.

Step 5: Driver detection

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if a driver of risk is available according to Step 5. Further in-depth justification and explanation are documented in the attached mixture risk calculation file. Further information for the availability of a driver for the risk assessment of particular FOCUS Scenarios is given in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) and

Table 9.5.2.2-4 (FOCUS Step 4) below.

Step 4 and Step 8a: Mixture risk assessment based on measured and calculated mixture toxicity

Decisions taken when using the scheme as provided by EFSA (2013, section 10.3.11) lead to several assessment steps, which give a conclusion on the risk of a mixture or provide additional information important for the assessment. In the tables below the conclusions of different steps of the mixture risk assessment are summarized for the FOCUS Scenarios of concern. Information is reported on:

a) Step 2 and associated steps, in which the question is answered if concentration addition can be assumed (i.e. a standard mixture toxicity risk assessment is appropriate) or if an antagonism/synergism is possible (more detailed information on Step 2 is given above). This is important to derive if further, specific considerations have to be made in the risk assessment. Associated steps are Step 7, Step 9 and Step 10.
b) Step 5, in which the question is answered if there is a driver of risk and if so, which of the substance can be classified as driver (more detailed information on Step 5 is given the attached mixture risk calculation file). This is reported as additional information in case an assessment based on a driver would also be possible; for comparative reasons the table always lists the results from the mixture risk assessment according to Step 4 and/or Step 8. For an assessment based on a particular a.s. (the driver) please be referred to the individual a.s. risk assessment.
c) Step 4 with the assessment results for cases where product data are usable (according to Step 3) and the risk assessment can be carried out based on the measured toxicity.
d) Step 8 (a/b) with the assessment results for cases where product data are not usable (according to Step 3) and the risk assessment has to be based on calculated mixture toxicity.

The intermediate results of the mixture toxicity risk assessment are presented below for the respective FOCUS steps.

Table 9.5.2.2.3-35: Results of the mixture toxicity risk assessment (related to Step 8a) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in Leafy vegetables

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	Go to Step 4	0.422	0.854
Step 2			
N-Europe	Go to Step 4	0.066	0.132
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
D4/ pond	0.002	0.005	0.004
D4/ stream	Go to Step 4	Go to Step 4	0.022
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	Go to Step 4	Go to Step 4	Go to Step 4
R1/ stream	0.011	0.022	0.033
R2/ stream	Go to Step 4	Go to Step 4	0.023
R3/ stream	Go to Step 4	0.017	0.030
R4/ stream	Go to Step 4	0.030	0.048
Step 4	10 m vegetative strip, 10 m no spray buffer and no nozzle reduction		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
D4/ stream	0.002	0.005	0.007
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ stream	0.005	0.010	0.013
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	Go to Step 4	0.008	0.013
R4/ stream	Go to Step 4	0.014	0.022
Step 4	20 m vegetative strip, 10 m no spray buffer and no nozzle reduction		
R1/ stream	0.003	0.005	0.007
R4/ stream	0.004	0.007	0.010

Table 9.5.2.2.3-4: Results of the mixture toxicity risk assessment (related to Step 4) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in Leafy vegetables.

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	0.223	Go to Step 5/8	Go to Step 5/8
Step 2			
N-Europe	0.035	Go to Step 5/8	Go to Step 5/8
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	0.0045	0.006	0.010
D4/ pond	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
D4/ stream	0.00	0.007	Go to Step 5/8
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	0.001	0.002	0.004
R1/ stream	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
R2/ stream	0.004	0.007	Go to Step 5/8
R3/ stream	0.009	Go to Step 5/8	Go to Step 5/8
R4/ stream	0.015	Go to Step 5/8	Go to Step 5/8
Step 4	**10 m vegetative strip, 10 m no spray buffer and no nozzle reduction**		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	0.000	0.001	0.001
D4/ stream	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ stream	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	0.004	Go to Step 5/8	Go to Step 5/8
R4/ stream	0.007	Go to Step 5/8	Go to Step 5/8
Step 4	**20 m vegetative strip, 10 m no spray buffer and no nozzle reduction**		
R1/ stream	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
R4/ stream	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8

The respective assessment conclusions are presented in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) or

Table 9.5.2.2-4 (FOCUS Step 4). The assessment is based either on the exposure-toxicity ratio (ETR_{mix}) or the risk quotient (RQ_{mix}); the ETR_{mix} and RQ_{mix} are compared to respective trigger values: 1/10 or 1/100 for the ETR_{mix} (depending on the species assessed) and 1 for RQ_{mix}. For the sake of a concise assessment the results below are limited to the organism groups most at risk. Further in-depth justification and explanation for other organism groups are documented in the attached mixture risk calculation file.

Table 9.5.2.2.3-5: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for fish, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Leafy vegetables

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	0.223	Go to Step 4
Step 2				
N-Europe		Azoxystrobin	0.035	Go to Step 4
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.004	Go to Step 4
D4/ pond		Azoxystrobin	Go to Step 5/8	0.002
D4/ stream		no driver	0.005	Go to Step 4
D6/ ditch		Scenario is not relevant for Central Zone		
R1/ pond		no driver	0.001	Go to Step 4
R1/ stream		Azoxystrobin	Go to Step 5/8	0.011
R2/ stream		no driver	0.004	Go to Step 4
R3/ stream		Azoxystrobin	0.009	Go to Step 4
R4/ stream		Azoxystrobin	0.015	Go to Step 4

Table 9.5.2.2.3-6: Summary of the mixture toxicity risk assessment (related to Step 4) for fish based on FOCUS Step 4 calculations for application of Clapton 325 SC in Leafy vegetables

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.000		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.002		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.005		0.003
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.004		
50%										
75%										
90%										
None	R4 stream							0.007		0.004
50%										
75%										
90%										

Table 9.5.2.2.3-7: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for invertebrates, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Leafy vegetables

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	Go to Step 5/8	0.422
Step 2				
N-Europe		Azoxystrobin	Go to Step 5/8	0.066
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.006	Go to Step 4
D4/ pond		Azoxystrobin	Go to Step 5/8	0.005
D4/ stream		Azoxystrobin	0.007	Go to Step 4
D6/ ditch		Scenario is not relevant for Central Zone		
R1/ pond		no driver	0.002	Go to Step 4
R1/ stream		Azoxystrobin	Go to Step 5/8	0.022
R2/ stream		Azoxystrobin	0.007	Go to Step 4
R3/ stream		Azoxystrobin	Go to Step 5/8	0.017
R4/ stream		Azoxystrobin	Go to Step 5/8	0.030

Table 9.5.2.2.3-8: Summary of the mixture toxicity risk assessment (related to Step 4) for invertebrates based on FOCUS Step 4 calculations for application of Clapton 325 SC in Leafy vegetables

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.001		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.005		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.010		0.005
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.008		
50%										
75%										
90%										
None	R4 stream							0.014		0.007
50%										
75%										
90%										

Table 9.5.2.2.3-9: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for algae, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Leafy vegetables

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	no driver	Go to Step 5/8	0.854
Step 2				
N-Europe		no driver	Go to Step 5/8	0.132
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.010	Go to Step 4
D4/ pond		no driver	Go to Step 5/8	0.004
D4/ stream		no driver	Go to Step 5/8	0.022
D6/ ditch		Scenario is not relevant for Central Zone		
R1/ pond		no driver	0.004	Go to Step 4
R1/ stream		no driver	Go to Step 5/8	0.033
R2/ stream		no driver	Go to Step 5/8	0.023
R3/ stream		no driver	Go to Step 5/8	0.030
R4/ stream		no driver	Go to Step 5/8	0.048

Table 9.5.2.2.3-10: Summary of the mixture toxicity risk assessment (related to Step 4) for algae based on FOCUS Step 4 calculations for application of Clapton 325 SC in Leafy vegetables

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								

None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.001		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.007		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.013		0.007
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.013		
50%										
75%										
90%										
None	R4 stream							0.022		0.010
50%										
75%										
90%										

Table 9.5.2.2.3-361: Summary of mixture toxicity assessment for SCORPIO 325 SC for aquatic organisms for the use according to the GAP table for Leafy vegetables

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50}	E_rC_{50}	E_rC_{50}
AF		100	100	10
RAC_{mix} (µg/L)		496.227	321.088	171.345
FOCUS scenerio	PEC_{max} (µg/L)			
Step 1	110.5000	0.2227	0.3441	0.6449
Step 2				
N-Europe	17.2700	0.0348	0.0538	0.1008
Step 3				
D3 / Ditch	1.7972	0.0036	0.0056	0.0105
D4 / Pond	1.1086	0.0022	0.0035	0.0065

D4 / Stream	2.2476	0.0045	0.0070	0.0131
R1 / Pond	0.6291	0.0013	0.0020	0.0037
R1 / Stream	5.5504	0.0112	0.0173	0.0324
R2 / Stream	2.2146	0.0045	0.0069	0.0129
R3 / Stream	4.3106	0.0087	0.0134	0.0252
R4 / Stream	7.5450	0.0152	0.0235	0.0440
Step 4				
D3 / Ditch	0.2422	0.0005	0.0008	0.0014
D4 / Stream	1.2002	0.0024	0.0037	0.0070
R1 / Stream	1.2842	0.0026	0.0040	0.0075
R3 / Stream	2.1187	0.0043	0.0066	0.0124
R4 / Stream	1.7449	0.0035	0.0054	0.0102

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50} 496.227	E_rC_{50} 321.088	E_bC_{50} 171.345
AF		100	100	10
RAC_{mix} (µg/L)		4.962	3.211	17.135
FOCUS scenerio	**PEC_{max} (µg/L)**			
Step 1	110.5000	>1	>1	>1
Step 2				
N-Europe	17.2700	>1	>1	>1
Step 3				
D3 / Ditch	1.7972	<1	<1	<1
D4 / Pond	1.1086	<1	<1	<1
D4 / Stream	2.2476	<1	<1	<1
R1 / Pond	0.6291	<1	<1	<1
R1 / Stream	5.5504	>1	>1	<1
R3 / Stream	4.3106	<1	>1	<1
R4 / Stream	7.5450	>1	>1	<1
Step 4	**10 m vegetative strip + 10 m no spray buffer**			
R1 / Stream	1.2842	<1	<1	-
R3 / Stream	2.1187	<1	<1	-
R4 / Stream	1.7449	<1	<1	-

9.5.2.2.9 Risk assessment of mixture toxicity based on Maize (BBCH 31)

Table 9.5.2.2.3-37: Summary of assessment steps considered for the mixture risk assessment

Steps	Conclusion on the Steps		
	Fish	Invertebrates	Algae
Screening 1: ETR trigger (optional Step)	-	-	-
Screening 2: Driver (optional Step)	-	-	-
Step 1: data available?	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.
Step 2: apparent synergism or antagonism?	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.
Step 3: mixture similar or not?	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.
Step 4: ETRmix assessment (ECxPPP)	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).
Step 5: driver available?	There is no driver for fish in all scenarios. Go to Step 8.	There is no driver for invertebrates in all scenarios. Go to Step 8.	There is no driver for algae in all scenarios. Go to Step 8.
Step 6: driver assessment	-	-	-

Step 7: synergism assessment (few data)	-	-	-
Step 8a: ETRmix assessment	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**
Step 8b: RQmix assessment	-	-	-
Step 9: antagonism assessment	-	-	-
Step 10: synergism assessment	-	-	-

Overview of the assessment steps: Table 9.5.2.2-1 gives a summary of the decisions made for each organism group during the mixture risk assessment with respect to the decision scheme as provided by EFSA (2013, section 10.3.11). A discussion of all details of every decision is not intended in this section of this registration report. Further in-depth justification and explanation for the decisions made are documented in the attached mixture risk calculation file. However, at least data for some important steps are documented in this section of this registration report, beginning with the check for (and potentially assessment of) synergistic or antagonistic effects (Step 2 and Steps 7, 9 and 10) as well as the ETR_{mix} or RQ_{mix} calculation results for the assessed FOCUS Scenarios (Steps 4 and 8a/b).

Step 2: MDR calculation to check for synergistic or antagonistic effects

Table 9.5.2.2.3-38: Calculated mixture toxicity and MDR for each group of organisms (see sections 10.3.3 and 10.3.4 of EFSA (2013) for more details)

Species	Substance	Concentration (Ci) in formulation (g a.s./L)	Pi	ECxi (mg a.s./L)	ECxmix-CA (mg sum a.s. /L)	ECxPPP (mg sum a.s. /L)	MDR
Fish, acute toxicity 1							
Oncorhynchus mykiss	Azoxystrobin	200	0.62	0.47	0.603	0.496227771	1.21
Oncorhynchus mykiss	Difenoconazole	125	0.38	1.1			
Invertebrates, acute toxicity 1							
Daphnia	Azoxystrobin	200	0.62	0.23	0.315	0.321088558	0.98
Daphnia	Difenoconazole	125	0.38	0.77			
Algae							
Selenastrum capricornutum (green algae)	Azoxystrobin	200	0.62	0.36	0.073	0.17134453	0.43
Scenedesmus subspicatus (green alage)	Difenoconazole	125	0.38	0.032			

[1] For a possible inclusion of chronic toxicity please refer to the FAQ document distributed alongside the aquatic mixture toxicity calculation tool "AGD_AquaMix".

[2] MDR = 0.2 – 5 → Go to Step 3 (concentration addition (CA) approximately holds for the calculated mixture);

MDR > 5 → Go to Step 10 (the calculated mixture is more toxic than CA, i.e. synergistic);

MDR < 0.2 → Go to Step 9 (the calculated mixture is less toxic than CA, i.e. antagonistic)

The density of the liquid formulation of SCORPIO 3250 SC, equal to 1.1134 g/ml, was used in the performed calculations.

Step 3 Comparison of mixture composition of PPP and PEC_{mix}

According to Step 3 it has to be checked whether the mixture composition in the formulation is similar to the mixture composition at PEC_{mix} (which is the sum of PEC_i of individual active substances). Therefore,

the "ECx_{mix-CA} (a.s. in PPP) / ECx_{mix-CA} (a.s. in PEC_{mix})" ratios were calculated.

In case the ratio is in the range of 0.8–1.2 (mixture similar), the risk assessment can be based on the ECx_{PPP} (Step 4).

In case the ratio is outside the range of 0.8–1.2 (i.e. mixture not similar), the endpoint ECx_{mix-CA} normalized to the mixture composition at PEC_{mix} (reported as "ECx_{mix-CA} (a.s. in PEC_{mix})" in EFSA, 2013, and the following parts of this report) has to be used to calculate the risk (Step 5 or Step 8, respectively).

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if product or calculated endpoint data (according to Step 3) have to be used. Further in-depth justification and explanation are documented in the attached mixture risk calculation file.

Step 5: Driver detection

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if a driver of risk is available according to Step 5. Further in-depth justification and explanation are documented in the attached mixture risk calculation file. Further information for the availability of a driver for the risk assessment of particular FOCUS Scenarios is given in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) and

Table 9.5.2.2-4 (FOCUS Step 4) below.

Step 4 and Step 8a: Mixture risk assessment based on measured and calculated mixture toxicity

Decisions taken when using the scheme as provided by EFSA (2013, section 10.3.11) lead to several assessment steps, which give a conclusion on the risk of a mixture or provide additional information important for the assessment. In the tables below the conclusions of different steps of the mixture risk assessment are summarized for the FOCUS Scenarios of concern. Information is reported on:

cc) Step 2 and associated steps, in which the question is answered if concentration addition can be assumed (i.e. a standard mixture toxicity risk assessment is appropriate) or if an antagonism/synergism is possible (more detailed information on Step 2 is given above). This is important to derive if further, specific considerations have to be made in the risk assessment. Associated steps are Step 7, Step 9 and Step 10.

dd) Step 5, in which the question is answered if there is a driver of risk and if so, which of the substance can be classified as driver (more detailed information on Step 5 is given the attached mixture risk calculation file). This is reported as additional information in case an assessment based on a driver would also be possible; for comparative reasons the table always lists the results from the mixture risk assessment according to Step 4 and/or Step 8. For an assessment based on a particular a.s. (the driver) please be referred to the individual a.s. risk assessment.

ee) Step 4 with the assessment results for cases where product data are usable (according to Step 3) and the risk assessment can be carried out based on the measured toxicity.

ff) Step 8 (a/b) with the assessment results for cases where product data are not usable (according to Step 3) and the risk assessment has to be based on calculated mixture toxicity.

The intermediate results of the mixture toxicity risk assessment are presented below for the respective FOCUS steps.

Table 9.5.2.2.3-39: Results of the mixture toxicity risk assessment (related to Step 8a) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in maize (BBCH 31).

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	Go to Step 4	0.211	0.427
Step 2			
N-Europe	Go to Step 4	0.026	0.051
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
D4/ pond	0.001	0.003	0.002
D4/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D5/ pond	0.001	0.002	0.002
D5/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D6/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
R1/ pond	Go to Step 4	0.002	0.004
R1/ stream	Go to Step 4	0.011	0.021
R2/ stream	Go to Step 4	Go to Step 4	Go to Step 4
R3/ stream	Go to Step 4	Go to Step 4	0.027
R4/ stream	0.009	0.019	0.025
Step 4	10 m vegetative strip, 5 m no spray buffer and no nozzle reduction		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
D4/ stream	Go to Step 4	Go to Step 4	0.009
D5/ stream	Go to Step 4	Go to Step 4	Go to Step 4
R1/ stream	Go to Step 4	0.005	0.009
R3/ stream	Go to Step 4	Go to Step 4	0.012
R4/ stream	0.004	0.009	0.011

Table 9.5.2.2.3-4: Results of the mixture toxicity risk assessment (related to Step 4) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in maize (BBCH 31).

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	0.111	Go to Step 5/8	Go to Step 5/8
Step 2			
N-Europe	0.014	Go to Step 5/8	Go to Step 5/8
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	0.003	0.005	0.010
D4/ pond	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
D4/ stream	0.003	0.005	0.009
D5/ pond	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
D5/ stream	0.003	0.005	0.009
D6/ ditch	0.003	0.005	0.010
R1/ pond	0.001	Go to Step 5/8	Go to Step 5/8
R1/ stream	0.006	Go to Step 5/8	Go to Step 5/8
R2/ stream	0.003	0.005	0.009
R3/ stream	0.007	0.010	Go to Step 5/8
R4/ stream	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
Step 4	10 m vegetative strip, 5 m no spray buffer and no nozzle reduction		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	0.001	0.002	0.003
D4/ stream	0.002	0.003	Go to Step 5/8
D5/ stream	0.002	0.003	0.005
R1/ stream	0.003	Go to Step 5/8	Go to Step 5/8
R3/ stream	0.003	0.005	Go to Step 5/8
R4/ stream	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8

The respective assessment conclusions are presented in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) or

Table 9.5.2.2-4 (FOCUS Step 4). The assessment is based either on the exposure-toxicity ratio (ETR_{mix}) or the risk quotient (RQ_{mix}); the ETR_{mix} and RQ_{mix} are compared to respective trigger values: 1/10 or 1/100 for the ETR_{mix} (depending on the species assessed) and 1 for RQ_{mix}. For the sake of a concise assessment the results below are limited to the organism groups most at risk. Further in-depth justification and explanation for other organism groups are documented in the attached mixture risk calculation file.

Table 9.5.2.2.3-5: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for fish, for FOCUS Step 1 – 3 for application of Clapton 325 SC in maize (BBCH 31).

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	0.111	Go to Step 4
Step 2				
N-Europe		Azoxystrobin	0.014	Go to Step 4
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.003	Go to Step 4
D4/ pond		Azoxystrobin	Go to Step 5/8	0.001
D4/ stream		no driver	0.003	Go to Step 4
D5/ pond		Azoxystrobin	Go to Step 5/8	0.001
D5/ stream		no driver	0.003	Go to Step 4
D6/ ditch		no driver	0.003	Go to Step 4
R1/ pond		Azoxystrobin	0.001	Go to Step 4
R1/ stream		Azoxystrobin	0.006	Go to Step 4
R2/ stream		no driver	0.003	Go to Step 4
R3/ stream		Azoxystrobin	0.007	Go to Step 4
R4/ stream		Azoxystrobin	Go to Step 5/8	0.009

Table 9.5.2.2.3-6: Summary of the mixture toxicity risk assessment (related to Step 4) for fish based on FOCUS Step 4 calculations for application of Clapton 325 SC in maize (BBCH 31).

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.001		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.002		
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream							0.002		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.003		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.003		
50%										
75%										
90%										
None	R4 stream							0.004		
50%										

75%										
90%										

Table 9.5.2.2.3-7: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for invertebrates, for FOCUS Step 1 – 3 for application of Clapton 325 SC in maize (BBCH 31).

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	Go to Step 5/8	0.211
Step 2				
N-Europe		Azoxystrobin	Go to Step 5/8	0.026
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.005	Go to Step 4
D4/ pond		Azoxystrobin	Go to Step 5/8	0.003
D4/ stream		no driver	0.005	Go to Step 4
D5/ pond		Azoxystrobin	Go to Step 5/8	0.002
D5/ stream		no driver	0.005	Go to Step 4
D6/ ditch		no driver	0.005	Go to Step 4
R1/ pond		Azoxystrobin	Go to Step 5/8	0.002
R1/ stream		Azoxystrobin	Go to Step 5/8	0.011
R2/ stream		no driver	0.005	Go to Step 4
R3/ stream		Azoxystrobin	0.010	Go to Step 4
R4/ stream		Azoxystrobin	Go to Step 5/8	0.019

Table 9.5.2.2.3-8: Summary of the mixture toxicity risk assessment (related to Step 4) for invertebrates based on FOCUS Step 4 calculations for application of Clapton 325 SC in maize (BBCH 31).

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.002		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.003		
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream							0.003		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.005		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.005		
50%										
75%										
90%										
None	R4 stream							0.009		
50%										

75%										
90%										

Table 9.5.2.2.3-9: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for algae, for FOCUS Step 1 – 3 for application of Clapton 325 SC in maize (BBCH 31).

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	no driver	Go to Step 5/8	0.427
Step 2				
N-Europe		no driver	Go to Step 5/8	0.051
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.010	Go to Step 4
D4/ pond		no driver	Go to Step 5/8	0.002
D4/ stream		no driver	0.009	Go to Step 4
D5/ pond		no driver	Go to Step 5/8	0.002
D5/ stream		no driver	0.009	Go to Step 4
D6/ ditch		no driver	0.010	Go to Step 4
R1/ pond		no driver	Go to Step 5/8	0.004
R1/ stream		no driver	Go to Step 5/8	0.021
R2/ stream		no driver	0.009	Go to Step 4
R3/ stream		no driver	Go to Step 5/8	0.027
R4/ stream		no driver	Go to Step 5/8	0.025

Table 9.5.2.2.3-10: Summary of the mixture toxicity risk assessment (related to Step 4) for algae based on FOCUS Step 4 calculations for application of Clapton 325 SC in maize (BBCH 31).

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.003		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.009		
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream							0.005		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.009		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.012		
50%										
75%										
90%										
None	R4 stream							0.011		
50%										
75%										

90%										

Table 9.5.2.2.3-401: Summary of mixture toxicity assessment for SCORPIO 325 SC for aquatic organisms for the use according to the GAP table for Maize (BBCH 31)

Group		Fish acute	Inverteb. acute	Algae
Test species		Oncorhynchus mykiss	Daphnia magna	Pseudokirchn. subcapitata
Endpoint (µg/L)		E_rC_{50}	E_rC_{50}	E_bC_{50}
AF		100	100	10
RAC_{mix} (µg/L)		496.227	321.088	171.345
FOCUS scenerio	PEC_{max} (µg/L)			
Step 1	55.2500	0.1113	0.1721	0.3224
Step 2				
N-Europe	6.7400	0.0136	0.0210	0.0393
Step 3				
D3 / Ditch	1.6974	0.0034	0.0053	0.0099
D4 / Pond	0.6186	0.0012	0.0019	0.0036
D4 / Stream	1.5048	0.0030	0.0047	0.0088
D5 / Pond	0.4473	0.0009	0.0014	0.0026
D5 / Stream	1.6056	0.0032	0.0050	0.0094
D6 / Ditch	1.6916	0.0034	0.0053	0.0099
R1 / Pond	0.4621	0.0009	0.0014	0.0027
R1 / Stream	2.9185	0.0059	0.0091	0.0170
R2 / Stream	1.5800	0.0032	0.0049	0.0092
R3 / Stream	3.2826	0.0066	0.0102	0.0192
R4 / Stream	4.6452	0.0094	0.0145	0.0271
Step 4				
D3 / Ditch	0.5559	0.0011	0.0017	0.0032
D4 / Stream	0.8967	0.0018	0.0028	0.0052
D5 / Stream	0.8241	0.0017	0.0026	0.0048
R1 / Stream	1.3130	0.0026	0.0041	0.0077
R3 / Stream	1.4759	0.0030	0.0046	0.0086
R4 / Stream	2.0893	0.0042	0.0065	0.0122

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50} 496.227	E_rC_{50} 321.088	E_bC_{50} 171.345
AF		100	100	10
RAC_{mix} (µg/L)		4.962	3.211	17.135
FOCUS scenerio	PEC_{max} (µg/L)			
Step 1	55.2500	>1	>1	>1
Step 2				
N-Europe	6.7400	>1	>1	<1
Step 3				
D3 / Ditch	1.6974	<1	<1	-
D4 / Pond	0.6186	<1	<1	-
D4 / Stream	1.5048	<1	<1	-
D5 / Pond	0.4473	<1	<1	-
D5 / Stream	1.6056	<1	<1	-
R1 / Pond	0.4621	<1	<1	-
R1 / Stream	2.9185	<1	<1	-
R3 / Stream	3.2826	<1	>1	-
R4 / Stream	4.6452	<1	>1	-

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50} 496.227	E_rC_{50} 321.088	E_bC_{50} 171.345
AF		100	100	10
RAC_{mix} (µg/L)		4.962	3.211	17.135
FOCUS scenerio	**PEC_{max} (µg/L)**			
Step 4	**10 m vegetative strip + 5 m no spray buffer**			
R3 / Stream	1.4759	-	<1	-
R4 / Stream	2.0893	-	<1	-

9.5.2.2.10 Risk assessment of mixture toxicity based on Maize

Table 9.5.2.2.3-41: Summary of assessment steps considered for the mixture risk assessment

Steps	Conclusion on the Steps		
	Fish	Invertebrates	Algae
Screening 1: ETR trigger (optional Step)	-	-	-
Screening 2: Driver (optional Step)	-	-	-
Step 1: data available?	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.
Step 2: apparent synergism or antagonism?	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.
Step 3: mixture similar or not?	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.
Step 4: ETRmix assessment (ECxPPP)	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).
Step 5: driver available?	There is no driver for fish in all scenarios. Go to Step 8.	There is no driver for invertebrates in all scenarios. Go to Step 8.	There is no driver for algae in all scenarios. Go to Step 8.
Step 6: driver assessment	-	-	-

Step 7: synergism assessment (few data)	-	-	-
Step 8a: ETRmix assessment	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**
Step 8b: RQmix assessment	-	-	-
Step 9: antagonism assessment	-	-	-
Step 10: synergism assessment	-	-	-

Overview of the assessment steps: Table 9.5.2.2-1 gives a summary of the decisions made for each organism group during the mixture risk assessment with respect to the decision scheme as provided by EFSA (2013, section 10.3.11). A discussion of all details of every decision is not intended in this section of this registration report. Further in-depth justification and explanation for the decisions made are documented in the attached mixture risk calculation file. However, at least data for some important steps are documented in this section of this registration report, beginning with the check for (and potentially assessment of) synergistic or antagonistic effects (Step 2 and Steps 7, 9 and 10) as well as the ETR_{mix} or RQ_{mix} calculation results for the assessed FOCUS Scenarios (Steps 4 and 8a/b).

Step 2: MDR calculation to check for synergistic or antagonistic effects

Table 9.5.2.2.3-42: Calculated mixture toxicity and MDR for each group of organisms (see sections 10.3.3 and 10.3.4 of EFSA (2013) for more details)

Species	Substance	Concentration (Ci) in formulation (g a.s./L)	Pi	ECxi (mg a.s./L)	ECxmix-CA (mg sum a.s. /L)	ECxPPP (mg sum a.s. /L)	MDR
Fish, acute toxicity 1							
Oncorhynchus mykiss	Azoxystrobin	200	0.62	0.47	0.603	0.496227771	1.21
Oncorhynchus mykiss	Difenoconazole	125	0.38	1.1			
Invertebrates, acute toxicity 1							
Daphnia	Azoxystrobin	200	0.62	0.23	0.315	0.321088558	0.98
Daphnia	Difenoconazole	125	0.38	0.77			
Algae							
Selenastrum capricornutum (green algae)	Azoxystrobin	200	0.62	0.36	0.073	0.17134453	0.43
Scenedesmus subspicatus (green alage)	Difenoconazole	125	0.38	0.032			

[1] For a possible inclusion of chronic toxicity please refer to the FAQ document distributed alongside the aquatic mixture toxicity calculation tool "AGD_AquaMix".

[2] MDR = 0.2 – 5 → Go to Step 3 (concentration addition (CA) approximately holds for the calculated mixture);

MDR > 5 → Go to Step 10 (the calculated mixture is more toxic than CA, i.e. synergistic);

MDR < 0.2 → Go to Step 9 (the calculated mixture is less toxic than CA, i.e. antagonistic)

The density of the liquid formulation of SCORPIO 3250 SC, equal to 1.1134 g/ml, was used in the performed calculations.

Step 3 Comparison of mixture composition of PPP and PEC_{mix}

According to Step 3 it has to be checked whether the mixture composition in the formulation is similar to the mixture composition at PEC_{mix} (which is the sum of PEC_i of individual active substances). Therefore,

the "ECx_{mix-CA} (a.s. in PPP) / ECx_{mix-CA} (a.s. in PEC_{mix})" ratios were calculated.

In case the ratio is in the range of 0.8–1.2 (mixture similar), the risk assessment can be based on the ECx_{PPP} (Step 4).

In case the ratio is outside the range of 0.8–1.2 (i.e. mixture not similar), the endpoint ECx_{mix-CA} normalized to the mixture composition at PEC_{mix} (reported as "ECx_{mix-CA} (a.s. in PEC_{mix})" in EFSA, 2013, and the following parts of this report) has to be used to calculate the risk (Step 5 or Step 8, respectively).

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if product or calculated endpoint data (according to Step 3) have to be used. Further in-depth justification and explanation are documented in the attached mixture risk calculation file.

Step 5: Driver detection

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if a driver of risk is available according to Step 5. Further in-depth justification and explanation are documented in the attached mixture risk calculation file. Further information for the availability of a driver for the risk assessment of particular FOCUS Scenarios is given in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) and

Table 9.5.2.2-4 (FOCUS Step 4) below.

Step 4 and Step 8a: Mixture risk assessment based on measured and calculated mixture toxicity

Decisions taken when using the scheme as provided by EFSA (2013, section 10.3.11) lead to several assessment steps, which give a conclusion on the risk of a mixture or provide additional information important for the assessment. In the tables below the conclusions of different steps of the mixture risk assessment are summarized for the FOCUS Scenarios of concern. Information is reported on:

gg) Step 2 and associated steps, in which the question is answered if concentration addition can be assumed (i.e. a standard mixture toxicity risk assessment is appropriate) or if an antagonism/synergism is possible (more detailed information on Step 2 is given above). This is important to derive if further, specific considerations have to be made in the risk assessment. Associated steps are Step 7, Step 9 and Step 10.

hh) Step 5, in which the question is answered if there is a driver of risk and if so, which of the substance can be classified as driver (more detailed information on Step 5 is given the attached mixture risk calculation file). This is reported as additional information in case an assessment based on a driver would also be possible; for comparative reasons the table always lists the results from the mixture risk assessment according to Step 4 and/or Step 8. For an assessment based on a particular a.s. (the driver) please be referred to the individual a.s. risk assessment.

ii) Step 4 with the assessment results for cases where product data are usable (according to Step 3) and the risk assessment can be carried out based on the measured toxicity.

jj) Step 8 (a/b) with the assessment results for cases where product data are not usable (according to Step 3) and the risk assessment has to be based on calculated mixture toxicity.

The intermediate results of the mixture toxicity risk assessment are presented below for the respective FOCUS steps.

Table 9.5.2.2.3-43: Results of the mixture toxicity risk assessment (related to Step 8a) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in maize.

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	Go to Step 4	0.211	0.427
Step 2			
N-Europe	Go to Step 4	0.036	0.070
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
D4/ pond	0.001	0.002	0.002
D4/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D5/ pond	0.001	0.002	0.002
D5/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D6/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
R1/ pond	Go to Step 4	Go to Step 4	0.002
R1/ stream	Go to Step 4	0.011	0.021
R2/ stream	Go to Step 4	Go to Step 4	Go to Step 4
R3/ stream	Go to Step 4	0.015	0.029
R4/ stream	0.010	0.020	0.027
Step 4	10 m vegetative strip, 10 m no spray buffer and no nozzle reduction		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
D4/ stream	Go to Step 4	0.003	0.006
D5/ stream	Go to Step 4	Go to Step 4	0.006
R1/ stream	0.002	0.005	0.006
R3/ stream	0.003	0.007	0.009
R4/ stream	0.005	0.009	0.012

Table 9.5.2.2.3-4: Results of the mixture toxicity risk assessment (related to Step 4) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in maize.

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	0.111	Go to Step 5/8	Go to Step 5/8
Step 2			
N-Europe	0.019	Go to Step 5/8	Go to Step 5/8
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	0.003	0.005	0.010
D4/ pond	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
D4/ stream	0.003	0.005	0.009
D5/ pond	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
D5/ stream	0.003	0.005	0.009
D6/ ditch	0.003	0.005	0.010
R1/ pond	0.000	0.001	Go to Step 5/8
R1/ stream	0.006	Go to Step 5/8	Go to Step 5/8
R2/ stream	0.003	0.005	0.009
R3/ stream	0.008	Go to Step 5/8	Go to Step 5/8
R4/ stream	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
Step 4	10 m vegetative strip, 10 m no spray buffer and no nozzle reduction		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	0.001	0.001	0.002
D4/ stream	0.001	Go to Step 5/8	Go to Step 5/8
D5/ stream	0.001	0.002	Go to Step 5/8
R1/ stream	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
R3/ stream	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
R4/ stream	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8

The respective assessment conclusions are presented in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) or

Table 9.5.2.2-4 (FOCUS Step 4). The assessment is based either on the exposure-toxicity ratio (ETR_{mix}) or the risk quotient (RQ_{mix}); the ETR_{mix} and RQ_{mix} are compared to respective trigger values: 1/10 or 1/100 for the ETR_{mix} (depending on the species assessed) and 1 for RQ_{mix}. For the sake of a concise assessment the results below are limited to the organism groups most at risk. Further in-depth justification and explanation for other organism groups are documented in the attached mixture risk calculation file.

Table 9.5.2.2.3-5: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for fish, for FOCUS Step 1 – 3 for application of Clapton 325 SC in maize

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	0.111	Go to Step 4
Step 2				
N-Europe		Azoxystrobin	0.019	Go to Step 4
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.003	Go to Step 4
D4/ pond		Azoxystrobin	Go to Step 5/8	0.001
D4/ stream		no driver	0.003	Go to Step 4
D5/ pond		Azoxystrobin	Go to Step 5/8	0.001
D5/ stream		no driver	0.003	Go to Step 4
D6/ ditch		no driver	0.003	Go to Step 4
R1/ pond		no driver	0.000	Go to Step 4
R1/ stream		Azoxystrobin	0.006	Go to Step 4
R2/ stream		no driver	0.003	Go to Step 4
R3/ stream		Azoxystrobin	0.008	Go to Step 4
R4/ stream		Azoxystrobin	Go to Step 5/8	0.010

Table 9.5.2.2.3-6: Summary of the mixture toxicity risk assessment (related to Step 4) for fish based on FOCUS Step 4 calculations for application of Clapton 325 SC in maize

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.001		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.001		
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream							0.001		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.002		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.003		
50%										
75%										
90%										
None	R4 stream							0.005		
50%										
75%										

90%										

Table 9.5.2.2.3-7: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for invertebrates, for FOCUS Step 1 – 3 for application of Clapton 325 SC in maize

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	Go to Step 5/8	0.211
Step 2				
N-Europe		Azoxystrobin	Go to Step 5/8	0.036
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.005	Go to Step 4
D4/ pond		Azoxystrobin	Go to Step 5/8	0.002
D4/ stream		no driver	0.005	Go to Step 4
D5/ pond		Azoxystrobin	Go to Step 5/8	0.002
D5/ stream		no driver	0.005	Go to Step 4
D6/ ditch		no driver	0.005	Go to Step 4
R1/ pond		Azoxystrobin	0.001	Go to Step 4
R1/ stream		Azoxystrobin	Go to Step 5/8	0.011
R2/ stream		no driver	0.005	Go to Step 4
R3/ stream		Azoxystrobin	Go to Step 5/8	0.015
R4/ stream		Azoxystrobin	Go to Step 5/8	0.020

Table 9.5.2.2.3-8: Summary of the mixture toxicity risk assessment (related to Step 4) for invertebrates based on FOCUS Step 4 calculations for application of Clapton 325 SC in maize

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.001		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.003		
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream							0.002		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.005		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.007		
50%										
75%										
90%										
None	R4 stream							0.009		
50%										

75%										
90%										

Table 9.5.2.2.3-9: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for algae, for FOCUS Step 1 – 3 for application of Clapton 325 SC in maize

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	no driver	Go to Step 5/8	0.427
Step 2				
N-Europe		no driver	Go to Step 5/8	0.070
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.010	Go to Step 4
D4/ pond		no driver	Go to Step 5/8	0.002
D4/ stream		no driver	0.009	Go to Step 4
D5/ pond		no driver	Go to Step 5/8	0.002
D5/ stream		no driver	0.009	Go to Step 4
D6/ ditch		no driver	0.010	Go to Step 4
R1/ pond		no driver	Go to Step 5/8	0.002
R1/ stream		no driver	Go to Step 5/8	0.021
R2/ stream		no driver	0.009	Go to Step 4
R3/ stream		no driver	Go to Step 5/8	0.029
R4/ stream		no driver	Go to Step 5/8	0.027

Table 9.5.2.2.3-10: Summary of the mixture toxicity risk assessment (related to Step 4) for algae based on FOCUS Step 4 calculations for application of Clapton 325 SC in maize

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.002		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.006		
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream							0.006		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.006		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.009		
50%										
75%										
90%										
None	R4 stream							0.012		
50%										
75%										

90%										

Table 9.5.2.2.3-441: Summary of mixture toxicity assessment for SCORPIO 325 SC for aquatic organisms for the use according to the GAP table for Maize

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50}	E_rC_{50}	E_bC_{50}
AF		100	100	10
RAC_{mix} (µg/L)		496.227	321.088	171.345
FOCUS scenerio	PEC_{max} (µg/L)			
Step 1	55.2500	0.1113	0.1721	0.3224
Step 2				
N-Europe	9.2600	0.0187	0.0288	0.0540
Step 3				
D3 / Ditch	1.7007	0.0034	0.0053	0.0099
D4 / Pond	0.5470	0.0011	0.0017	0.0032
D4 / Stream	1.4568	0.0029	0.0045	0.0085
D5 / Pond	0.4266	0.0009	0.0013	0.0025
D5 / Stream	1.5239	0.0031	0.0047	0.0089
D6 / Ditch	1.7051	0.0034	0.0053	0.0100
R1 / Pond	0.2351	0.0005	0.0007	0.0014
R1 / Stream	2.9031	0.0059	0.0090	0.0169
R2 / Stream	1.5755	0.0032	0.0049	0.0092
R3 / Stream	3.9505	0.0080	0.0123	0.0231
R4 / Stream	4.9390	0.0100	0.0154	0.0288
Step 4				
D3 / Ditch	0.2951	0.0006	0.0009	0.0017
D4 / Stream	0.7131	0.0014	0.0022	0.0042
D5 / Stream	0.6763	0.0014	0.0021	0.0039
R1 / Stream	1.2221	0.0025	0.0038	0.0071
R3 / Stream	1.6374	0.0033	0.0051	0.0096
R4 / Stream	2.2363	0.0045	0.0070	0.0131

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50} 496.227	E_rC_{50} 321.088	E_bC_{50} 171.345
AF		100	100	10
RAC_{mix} (µg/L)		4.962	3.211	17.135
FOCUS scenerio	PEC_{max} (µg/L)			
Step 1	55.2500	>1	>1	>1
Step 2				
N-Europe	9.2600	>1	>1	<1
Step 3				
D3 / Ditch	1.7007	<1	<1	-
D4 / Pond	0.5470	<1	<1	-
D4 / Stream	1.4568	<1	<1	-
D5 / Pond	0.4266	<1	<1	-
D5 / Stream	1.5239	<1	<1	-
R1 / Pond	0.2351	<1	<1	-
R1 / Stream	2.9031	<1	<1	-
R3 / Stream	3.9505	<1	>1	-
R4 / Stream	4.9390	<1	>1	-

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50} 496.227	E_rC_{50} 321.088	E_bC_{50} 171.345
AF		100	100	10
RAC_{mix} (µg/L)		4.962	3.211	17.135
FOCUS scenerio	**PEC_{max} (µg/L)**			
Step 4	**10 m vegetative strip + 10 m no spray buffer**			
R3 / Stream	1.6374	-	<1	-
R4 / Stream	2.2363	-	<1	-

9.5.2.2.11 Risk assessment of mixture toxicity based on Pome Fruit

Table 9.5.2.2.3-45: Summary of assessment steps considered for the mixture risk assessment

Steps	Conclusion on the Steps		
	Fish	Invertebrates	Algae
Screening 1: ETR trigger (optional Step)	-	-	-
Screening 2: Driver (optional Step)	-	-	-
Step 1: data available?	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.
Step 2: apparent synergism or antagonism?	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.
Step 3: mixture similar or not?	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.
Step 4: ETRmix assessment (ECxPPP)	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).
Step 5: driver available?	There is no driver for fish in all scenarios. Go to Step 8.	There is no driver for invertebrates in all scenarios. Go to Step 8.	There is no driver for algae in all scenarios. Go to Step 8.
Step 6: driver assessment	-	-	-

Step 7: synergism assessment (few data)	-	-	-
Step 8a: ETRmix assessment	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**
Step 8b: RQmix assessment	-	-	-
Step 9: antagonism assessment	-	-	-
Step 10: synergism assessment	-	-	-

Overview of the assessment steps: Table 9.5.2.2-1 gives a summary of the decisions made for each organism group during the mixture risk assessment with respect to the decision scheme as provided by EFSA (2013, section 10.3.11). A discussion of all details of every decision is not intended in this section of this registration report. Further in-depth justification and explanation for the decisions made are documented in the attached mixture risk calculation file. However, at least data for some important steps are documented in this section of this registration report, beginning with the check for (and potentially assessment of) synergistic or antagonistic effects (Step 2 and Steps 7, 9 and 10) as well as the ETR_{mix} or RQ_{mix} calculation results for the assessed FOCUS Scenarios (Steps 4 and 8a/b).

Step 2: MDR calculation to check for synergistic or antagonistic effects

Table 9.5.2.2.3-46: Calculated mixture toxicity and MDR for each group of organisms (see sections 10.3.3 and 10.3.4 of EFSA (2013) for more details)

Species	Substance	Concentration (Ci) in formulation (g a.s./L)	Pi	ECxi (mg a.s./L)	ECxmix-CA (mg sum a.s. /L)	ECxPPP (mg sum a.s. /L)	MDR
Fish, acute toxicity 1							
Oncorhynchus mykiss	Azoxystrobin	200	0.62	0.47	0.603	0.496227771	1.21
Oncorhynchus mykiss	Difenoconazole	125	0.38	1.1			
Invertebrates, acute toxicity 1							
Daphnia	Azoxystrobin	200	0.62	0.23	0.315	0.321088558	0.98
Daphnia	Difenoconazole	125	0.38	0.77			
Algae							
Selenastrum capricornutum (green algae)	Azoxystrobin	200	0.62	0.36	0.073	0.17134453	0.43
Scenedesmus subspicatus (green alage)	Difenoconazole	125	0.38	0.032			

[1] For a possible inclusion of chronic toxicity please refer to the FAQ document distributed alongside the aquatic mixture toxicity calculation tool "AGD_AquaMix".

[2] MDR = 0.2 – 5 → Go to Step 3 (concentration addition (CA) approximately holds for the calculated mixture);

MDR > 5 → Go to Step 10 (the calculated mixture is more toxic than CA, i.e. synergistic);

MDR < 0.2 → Go to Step 9 (the calculated mixture is less toxic than CA, i.e. antagonistic)

The density of the liquid formulation of SCORPIO 3250 SC, equal to 1.1134 g/ml, was used in the performed calculations.

Step 3 Comparison of mixture composition of PPP and PEC_{mix}

According to Step 3 it has to be checked whether the mixture composition in the formulation is similar to the mixture composition at PEC_{mix} (which is the sum of PEC_i of individual active substances). Therefore,

the "ECx_{mix-CA} (a.s. in PPP) / ECx_{mix-CA} (a.s. in PEC_{mix})" ratios were calculated.

In case the ratio is in the range of 0.8–1.2 (mixture similar), the risk assessment can be based on the ECx_{PPP} (Step 4).

In case the ratio is outside the range of 0.8–1.2 (i.e. mixture not similar), the endpoint ECx_{mix-CA} normalized to the mixture composition at PEC_{mix} (reported as "ECx_{mix-CA} (a.s. in PEC_{mix})" in EFSA, 2013, and the following parts of this report) has to be used to calculate the risk (Step 5 or Step 8, respectively).

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if product or calculated endpoint data (according to Step 3) have to be used. Further in-depth justification and explanation are documented in the attached mixture risk calculation file.

Step 5: Driver detection

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if a driver of risk is available according to Step 5. Further in-depth justification and explanation are documented in the attached mixture risk calculation file. Further information for the availability of a driver for the risk assessment of particular FOCUS Scenarios is given in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) and

Table 9.5.2.2-4 (FOCUS Step 4) below.

Step 4 and Step 8a: Mixture risk assessment based on measured and calculated mixture toxicity

Decisions taken when using the scheme as provided by EFSA (2013, section 10.3.11) lead to several assessment steps, which give a conclusion on the risk of a mixture or provide additional information important for the assessment. In the tables below the conclusions of different steps of the mixture risk assessment are summarized for the FOCUS Scenarios of concern. Information is reported on:

kk) Step 2 and associated steps, in which the question is answered if concentration addition can be assumed (i.e. a standard mixture toxicity risk assessment is appropriate) or if an antagonism/synergism is possible (more detailed information on Step 2 is given above). This is important to derive if further, specific considerations have to be made in the risk assessment. Associated steps are Step 7, Step 9 and Step 10.

ll) Step 5, in which the question is answered if there is a driver of risk and if so, which of the substance can be classified as driver (more detailed information on Step 5 is given the attached mixture risk calculation file). This is reported as additional information in case an assessment based on a driver would also be possible; for comparative reasons the table always lists the results from the mixture risk assessment according to Step 4 and/or Step 8. For an assessment based on a particular a.s. (the driver) please be referred to the individual a.s. risk assessment.

mm) Step 4 with the assessment results for cases where product data are usable (according to Step 3) and the risk assessment can be carried out based on the measured toxicity.

nn) Step 8 (a/b) with the assessment results for cases where product data are not usable (according to Step 3) and the risk assessment has to be based on calculated mixture toxicity.

The intermediate results of the mixture toxicity risk assessment are presented below for the respective FOCUS steps.

Table 9.5.2.2.3-47: Results of the mixture toxicity risk assessment (related to Step 8a) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in pome fruit.

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	Go to Step 4	Go to Step 4	1.641
Step 2			
N-Europe	Go to Step 4	Go to Step 4	0.517
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	Go to Step 4	Go to Step 4	0.283
D4/ pond	Go to Step 4	Go to Step 4	Go to Step 4
D4/ stream	Go to Step 4	Go to Step 4	0.286
D5/ pond	Go to Step 4	Go to Step 4	Go to Step 4
D5/ stream	Go to Step 4	Go to Step 4	0.303
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	Go to Step 4	Go to Step 4	0.029
R1/ stream	Go to Step 4	Go to Step 4	0.227
R2/ stream	Go to Step 4	Go to Step 4	0.301
R3/ stream	Go to Step 4	Go to Step 4	0.321
R4/ stream	Go to Step 4	Go to Step 4	0.228
Step 4	20 m vegetative strip, 20 m no spray buffer and 75% nozzle reduction		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	Go to Step 4	Go to Step 4	0.008
D4/ pond	Go to Step 4	Go to Step 4	0.009
D5/ stream	Go to Step 4	Go to Step 4	0.010
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ stream	Go to Step 4	Go to Step 4	0.007
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	Go to Step 4	Go to Step 4	Go to Step 4
R4/ stream	Go to Step 4	Go to Step 4	Go to Step 4

Table 9.5.2.2.3-4: Results of the mixture toxicity risk assessment (related to Step 4) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in pome fruit.

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	0.338	0.523	Go to Step 5/8
Step 2			
N-Europe	0.097	0.149	Go to Step 5/8
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	0.034	0.052	Go to Step 5/8
D4/ pond	0.003	0.005	0.009
D4/ stream	0.034	0.052	Go to Step 5/8
D5/ pond	0.004	0.006	0.011
D5/ stream	0.036	0.056	Go to Step 5/8
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	0.004	0.006	Go to Step 5/8
R1/ stream	0.027	0.042	Go to Step 5/8
R2/ stream	0.036	0.055	Go to Step 5/8
R3/ stream	0.038	0.059	Go to Step 5/8
R4/ stream	0.027	0.042	Go to Step 5/8
Step 4	20 m vegetative strip, 20 m no spray buffer and 75% nozzle reduction		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	0.001	0.002	Go to Step 5/8
D4/ stream	0.001	0.002	Go to Step 5/8
D5/ stream	0.001	0.002	Go to Step 5/8
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ stream	0.001	0.001	Go to Step 5/8
R3/ stream	0.001	0.002	0.004
R4/ stream	0.001	0.001	0.003

The respective assessment conclusions are presented in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) or

Table 9.5.2.2-4 (FOCUS Step 4). The assessment is based either on the exposure-toxicity ratio (ETR_{mix}) or the risk quotient (RQ_{mix}); the ETR_{mix} and RQ_{mix} are compared to respective trigger values: 1/10 or 1/100 for the ETR_{mix} (depending on the species assessed) and 1 for RQ_{mix}. For the sake of a concise assessment the results below are limited to the organism groups most at risk. Further in-depth justification and explanation for other organism groups are documented in the attached mixture risk calculation file.

Table 9.5.2.2.3-5: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for fish, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Pome fruit

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	no driver	**0.338**	Go to Step 4
Step 2				
N-Europe		no driver	**0.097**	Go to Step 4
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.033	Go to Step 4
D4/ pond		no driver	0.003	Go to Step 4
D4/ stream		no driver	0.034	Go to Step 4
D5/ pond		no driver	0.004	Go to Step 4
D5/ stream		no driver	0.036	Go to Step 4
D6/ ditch		Scenario is not relevant for Central Zone		
R1/ pond		no driver	0.004	Go to Step 4
R1/ stream		no driver	0.027	Go to Step 4
R2/ stream		no driver	0.036	Go to Step 4
R3/ stream		no driver	0.038	Go to Step 4
R4/ stream		no driver	0.027	Go to Step 4

Table 9.5.2.2.3-6: Summary of the mixture toxicity risk assessment (related to Step 4) for fish based on FOCUS Step 4 calculations for application of Clapton 325 SC in Pome fruit

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch									
50%										
75%										0.001
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream									
50%										
75%										0.001
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream									
50%										
75%										0.001
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream									
50%										
75%										0.001
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream									
50%										
75%										0.001
90%										
None	R4 stream									
50%										
75%										0.001

90%										

Table 9.5.2.2.3-7: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for invertebrates, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Pome fruit

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	0.523	Go to Step 4
Step 2				
N-Europe		no driver	0.149	Go to Step 4
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.052	Go to Step 4
D4/ pond		no driver	0.005	Go to Step 4
D4/ stream		no driver	0.052	Go to Step 4
D5/ pond		no driver	0.006	Go to Step 4
D5/ stream		no driver	0.056	Go to Step 4
D6/ ditch		Scenario is not relevant for Central Zone		
R1/ pond		no driver	0.006	Go to Step 4
R1/ stream		no driver	0.042	Go to Step 4
R2/ stream		no driver	0.055	Go to Step 4
R3/ stream		no driver	0.059	Go to Step 4
R4/ stream		no driver	0.042	Go to Step 4

Table 9.5.2.2.3-8: Summary of the mixture toxicity risk assessment (related to Step 4) for invertebrates based on FOCUS Step 4 calculations for application of Clapton 325 SC in Pome fruit

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch									
50%										
75%										0.002
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream									
50%										
75%										0.002
90%										
None	D5 stream									
50%										
75%										0.002
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream									
50%										
75%										0.001
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream									
50%										
75%										0.002
90%										

None	R4 stream									
50%										
75%										0.001
90%										

Table 9.5.2.2.3-9: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for algae, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Pome fruit

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	no driver	Go to Step 5/8	1.641
Step 2				
N-Europe		no driver	Go to Step 5/8	0.517
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		Difenoconazole	Go to Step 5/8	0.283
D4/ pond		Difenoconazole	0.01	Go to Step 4
D4/ stream		Difenoconazole	Go to Step 5/8	0.286
D5/ pond		Difenoconazole	0.01	Go to Step 4
D5/ stream		Difenoconazole	Go to Step 5/8	0.303
D6/ ditch		Scenario is not relevant for Central Zone		
R1/ pond		Difenoconazole	Go to Step 5/8	0.029
R1/ stream		Difenoconazole	Go to Step 5/8	0.227
R2/ stream		Difenoconazole	Go to Step 5/8	0.301
R3/ stream		Difenoconazole	Go to Step 5/8	0.321
R4/ stream		Difenoconazole	Go to Step 5/8	0.228

Table 9.5.2.2.3-10: Summary of the mixture toxicity risk assessment (related to Step 4) for algae based on FOCUS Step 4 calculations for application of Clapton 325 SC in Pome fruit

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch									
50%										
75%										0.008
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream									
50%										
75%										0.009
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream									
50%										
75%										0.010
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream									
50%										
75%										0.007
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream									
50%										
75%										0.004
90%										
None	R4 stream									
50%										
75%										0.003

90%										

Table 9.5.2.2.3-481: Summary of mixture toxicity assessment for SCORPIO 325 SC for aquatic organisms for the use according to the GAP table for Pome Fruit

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50}	E_rC_{50}	E_bC_{50}
AF		100	100	10
RAC_{mix} (µg/L)		496.227	321.088	171.345
FOCUS scenerio	PEC_{max} (µg/L)			
Step 1	167.7900	0.3381	0.5226	0.9793
Step 2				
N-Europe	47.9400	0.0966	0.1493	0.2798
Step 3				
D3 / Ditch	16.6820	0.0336	0.0520	0.0974
D4 / Pond	1.5743	0.0032	0.0049	0.0092
D4 / Stream	16.8560	0.0340	0.0525	0.0984
D5 / Pond	1.8611	0.0038	0.0058	0.0109
D5 / Stream	17.8630	0.0360	0.0556	0.1043
R1 / Pond	1.7670	0.0036	0.0055	0.0103
R1 / Stream	13.3670	0.0269	0.0416	0.0780
R2 / Stream	17.7360	0.0357	0.0552	0.1035
R3 / Stream	18.9220	0.0381	0.0589	0.1104
R4 / Stream	13.4460	0.0271	0.0419	0.0785
Step 4				
D3 / Ditch	0.4911	0.0010	0.0015	0.0029
D4 / Stream	0.5461	0.0011	0.0017	0.0032
D5 / Stream	0.5795	0.0012	0.0018	0.0034
R1 / Stream	0.4331	0.0009	0.0013	0.0025
R3 / Stream	0.6579	0.0013	0.0020	0.0038
R4 / Stream	0.4512	0.0009	0.0014	0.0026

Summary of mixture toxicity assessment for SCORPIO 325 SC for aquatic organisms for the use according to the GAP table for Pome Fruit (BBCH 10)

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50} 496.227	E_rC_{50} 321.088	E_bC_{50} 171.345
AF		100	100	10
RAC_{mix} (µg/L)		4.962	3.211	17.135
FOCUS scenerio	PEC_{max} (µg/L)			
Step 1	167.8	>1	>1	>1
Step 2				
N-Europe	47.94	>1	>1	>1
Step 3				
D3 / Ditch	16.682	>1	>1	<1
D4 / Pond	1.5743	<1	<1	<1
D4 / Stream	16.856	>1	>1	<1
D5 / Pond	1.861	<1	<1	<1
D5 / Stream	17.86	>1	>1	>1
R1 / Pond	1.767	<1	<1	<1
R1 / Stream	13.367	>1	>1	<1
R3 / Stream	18.922	>1	>1	>1
R4 / Stream	13.446	>1	>1	<1

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50} 496.227	E_rC_{50} 321.088	E_bC_{50} 171.345
AF		100	100	10
RAC_{mix} (µg/L)		4.962	3.211	17.135
FOCUS scenerio	**PEC_{max} (µg/L)**			
Step 4	**20 vegetative strip + 20 no spray buffer + 75% nozzle reduction**			
D3 / Ditch	0.4911	<1	<1	<1
D4 / Stream	0.5461	<1	<1	<1
D5 / Stream	0.5795	<1	<1	<1
R1 / Stream	0.4331	<1	<1	<1
R3 / Stream	0.6579	<1	<1	<1
R4 / Stream	0.4512	<1	<1	<1

9.5.2.2.12 Risk assessment of mixture toxicity based on Potatoes (BBCH 31)

Table 9.5.2.2.3-49: Summary of assessment steps considered for the mixture risk assessment

Steps	Conclusion on the Steps		
	Fish	Invertebrates	Algae
Screening 1: ETR trigger (optional Step)	-	-	-
Screening 2: Driver (optional Step)	-	-	-
Step 1: data available?	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.
Step 2: apparent synergism or antagonism?	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.
Step 3: mixture similar or not?	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.
Step 4: ETRmix assessment (ECxPPP)	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).
Step 5: driver available?	There is no driver for fish in all scenarios. Go to Step 8.	There is no driver for invertebrates in all scenarios. Go to Step 8.	There is no driver for algae in all scenarios. Go to Step 8.
Step 6: driver assessment	-	-	-

Step 7: synergism assessment (few data)	-	-	-
Step 8a: ETRmix assessment	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**
Step 8b: RQmix assessment	-	-	-
Step 9: antagonism assessment	-	-	-
Step 10: synergism assessment	-	-	-

Overview of the assessment steps: Table 9.5.2.2-1 gives a summary of the decisions made for each organism group during the mixture risk assessment with respect to the decision scheme as provided by EFSA (2013, section 10.3.11). A discussion of all details of every decision is not intended in this section of this registration report. Further in-depth justification and explanation for the decisions made are documented in the attached mixture risk calculation file. However, at least data for some important steps are documented in this section of this registration report, beginning with the check for (and potentially assessment of) synergistic or antagonistic effects (Step 2 and Steps 7, 9 and 10) as well as the ETR_{mix} or RQ_{mix} calculation results for the assessed FOCUS Scenarios (Steps 4 and 8a/b).

Step 2: MDR calculation to check for synergistic or antagonistic effects

Table 9.5.2.2.3-50: Calculated mixture toxicity and MDR for each group of organisms (see sections 10.3.3 and 10.3.4 of EFSA (2013) for more details)

Species	Substance	Concentration (Ci) in formulation (g a.s./L)	Pi	ECxi (mg a.s./L)	ECxmix-CA (mg sum a.s. /L)	ECxPPP (mg sum a.s. /L)	MDR
Fish, acute toxicity 1							
Oncorhynchus mykiss	Azoxystrobin	200	0.62	0.47	0.603	0.496227771	1.21
Oncorhynchus mykiss	Difenoconazole	125	0.38	1.1			
Invertebrates, acute toxicity 1							
Daphnia	Azoxystrobin	200	0.62	0.23	0.315	0.321088558	0.98
Daphnia	Difenoconazole	125	0.38	0.77			
Algae							
Selenastrum capricornutum (green algae)	Azoxystrobin	200	0.62	0.36	0.073	0.17134453	0.43
Scenedesmus subspicatus (green alage)	Difenoconazole	125	0.38	0.032			

[1] For a possible inclusion of chronic toxicity please refer to the FAQ document distributed alongside the aquatic mixture toxicity calculation tool "AGD_AquaMix".

[2] MDR = 0.2 – 5 → Go to Step 3 (concentration addition (CA) approximately holds for the calculated mixture);

MDR > 5 → Go to Step 10 (the calculated mixture is more toxic than CA, i.e. synergistic);

MDR < 0.2 → Go to Step 9 (the calculated mixture is less toxic than CA, i.e. antagonistic)

The density of the liquid formulation of SCORPIO 3250 SC, equal to 1.1134 g/ml, was used in the performed calculations.

Step 3 Comparison of mixture composition of PPP and PEC_{mix}

According to Step 3 it has to be checked whether the mixture composition in the formulation is similar to the mixture composition at PEC_{mix} (which is the sum of PEC_i of individual active substances). Therefore,

the "ECx_{mix-CA} (a.s. in PPP) / ECx_{mix-CA} (a.s. in PEC_{mix})" ratios were calculated.

In case the ratio is in the range of 0.8–1.2 (mixture similar), the risk assessment can be based on the ECx_{PPP} (Step 4).

In case the ratio is outside the range of 0.8–1.2 (i.e. mixture not similar), the endpoint ECx_{mix-CA} normalized to the mixture composition at PEC_{mix} (reported as "ECx_{mix-CA} (a.s. in PEC_{mix})" in EFSA, 2013, and the following parts of this report) has to be used to calculate the risk (Step 5 or Step 8, respectively).

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if product or calculated endpoint data (according to Step 3) have to be used. Further in-depth justification and explanation are documented in the attached mixture risk calculation file.

Step 5: Driver detection

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if a driver of risk is available according to Step 5. Further in-depth justification and explanation are documented in the attached mixture risk calculation file. Further information for the availability of a driver for the risk assessment of particular FOCUS Scenarios is given in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) and

Table 9.5.2.2-4 (FOCUS Step 4) below.

Step 4 and Step 8a: Mixture risk assessment based on measured and calculated mixture toxicity

Decisions taken when using the scheme as provided by EFSA (2013, section 10.3.11) lead to several assessment steps, which give a conclusion on the risk of a mixture or provide additional information important for the assessment. In the tables below the conclusions of different steps of the mixture risk assessment are summarized for the FOCUS Scenarios of concern. Information is reported on:

oo) Step 2 and associated steps, in which the question is answered if concentration addition can be assumed (i.e. a standard mixture toxicity risk assessment is appropriate) or if an antagonism/synergism is possible (more detailed information on Step 2 is given above). This is important to derive if further, specific considerations have to be made in the risk assessment. Associated steps are Step 7, Step 9 and Step 10.

pp) Step 5, in which the question is answered if there is a driver of risk and if so, which of the substance can be classified as driver (more detailed information on Step 5 is given the attached mixture risk calculation file). This is reported as additional information in case an assessment based on a driver would also be possible; for comparative reasons the table always lists the results from the mixture risk assessment according to Step 4 and/or Step 8. For an assessment based on a particular a.s. (the driver) please be referred to the individual a.s. risk assessment.

qq) Step 4 with the assessment results for cases where product data are usable (according to Step 3) and the risk assessment can be carried out based on the measured toxicity.

rr) Step 8 (a/b) with the assessment results for cases where product data are not usable (according to Step 3) and the risk assessment has to be based on calculated mixture toxicity.

The intermediate results of the mixture toxicity risk assessment are presented below for the respective FOCUS steps.

Table 9.5.2.2.3-51: Results of the mixture toxicity risk assessment (related to Step 8a) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in Potatoes (BBCH 31).

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	Go to Step 4	0.211	0.427
Step 2			
N-Europe	Go to Step 4	Go to Step 4	0.047
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
D4/ pond	0.002	0.004	0.003
D4/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D6/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
R1/ pond	Go to Step 4	Go to Step 4	0.003
R1/ stream	Go to Step 4	Go to Step 4	0.020
R2/ stream	Go to Step 4	Go to Step 4	Go to Step 4
R3/ stream	Go to Step 4	Go to Step 4	0.027
Step 4	10 m vegetative strip, 5 m no spray buffer and no nozzle reduction		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
D4/ stream	Go to Step 4	Go to Step 4	0.009
R1/ stream	Go to Step 4	0.004	0.008
R3/ stream	Go to Step 4	Go to Step 4	0.012

Table 9.5.2.2.3-4: Results of the mixture toxicity risk assessment (related to Step 4) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in Potatoes (BBCH 31).

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	0.111	Go to Step 5/8	Go to Step 5/8
Step 2			
N-Europe	0.010	0.016	Go to Step 5/8
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	0.003	0.005	0.010
D4/ pond	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
D4/ stream	0.003	0.004	0.008
D6/ ditch	0.003	0.005	0.010
R1/ pond	0.001	0.001	Go to Step 5/8
R1/ stream	0.005	0.008	Go to Step 5/8
R2/ stream	0.003	0.005	0.009
R3/ stream	0.007	0.010	Go to Step 5/8
Step 4	10 m vegetative strip, 5 m no spray buffer and no nozzle reduction		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	0.001	0.002	0.003
D4/ stream	0.002	0.003	Go to Step 5/8
R1/ stream	0.002	Go to Step 5/8	Go to Step 5/8
R3/ stream	0.003	0.005	Go to Step 5/8

The respective assessment conclusions are presented in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) or

Table 9.5.2.2-4 (FOCUS Step 4). The assessment is based either on the exposure-toxicity ratio (ETR_{mix}) or the risk quotient (RQ_{mix}); the ETR_{mix} and RQ_{mix} are compared to respective trigger values: 1/10 or 1/100 for the ETR_{mix} (depending on the species assessed) and 1 for RQ_{mix}. For the sake of a concise assessment the results below are limited to the organism groups most at risk. Further in-depth justification and explanation for other organism groups are documented in the attached mixture risk calculation file.

Table 9.5.2.2.3-5: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for fish, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Potatoes (BBCH 31).

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	0.111	Go to Step 4
Step 2				
N-Europe		no driver	0.010	Go to Step 4
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.003	Go to Step 4
D4/ pond		Azoxystrobin	Go to Step 5/8	0.002
D4/ stream		no driver	0.003	Go to Step 4
D6/ ditch		no driver	0.003	Go to Step 4
R1/ pond		Azoxystrobin	0.001	Go to Step 4
R1/ stream		Azoxystrobin	0.005	Go to Step 4
R2/ stream		no driver	0.003	Go to Step 4
R3/ stream		Azoxystrobin	0.007	Go to Step 4

Table 9.5.2.2.3-6: Summary of the mixture toxicity risk assessment (related to Step 4) for fish based on FOCUS Step 4 calculations for application of Clapton 325 SC in Potatoes (BBCH 31).

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.001		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.002		
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.002		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.003		
50%										
75%										
90%										

Table 9.5.2.2.3-7: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for invertebrates, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Potatoes (BBCH 31).

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	Go to Step 5/8	0.211
Step 2				
N-Europe		Azoxystrobin	0.016	Go to Step 4
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.005	Go to Step 4
D4/ pond		Azoxystrobin	Go to Step 5/8	0.004
D4/ stream		no driver	0.004	Go to Step 4
D6/ ditch		no driver	0.005	Go to Step 4
R1/ pond		Azoxystrobin	0.001	Go to Step 4
R1/ stream		Azoxystrobin	0.008	Go to Step 4
R2/ stream		no driver	0.005	Go to Step 4
R3/ stream		Azoxystrobin	0.010	Go to Step 4

Table 9.5.2.2.3-8: Summary of the mixture toxicity risk assessment (related to Step 4) for invertebrates based on FOCUS Step 4 calculations for application of Clapton 325 SC in Potatoes (BBCH 31).

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.002		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.003		
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.004		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.005		
50%										
75%										
90%										

Table 9.5.2.2.3-9: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for algae, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Potatoes (BBCH 31).

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	no driver	Go to Step 5/8	0.427
Step 2				
N-Europe		no driver	Go to Step 5/8	0.047
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.010	Go to Step 4
D4/ pond		no driver	Go to Step 5/8	0.003
D4/ stream		no driver	0.008	Go to Step 4
D6/ ditch		no driver	0.010	Go to Step 4
R1/ pond		no driver	Go to Step 5/8	0.003
R1/ stream		no driver	Go to Step 5/8	0.020
R2/ stream		no driver	0.009	Go to Step 4
R3/ stream		no driver	Go to Step 5/8	0.027

Table 9.5.2.2.3-10: Summary of the mixture toxicity risk assessment (related to Step 4) for algae based on FOCUS Step 4 calculations for application of Clapton 325 SC in Potatoes (BBCH 31).

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.003		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.009		
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.008		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.012		
50%										
75%										
90%										

Table 9.5.2.2.3-521: Summary of mixture toxicity assessment for SCORPIO 325 SC for aquatic organisms for the use according to the GAP table for Potatoes (BBCH 31)

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50}	E_rC_{50}	E_bC_{50}
AF		100	100	10
RAC_{mix} (µg/L)		496.227	321.088	171.345
FOCUS scenerio	PEC_{max} (µg/L)			
Step 1	55.2500	0.1113	0.1721	0.3224
Step 2				
N-Europe	5.0400	0.0102	0.0157	0.0294
Step 3				
D3 / Ditch	1.6990	0.0034	0.0053	0.0099
D4 / Pond	0.8714	0.0018	0.0027	0.0051
D4 / Stream	1.3224	0.0027	0.0041	0.0077
D6 / Ditch	1.6934	0.0034	0.0053	0.0099
R1 / Pond	0.3710	0.0007	0.0012	0.0022
R1 / Stream	2.4340	0.0049	0.0076	0.0142
R2 / Stream	1.5556	0.0031	0.0048	0.0091
R3 / Stream	3.3525	0.0068	0.0104	0.0196
Step 4				
D3 / Ditch	0.5564	0.0011	0.0017	0.0032
D4 / Stream	1.0498	0.0021	0.0033	0.0061
R1 / Stream	1.9220	0.0039	0.0060	0.0112
R3 / Stream	1.5010	0.0030	0.0047	0.0088

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50} 496.227	E_rC_{50} 321.088	E_bC_{50} 171.345
AF		100	100	10
RAC_{mix} (µg/L)		4.962	3.211	17.135
FOCUS scenerio	**PEC_{max} (µg/L)**			
Step 1	55.2500	>1	>1	>1
Step 2				
N-Europe	5.0400	>1	>1	<1
Step 3				
D3 / Ditch	1.6990	<1	<1	-
D4 / Pond	0.8714	<1	<1	-
D4 / Stream	1.3224	<1	<1	-
R1 / Pond	0.3710	<1	<1	-
R1 / Stream	2.4340	<1	<1	-
R3 / Stream	3.3525	<1	>1	-
Step 4	**10 m vegetative strip + 5 m no spray buffer**			
R3 / Stream	1.5010	-	<1	-

9.5.2.2.13 Risk assessment of mixture toxicity based on Potatoes

Table 9.5.2.2.3-53: Summary of assessment steps considered for the mixture risk assessment

Steps	Conclusion on the Steps		
	Fish	Invertebrates	Algae
Screening 1: ETR trigger (optional Step)	-	-	-
Screening 2: Driver (optional Step)	-	-	-
Step 1: data available?	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.
Step 2: apparent synergism or antagonism?	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.
Step 3: mixture similar or not?	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.
Step 4: ETRmix assessment (ECxPPP)	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).
Step 5: driver available?	There is no driver for fish in all scenarios. Go to Step 8.	There is no driver for invertebrates in all scenarios. Go to Step 8.	There is no driver for algae in all scenarios. Go to Step 8.
Step 6: driver assessment	-	-	-

Step 7: synergism assessment (few data)	-	-	-
Step 8a: ETRmix assessment	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**
Step 8b: RQmix assessment	-	-	-
Step 9: antagonism assessment	-	-	-
Step 10: synergism assessment	-	-	-

Overview of the assessment steps: Table 9.5.2.2-1 gives a summary of the decisions made for each organism group during the mixture risk assessment with respect to the decision scheme as provided by EFSA (2013, section 10.3.11). A discussion of all details of every decision is not intended in this section of this registration report. Further in-depth justification and explanation for the decisions made are documented in the attached mixture risk calculation file. However, at least data for some important steps are documented in this section of this registration report, beginning with the check for (and potentially assessment of) synergistic or antagonistic effects (Step 2 and Steps 7, 9 and 10) as well as the ETR_{mix} or RQ_{mix} calculation results for the assessed FOCUS Scenarios (Steps 4 and 8a/b).

Step 2: MDR calculation to check for synergistic or antagonistic effects

Table 9.5.2.2.3-54: Calculated mixture toxicity and MDR for each group of organisms (see sections 10.3.3 and 10.3.4 of EFSA (2013) for more details)

Species	Substance	Concentration (Ci) in formulation (g a.s./L)	Pi	ECxi (mg a.s./L)	ECxmix-CA (mg sum a.s. /L)	ECxPPP (mg sum a.s. /L)	MDR
Fish, acute toxicity 1							
Oncorhynchus mykiss	Azoxystrobin	200	0.62	0.47	0.603	0.496227771	1.21
Oncorhynchus mykiss	Difenoconazole	125	0.38	1.1			
Invertebrates, acute toxicity 1							
Daphnia	Azoxystrobin	200	0.62	0.23	0.315	0.321088558	0.98
Daphnia	Difenoconazole	125	0.38	0.77			
Algae							
Selenastrum capricornutum (green algae)	Azoxystrobin	200	0.62	0.36	0.073	0.17134453	0.43
Scenedesmus subspicatus (green alage)	Difenoconazole	125	0.38	0.032			

[1] For a possible inclusion of chronic toxicity please refer to the FAQ document distributed alongside the aquatic mixture toxicity calculation tool "AGD_AquaMix".

[2] MDR = 0.2 – 5 → Go to Step 3 (concentration addition (CA) approximately holds for the calculated mixture);

MDR > 5 → Go to Step 10 (the calculated mixture is more toxic than CA, i.e. synergistic);

MDR < 0.2 → Go to Step 9 (the calculated mixture is less toxic than CA, i.e. antagonistic)

The density of the liquid formulation of SCORPIO 3250 SC, equal to 1.1134 g/ml, was used in the performed calculations.

Step 3 Comparison of mixture composition of PPP and PEC_{mix}

According to Step 3 it has to be checked whether the mixture composition in the formulation is similar to the mixture composition at PEC_{mix} (which is the sum of PEC_i of individual active substances). Therefore,

the "ECx_{mix-CA} (a.s. in PPP) / ECx_{mix-CA} (a.s. in PEC_{mix})" ratios were calculated.

In case the ratio is in the range of 0.8–1.2 (mixture similar), the risk assessment can be based on the ECx_{PPP} (Step 4).

In case the ratio is outside the range of 0.8–1.2 (i.e. mixture not similar), the endpoint ECx_{mix-CA} normalized to the mixture composition at PEC_{mix} (reported as "ECx_{mix-CA} (a.s. in PEC_{mix})" in EFSA, 2013, and the following parts of this report) has to be used to calculate the risk (Step 5 or Step 8, respectively).

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if product or calculated endpoint data (according to Step 3) have to be used. Further in-depth justification and explanation are documented in the attached mixture risk calculation file.

Step 5: Driver detection

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if a driver of risk is available according to Step 5. Further in-depth justification and explanation are documented in the attached mixture risk calculation file. Further information for the availability of a driver for the risk assessment of particular FOCUS Scenarios is given in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) and

Table 9.5.2.2-4 (FOCUS Step 4) below.

Step 4 and Step 8a: Mixture risk assessment based on measured and calculated mixture toxicity

Decisions taken when using the scheme as provided by EFSA (2013, section 10.3.11) lead to several assessment steps, which give a conclusion on the risk of a mixture or provide additional information important for the assessment. In the tables below the conclusions of different steps of the mixture risk assessment are summarized for the FOCUS Scenarios of concern. Information is reported on:

ss) Step 2 and associated steps, in which the question is answered if concentration addition can be assumed (i.e. a standard mixture toxicity risk assessment is appropriate) or if an antagonism/synergism is possible (more detailed information on Step 2 is given above). This is important to derive if further, specific considerations have to be made in the risk assessment. Associated steps are Step 7, Step 9 and Step 10.

tt) Step 5, in which the question is answered if there is a driver of risk and if so, which of the substance can be classified as driver (more detailed information on Step 5 is given the attached mixture risk calculation file). This is reported as additional information in case an assessment based on a driver would also be possible; for comparative reasons the table always lists the results from the mixture risk assessment according to Step 4 and/or Step 8. For an assessment based on a particular a.s. (the driver) please be referred to the individual a.s. risk assessment.

uu) Step 4 with the assessment results for cases where product data are usable (according to Step 3) and the risk assessment can be carried out based on the measured toxicity.

vv) Step 8 (a/b) with the assessment results for cases where product data are not usable (according to Step 3) and the risk assessment has to be based on calculated mixture toxicity.

The intermediate results of the mixture toxicity risk assessment are presented below for the respective FOCUS steps.

Table 9.5.2.2.3-55: Results of the mixture toxicity risk assessment (related to Step 8a) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in Potatoes.

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	Go to Step 4	0.211	0.427
Step 2			
N-Europe	Go to Step 4	0.039	0.078
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
D4/ pond	0.001	0.003	0.002
D4/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D6/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
R1/ pond	Go to Step 4	0.001	0.002
R1/ stream	Go to Step 4	0.013	0.022
R2/ stream	Go to Step 4	Go to Step 4	Go to Step 4
R3/ stream	Go to Step 4	0.015	0.029
Step 4	10 m vegetative strip, 5 m no spray buffer and no nozzle reduction		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
D4/ stream	Go to Step 4	Go to Step 4	0.009
R1/ stream	Go to Step 4	0.006	0.010
R3/ stream	Go to Step 4	0.007	0.013

Table 9.5.2.2.3-4: Results of the mixture toxicity risk assessment (related to Step 4) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in Potatoes.

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	0.111	Go to Step 5/8	Go to Step 5/8
Step 2			
N-Europe	0.021	Go to Step 5/8	Go to Step 5/8
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	0.003	0.005	0.01
D4/ pond	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
D4/ stream	0.003	0.004	0.008
D6/ ditch	0.003	0.005	0.010
R1/ pond	0.001	Go to Step 5/8	Go to Step 5/8
R1/ stream	0.007	Go to Step 5/8	Go to Step 5/8
R2/ stream	0.003	0.005	0.009
R3/ stream	0.008	Go to Step 5/8	Go to Step 5/8
Step 4	10 m vegetative strip, 5 m no spray buffer and no nozzle reduction		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	0.001	0.002	0.003
D4/ stream	0.002	0.003	Go to Step 5/8
R1/ stream	0.003	Go to Step 5/8	Go to Step 5/8
R3/ stream	0.004	Go to Step 5/8	Go to Step 5/8

The respective assessment conclusions are presented in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) or

Table 9.5.2.2-4 (FOCUS Step 4). The assessment is based either on the exposure-toxicity ratio (ETR_{mix}) or the risk quotient (RQ_{mix}); the ETR_{mix} and RQ_{mix} are compared to respective trigger values: 1/10 or 1/100 for the ETR_{mix} (depending on the species assessed) and 1 for RQ_{mix}. For the sake of a concise assessment the results below are limited to the organism groups most at risk. Further in-depth justification and explanation for other organism groups are documented in the attached mixture risk calculation file.

Table 9.5.2.2.3-5: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for fish, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Potatoes.

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	0.111	Go to Step 4
Step 2				
N-Europe		Azoxystrobin	0.021	Go to Step 4
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.003	Go to Step 4
D4/ pond		Azoxystrobin	Go to Step 5/8	0.001
D4/ stream		no driver	0.003	Go to Step 4
D6/ ditch		no driver	0.003	Go to Step 4
R1/ pond		Azoxystrobin	0.001	Go to Step 4
R1/ stream		Azoxystrobin	0.007	Go to Step 4
R2/ stream		no driver	0.003	Go to Step 4
R3/ stream		Azoxystrobin	0.008	Go to Step 4

Table 9.5.2.2.3-6: Summary of the mixture toxicity risk assessment (related to Step 4) for fish based on FOCUS Step 4 calculations for application of Clapton 325 SC in Potatoes.

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.001		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.002		
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.003		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.004		
50%										
75%										
90%										

Table 9.5.2.2.3-7: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for invertebrates, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Potatoes.

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	Go to Step 5/8	0.211
Step 2				
N-Europe		Azoxystrobin	Go to Step 5/8	0.039
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.005	Go to Step 4
D4/ pond		Azoxystrobin	Go to Step 5/8	0.003
D4/ stream		no driver	0.004	Go to Step 4
D6/ ditch		no driver	0.005	Go to Step 4
R1/ pond		Azoxystrobin	Go to Step 5/8	0.001
R1/ stream		Azoxystrobin	Go to Step 5/8	0.013
R2/ stream		no driver	0.005	Go to Step 4
R3/ stream		Azoxystrobin	Go to Step 5/8	0.015

Table 9.5.2.2.3-8: Summary of the mixture toxicity risk assessment (related to Step 4) for invertebrates based on FOCUS Step 4 calculations for application of Clapton 325 SC in Potatoes.

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.002		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.003		
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.006		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.007		
50%										
75%										
90%										

Table 9.5.2.2.3-9: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for algae, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Potatoes.

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	no driver	Go to Step 5/8	0.427
Step 2				
N-Europe		no driver	Go to Step 5/8	0.078
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.010	Go to Step 4
D4/ pond		no driver	Go to Step 5/8	0.002
D4/ stream		no driver	0.08	Go to Step 4
D6/ ditch		no driver	0.010	Go to Step 4
R1/ pond		no driver	Go to Step 5/8	0.002
R1/ stream		no driver	Go to Step 5/8	0.022
R2/ stream		no driver	0.009	Go to Step 4
R3/ stream		no driver	Go to Step 5/8	0.029

Table 9.5.2.2.3-10: Summary of the mixture toxicity risk assessment (related to Step 4) for algae based on FOCUS Step 4 calculations for application of Clapton 325 SC in Potatoes.

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.003		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.009		
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.010		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.013		
50%										
75%										
90%										

Table 9.5.2.2.3-561: Summary of mixture toxicity assessment for SCORPIO 325 SC for aquatic organisms for the use according to the GAP table for Potatoes BBCH 14

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50}	E_rC_{50}	E_bC_{50}
AF		100	100	10
RAC_{mix} (µg/L)		496.227	321.088	171.345
FOCUS scenerio	**PEC_{max} (µg/L)**			
Step 1	55.2500	55.2500	0.1721	0.3224
Step 2				
N-Europe	5.0400	10.2700	0.0157	0.0294
Step 3				
D3 / Ditch	1.7005	0.0034	0.0053	0.0099
D4 / Pond	0.6062	0.0012	0.0019	0.0035
D4 / Stream	1.4164	0.0029	0.0044	0.0083
D6 / Ditch	1.6767	0.0034	0.0052	0.0098
R1 / Pond	0.3069	0.0006	0.0010	0.0018
R1 / Stream	3.3716	0.0068	0.0105	0.0197
R2 / Stream	1.5556	0.0031	0.0048	0.0091
R3 / Stream	3.9444	0.0079	0.0123	0.0230
R4 / Stream	-	0.0000	0.0000	0.0000
Step 4				
D3 / Ditch	0.5569	0.0011	0.0017	0.0033
D4 / Stream	0.8091	0.0016	0.0025	0.0047
R1 / Stream	1.5122	0.0030	0.0047	0.0088
R3 / Stream	1.7764	0.0036	0.0055	0.0104

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50} 496.227	E_rC_{50} 321.088	E_bC_{50} 171.345
AF		100	100	10
RAC_{mix} (µg/L)		4.962	3.211	17.135
FOCUS scenerio	**PEC_{max} (µg/L)**			
Step 1	55.2500	>1	>1	>1
Step 2				
N-Europe	5.0400	>1	>1	<1
Step 3				
D3 / Ditch	1.7005	<1	<1	-
D4 / Pond	0.6062	<1	<1	-
D4 / Stream	1.4164	<1	<1	-
R1 / Pond	0.3069	<1	<1	-
R1 / Stream	3.3716	<1	>1	-
R3 / Stream	3.9444	<1	>1	-
Step 4	**10 m vegetative strip + 5 m no spray buffer**			
R1 / Stream	1.5122		<1	-
R3 / Stream	1.7764		<1	-

9.5.2.2.14 Risk assessment of mixture toxicity based on Spring oilseed rape (BBCH 31)

Table 9.5.2.2.3-57: Summary of assessment steps considered for the mixture risk assessment

Steps	Conclusion on the Steps		
	Fish	Invertebrates	Algae
Screening 1: ETR trigger (optional Step)	-	-	-
Screening 2: Driver (optional Step)	-	-	-
Step 1: data available?	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.
Step 2: apparent synergism or antagonism?	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.
Step 3: mixture similar or not?	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.
Step 4: ETRmix assessment (ECxPPP)	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).
Step 5: driver available?	There is no driver for fish in all scenarios. Go to Step 8.	There is no driver for invertebrates in all scenarios. Go to Step 8.	There is no driver for algae in all scenarios. Go to Step 8.
Step 6: driver assessment	-	-	-

Step 7: synergism assessment (few data)	-	-	-
Step 8a: ETRmix assessment	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**
Step 8b: RQmix assessment	-	-	-
Step 9: antagonism assessment	-	-	-
Step 10: synergism assessment	-	-	-

Overview of the assessment steps: Table 9.5.2.2-1 gives a summary of the decisions made for each organism group during the mixture risk assessment with respect to the decision scheme as provided by EFSA (2013, section 10.3.11). A discussion of all details of every decision is not intended in this section of this registration report. Further in-depth justification and explanation for the decisions made are documented in the attached mixture risk calculation file. However, at least data for some important steps are documented in this section of this registration report, beginning with the check for (and potentially assessment of) synergistic or antagonistic effects (Step 2 and Steps 7, 9 and 10) as well as the ETR_{mix} or RQ_{mix} calculation results for the assessed FOCUS Scenarios (Steps 4 and 8a/b).

Step 2: MDR calculation to check for synergistic or antagonistic effects

Table 9.5.2.2.3-58: Calculated mixture toxicity and MDR for each group of organisms (see sections 10.3.3 and 10.3.4 of EFSA (2013) for more details)

Species	Substance	Concentration (Ci) in formulation (g a.s./L)	Pi	ECxi (mg a.s./L)	ECxmix-CA (mg sum a.s. /L)	ECxPPP (mg sum a.s. /L)	MDR
Fish, acute toxicity 1							
Oncorhynchus mykiss	Azoxystrobin	200	0.62	0.47	0.603	0.496227771	1.21
Oncorhynchus mykiss	Difenoconazole	125	0.38	1.1			
Invertebrates, acute toxicity 1							
Daphnia	Azoxystrobin	200	0.62	0.23	0.315	0.321088558	0.98
Daphnia	Difenoconazole	125	0.38	0.77			
Algae							
Selenastrum capricornutum (green algae)	Azoxystrobin	200	0.62	0.36	0.073	0.17134453	0.43
Scenedesmus subspicatus (green alage)	Difenoconazole	125	0.38	0.032			

[1] For a possible inclusion of chronic toxicity please refer to the FAQ document distributed alongside the aquatic mixture toxicity calculation tool "AGD_AquaMix".

[2] MDR = 0.2 – 5 → Go to Step 3 (concentration addition (CA) approximately holds for the calculated mixture);

MDR > 5 → Go to Step 10 (the calculated mixture is more toxic than CA, i.e. synergistic);

MDR < 0.2 → Go to Step 9 (the calculated mixture is less toxic than CA, i.e. antagonistic)

The density of the liquid formulation of SCORPIO 3250 SC, equal to 1.1134 g/ml, was used in the performed calculations.

Step 3 Comparison of mixture composition of PPP and PEC_{mix}

According to Step 3 it has to be checked whether the mixture composition in the formulation is similar to the mixture composition at PEC_{mix} (which is the sum of PEC_i of individual active substances). Therefore, the "$ECx_{mix\text{-}CA}$ (a.s. in PPP) / $ECx_{mix\text{-}CA}$ (a.s. in PEC_{mix})" ratios were calculated.

In case the ratio is in the range of 0.8–1.2 (mixture similar), the risk assessment can be based on the ECx_{PPP} (Step 4).

In case the ratio is outside the range of 0.8–1.2 (i.e. mixture not similar), the endpoint $ECx_{mix\text{-}CA}$ normalized to the mixture composition at PEC_{mix} (reported as "$ECx_{mix\text{-}CA}$ (a.s. in PEC_{mix})" in EFSA, 2013, and the following parts of this report) has to be used to calculate the risk (Step 5 or Step 8, respectively).

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if product or calculated endpoint data (according to Step 3) have to be used. Further in-depth justification and explanation are documented in the attached mixture risk calculation file.

Step 5: Driver detection

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if a driver of risk is available according to Step 5. Further in-depth justification and explanation are documented in the attached mixture risk calculation file. Further information for the availability of a driver for the risk assessment of particular FOCUS Scenarios is given in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) and

Table 9.5.2.2-4 (FOCUS Step 4) below.

Step 4 and Step 8a: Mixture risk assessment based on measured and calculated mixture toxicity

Decisions taken when using the scheme as provided by EFSA (2013, section 10.3.11) lead to several assessment steps, which give a conclusion on the risk of a mixture or provide additional information important for the assessment. In the tables below the conclusions of different steps of the mixture risk assessment are summarized for the FOCUS Scenarios of concern. Information is reported on:

ww) Step 2 and associated steps, in which the question is answered if concentration addition can be assumed (i.e. a standard mixture toxicity risk assessment is appropriate) or if an antagonism/synergism is possible (more detailed information on Step 2 is given above). This is important to derive if further, specific considerations have to be made in the risk assessment. Associated steps are Step 7, Step 9 and Step 10.

xx) Step 5, in which the question is answered if there is a driver of risk and if so, which of the substance can be classified as driver (more detailed information on Step 5 is given the attached mixture risk calculation file). This is reported as additional information in case an assessment based on a driver would also be possible; for comparative reasons the table always lists the results from the mixture risk assessment according to Step 4 and/or Step 8. For an assessment based on a particular a.s. (the driver) please be referred to the individual a.s. risk assessment.

yy) Step 4 with the assessment results for cases where product data are usable (according to Step 3) and the risk assessment can be carried out based on the measured toxicity.

zz) Step 8 (a/b) with the assessment results for cases where product data are not usable (according to Step 3) and the risk assessment has to be based on calculated mixture toxicity.

The intermediate results of the mixture toxicity risk assessment are presented below for the respective FOCUS steps.

Table 9.5.2.2.3-59: Results of the mixture toxicity risk assessment (related to Step 8a) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in Spring Oilseed Rape (BBCH 31).

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	Go to Step 4	0.211	0.427
Step 2			
N-Europe	Go to Step 4	Go to Step 4	0.047
Step 3			
D1/ ditch	Go to Step 4	Go to Step 4	0.032
D1/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
D4/ pond	0.001	0.002	0.002
D4/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D5/ pond	Go to Step 4	0.001	0.001
D5/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	Go to Step 4	0.001	0.002
R1/ stream	Go to Step 4	0.012	0.023
R2/ stream	Scenario is not relevant for Central Zone		
Step 4	**10 m vegetative strip, 5 m no spray buffer and no nozzle reduction**		
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
D4/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D5/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ stream	Go to Step 4	0.005	0.009

Table 9.5.2.2.3-4: Results of the mixture toxicity risk assessment (related to Step 4) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in Spring Oilseed Rape (BBCH 31).

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	0.111	Go to Step 5/8	Go to Step 5/8
Step 2			
N-Europe	0.010	0.016	Go to Step 5/8
Step 3			
D1/ ditch	0.007	0.011	Go to Step 5/8
D1/ stream	0.005	0.007	0.01
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	0.004	0.006	0.012
D4/ pond	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
D4/ stream	0.003	0.005	0.010
D5/ pond	0.000	Go to Step 5/8	Go to Step 5/8
D5/ stream	0.004	0.0064	0.010
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	0.001	Go to Step 5/8	Go to Step 5/8
R1/ stream	0.006	Go to Step 5/8	Go to Step 5/8
R2/ stream	Scenario is not relevant for Central Zone		
Step 4	**10 m vegetative strip, 5 m no spray buffer and no nozzle reduction**		
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	0.001	0.002	0.003
D4/ stream	0.001	0.002	0.004
D5/ stream	0.001	0.002	0.004
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ stream	0.003	Go to Step 5/8	Go to Step 5/8

The respective assessment conclusions are presented in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) or

Table 9.5.2.2-4 (FOCUS Step 4). The assessment is based either on the exposure-toxicity ratio (ETR_{mix}) or the risk quotient (RQ_{mix}); the ETR_{mix} and RQ_{mix} are compared to respective trigger values: 1/10 or 1/100 for the ETR_{mix} (depending on the species assessed) and 1 for RQ_{mix}. For the sake of a concise assessment the results below are limited to the organism groups most at risk. Further in-depth justification and explanation for other organism groups are documented in the attached mixture risk calculation file.

Table 9.5.2.2.3-5: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for fish, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Spring Oilseed Rape (BBCH 31).

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	0.111	Go to Step 4
Step 2				
N-Europe		no driver	0.010	Go to Step 4
Step 3				
D1/ ditch		no driver	0.007	Go to Step 4
D1/ stream		no driver	0.005	Go to Step 4
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.004	Go to Step 4
D4/ pond		Azoxystrobin	Go to Step 5/8	0.001
D4/ stream		no driver	0.003	Go to Step 4
D5/ pond		Azoxystrobin	0.000	Go to Step 4
D5/ stream		no driver	0.004	Go to Step 4
D6/ ditch		Scenario is not relevant for Central Zone		
R1/ pond		Azoxystrobin	0.001	Go to Step 4
R1/ stream		Azoxystrobin	0.006	Go to Step 4
R2/ stream		Scenario is not relevant for Central Zone		

Table 9.5.2.2.3-6: Summary of the mixture toxicity risk assessment (related to Step 4) for fish based on FOCUS Step 4 calculations for application of Clapton 325 SC in Spring Oilseed Rape (BBCH 31).

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.001		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.001		
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream							0.001		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.003		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								

Table 9.5.2.2.3-7: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for invertebrates, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Spring Oilseed Rape (BBCH 31).

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	Go to Step 5/8	0.211
Step 2				
N-Europe		Azoxystrobin	0.001	Go to Step 4
Step 3				
D1/ ditch		Azoxystrobin	0.011	Go to Step 4
D1/ stream		no driver	0.007	Go to Step 4
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.006	Go to Step 4
D4/ pond		Azoxystrobin	Go to Step 5/8	0.002
D4/ stream		no driver	0.005	Go to Step 4
D5/ pond		Azoxystrobin	Go to Step 5/8	0.001
D5/ stream		no driver	0.006	Go to Step 4
D6/ ditch		Scenario is not relevant for Central Zone		
R1/ pond		Azoxystrobin	Go to Step 5/8	0.001
R1/ stream		Azoxystrobin	Go to Step 5/8	0.012
R2/ stream		Scenario is not relevant for Central Zone		

Table 9.5.2.2.3-8: Summary of the mixture toxicity risk assessment (related to Step 4) for invertebrates based on FOCUS Step 4 calculations for application of Clapton 325 SC in Spring Oilseed Rape (BBCH 31).

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.002		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.002		
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream							0.002		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.005		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								

Table 9.5.2.2.3-9: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for algae, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Spring Oilseed Rape (BBCH 31).

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	no driver	Go to Step 5/8	0.427
Step 2				
N-Europe		no driver	Go to Step 5/8	0.047
Step 3				
D1/ ditch		no driver	Go to Step 5/8	0.032
D1/ stream		no driver	0.014	Go to Step 4
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.012	Go to Step 4
D4/ pond		no driver	Go to Step 5/8	0.002
D4/ stream		no driver	0.010	Go to Step 4
D5/ pond		no driver	Go to Step 5/8	0.001
D5/ stream		no driver	0.010	Go to Step 4
D6/ ditch		Scenario is not relevant for Central Zone		
R1/ pond		no driver	Go to Step 5/8	0.002
R1/ stream		no driver	Go to Step 5/8	0.023
R2/ stream		Scenario is not relevant for Central Zone		

Table 9.5.2.2.3-10: Summary of the mixture toxicity risk assessment (related to Step 4) for algae based on FOCUS Step 4 calculations for application of Clapton 325 SC in Spring Oilseed Rape (BBCH 31).

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.003		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.004		
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream							0.004		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.009		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								

Table 9.5.2.2.3-601: Summary of mixture toxicity assessment for SCORPIO 325 SC for aquatic organisms for the use according to the GAP table for Spring oilseed rape (BBCH 31)

Group		Fish acute	Inverteb. acute	Algae
Test species		Oncorhynchus mykiss	Daphnia magna	Pseudokirchn. subcapitata
Endpoint (µg/L)		E_rC_{50}	E_rC_{50}	E_bC_{50}
AF		100	100	10
RAC_{mix} (µg/L)		496.227	321.088	171.345
FOCUS scenerio	PEC_{max} (µg/L)			
Step 1	55.2500	55.2500	0.1721	0.3224
Step 2				
N-Europe	5.0400	10.2700	0.0157	0.0294
Step 3				
D1 / Ditch	3.4915	0.0070	0.0109	0.0204
D1 / Stream	2.3865	0.0048	0.0074	0.0139
D3 / Ditch	2.0562	0.0041	0.0064	0.0120
D4 / Pond	0.4017	0.0008	0.0013	0.0023
D4 / Stream	1.6828	0.0034	0.0052	0.0098
D5 / Pond	0.1865	0.0004	0.0006	0.0011
D5 / Stream	1.7902	0.0036	0.0056	0.0104
R1 / Pond	0.2851	0.0006	0.0009	0.0017
R1 / Stream	3.1461	0.0063	0.0098	0.0184
Step 4				
D3 / Ditch	0.5572	0.0011	0.0017	0.0033
D4 / Stream	0.6739	0.0014	0.0021	0.0039
D5 / Stream	0.6553	0.0013	0.0020	0.0038
R1 / Stream	1.3828	0.0028	0.0043	0.0081

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50} 496.227	E_rC_{50} 321.088	E_bC_{50} 171.345
AF		100	100	10
RAC_{mix} (µg/L)		4.962	3.211	17.135
FOCUS scenerio	PEC_{max} (µg/L)			
Step 1	55.2500	>1	>1	>1
Step 2				
N-Europe	5.0400	>1	>1	<1
Step 3				
D3 / Ditch	2.0562	<1	<1	-
D4 / Pond	0.4017	<1	<1	-
D4 / Stream	1.6828	<1	<1	-
D5 / Pond	0.1865	<1	<1	-
D5 / Stream	1.7902	<1	>1	-
R1 / Pond	0.2851	<1	<1	-
R1 / Stream	3.1461	<1	<1	-

9.5.2.2.15 Risk assessment of mixture toxicity based on Spring oilseed rape

Table 9.5.2.2.3-61: Summary of assessment steps considered for the mixture risk assessment

Steps	Conclusion on the Steps		
	Fish	Invertebrates	Algae
Screening 1: ETR trigger (optional Step)	-	-	-
Screening 2: Driver (optional Step)	-	-	-
Step 1: data available?	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.
Step 2: apparent synergism or antagonism?	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.
Step 3: mixture similar or not?	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.
Step 4: ETRmix assessment (ECxPPP)	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).
Step 5: driver available?	There is no driver for fish in all scenarios. Go to Step 8.	There is no driver for invertebrates in all scenarios. Go to Step 8.	There is no driver for algae in all scenarios. Go to Step 8.
Step 6: driver assessment	-	-	-

Step 7: synergism assessment (few data)	-	-	-
Step 8a: ETRmix assessment	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**
Step 8b: RQmix assessment	-	-	-
Step 9: antagonism assessment	-	-	-
Step 10: synergism assessment	-	-	-

Overview of the assessment steps: Table 9.5.2.2-1 gives a summary of the decisions made for each organism group during the mixture risk assessment with respect to the decision scheme as provided by EFSA (2013, section 10.3.11). A discussion of all details of every decision is not intended in this section of this registration report. Further in-depth justification and explanation for the decisions made are documented in the attached mixture risk calculation file. However, at least data for some important steps are documented in this section of this registration report, beginning with the check for (and potentially assessment of) synergistic or antagonistic effects (Step 2 and Steps 7, 9 and 10) as well as the ETR_{mix} or RQ_{mix} calculation results for the assessed FOCUS Scenarios (Steps 4 and 8a/b).

Step 2: MDR calculation to check for synergistic or antagonistic effects

Table 9.5.2.2.3-62: Calculated mixture toxicity and MDR for each group of organisms (see sections 10.3.3 and 10.3.4 of EFSA (2013) for more details)

Species	Substance	Concentration (Ci) in formulation (g a.s./L)	Pi	ECxi (mg a.s./L)	ECxmix-CA (mg sum a.s. /L)	ECxPPP (mg sum a.s. /L)	MDR
Fish, acute toxicity 1							
Oncorhynchus mykiss	Azoxystrobin	200	0.62	0.47	0.603	0.496227771	1.21
Oncorhynchus mykiss	Difenoconazole	125	0.38	1.1			
Invertebrates, acute toxicity 1							
Daphnia	Azoxystrobin	200	0.62	0.23	0.315	0.321088558	0.98
Daphnia	Difenoconazole	125	0.38	0.77			
Algae							
Selenastrum capricornutum (green algae)	Azoxystrobin	200	0.62	0.36	0.073	0.17134453	0.43
Scenedesmus subspicatus (green alage)	Difenoconazole	125	0.38	0.032			

[1] For a possible inclusion of chronic toxicity please refer to the FAQ document distributed alongside the aquatic mixture toxicity calculation tool "AGD_AquaMix".

[2] MDR = 0.2 – 5 → Go to Step 3 (concentration addition (CA) approximately holds for the calculated mixture);

MDR > 5 → Go to Step 10 (the calculated mixture is more toxic than CA, i.e. synergistic);

MDR < 0.2 → Go to Step 9 (the calculated mixture is less toxic than CA, i.e. antagonistic)

The density of the liquid formulation of SCORPIO 3250 SC, equal to 1.1134 g/ml, was used in the performed calculations.

Step 3 Comparison of mixture composition of PPP and PEC_{mix}

According to Step 3 it has to be checked whether the mixture composition in the formulation is similar to the mixture composition at PEC_{mix} (which is the sum of PEC_i of individual active substances). Therefore,

the "ECx_{mix-CA} (a.s. in PPP) / ECx_{mix-CA} (a.s. in PEC_{mix})" ratios were calculated.

In case the ratio is in the range of 0.8–1.2 (mixture similar), the risk assessment can be based on the ECx_{PPP} (Step 4).

In case the ratio is outside the range of 0.8–1.2 (i.e. mixture not similar), the endpoint ECx_{mix-CA} normalized to the mixture composition at PEC_{mix} (reported as "ECx_{mix-CA} (a.s. in PEC_{mix})" in EFSA, 2013, and the following parts of this report) has to be used to calculate the risk (Step 5 or Step 8, respectively).

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if product or calculated endpoint data (according to Step 3) have to be used. Further in-depth justification and explanation are documented in the attached mixture risk calculation file.

Step 5: Driver detection

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if a driver of risk is available according to Step 5. Further in-depth justification and explanation are documented in the attached mixture risk calculation file. Further information for the availability of a driver for the risk assessment of particular FOCUS Scenarios is given in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) and

Table 9.5.2.2-4 (FOCUS Step 4) below.

Step 4 and Step 8a: Mixture risk assessment based on measured and calculated mixture toxicity

Decisions taken when using the scheme as provided by EFSA (2013, section 10.3.11) lead to several assessment steps, which give a conclusion on the risk of a mixture or provide additional information important for the assessment. In the tables below the conclusions of different steps of the mixture risk assessment are summarized for the FOCUS Scenarios of concern. Information is reported on:

aaa) Step 2 and associated steps, in which the question is answered if concentration addition can be assumed (i.e. a standard mixture toxicity risk assessment is appropriate) or if an antagonism/synergism is possible (more detailed information on Step 2 is given above). This is important to derive if further, specific considerations have to be made in the risk assessment. Associated steps are Step 7, Step 9 and Step 10.

bbb) Step 5, in which the question is answered if there is a driver of risk and if so, which of the substance can be classified as driver (more detailed information on Step 5 is given the attached mixture risk calculation file). This is reported as additional information in case an assessment based on a driver would also be possible; for comparative reasons the table always lists the results from the mixture risk assessment according to Step 4 and/or Step 8. For an assessment based on a particular a.s. (the driver) please be referred to the individual a.s. risk assessment.

ccc) Step 4 with the assessment results for cases where product data are usable (according to Step 3) and the risk assessment can be carried out based on the measured toxicity.

ddd) Step 8 (a/b) with the assessment results for cases where product data are not usable (according to Step 3) and the risk assessment has to be based on calculated mixture toxicity.

The intermediate results of the mixture toxicity risk assessment are presented below for the respective FOCUS steps.

Table 9.5.2.2.3-63: Results of the mixture toxicity risk assessment (related to Step 8a) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in Spring Oilseed Rape.

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	Go to Step 4	0.211	0.427
Step 2			
N-Europe	Go to Step 4	Go to Step 4	0.047
Step 3			
D1/ ditch	Go to Step 4	Go to Step 4	0.032
D1/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
D4/ pond	0.001	0.002	0.002
D4/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D5/ pond	Go to Step 4	0.001	0.001
D5/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	Go to Step 4	Go to Step 4	0.002
R1/ stream	Go to Step 4	Go to Step 4	0.020
R2/ stream	Scenario is not relevant for Central Zone		
Step 4	10 m vegetative strip, 10 m no spray buffer and no nozzle reduction		
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
D4/ stream	Go to Step 4	Go to Step 4	0.005
D5/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ stream	Go to Step 4	0.003	0.005

Table 9.5.2.2.3-4: Results of the mixture toxicity risk assessment (related to Step 4) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in Spring Oilseed Rape.

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	0.111	Go to Step 5/8	Go to Step 5/8
Step 2			
N-Europe	0.010	0.016	Go to Step 5/8
Step 3			
D1/ ditch	0.007	0.011	Go to Step 5/8
D1/ stream	0.005	0.007	0.014
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	0.004	0.006	0.012
D4/ pond	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
D4/ stream	0.003	0.005	0.010
D5/ pond	0.000	Go to Step 5/8	Go to Step 5/8
D5/ stream	0.003	0.005	0.010
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	0.000	0.001	Go to Step 5/8
R1/ stream	0.004	0.006	Go to Step 5/8
R2/ stream	Scenario is not relevant for Central Zone		
Step 4	**10 m vegetative strip, 5 m no spray buffer and no nozzle reduction**		
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	0.001	0.001	0.002
D4/ stream	0.001	0.001	Go to Step 5/8
D5/ stream	0.001	0.001	0.002
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ stream	0.002	Go to Step 5/8	Go to Step 5/8

The respective assessment conclusions are presented in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) or

Table 9.5.2.2-4 (FOCUS Step 4). The assessment is based either on the exposure-toxicity ratio (ETR_{mix}) or the risk quotient (RQ_{mix}); the ETR_{mix} and RQ_{mix} are compared to respective trigger values: 1/10 or 1/100 for the ETR_{mix} (depending on the species assessed) and 1 for RQ_{mix}. For the sake of a concise assessment the results below are limited to the organism groups most at risk. Further in-depth justification and explanation for other organism groups are documented in the attached mixture risk calculation file.

Table 9.5.2.2.3-5: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for fish, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Spring Oilseed Rape.

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	0.111	Go to Step 4
Step 2				
N-Europe		no driver	0.010	Go to Step 4
Step 3				
D1/ ditch		no driver	0.007	Go to Step 4
D1/ stream		no driver	0.005	Go to Step 4
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.004	Go to Step 4
D4/ pond		Azoxystrobin	Go to Step 5/8	0.001
D4/ stream		no driver	0.003	Go to Step 4
D5/ pond		Azoxystrobin	0.000	Go to Step 4
D5/ stream		no driver	0.003	Go to Step 4
D6/ ditch		Scenario is not relevant for Central Zone		
R1/ pond		Azoxystrobin	0.000	Go to Step 4
R1/ stream		Azoxystrobin	0.004	Go to Step 4
R2/ stream		Scenario is not relevant for Central Zone		

Table 9.5.2.2.3-6: Summary of the mixture toxicity risk assessment (related to Step 4) for fish based on FOCUS Step 4 calculations for application of Clapton 325 SC in Spring Oilseed Rape.

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.001		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.001		
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream							0.001		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.002		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								

Table 9.5.2.2.3-7: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for invertebrates, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Spring Oilseed Rape.

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	Go to Step 5/8	0.211
Step 2				
N-Europe		Azoxystrobin	0.016	Go to Step 4
Step 3				
D1/ ditch		Azoxystrobin	0.011	Go to Step 4
D1/ stream		no driver	0.007	Go to Step 4
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.006	Go to Step 4
D4/ pond		Azoxystrobin	Go to Step 5/8	0.002
D4/ stream		no driver	0.005	Go to Step 4
D5/ pond		Azoxystrobin	Go to Step 5/8	0.001
D5/ stream		no driver	0.005	Go to Step 4
D6/ ditch		Scenario is not relevant for Central Zone		
R1/ pond		Azoxystrobin	0.001	Go to Step 4
R1/ stream		Azoxystrobin	0.006	Go to Step 4
R2/ stream		Scenario is not relevant for Central Zone		

Table 9.5.2.2.3-8: Summary of the mixture toxicity risk assessment (related to Step 4) for invertebrates based on FOCUS Step 4 calculations for application of Clapton 325 SC in Spring Oilseed Rape.

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.001		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.002		
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream							0.001		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.003		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								

Table 9.5.2.2.3-9: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for algae, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Spring Oilseed Rape.

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	no driver	Go to Step 5/8	0.427
Step 2				
N-Europe		no driver	Go to Step 5/8	0.047
Step 3				
D1/ ditch		no driver	Go to Step 5/8	0.032
D1/ stream		no driver	0.014	Go to Step 4
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.012	Go to Step 4
D4/ pond		no driver	Go to Step 5/8	0.002
D4/ stream		no driver	0.010	Go to Step 4
D5/ pond		no driver	Go to Step 5/8	0.001
D5/ stream		no driver	0.010	Go to Step 4
D6/ ditch		Scenario is not relevant for Central Zone		
R1/ pond		no driver	Go to Step 5/8	0.002
R1/ stream		no driver	Go to Step 5/8	0.020
R2/ stream		Scenario is not relevant for Central Zone		

Table 9.5.2.2.3-10: Summary of the mixture toxicity risk assessment (related to Step 4) for algae based on FOCUS Step 4 calculations for application of Clapton 325 SC in Spring Oilseed Rape.

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.002		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.05		
50%										
75%										
90%										
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream							0.002		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.005		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								

Table 9.5.2.2.3-641: Summary of mixture toxicity assessment for SCORPIO 325 SC for aquatic organisms for the use according to the GAP table for Spring Oilseed rape BBCH 14

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50}	E_rC_{50}	E_bC_{50}
AF		100	100	10
RAC_{mix} (µg/L)		496.227	321.088	171.345
FOCUS scenerio	PEC_{max} (µg/L)			
Step 1	55.2500	55.2500	0.1721	0.3224
Step 2				
N-Europe	5.0400	10.2700	0.0157	0.0294
Step 3				
D1 / Ditch	3.4925	0.0070	0.0109	0.0204
D1 / Stream	2.3865	0.0048	0.0074	0.0139
D3 / Ditch	2.0564	0.0041	0.0064	0.0120
D4 / Pond	0.4024	0.0008	0.0013	0.0023
D4 / Stream	1.6938	0.0034	0.0053	0.0099
D5 / Pond	0.1957	0.0004	0.0006	0.0011
D5 / Stream	1.7336	0.0035	0.0054	0.0101
R1 / Pond	0.2088	0.0004	0.0007	0.0012
R1 / Stream	2.0632	0.0042	0.0064	0.0120
Step 4				
D3 / Ditch	0.2951	0.0006	0.0009	0.0017
D4 / Stream	0.5642	0.0011	0.0018	0.0033
D5 / Stream	0.3739	0.0008	0.0012	0.0022
R1 / Stream	0.8119	0.0016	0.0025	0.0047

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50} 496.227	E_rC_{50} 321.088	E_bC_{50} 171.345
AF		100	100	10
RAC_{mix} (µg/L)		4.962	3.211	17.135
FOCUS scenerio	PEC_{max} (µg/L)			
Step 1	55.2500	>1	>1	>1
Step 2				
N-Europe	5.0400	>1	>1	<1
Step 3				
D3 / Ditch	2.0564	<1	<1	-
D4 / Pond	0.4024	<1	<1	-
D4 / Stream	1.6938	<1	<1	-
D5 / Pond	0.1957	<1	<1	-
D5 / Stream	1.7336	<1	<1	-
R1 / Pond	0.2088	<1	<1	-
R1 / Stream	2.0632	<1	<1	-

9.5.2.2.16 Risk assessment of mixture toxicity based on Sugar beets (BBCH 31)

Table 9.5.2.2.3-65: Summary of assessment steps considered for the mixture risk assessment

Steps	Conclusion on the Steps		
	Fish	Invertebrates	Algae
Screening 1: ETR trigger (optional Step)	-	-	-
Screening 2: Driver (optional Step)	-	-	-
Step 1: data available?	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.
Step 2: apparent synergism or antagonism?	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.
Step 3: mixture similar or not?	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.
Step 4: ETRmix assessment (ECxPPP)	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).
Step 5: driver available?	There is no driver for fish in all scenarios. Go to Step 8.	There is no driver for invertebrates in all scenarios. Go to Step 8.	There is no driver for algae in all scenarios. Go to Step 8.
Step 6: driver assessment	-	-	-

Step 7: synergism assessment (few data)	-	-	-
Step 8a: ETRmix assessment	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**
Step 8b: RQmix assessment	-	-	-
Step 9: antagonism assessment	-	-	-
Step 10: synergism assessment	-	-	-

Overview of the assessment steps: Table 9.5.2.2-1 gives a summary of the decisions made for each organism group during the mixture risk assessment with respect to the decision scheme as provided by EFSA (2013, section 10.3.11). A discussion of all details of every decision is not intended in this section of this registration report. Further in-depth justification and explanation for the decisions made are documented in the attached mixture risk calculation file. However, at least data for some important steps are documented in this section of this registration report, beginning with the check for (and potentially assessment of) synergistic or antagonistic effects (Step 2 and Steps 7, 9 and 10) as well as the ETR_{mix} or RQ_{mix} calculation results for the assessed FOCUS Scenarios (Steps 4 and 8a/b).

Step 2: MDR calculation to check for synergistic or antagonistic effects

Table 9.5.2.2.3-66: Calculated mixture toxicity and MDR for each group of organisms (see sections 10.3.3 and 10.3.4 of EFSA (2013) for more details)

Species	Substance	Concentration (Ci) in formulation (g a.s./L)	Pi	ECxi (mg a.s./L)	ECxmix-CA (mg sum a.s. /L)	ECxPPP (mg sum a.s. /L)	MDR
Fish, acute toxicity 1							
Oncorhynchus mykiss	Azoxystrobin	200	0.62	0.47	0.603	0.496227771	1.21
Oncorhynchus mykiss	Difenoconazole	125	0.38	1.1			
Invertebrates, acute toxicity 1							
Daphnia	Azoxystrobin	200	0.62	0.23	0.315	0.321088558	0.98
Daphnia	Difenoconazole	125	0.38	0.77			
Algae							
Selenastrum capricornutum (green algae)	Azoxystrobin	200	0.62	0.36	0.073	0.17134453	0.43
Scenedesmus subspicatus (green alage)	Difenoconazole	125	0.38	0.032			

[1] For a possible inclusion of chronic toxicity please refer to the FAQ document distributed alongside the aquatic mixture toxicity calculation tool "AGD_AquaMix".

[2] MDR = 0.2 – 5 → Go to Step 3 (concentration addition (CA) approximately holds for the calculated mixture);

MDR > 5 → Go to Step 10 (the calculated mixture is more toxic than CA, i.e. synergistic);

MDR < 0.2 → Go to Step 9 (the calculated mixture is less toxic than CA, i.e. antagonistic)

The density of the liquid formulation of SCORPIO 3250 SC, equal to 1.1134 g/ml, was used in the performed calculations.

Step 3 Comparison of mixture composition of PPP and PEC_{mix}

According to Step 3 it has to be checked whether the mixture composition in the formulation is similar to the mixture composition at PEC_{mix} (which is the sum of PEC_i of individual active substances). Therefore,

the "ECx_{mix-CA} (a.s. in PPP) / ECx_{mix-CA} (a.s. in PEC_{mix})" ratios were calculated.

In case the ratio is in the range of 0.8–1.2 (mixture similar), the risk assessment can be based on the ECx_{PPP} (Step 4).

In case the ratio is outside the range of 0.8–1.2 (i.e. mixture not similar), the endpoint ECx_{mix-CA} normalized to the mixture composition at PEC_{mix} (reported as "ECx_{mix-CA} (a.s. in PEC_{mix})" in EFSA, 2013, and the following parts of this report) has to be used to calculate the risk (Step 5 or Step 8, respectively).

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if product or calculated endpoint data (according to Step 3) have to be used. Further in-depth justification and explanation are documented in the attached mixture risk calculation file.

Step 5: Driver detection

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if a driver of risk is available according to Step 5. Further in-depth justification and explanation are documented in the attached mixture risk calculation file. Further information for the availability of a driver for the risk assessment of particular FOCUS Scenarios is given in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) and

Table 9.5.2.2-4 (FOCUS Step 4) below.

Step 4 and Step 8a: Mixture risk assessment based on measured and calculated mixture toxicity

Decisions taken when using the scheme as provided by EFSA (2013, section 10.3.11) lead to several assessment steps, which give a conclusion on the risk of a mixture or provide additional information important for the assessment. In the tables below the conclusions of different steps of the mixture risk assessment are summarized for the FOCUS Scenarios of concern. Information is reported on:

eee) Step 2 and associated steps, in which the question is answered if concentration addition can be assumed (i.e. a standard mixture toxicity risk assessment is appropriate) or if an antagonism/synergism is possible (more detailed information on Step 2 is given above). This is important to derive if further, specific considerations have to be made in the risk assessment. Associated steps are Step 7, Step 9 and Step 10.

fff) Step 5, in which the question is answered if there is a driver of risk and if so, which of the substance can be classified as driver (more detailed information on Step 5 is given the attached mixture risk calculation file). This is reported as additional information in case an assessment based on a driver would also be possible; for comparative reasons the table always lists the results from the mixture risk assessment according to Step 4 and/or Step 8. For an assessment based on a particular a.s. (the driver) please be referred to the individual a.s. risk assessment.

ggg) Step 4 with the assessment results for cases where product data are usable (according to Step 3) and the risk assessment can be carried out based on the measured toxicity.

hhh) Step 8 (a/b) with the assessment results for cases where product data are not usable (according to Step 3) and the risk assessment has to be based on calculated mixture toxicity.

The intermediate results of the mixture toxicity risk assessment are presented below for the respective FOCUS steps.

Table 9.5.2.2.3-67: Results of the mixture toxicity risk assessment (related to Step 8a) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in sugar beets (BBCH 31).

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	Go to Step 4	0.211	0.427
Step 2			
N-Europe	Go to Step 4	Go to Step 4	0.047
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
D4/ pond	0.001	0.003	0.00
D4/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	Go to Step 4	0.002	0.003
R1/ stream	Go to Step 4	0.0102	0.020
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	Go to Step 4	Go to Step 4	0.028
Step 4	10 m vegetative strip, 5 m no spray buffer and no nozzle reduction		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
D4/ stream	Go to Step 4	Go to Step 4	0.009
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ stream	Go to Step 4	0.005	0.009
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	Go to Step 4	0.006	0.012

Table 9.5.2.2.3-4: Results of the mixture toxicity risk assessment (related to Step 4) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in sugar beets (BBCH 31).

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	0.111	Go to Step 5/8	Go to Step 5/8
Step 2			
N-Europe	0.010	0.016	Go to Step 5/8
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	0.003	0.005	0.010
D4/ pond	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
D4/ stream	0.003	0.004	0.008
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	0.001	Go to Step 5/8	Go to Step 5/8
R1/ stream	0.005	Go to Step 5/8	Go to Step 5/8
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	0.007	0.011	Go to Step 5/8
Step 4	**10 m vegetative strip, 5 m no spray buffer and no nozzle reduction**		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	0.001	0.002	0.003
D4/ stream	0.002	0.003	Go to Step 5/8
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ stream	0.002	Go to Step 5/8	Go to Step 5/8
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	0.003	Go to Step 5/8	Go to Step 5/8

The respective assessment conclusions are presented in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) or

Table 9.5.2.2-4 (FOCUS Step 4). The assessment is based either on the exposure-toxicity ratio (ETR_{mix}) or the risk quotient (RQ_{mix}); the ETR_{mix} and RQ_{mix} are compared to respective trigger values: 1/10 or 1/100 for the ETR_{mix} (depending on the species assessed) and 1 for RQ_{mix}. For the sake of a concise assessment the results below are limited to the organism groups most at risk. Further in-depth justification and explanation for other organism groups are documented in the attached mixture risk calculation file.

Table 9.5.2.2.3-5: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for fish, for FOCUS Step 1 – 3 for application of Clapton 325 SC in sugar beets (BBCH 31).

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	0.111	Go to Step 4
Step 2				
N-Europe		no driver	0.010	Go to Step 4
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.003	Go to Step 4
D4/ pond		Azoxystrobin	Go to Step 5/8	0.001
D4/ stream		no driver	0.003	Go to Step 4
D6/ ditch		Scenario is not relevant for Central Zone		
R1/ pond		Azoxystrobin	0.001	Go to Step 4
R1/ stream		Azoxystrobin	0.005	Go to Step 4
R2/ stream		Scenario is not relevant for Central Zone		
R3/ stream		Azoxystrobin	0.007	Go to Step 4

Table 9.5.2.2.3-6: Summary of the mixture toxicity risk assessment (related to Step 4) for fish based on FOCUS Step 4 calculations for application of Clapton 325 SC in sugar beets (BBCH 31).

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.001		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.002		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.002		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.003		
50%										
75%										
90%										

Table 9.5.2.2.3-7: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for invertebrates, for FOCUS Step 1 – 3 for application of Clapton 325 SC in sugar beets (BBCH 31).

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	Go to Step 5/8	0.211
Step 2				
N-Europe		Azoxystrobin	0.016	Go to Step 4
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.005	Go to Step 4
D4/ pond		Azoxystrobin	Go to Step 5/8	0.003
D4/ stream		no driver	0.004	Go to Step 4
D6/ ditch		Scenario is not relevant for Central Zone		
R1/ pond		Azoxystrobin	Go to Step 5/8	0.002
R1/ stream		Azoxystrobin	Go to Step 5/8	0.010
R2/ stream		Scenario is not relevant for Central Zone		
R3/ stream		Azoxystrobin	0.011	Go to Step 4

Table 9.5.2.2.3-8: Summary of the mixture toxicity risk assessment (related to Step 4) for invertebrates based on FOCUS Step 4 calculations for application of Clapton 325 SC in sugar beets (BBCH 31).

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.002		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.003		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.005		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.006		
50%										
75%										
90%										

Table 9.5.2.2.3-9: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for algae, for FOCUS Step 1 – 3 for application of Clapton 325 SC in sugar beets (BBCH 31).

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	no driver	Go to Step 5/8	0.427
Step 2				
N-Europe		no driver	Go to Step 5/8	0.047
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.010	Go to Step 4
D4/ pond		no driver	Go to Step 5/8	0.002
D4/ stream		no driver	0.008	Go to Step 4
D6/ ditch		Scenario is not relevant for Central Zone		
R1/ pond		no driver	Go to Step 5/8	0.003
R1/ stream		no driver	Go to Step 5/8	0.020
R2/ stream		Scenario is not relevant for Central Zone		
R3/ stream		no driver	Go to Step 5/8	0.028

Table 9.5.2.2.3-10: Summary of the mixture toxicity risk assessment (related to Step 4) for algae based on FOCUS Step 4 calculations for application of Clapton 325 SC in sugar beets (BBCH 31).

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.003		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.009		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.009		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.012		
50%										
75%										
90%										

Table 9.5.2.2.3-681: Summary of mixture toxicity assessment for SCORPIO 325 SC for aquatic organisms for the use according to the GAP table for Sugar beets (BBCH 31)

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50}	E_rC_{50}	E_bC_{50}
AF		100	100	10
RAC_{mix} (µg/L)		496.227	321.088	171.345
FOCUS scenerio	PEC_{max} (µg/L)			
Step 1	55.2500	55.2500	0.1721	0.3224
Step 2				
N-Europe	5.0400	10.2700	0.0157	0.0294
Step 3				
D1 / Ditch	3.4925	0.0070	0.0109	0.0204
D1 / Stream	2.3865	0.0048	0.0074	0.0139
D3 / Ditch	2.0564	0.0041	0.0064	0.0120
D4 / Pond	0.4024	0.0008	0.0013	0.0023
D4 / Stream	1.6938	0.0034	0.0053	0.0099
D5 / Pond	0.1957	0.0004	0.0006	0.0011
D5 / Stream	1.7336	0.0035	0.0054	0.0101
R1 / Pond	0.2088	0.0004	0.0007	0.0012
R1 / Stream	2.0632	0.0042	0.0064	0.0120
Step 4				
D3 / Ditch	0.5561	0.0011	0.0017	0.0032
D4 / Stream	0.8504	0.0017	0.0026	0.0050
R1 / Stream	1.1950	0.0024	0.0037	0.0070
R3 / Stream	1.5449	0.0031	0.0048	0.0090

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50} 496.227	E_rC_{50} 321.088	E_bC_{50} 171.345
AF		100	100	10
RAC_{mix} (µg/L)		4.962	3.211	17.135
FOCUS scenerio	PEC_{max} (µg/L)			
Step 1	55.2500	>1	>1	>1
Step 2				
N-Europe	5.0400	>1	>1	<1
Step 3				
D3 / Ditch	2.0564	<1	<1	-
D4 / Pond	0.4024	<1	<1	-
D4 / Stream	1.6938	<1	<1	-
D5 / Pond	0.1957	<1	<1	-
D5 / Stream	1.7336	<1	<1	-
R1 / Pond	0.2088	<1	<1	-
R1 / Stream	2.0632	<1	<1	-

9.5.2.2.1 Risk assessment of mixture toxicity based on Sugar beets

Table 9.5.2.2.3-69: Summary of assessment steps considered for the mixture risk assessment

Steps	Conclusion on the Steps		
	Fish	Invertebrates	Algae
Screening 1: ETR trigger (optional Step)	-	-	-
Screening 2: Driver (optional Step)	-	-	-
Step 1: data available?	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.
Step 2: apparent synergism or antagonism?	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.
Step 3: mixture similar or not?	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.
Step 4: ETRmix assessment (ECxPPP)	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).
Step 5: driver available?	There is no driver for fish in all scenarios. Go to Step 8.	There is no driver for invertebrates in all scenarios. Go to Step 8.	There is no driver for algae in all scenarios. Go to Step 8.
Step 6: driver assessment	-	-	-

Step 7: synergism assessment (few data)	-	-	-
Step 8a: ETRmix assessment	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**
Step 8b: RQmix assessment	-	-	-
Step 9: antagonism assessment	-	-	-
Step 10: synergism assessment	-	-	-

Overview of the assessment steps: Table 9.5.2.2-1 gives a summary of the decisions made for each organism group during the mixture risk assessment with respect to the decision scheme as provided by EFSA (2013, section 10.3.11). A discussion of all details of every decision is not intended in this section of this registration report. Further in-depth justification and explanation for the decisions made are documented in the attached mixture risk calculation file. However, at least data for some important steps are documented in this section of this registration report, beginning with the check for (and potentially assessment of) synergistic or antagonistic effects (Step 2 and Steps 7, 9 and 10) as well as the ETR_{mix} or RQ_{mix} calculation results for the assessed FOCUS Scenarios (Steps 4 and 8a/b).

Step 2: MDR calculation to check for synergistic or antagonistic effects

Table 9.5.2.2.3-70: Calculated mixture toxicity and MDR for each group of organisms (see sections 10.3.3 and 10.3.4 of EFSA (2013) for more details)

Species	Substance	Concentration (Ci) in formulation (g a.s./L)	Pi	ECxi (mg a.s./L)	ECxmix-CA (mg sum a.s. /L)	ECxPPP (mg sum a.s. /L)	MDR
Fish, acute toxicity 1							
Oncorhynchus mykiss	Azoxystrobin	200	0.62	0.47	0.603	0.496227771	1.21
Oncorhynchus mykiss	Difenoconazole	125	0.38	1.1			
Invertebrates, acute toxicity 1							
Daphnia	Azoxystrobin	200	0.62	0.23	0.315	0.321088558	0.98
Daphnia	Difenoconazole	125	0.38	0.77			
Algae							
Selenastrum capricornutum (green algae)	Azoxystrobin	200	0.62	0.36	0.073	0.17134453	0.43
Scenedesmus subspicatus (green alage)	Difenoconazole	125	0.38	0.032			

[1] For a possible inclusion of chronic toxicity please refer to the FAQ document distributed alongside the aquatic mixture toxicity calculation tool "AGD_AquaMix".

[2] MDR = 0.2 – 5 → Go to Step 3 (concentration addition (CA) approximately holds for the calculated mixture);

MDR > 5 → Go to Step 10 (the calculated mixture is more toxic than CA, i.e. synergistic);

MDR < 0.2 → Go to Step 9 (the calculated mixture is less toxic than CA, i.e. antagonistic)

The density of the liquid formulation of SCORPIO 3250 SC, equal to 1.1134 g/ml, was used in the performed calculations.

Step 3 Comparison of mixture composition of PPP and PEC_{mix}

According to Step 3 it has to be checked whether the mixture composition in the formulation is similar to the mixture composition at PEC_{mix} (which is the sum of PEC_i of individual active substances). Therefore, the "$ECx_{mix\text{-}CA}$ (a.s. in PPP) / $ECx_{mix\text{-}CA}$ (a.s. in PEC_{mix})" ratios were calculated.

In case the ratio is in the range of 0.8–1.2 (mixture similar), the risk assessment can be based on the ECx_{PPP} (Step 4).

In case the ratio is outside the range of 0.8–1.2 (i.e. mixture not similar), the endpoint $ECx_{mix\text{-}CA}$ normalized to the mixture composition at PEC_{mix} (reported as "$ECx_{mix\text{-}CA}$ (a.s. in PEC_{mix})" in EFSA, 2013, and the following parts of this report) has to be used to calculate the risk (Step 5 or Step 8, respectively).

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if product or calculated endpoint data (according to Step 3) have to be used. Further in-depth justification and explanation are documented in the attached mixture risk calculation file.

Step 5: Driver detection

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if a driver of risk is available according to Step 5. Further in-depth justification and explanation are documented in the attached mixture risk calculation file. Further information for the availability of a driver for the risk assessment of particular FOCUS Scenarios is given in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) and

Table 9.5.2.2-4 (FOCUS Step 4) below.

Step 4 and Step 8a: Mixture risk assessment based on measured and calculated mixture toxicity

Decisions taken when using the scheme as provided by EFSA (2013, section 10.3.11) lead to several assessment steps, which give a conclusion on the risk of a mixture or provide additional information important for the assessment. In the tables below the conclusions of different steps of the mixture risk assessment are summarized for the FOCUS Scenarios of concern. Information is reported on:

iii) Step 2 and associated steps, in which the question is answered if concentration addition can be assumed (i.e. a standard mixture toxicity risk assessment is appropriate) or if an antagonism/synergism is possible (more detailed information on Step 2 is given above). This is important to derive if further, specific considerations have to be made in the risk assessment. Associated steps are Step 7, Step 9 and Step 10.

jjj) Step 5, in which the question is answered if there is a driver of risk and if so, which of the substance can be classified as driver (more detailed information on Step 5 is given the attached mixture risk calculation file). This is reported as additional information in case an assessment based on a driver would also be possible; for comparative reasons the table always lists the results from the mixture risk assessment according to Step 4 and/or Step 8. For an assessment based on a particular a.s. (the driver) please be referred to the individual a.s. risk assessment.

kkk) Step 4 with the assessment results for cases where product data are usable (according to Step 3) and the risk assessment can be carried out based on the measured toxicity.

lll) Step 8 (a/b) with the assessment results for cases where product data are not usable (according to Step 3) and the risk assessment has to be based on calculated mixture toxicity.

The intermediate results of the mixture toxicity risk assessment are presented below for the respective FOCUS steps.

Table 9.5.2.2.3-71: Results of the mixture toxicity risk assessment (related to Step 8a) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in sugar beets.

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	Go to Step 4	0.211	0.427
Step 2			
N-Europe	Go to Step 4	Go to Step 4	0.046
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
D4/ pond	0.001	0.003	0.002
D4/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	Go to Step 4	Go to Step 4	0.002
R1/ stream	Go to Step 4	Go to Step 4	0.019
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	Go to Step 4	Go to Step 4	0.025
Step 4	10 m vegetative strip, 5 m no spray buffer and no nozzle reduction		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	Go to Step 4	Go to Step 4	Go to Step 4
D4/ stream	Go to Step 4	0.003	0.006
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ stream	0.002	0.004	0.006
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	Go to Step 4	0.004	0.007

Table 9.5.2.2.3-4: Results of the mixture toxicity risk assessment (related to Step 4) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in sugar beets.

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	0.111	Go to Step 5/8	Go to Step 5/8
Step 2			
N-Europe	0.009	0.014	Go to Step 5/8
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	0.003	0.005	0.010
D4/ pond	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
D4/ stream	0.003	0.004	0.008
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	0.000	0.001	Go to Step 5/8
R1/ stream	0.005	0.007	Go to Step 5/8
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	0.005	0.008	Go to Step 5/8
Step 4	10 m vegetative strip, 5 m no spray buffer and no nozzle reduction		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D3/ ditch	0.001	0.001	0.002
D4/ stream	0.002	Go to Step 5/8	Go to Step 5/8
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ stream	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	0.002	Go to Step 5/8	Go to Step 5/8

The respective assessment conclusions are presented in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) or

Table 9.5.2.2-4 (FOCUS Step 4). The assessment is based either on the exposure-toxicity ratio (ETR_{mix}) or the risk quotient (RQ_{mix}); the ETR_{mix} and RQ_{mix} are compared to respective trigger values: 1/10 or 1/100 for the ETR_{mix} (depending on the species assessed) and 1 for RQ_{mix}. For the sake of a concise assessment the results below are limited to the organism groups most at risk. Further in-depth justification and explanation for other organism groups are documented in the attached mixture risk calculation file.

Table 9.5.2.2.3-5: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for fish, for FOCUS Step 1 – 3 for application of Clapton 325 SC in sugar beets.

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	0.111	Go to Step 4
Step 2				
N-Europe		no driver	0.009	Go to Step 4
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.003	Go to Step 4
D4/ pond		Azoxystrobin	Go to Step 5/8	0.001
D4/ stream		no driver	0.003	Go to Step 4
D6/ ditch		Scenario is not relevant for Central Zone		
R1/ pond		Azoxystrobin	0.000	Go to Step 4
R1/ stream		Azoxystrobin	0.005	Go to Step 4
R2/ stream		Scenario is not relevant for Central Zone		
R3/ stream		Azoxystrobin	0.005	Go to Step 4

Table 9.5.2.2.3-6: Summary of the mixture toxicity risk assessment (related to Step 4) for fish based on FOCUS Step 4 calculations for application of Clapton 325 SC in sugar beets.

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.001		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.002		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.002		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.002		
50%										
75%										
90%										

Table 9.5.2.2.3-7: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for invertebrates, for FOCUS Step 1 – 3 for application of Clapton 325 SC in sugar beets.

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	Go to Step 5/8	0.211
Step 2				
N-Europe		Azoxystrobin	0.014	Go to Step 4
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.005	Go to Step 4
D4/ pond		Azoxystrobin	Go to Step 5/8	0.003
D4/ stream		no driver	0.004	Go to Step 4
D6/ ditch		Scenario is not relevant for Central Zone		
R1/ pond		Azoxystrobin	0.001	Go to Step 4
R1/ stream		Azoxystrobin	0.007	Go to Step 4
R2/ stream		Scenario is not relevant for Central Zone		
R3/ stream		Azoxystrobin	0.008	Go to Step 4

Table 9.5.2.2.3-8: Summary of the mixture toxicity risk assessment (related to Step 4) for invertebrates based on FOCUS Step 4 calculations for application of Clapton 325 SC in sugar beets.

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.001		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.003		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.004		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.004		
50%										
75%										
90%										

Table 9.5.2.2.3-9: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for algae, for FOCUS Step 1 – 3 for application of Clapton 325 SC in sugar beets.

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	no driver	Go to Step 5/8	0.427
Step 2				
N-Europe		no driver	Go to Step 5/8	0.046
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D3/ ditch		no driver	0.010	Go to Step 4
D4/ pond		Azoxystrobin	Go to Step 5/8	0.002
D4/ stream		no driver	0.008	Go to Step 4
D6/ ditch		Scenario is not relevant for Central Zone		
R1/ pond		no driver	Go to Step 5/8	0.002
R1/ stream		no driver	Go to Step 5/8	0.019
R2/ stream		Scenario is not relevant for Central Zone		
R3/ stream		no driver	Go to Step 5/8	0.025

Table 9.5.2.2.3-10: Summary of the mixture toxicity risk assessment (related to Step 4) for algae based on FOCUS Step 4 calculations for application of Clapton 325 SC in sugar beets.

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D3 Ditch							0.002		
50%										
75%										
90%										
None	D4 Pond	The risk was considered acceptable at Step 3								
None	D4 Stream							0.006		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.006		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.007		
50%										
75%										
90%										

Table 9.5.2.2.3-721: Summary of mixture toxicity assessment for SCORPIO 325 SC for aquatic organisms for the use according to the GAP table for Sugar beets BBCH 39

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50}	E_rC_{50}	E_bC_{50}
AF		100	100	10
RAC_{mix} (µg/L)		496.227	321.088	171.345
FOCUS scenerio	PEC_{max} (µg/L)			
Step 1	55.2500	55.2500	0.1721	0.3224
Step 2				
N-Europe	4.6200	10.2700	0.0144	0.0270
Step 3				
D1 / Ditch	3.4925	0.0070	0.0109	0.0204
D1 / Stream	2.3865	0.0048	0.0074	0.0139
D3 / Ditch	1.6996	0.0034	0.0053	0.0099
D4 / Pond	0.6252	0.0013	0.0019	0.0036
D4 / Stream	1.3954	0.0028	0.0043	0.0081
R1 / Pond	0.1761	0.0004	0.0005	0.0010
R1 / Stream	2.3221	0.0047	0.0072	0.0136
R3 / Stream	2.6015	0.0052	0.0081	0.0152
Step 4				
D3 / Ditch	0.2949	0.0006	0.0009	0.0017
D4 / Stream	0.8014	0.0016	0.0025	0.0047
R1 / Stream	0.9562	0.0019	0.0030	0.0056
R3 / Stream	1.0379	0.0021	0.0032	0.0061

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50} 496.227	E_rC_{50} 321.088	E_bC_{50} 171.345
AF		100	100	10
RAC_{mix} (µg/L)		4.962	3.211	17.135
FOCUS scenerio	**PEC_{max} (µg/L)**			
Step 1	55.2500	>1	>1	>1
Step 2				
N-Europe	4.6200	>1	>1	<1
Step 3				
D3 / Ditch	1.6996	<1	<1	-
D4 / Pond	0.6252	<1	<1	-
D4 / Stream	1.3954	<1	<1	-
R1 / Pond	0.1761	<1	<1	-
R1 / Stream	2.3221	<1	<1	-
R3 / Stream	2.6015	<1	<1	-

9.5.2.2.2 Risk assessment of mixture toxicity based on Sunflower (BBCH 31)

Table 9.5.2.2.3-73: Summary of assessment steps considered for the mixture risk assessment

Steps	Conclusion on the Steps		
	Fish	Invertebrates	Algae
Screening 1: ETR trigger (optional Step)	-	-	-
Screening 2: Driver (optional Step)	-	-	-
Step 1: data available?	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.
Step 2: apparent synergism or antagonism?	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.
Step 3: mixture similar or not?	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.
Step 4: ETRmix assessment (ECxPPP)	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).
Step 5: driver available?	There is no driver for fish in all scenarios. Go to Step 8.	There is no driver for invertebrates in all scenarios. Go to Step 8.	There is no driver for algae in all scenarios. Go to Step 8.
Step 6: driver assessment	-	-	-

Step 7: synergism assessment (few data)	-	-	-
Step 8a: ETRmix assessment	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**
Step 8b: RQmix assessment	-	-	-
Step 9: antagonism assessment	-	-	-
Step 10: synergism assessment	-	-	-

Overview of the assessment steps: Table 9.5.2.2-1 gives a summary of the decisions made for each organism group during the mixture risk assessment with respect to the decision scheme as provided by EFSA (2013, section 10.3.11). A discussion of all details of every decision is not intended in this section of this registration report. Further in-depth justification and explanation for the decisions made are documented in the attached mixture risk calculation file. However, at least data for some important steps are documented in this section of this registration report, beginning with the check for (and potentially assessment of) synergistic or antagonistic effects (Step 2 and Steps 7, 9 and 10) as well as the ETR_{mix} or RQ_{mix} calculation results for the assessed FOCUS Scenarios (Steps 4 and 8a/b).

Step 2: MDR calculation to check for synergistic or antagonistic effects

Table 9.5.2.2.3-74: Calculated mixture toxicity and MDR for each group of organisms (see sections 10.3.3 and 10.3.4 of EFSA (2013) for more details)

Species	Substance	Concentration (Ci) in formulation (g a.s./L)	Pi	ECxi (mg a.s./L)	ECxmix-CA (mg sum a.s. /L)	ECxPPP (mg sum a.s. /L)	MDR
Fish, acute toxicity 1							
Oncorhynchus mykiss	Azoxystrobin	200	0.62	0.47	0.603	0.496227771	1.21
Oncorhynchus mykiss	Difenoconazole	125	0.38	1.1			
Invertebrates, acute toxicity 1							
Daphnia	Azoxystrobin	200	0.62	0.23	0.315	0.321088558	0.98
Daphnia	Difenoconazole	125	0.38	0.77			
Algae							
Selenastrum capricornutum (green algae)	Azoxystrobin	200	0.62	0.36	0.073	0.17134453	0.43
Scenedesmus subspicatus (green alage)	Difenoconazole	125	0.38	0.032			

[1] For a possible inclusion of chronic toxicity please refer to the FAQ document distributed alongside the aquatic mixture toxicity calculation tool "AGD_AquaMix".

[2] MDR = 0.2 – 5 → Go to Step 3 (concentration addition (CA) approximately holds for the calculated mixture);

MDR > 5 → Go to Step 10 (the calculated mixture is more toxic than CA, i.e. synergistic);

MDR < 0.2 → Go to Step 9 (the calculated mixture is less toxic than CA, i.e. antagonistic)

The density of the liquid formulation of SCORPIO 3250 SC, equal to 1.1134 g/ml, was used in the performed calculations.

Step 3 Comparison of mixture composition of PPP and PEC_{mix}

According to Step 3 it has to be checked whether the mixture composition in the formulation is similar to the mixture composition at PEC_{mix} (which is the sum of PEC_i of individual active substances). Therefore,

the "ECx_{mix-CA} (a.s. in PPP) / ECx_{mix-CA} (a.s. in PEC_{mix})" ratios were calculated.

In case the ratio is in the range of 0.8–1.2 (mixture similar), the risk assessment can be based on the ECx_{PPP} (Step 4).

In case the ratio is outside the range of 0.8–1.2 (i.e. mixture not similar), the endpoint ECx_{mix-CA} normalized to the mixture composition at PEC_{mix} (reported as "ECx_{mix-CA} (a.s. in PEC_{mix})" in EFSA, 2013, and the following parts of this report) has to be used to calculate the risk (Step 5 or Step 8, respectively).

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if product or calculated endpoint data (according to Step 3) have to be used. Further in-depth justification and explanation are documented in the attached mixture risk calculation file.

Step 5: Driver detection

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if a driver of risk is available according to Step 5. Further in-depth justification and explanation are documented in the attached mixture risk calculation file. Further information for the availability of a driver for the risk assessment of particular FOCUS Scenarios is given in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) and

Table 9.5.2.2-4 (FOCUS Step 4) below.

Step 4 and Step 8a: Mixture risk assessment based on measured and calculated mixture toxicity

Decisions taken when using the scheme as provided by EFSA (2013, section 10.3.11) lead to several assessment steps, which give a conclusion on the risk of a mixture or provide additional information important for the assessment. In the tables below the conclusions of different steps of the mixture risk assessment are summarized for the FOCUS Scenarios of concern. Information is reported on:

mmm) Step 2 and associated steps, in which the question is answered if concentration addition can be assumed (i.e. a standard mixture toxicity risk assessment is appropriate) or if an antagonism/synergism is possible (more detailed information on Step 2 is given above). This is important to derive if further, specific considerations have to be made in the risk assessment. Associated steps are Step 7, Step 9 and Step 10.

nnn) Step 5, in which the question is answered if there is a driver of risk and if so, which of the substance can be classified as driver (more detailed information on Step 5 is given the attached mixture risk calculation file). This is reported as additional information in case an assessment based on a driver would also be possible; for comparative reasons the table always lists the results from the mixture risk assessment according to Step 4 and/or Step 8. For an assessment based on a particular a.s. (the driver) please be referred to the individual a.s. risk assessment.

ooo) Step 4 with the assessment results for cases where product data are usable (according to Step 3) and the risk assessment can be carried out based on the measured toxicity.

ppp) Step 8 (a/b) with the assessment results for cases where product data are not usable (according to Step 3) and the risk assessment has to be based on calculated mixture toxicity.

The intermediate results of the mixture toxicity risk assessment are presented below for the respective FOCUS steps.

Table 9.5.2.2.3-75: Results of the mixture toxicity risk assessment (related to Step 8a) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in Sunflower (BBCH 31)

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	Go to Step 4	0.211	0.427
Step 2			
N-Europe	Go to Step 4	0.026	0.051
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D5/ pond	0.001	0.002	0.002
D5/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	Go to Step 4	Go to Step 4	0.002
R1/ stream	Go to Step 4	0.010	0.020
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	Go to Step 4	0.014	0.028
R4/ stream	0.008	0.017	0.024
Step 4	10 m vegetative strip, 5 m no spray buffer and no nozzle reduction		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D5/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ stream	Go to Step 4	0.004	0.009
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	Go to Step 4	0.006	0.012
R4/ stream	0.004	0.007	0.010

Table 9.5.2.2.3-4: Results of the mixture toxicity risk assessment (related to Step 4) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in Sunflower (BBCH 31)

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	0.111	Go to Step 5/8	Go to Step 5/8
Step 2			
N-Europe	0.014	Go to Step 5/8	Go to Step 5/8
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D5/ pond	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
D5/ stream	0.003	0.005	0.009
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	0.001	0.001	Go to Step 5/8
R1/ stream	0.005	Go to Step 5/8	Go to Step 5/8
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	0.007	Go to Step 5/8	Go to Step 5/8
R4/ stream	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
Step 4	**10 m vegetative strip, 5 m no spray buffer and no nozzle reduction**		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D5/ stream	0.001	0.002	0.004
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ stream	0.002	Go to Step 5/8	Go to Step 5/8
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	0.003	Go to Step 5/8	Go to Step 5/8
R4/ stream	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8

The respective assessment conclusions are presented in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) or

Table 9.5.2.2-4 (FOCUS Step 4). The assessment is based either on the exposure-toxicity ratio (ETR_{mix}) or the risk quotient (RQ_{mix}); the ETR_{mix} and RQ_{mix} are compared to respective trigger values: 1/10 or 1/100 for the ETR_{mix} (depending on the species assessed) and 1 for RQ_{mix}. For the sake of a concise assessment the results below are limited to the organism groups most at risk. Further in-depth justification and explanation for other organism groups are documented in the attached mixture risk calculation file.

Table 9.5.2.2.3-5: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for fish, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Sunflower (BBCH 31)

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	0.111	Go to Step 4
Step 2				
N-Europe		Azoxystrobin	0.014	Go to Step 4
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D5/ pond		Azoxystrobin	Go to Step 5/8	0.001
D5/ stream		no driver	0.003	Go to Step 4
D6/ ditch		Scenario is not relevant for Central Zone		
R1/ pond		Azoxystrobin	0.001	Go to Step 4
R1/ stream		Azoxystrobin	0.005	Go to Step 4
R2/ stream		Scenario is not relevant for Central Zone		
R3/ stream		Azoxystrobin	0.007	Go to Step 4
R4/ stream		Azoxystrobin	Go to Step 5/8	0.008

Table 9.5.2.2.3-6: Summary of the mixture toxicity risk assessment (related to Step 4) for fish based on FOCUS Step 4 calculations for application of Clapton 325 SC in Sunflower (BBCH 31)

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream							0.001		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.002		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.003		
50%										
75%										
90%										
None	R4 stream							0.004		
50%										
75%										
90%										

Table 9.5.2.2.3-7: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for invertebrates, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Sunflower (BBCH 31)

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	Go to Step 5/8	0.211
Step 2				
N-Europe		Azoxystrobin	Go to Step 5/8	0.026
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D5/ pond		Azoxystrobin	Go to Step 5/8	0.002
D5/ stream		no driver	0.005	Go to Step 4
D6/ ditch		Scenario is not relevant for Central Zone		
R1/ pond		Azoxystrobin	0.001	Go to Step 4
R1/ stream		Azoxystrobin	Go to Step 5/8	0.010
R2/ stream		Scenario is not relevant for Central Zone		
R3/ stream		Azoxystrobin	Go to Step 5/8	0.014
R4/ stream		Azoxystrobin	Go to Step 5/8	0.017

Table 9.5.2.2.3-8: Summary of the mixture toxicity risk assessment (related to Step 4) for invertebrates based on FOCUS Step 4 calculations for application of Clapton 325 SC in Sunflower (BBCH 31)

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream							0.002		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.004		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.006		
50%										
75%										
90%										
None	R4 stream							0.007		
50%										
75%										
90%										

Table 9.5.2.2.3-7: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for algae, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Sunflower (BBCH 31)

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	no driver	Go to Step 5/8	0.427
Step 2				
N-Europe		no driver	Go to Step 5/8	0.051
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D5/ pond		no driver	Go to Step 5/8	0.002
D5/ stream		no driver	0.009	Go to Step 4
D6/ ditch		Scenario is not relevant for Central Zone		
R1/ pond		no driver	Go to Step 5/8	0.002
R1/ stream		no driver	Go to Step 5/8	0.020
R2/ stream		Scenario is not relevant for Central Zone		
R3/ stream		no driver	Go to Step 5/8	0.028
R4/ stream		no driver	Go to Step 5/8	0.024

Table 9.5.2.2.3-10: Summary of the mixture toxicity risk assessment (related to Step 4) for algae based on FOCUS Step 4 calculations for application of Clapton 325 SC in Sunflower (BBCH 31)

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream							0.004		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.009		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.012		
50%										
75%										
90%										
None	R4 stream							0.010		
50%										
75%										
90%										

Table 9.5.2.2.3-761: Summary of mixture toxicity assessment for SCORPIO 325 SC for aquatic organisms for the use according to the GAP table for Sunflower (BBCH 31)

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50}	E_rC_{50}	E_bC_{50}
AF		100	100	10
RAC_{mix} (µg/L)		496.227	321.088	171.345
FOCUS scenerio	**PEC_{max} (µg/L)**			
Step 1	55.2500	55.2500	0.1721	0.3224
Step 2				
N-Europe	6.7400	10.2700	0.0210	0.0393
Step 3				
D1 / Ditch	3.4925	0.0070	0.0109	0.0204
D1 / Stream	2.3865	0.0048	0.0074	0.0139
D5 / Pond	0.3899	0.0008	0.0012	0.0023
D5 / Stream	1.5259	0.0031	0.0048	0.0089
R1 / Pond	0.2489	0.0005	0.0008	0.0015
R1 / Stream	2.5729	0.0052	0.0080	0.0150
R3 / Stream	3.6452	0.0073	0.0114	0.0213
R4 / Stream	4.1205	0.0083	0.0128	0.0240
Step 4				
D5 / Stream	0.7312	0.0015	0.0023	0.0043
R1 / Stream	1.1548	0.0023	0.0036	0.0067
R3 / Stream	1.6375	0.0033	0.0051	0.0096
R4 / Stream	1.8408	0.0037	0.0057	0.0107

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50} 496.227	E_rC_{50} 321.088	E_bC_{50} 171.345
AF		100	100	10
RAC_{mix} (µg/L)		4.962	3.211	17.135
FOCUS scenerio	**PEC_{max} (µg/L)**			
Step 1	55.2500	>1	>1	>1
Step 2				
N-Europe	6.7400	>1	>1	<1
Step 3				
D5 / Pond	0.3899	<1	<1	-
D5 / Stream	1.5259	<1	<1	-
R1 / Pond	0.2489	<1	<1	-
R1 / Stream	2.5729	<1	<1	-
R3 / Stream	3.6452	<1	>1	-
R4 / Stream	4.1205	<1	>1	-
Step 4	**10 m vegetative strip + 5 m no spray buffer**			
R3 / Stream	1.6375	-	<1	-
R4 / Stream	1.8408	-	<1	-

9.5.2.2.3 Risk assessment of mixture toxicity based on Sunflower

Table 9.5.2.2.3-77: Summary of assessment steps considered for the mixture risk assessment

Steps	Conclusion on the Steps		
	Fish	Invertebrates	Algae
Screening 1: ETR trigger (optional Step)	-	-	-
Screening 2: Driver (optional Step)	-	-	-
Step 1: data available?	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.
Step 2: apparent synergism or antagonism?	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.
Step 3: mixture similar or not?	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.
Step 4: ETRmix assessment (ECxPPP)	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).
Step 5: driver available?	There is no driver for fish in all scenarios. Go to Step 8.	There is no driver for invertebrates in all scenarios. Go to Step 8.	There is no driver for algae in all scenarios. Go to Step 8.
Step 6: driver assessment	-	-	-

Step 7: synergism assessment (few data)	-	-	-
Step 8a: ETRmix assessment	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**
Step 8b: RQmix assessment	-	-	-
Step 9: antagonism assessment	-	-	-
Step 10: synergism assessment	-	-	-

Overview of the assessment steps: Table 9.5.2.2-1 gives a summary of the decisions made for each organism group during the mixture risk assessment with respect to the decision scheme as provided by EFSA (2013, section 10.3.11). A discussion of all details of every decision is not intended in this section of this registration report. Further in-depth justification and explanation for the decisions made are documented in the attached mixture risk calculation file. However, at least data for some important steps are documented in this section of this registration report, beginning with the check for (and potentially assessment of) synergistic or antagonistic effects (Step 2 and Steps 7, 9 and 10) as well as the ETR_{mix} or RQ_{mix} calculation results for the assessed FOCUS Scenarios (Steps 4 and 8a/b).

Step 2: MDR calculation to check for synergistic or antagonistic effects

Table 9.5.2.2.3-78: Calculated mixture toxicity and MDR for each group of organisms (see sections 10.3.3 and 10.3.4 of EFSA (2013) for more details)

Species	Substance	Concentration (Ci) in formulation (g a.s./L)	Pi	ECxi (mg a.s./L)	ECxmix-CA (mg sum a.s. /L)	ECxPPP (mg sum a.s. /L)	MDR
Fish, acute toxicity 1							
Oncorhynchus mykiss	Azoxystrobin	200	0.62	0.47	0.603	0.496227771	1.21
Oncorhynchus mykiss	Difenoconazole	125	0.38	1.1			
Invertebrates, acute toxicity 1							
Daphnia	Azoxystrobin	200	0.62	0.23	0.315	0.321088558	0.98
Daphnia	Difenoconazole	125	0.38	0.77			
Algae							
Selenastrum capricornutum (green algae)	Azoxystrobin	200	0.62	0.36	0.073	0.17134453	0.43
Scenedesmus subspicatus (green alage)	Difenoconazole	125	0.38	0.032			

[1] For a possible inclusion of chronic toxicity please refer to the FAQ document distributed alongside the aquatic mixture toxicity calculation tool "AGD_AquaMix".

[2] MDR = 0.2 – 5 → Go to Step 3 (concentration addition (CA) approximately holds for the calculated mixture);

MDR > 5 → Go to Step 10 (the calculated mixture is more toxic than CA, i.e. synergistic);

MDR < 0.2 → Go to Step 9 (the calculated mixture is less toxic than CA, i.e. antagonistic)

The density of the liquid formulation of SCORPIO 3250 SC, equal to 1.1134 g/ml, was used in the performed calculations.

Step 3 Comparison of mixture composition of PPP and PEC_{mix}

According to Step 3 it has to be checked whether the mixture composition in the formulation is similar to the mixture composition at PEC_{mix} (which is the sum of PEC_i of individual active substances). Therefore, the "$ECx_{mix\text{-}CA}$ (a.s. in PPP) / $ECx_{mix\text{-}CA}$ (a.s. in PEC_{mix})" ratios were calculated.

In case the ratio is in the range of 0.8–1.2 (mixture similar), the risk assessment can be based on the ECx_{PPP} (Step 4).

In case the ratio is outside the range of 0.8–1.2 (i.e. mixture not similar), the endpoint ECx_{mix-CA} normalized to the mixture composition at PEC_{mix} (reported as "ECx_{mix-CA} (a.s. in PEC_{mix})" in EFSA, 2013, and the following parts of this report) has to be used to calculate the risk (Step 5 or Step 8, respectively).

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if product or calculated endpoint data (according to Step 3) have to be used. Further in-depth justification and explanation are documented in the attached mixture risk calculation file.

Step 5: Driver detection

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if a driver of risk is available according to Step 5. Further in-depth justification and explanation are documented in the attached mixture risk calculation file. Further information for the availability of a driver for the risk assessment of particular FOCUS Scenarios is given in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) and

Table 9.5.2.2-4 (FOCUS Step 4) below.

Step 4 and Step 8a: Mixture risk assessment based on measured and calculated mixture toxicity

Decisions taken when using the scheme as provided by EFSA (2013, section 10.3.11) lead to several assessment steps, which give a conclusion on the risk of a mixture or provide additional information important for the assessment. In the tables below the conclusions of different steps of the mixture risk assessment are summarized for the FOCUS Scenarios of concern. Information is reported on:

qqq) Step 2 and associated steps, in which the question is answered if concentration addition can be assumed (i.e. a standard mixture toxicity risk assessment is appropriate) or if an antagonism/synergism is possible (more detailed information on Step 2 is given above). This is important to derive if further, specific considerations have to be made in the risk assessment. Associated steps are Step 7, Step 9 and Step 10.

rrr) Step 5, in which the question is answered if there is a driver of risk and if so, which of the substance can be classified as driver (more detailed information on Step 5 is given the attached mixture risk calculation file). This is reported as additional information in case an assessment based on a driver would also be possible; for comparative reasons the table always lists the results from the mixture risk assessment according to Step 4 and/or Step 8. For an assessment based on a particular a.s. (the driver) please be referred to the individual a.s. risk assessment.

sss) Step 4 with the assessment results for cases where product data are usable (according to Step 3) and the risk assessment can be carried out based on the measured toxicity.

ttt) Step 8 (a/b) with the assessment results for cases where product data are not usable (according to Step 3) and the risk assessment has to be based on calculated mixture toxicity.

The intermediate results of the mixture toxicity risk assessment are presented below for the respective FOCUS steps.

Table 9.5.2.2.3-79: Results of the mixture toxicity risk assessment (related to Step 8a) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in sunflower.

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	Go to Step 4	0.211	0.427
Step 2			
N-Europe	Go to Step 4	0.036	0.073
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D5/ pond	0.001	0.001	0.002
D5/ stream	Go to Step 4	Go to Step 4	Go to Step 4
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	Go to Step 4	0.001	0.002
R1/ stream	Go to Step 4	0.013	0.022
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	Go to Step 4	Go to Step 4	0.025
R4/ stream	0.010	0.020	0.026
Step 4	10 m vegetative strip, 5 m no spray buffer and no nozzle reduction		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D5/ stream	Go to Step 4	Go to Step 4	0.005
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ stream	0.003	0.006	0.008
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	Go to Step 4	0.004	0.007
R4/ stream	0.004	0.009	0.012

Table 9.5.2.2.3-4: Results of the mixture toxicity risk assessment (related to Step 4) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in sunflower.

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	0.111	Go to Step 5/8	Go to Step 5/8
Step 2			
N-Europe	0.019	Go to Step 5/8	Go to Step 5/8
Step 3			
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D5/ pond	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
D5/ stream	0.003	0.005	0.008
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ pond	0.001	Go to Step 5/8	Go to Step 5/8
R1/ stream	0.007	Go to Step 5/8	Go to Step 5/8
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	0.005	0.008	Go to Step 5/8
R4/ stream	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
Step 4	**10 m vegetative strip, 5 m no spray buffer and no nozzle reduction**		
D1/ ditch	Scenarios are not relevant for Central Zone		
D1/ stream			
D2/ ditch	Scenarios are not relevant for Central Zone		
D2/ stream			
D5/ stream	0.001	0.002	Go to Step 5/8
D6/ ditch	Scenario is not relevant for Central Zone		
R1/ stream	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
R2/ stream	Scenario is not relevant for Central Zone		
R3/ stream	0.002	Go to Step 5/8	Go to Step 5/8
R4/ stream	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8

The respective assessment conclusions are presented in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) or

Table 9.5.2.2-4 (FOCUS Step 4). The assessment is based either on the exposure-toxicity ratio (ETR_{mix}) or the risk quotient (RQ_{mix}); the ETR_{mix} and RQ_{mix} are compared to respective trigger values: 1/10 or 1/100 for the ETR_{mix} (depending on the species assessed) and 1 for RQ_{mix}. For the sake of a concise assessment the results below are limited to the organism groups most at risk. Further in-depth justification and explanation for other organism groups are documented in the attached mixture risk calculation file.

Table 9.5.2.2.3-5: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for fish, for FOCUS Step 1 – 3 for application of Clapton 325 SC in sunflower.

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	0.111	Go to Step 4
Step 2				
N-Europe		Azoxystrobin	0.019	Go to Step 4
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D5/ pond		Azoxystrobin	Go to Step 5/8	0.001
D5/ stream		no driver	0.003	Go to Step 4
D6/ ditch		Scenario is not relevant for Central Zone		
R1/ pond		Azoxystrobin	0.001	Go to Step 4
R1/ stream		Azoxystrobin	0.007	Go to Step 4
R2/ stream		Scenario is not relevant for Central Zone		
R3/ stream		no driver	0.005	Go to Step 4
R4/ stream		Azoxystrobin	Go to Step 5/8	0.010

Table 9.5.2.2.3-6: Summary of the mixture toxicity risk assessment (related to Step 4) for fish based on FOCUS Step 4 calculations for application of Clapton 325 SC in sunflower.

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream							0.001		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.003		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.002		
50%										
75%										
90%										
None	R4 stream							0.004		
50%										
75%										
90%										

Table 9.5.2.2.3-7: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for invertebrates, for FOCUS Step 1 – 3 for application of Clapton 325 SC in sunflower.

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	Go to Step 5/8	0.211
Step 2				
N-Europe		Azoxystrobin	Go to Step 5/8	0.036
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D5/ pond		Azoxystrobin	Go to Step 5/8	0.001
D5/ stream		no driver	0.005	Go to Step 4
D6/ ditch		Scenario is not relevant for Central Zone		
R1/ pond		Azoxystrobin	Go to Step 5/8	0.001
R1/ stream		Azoxystrobin	Go to Step 5/8	0.013
R2/ stream		Scenario is not relevant for Central Zone		
R3/ stream		Azoxystrobin	0.008	Go to Step 4
R4/ stream		Azoxystrobin	Go to Step 5/8	0.020

Table 9.5.2.2.3-8: Summary of the mixture toxicity risk assessment (related to Step 4) for invertebrates based on FOCUS Step 4 calculations for application of Clapton 325 SC in sunflower.

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream							0.002		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.006		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.004		
50%										
75%										
90%										
None	R4 stream							0.009		
50%										
75%										
90%										

Table 9.5.2.2.3-9: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for algae, for FOCUS Step 1 – 3 for application of Clapton 325 SC in sunflower.

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	no driver	Go to Step 5/8	0.427
Step 2				
N-Europe		no driver	Go to Step 5/8	0.073
Step 3				
D1/ ditch		Scenarios are not relevant for Central Zone		
D1/ stream				
D2/ ditch		Scenarios are not relevant for Central Zone		
D2/ stream				
D5/ pond		no driver	Go to Step 5/8	0.002
D5/ stream		no driver	0.008	Go to Step 4
D6/ ditch		Scenario is not relevant for Central Zone		
R1/ pond		no driver	Go to Step 5/8	0.002
R1/ stream		no driver	Go to Step 5/8	0.022
R2/ stream		Scenario is not relevant for Central Zone		
R3/ stream		no driver	Go to Step 5/8	0.025
R4/ stream		no driver	Go to Step 5/8	0.026

Table 9.5.2.2.3-10: Summary of the mixture toxicity risk assessment (related to Step 4) for algae based on FOCUS Step 4 calculations for application of Clapton 325 SC in sunflower.

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	5	15	20
None	D1 Ditch	Scenarios are not relevant for Central Zone								
None	D1 stream									
None	D2 Ditch	Scenarios are not relevant for Central Zone								
None	D2 Stream									
None	D5 pond	The risk was considered acceptable at Step 3								
None	D5 stream							0.005		
50%										
75%										
90%										
None	D6 Ditch	Scenarios are not relevant for Central Zone								
None	R1 pond	The risk was considered acceptable at Step 3								
None	R1 stream							0.008		
50%										
75%										
90%										
None	R2 stream	Scenarios are not relevant for Central Zone								
None	R3 stream							0.007		
50%										
75%										
90%										
None	R4 stream							0.012		
50%										
75%										
90%										

Table 9.5.2.2.3-801: Summary of mixture toxicity assessment for SCORPIO 325 SC for aquatic organisms for the use according to the GAP table for Sunflower BBCH 14

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50}	E_rC_{50}	E_bC_{50}
AF		100	100	10
RAC_{mix} (µg/L)		496.227	321.088	171.345
FOCUS scenerio	PEC_{max} (µg/L)			
Step 1	55.2500	55.2500	0.1721	0.3224
Step 2				
N-Europe	9.3400	10.2700	0.0291	0.0545
Step 3				
D1 / Ditch	3.4925	0.0070	0.0109	0.0204
D1 / Stream	2.3865	0.0048	0.0074	0.0139
D5 / Pond	0.2710	0.0005	0.0008	0.0016
D5 / Stream	1.4513	0.0029	0.0045	0.0085
R1 / Pond	0.3332	0.0007	0.0010	0.0019
R1 / Stream	3.3840	0.0068	0.0105	0.0197
R3 / Stream	2.5639	0.0052	0.0080	0.0150
R4 / Stream	4.8277	0.0097	0.0150	0.0282
Step 4				
D5 / Stream	0.4891	0.0010	0.0015	0.0029
R1 / Stream	1.4554	0.0029	0.0045	0.0085
R3 / Stream	0.9864	0.0020	0.0031	0.0058
R4 / Stream	2.1850	0.0044	0.0068	0.0128

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50} 496.227	E_rC_{50} 321.088	E_bC_{50} 171.345
AF		100	100	10
RAC_{mix} (µg/L)		4.962	3.211	17.135
FOCUS scenerio	**PEC_{max} (µg/L)**			
Step 1	55.2500	>1	>1	>1
Step 2				
N-Europe	9.3400	>1	>1	<1
Step 3				
D5 / Pond	0.2710	<1	<1	-
D5 / Stream	1.4513	<1	<1	-
R1 / Pond	0.3332	<1	<1	-
R1 / Stream	3.3840	<1	>1	-
R3 / Stream	2.5639	<1	<1	-
R4 / Stream	4.8277	<1	>1	-
Step 4	**10 m vegetative strip + 10 m no spray buffer**			
R1 / Stream	1.4554	-	<1	-
R4 / Stream	2.1850	-	<1	-

9.5.2.2.4 Risk assessment of mixture toxicity based on Tobacco

Table 9.5.2.2.3-81: Summary of assessment steps considered for the mixture risk assessment

Steps	Conclusion on the Steps		
	Fish	Invertebrates	Algae
Screening 1: ETR trigger (optional Step)	-	-	-
Screening 2: Driver (optional Step)	-	-	-
Step 1: data available?	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.	Endpoints available for a.s. and the ppp, go to Step 2.
Step 2: apparent synergism or antagonism?	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.	The MDR is between 0.2-5. No antagonism or synergism is indicated. Thus, the "concentration addition" concept holds, go to Step 3.
Step 3: mixture similar or not?	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.	Mixture sometimes similar. Some scenario can be assessed via product test, go either to Step 4 or 5.
Step 4: ETRmix assessment (ECxPPP)	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).	Acceptable risk have been found in all scenarios, if risk mitigation is applied (FOCUS Step 4).
Step 5: driver available?	There is no driver for fish in all scenarios. Go to Step 8.	There is no driver for invertebrates in all scenarios. Go to Step 8.	There is no driver for algae in all scenarios. Go to Step 8.
Step 6: driver assessment	-	-	-

Step 7: synergism assessment (few data)	-	-	-
Step 8a: ETRmix assessment	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**	**Risk acceptable for all scenarios, if risk mitigation is applied (FOCUS Step 4).**
Step 8b: RQmix assessment	-	-	-
Step 9: antagonism assessment	-	-	-
Step 10: synergism assessment	-	-	-

Overview of the assessment steps: Table 9.5.2.2-1 gives a summary of the decisions made for each organism group during the mixture risk assessment with respect to the decision scheme as provided by EFSA (2013, section 10.3.11). A discussion of all details of every decision is not intended in this section of this registration report. Further in-depth justification and explanation for the decisions made are documented in the attached mixture risk calculation file. However, at least data for some important steps are documented in this section of this registration report, beginning with the check for (and potentially assessment of) synergistic or antagonistic effects (Step 2 and Steps 7, 9 and 10) as well as the ETR_{mix} or RQ_{mix} calculation results for the assessed FOCUS Scenarios (Steps 4 and 8a/b).

Step 2: MDR calculation to check for synergistic or antagonistic effects

Table 9.5.2.2.3-82: Calculated mixture toxicity and MDR for each group of organisms (see sections 10.3.3 and 10.3.4 of EFSA (2013) for more details)

Species	Substance	Concentration (Ci) in formulation (g a.s./L)	Pi	ECxi (mg a.s./L)	ECxmix-CA (mg sum a.s. /L)	ECxPPP (mg sum a.s. /L)	MDR
Fish, acute toxicity 1							
Oncorhynchus mykiss	Azoxystrobin	200	0.62	0.47	0.603	0.496227771	1.21
Oncorhynchus mykiss	Difenoconazole	125	0.38	1.1			
Invertebrates, acute toxicity 1							
Daphnia	Azoxystrobin	200	0.62	0.23	0.315	0.321088558	0.98
Daphnia	Difenoconazole	125	0.38	0.77			
Algae							
Selenastrum capricornutum (green algae)	Azoxystrobin	200	0.62	0.36	0.073	0.17134453	0.43
Scenedesmus subspicatus (green alage)	Difenoconazole	125	0.38	0.032			

[1] For a possible inclusion of chronic toxicity please refer to the FAQ document distributed alongside the aquatic mixture toxicity calculation tool "AGD_AquaMix".

[2] MDR = 0.2 – 5 → Go to Step 3 (concentration addition (CA) approximately holds for the calculated mixture);

MDR > 5 → Go to Step 10 (the calculated mixture is more toxic than CA, i.e. synergistic);

MDR < 0.2 → Go to Step 9 (the calculated mixture is less toxic than CA, i.e. antagonistic)

The density of the liquid formulation of SCORPIO 3250 SC, equal to 1.1134 g/ml, was used in the performed calculations.

Step 3 Comparison of mixture composition of PPP and PEC_{mix}

According to Step 3 it has to be checked whether the mixture composition in the formulation is similar to the mixture composition at PEC_{mix} (which is the sum of PEC_i of individual active substances). Therefore, the "$ECx_{mix\text{-}CA}$ (a.s. in PPP) / $ECx_{mix\text{-}CA}$ (a.s. in PEC_{mix})" ratios were calculated.

In case the ratio is in the range of 0.8–1.2 (mixture similar), the risk assessment can be based on the ECx_{PPP} (Step 4).

In case the ratio is outside the range of 0.8–1.2 (i.e. mixture not similar), the endpoint $ECx_{mix\text{-}CA}$ normalized to the mixture composition at PEC_{mix} (reported as "$ECx_{mix\text{-}CA}$ (a.s. in PEC_{mix})" in EFSA, 2013, and the following parts of this report) has to be used to calculate the risk (Step 5 or Step 8, respectively).

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if product or calculated endpoint data (according to Step 3) have to be used. Further in-depth justification and explanation are documented in the attached mixture risk calculation file.

Step 5: Driver detection

The decision how the mixture risk assessment is conducted depends on the organism group as well as the assessed FOCUS Scenarios. The overall mixture risk assessment results are given in **Błąd! Nie można odnaleźć źródła odwołania.**, in which it is documented if a driver of risk is available according to Step 5. Further in-depth justification and explanation are documented in the attached mixture risk calculation file. Further information for the availability of a driver for the risk assessment of particular FOCUS Scenarios is given in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) and

Table 9.5.2.2-4 (FOCUS Step 4) below.

Step 4 and Step 8a: Mixture risk assessment based on measured and calculated mixture toxicity

Decisions taken when using the scheme as provided by EFSA (2013, section 10.3.11) lead to several assessment steps, which give a conclusion on the risk of a mixture or provide additional information important for the assessment. In the tables below the conclusions of different steps of the mixture risk assessment are summarized for the FOCUS Scenarios of concern. Information is reported on:

a) Step 2 and associated steps, in which the question is answered if concentration addition can be assumed (i.e. a standard mixture toxicity risk assessment is appropriate) or if an antagonism/synergism is possible (more detailed information on Step 2 is given above). This is important to derive if further, specific considerations have to be made in the risk assessment. Associated steps are Step 7, Step 9 and Step 10.
b) Step 5, in which the question is answered if there is a driver of risk and if so, which of the substance can be classified as driver (more detailed information on Step 5 is given the attached mixture risk calculation file). This is reported as additional information in case an assessment based on a driver would also be possible; for comparative reasons the table always lists the results from the mixture risk assessment according to Step 4 and/or Step 8. For an assessment based on a particular a.s. (the driver) please be referred to the individual a.s. risk assessment.
c) Step 4 with the assessment results for cases where product data are usable (according to Step 3) and the risk assessment can be carried out based on the measured toxicity.
d) Step 8 (a/b) with the assessment results for cases where product data are not usable (according to Step 3) and the risk assessment has to be based on calculated mixture toxicity.

The intermediate results of the mixture toxicity risk assessment are presented below for the respective FOCUS steps.

Table 9.5.2.2.3-83: Results of the mixture toxicity risk assessment (related to Step 8a) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in Tobacco.

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	Go to Step 4	0.422	0.854
Step 2			
N-Europe	Go to Step 4	0.033	0.067
Step 3			
R3/ stream	0.013	0.025	0.032
Step 4	10 m vegetative strip, 5 m no spray buffer and no nozzle reduction		
R3/ stream	0.006	0.012	0.014
Step 4	20 m vegetative strip, 5 m no spray buffer and no nozzle reduction		
R3/ stream	0.003	0.006	0.006

Table 9.5.2.2.3-4: Results of the mixture toxicity risk assessment (related to Step 4) for fish, invertebrates and algae, for FOCUS Steps 1–4 for the application of Clapton 325 SC in Tobacco.

FOCUS Scenario	FOCUS Step 1, Step 2 and Step 3 ETRmix-PPP		
	Fish	Invertebrates	Algae
Step 1	0.223	Go to Step 5/8	Go to Step 5/8
Step 2			
N-Europe	0.017	Go to Step 5/8	Go to Step 5/8
Step 3			
R3/ stream	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
Step 4	10 m vegetative strip, 5 m no spray buffer and no nozzle reduction		
R3/ stream	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8
Step 4	20 m vegetative strip, 5 m no spray buffer and no nozzle reduction		
R3/ stream	Go to Step 5/8	Go to Step 5/8	Go to Step 5/8

The respective assessment conclusions are presented in **Błąd! Nie można odnaleźć źródła odwołania.** (FOCUS Step 1 – 3) or

Table 9.5.2.2-4 (FOCUS Step 4). The assessment is based either on the exposure-toxicity ratio (ETR_{mix}) or the risk quotient (RQ_{mix}); the ETR_{mix} and RQ_{mix} are compared to respective trigger values: 1/10 or 1/100 for the ETR_{mix} (depending on the species assessed) and 1 for RQ_{mix}.. For the sake of a concise assessment the results below are limited to the organism groups most at risk. Further in-depth justification and explanation for other organism groups are documented in the attached mixture risk calculation file.

Table 9.5.2.2.3-5: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for fish, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Tobacco.

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	0.223	Go to Step 4
Step 2				
N-Europe		Azoxystrobin	0.017	Go to Step 4
Step 3				
R3/ stream		Azoxystrobin	Go to Step 5/8	0.013

Table 9.5.2.2.3-6: Summary of the mixture toxicity risk assessment (related to Step 4) for fish based on FOCUS Step 4 calculations for application of Clapton 325 SC in Tobacco.

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	5
None	R3 stream							0.006		0.003
50%										
75%										
90%										

Table 9.5.2.2.3-7: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for invertebrates, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Tobacco.

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	Azoxystrobin	Go to Step 5/8	0.422
Step 2				
N-Europe		Azoxystrobin	Go to Step 5/8	0.033
Step 3				
R3/ stream		Azoxystrobin	Go to Step 5/8	0.025

Table 9.5.2.2.3-8: Summary of the mixture toxicity risk assessment (related to Step 4) for invertebrates based on FOCUS Step 4 calculations for application of Clapton 325 SC in Tobacco.

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	5
None	R3 stream							0.012		0.006
50%										
75%										
90%										

Table 9.5.2.2.3-9: Summary of the mixture toxicity risk assessment (related to Steps 2, 4, 5 and 8a/8b) for algae, for FOCUS Step 1 – 3 for application of Clapton 325 SC in Tobacco.

FOCUS Scenario	Synergism or Antagonism? (e.g. Step 2)	Driver? (Step 5)	$ETR_{mix-PPP}$ (Step 4)	ETR_{mix-CA} (Step 8a)
Step 1	not applicable	no driver	Go to Step 5/8	0.854
Step 2				
N-Europe		no driver	Go to Step 5/8	0.067
Step 3				
R3/ stream		no driver	Go to Step 5/8	0.032

Table 9.5.2.2.3-10: Summary of the mixture toxicity risk assessment (related to Step 4) for algae based on FOCUS Step 4 calculations for application of Clapton 325 SC in Tobacco.

FOCUS Step 4	Scenario	$ETR_{mix-PPP}$ or ETR_{mix-CA}								
Nozzle reduction	Vegetative strip [m]	None	None	None	None	None	5	10	15	20
	No spray buffer [m]	None, default	5	10	15	20	5	10	15	5
None	R3 stream							0.014		0.006
50%										
75%										
90%										

Table 9.5.2.2.3-841: Summary of mixture toxicity assessment for SCORPIO 325 SC for aquatic organisms for the use according to the GAP table for Tobacco

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50}	E_rC_{50}	E_bC_{50}
AF		100	100	10
RAC_{mix} (µg/L)		496.227	321.088	171.345
FOCUS scenerio	PEC_{max} (µg/L)			
Step 1	110.5000	55.2500	0.3441	0.6449
Step 2		-	-	-
N-Europe	8.6600	10.2700	0.0270	0.0505
Step 3		-	-	-
R3 / Stream	6.1855	0.0125	0.0193	0.0361
Step 4		-	-	-
R3 / Stream	1.4421	0.0029	0.0045	0.0084

Group		Fish acute	Inverteb. acute	Algae
Endpoint (µg/L)		E_rC_{50} 496.227	E_rC_{50} 321.088	E_bC_{50} 171.345
AF		100	100	10
RAC_{mix} (µg/L)		4.962	3.211	17.135
FOCUS scenerio	**PEC_{max} (µg/L)**			
Step 1	110.5000	>1	>1	>1
Step 2				
N-Europe	8.6600	>1	>1	<1
Step 3				
R3 / Stream	6.1855	>1	>1	-
Step 4	**10 m vegetative strip + 5 m no spray buffer**			
R3 / Stream	2.81	<1	<1	-

Review Comments:

MIXTURE TOXICITY

The risk assessment for aquatic organisms demonstrated that for following proposed uses of CHR/F/SCORPIO 325 SC the mitigation measures are required:

1. Winter oilseed rape BBCH 14-20 – for scenario R3 - 10 m vfs + 10 m nsb
2. Carrots BBCH 39 – for scenario R4 - 10 m vfs + 10 m nsb
3. Potato BBCH 14 – for scenarios R1, R3 - 10 m vfs + 5 m nsb
4. Potato BBCH 31 – for scenario R3 - 10 m vfs + 5 m nsb
5. Leafy vegetables BBCH 14 – for scenarios R1, R3, R4 – 10 m vfs + 10 m nsb
6. Tobacco – for R3 scenario – 10 m vfs + 5 m nsb
7. Orchards BBCH 10 and BBCH 31 – for scenarios D3, D4, D5, R1, R3, R4 – 20 m vfs + 20 m nsb + 75% drift reduction
8. Maize BBCH 14 – for scenarios R3, R4 – 10 m vfs + 10 m nsb
9. Maize BBCH 31 – for scenarios R3, R4 – 10 m vfs + 5 m nsb
10. Sunflower BBCH 14 - for scenarios R1, R4 - 10 m vfs + 10 m nsb
11. Sunflower BBCH 31 - for scenarios R3, R4 - 10 m vfs + 5 m nsb

9.5.3 Overall conclusions

~~Based on the predicted rates of CHR/F/SCORPIO 325 SC, the TER values describing the risk for aquatic species following exposure to CHR/F/SCORPIO 325 SC according to the GAP of the formulation CHR/F/SCORPIO 325 SC achieve the acceptability criteria with applying appropriate mitigation measures~~

The risk to aquatic organisms has been assessed using test species fish and invertebrates, and was found to be acceptable. ~~For the azoxystrobin, invertebrates was selected for risk refinement in accordance with the guidance provided in document EFSA Journal 2010; 8(4):1542. It was concluded that, after consideration of all lines of evidence and based on study of mesocosm, the RAC should be established at a level of 3.3 µg a.s./L. Therefore, study of mesocosm was applied as a risk refinement element and considered in the overall risk assessment of the mixture, i.e., product CHR/F/SCORPIO 325 SC.~~

The overall assessment indicates an acceptable risk to aquatic organisms for the evaluated active substances under the considered exposure scenarios. Representative species were selected to cover the main trophic levels of the aquatic ecosystem, including fish, aquatic invertebrates, and algae, in order to ensure a balanced and ecologically relevant evaluation.
Within the algal group, different test species were used for the two active substances: *Pseudokirchneriella subcapitata* for azoxystrobin and *Scenedesmus subspicatus* for difenoconazole. Although not identical, both species belong to the group of green algae, and therefore their comparison is considered scientifically appropriate and representative for assessing potential effects on primary producers.
Regarding the selection of endpoints, EC_{50} was used for azoxystrobin and EbC_{50} for difenoconazole, as these were the only values available from reliable studies. To ensure consistency in the overall evaluation and to maintain a precautionary approach, the E_bC_{50} from the formulation test was used for comparison, since it represents a more conservative endpoint (typically lower than EC_{50}). This choice provides a worst-case perspective and strengthens the robustness of the risk characterisation.

Based on the predicted application rates of CHR/F/SCORPIO 325 SC, the TER values for aquatic organisms exposed to CHR/F/SCORPIO 325 SC under the GAP meet the acceptability criteria when appropriate risk mitigation measures are applied.

Review Comments:

The risk assessment for aquatic organisms carried out by the Applicant was not accepted as the PEC/RAC calculations were based on unaccepted $PEC_{SW/SED}$ values.

Furthermore, for difenoconazole, in the revised eFate section (dRR B8) there are no sufficiently low FOCUS Step 4 $PEC_{SW/SED}$ values in case of several scenarios (including relevant for Poland D3, D4 and especially R1). Therefore, the risk assessment for difenoconazole is incomplete for all proposed uses.

No correction of the mixture toxicity was made by zRMS since, with the $PEC_{SW/SED}$ values currently available for difenoconazole, it is not possible to complete this assessment. In result, this evaluation was deleted from the report (crossed out was not possible because the assessment was inserted in the form of images from EXCEL).

Therefore, the risk assessment for difenoconazole needs to be completed and a new mixture toxicity assessment must be submitted.

At this stage, no safe use of the product for aquatic organisms can be demonstrated.

At the commenting stage, the Applicant submitted the appropriate $PEC_{SW/SED}$ values calculations that there considered by zRMS in updated risk assessment for difenoconazole. The updated mixture toxicity assessment for aquatic organisms carried out by the Applicant has been accepted.

The risk assessment for aquatic organisms demonstrated that for following proposed uses of CHR/F/SCORPIO 325 SC the mitigation measures are required:

I. AZOXISTROBIN

1. Potatoes BBCH 14 – for R3 scenario 10 m vfs + 5 m nsb
2. Leafy vegetables BBCH 14 – for scenarios R1, R3, R4 – 10 m vfs + 10 m nsb
3. Tobacco – for R3 scenario – 10 m vfs + 5 m nsb
4. Orchards BBCH 10 and BBCH 31 – for scenarios D3, D4, D5, R1, R3, R4 – 20 m vfs + 20 m nsb
5. Maize BBCH 14 – for scenarios R3, R4 – 10 m vfs + 10 m nsb
6. Maize BBCH 31 – for scenario R4 - 10 m vfs + 5 m nsb
7. Sunflower BBCH 14 - for scenario R4 - 10 m vfs + 10 m nsb
8. Sunflower BBCH 31 - for scenario R4 - 10 m vfs + 5 m nsb

II. DIFENOCONAZOLE

1. Winter oilseed rape BBCH 14-20 and BBCH 21-69 – for scenarios D3, D4, D5, R1, R3 – 10 m vfs + 10 m nsb
2. Winter oilseed rape BBCH 31 – for scenarios D3, D4, D5, R1, R3 – 10 m vfs + 5 m nsb
3. Spring oilseed rape BBCH 14 – for scenarios D3, D4, D5, R1 – 10 m vfs + 10 m nsb
4. Spring oilseed rape BBCH 31 – for scenarios D3, D4, D5, R1 – 10 m vfs + 5 m nsb
5. Sugar beet BBCH 39 – for scenarios D3, D4, R1, R3 - 10 m vfs + 10 m nsb
6. Sugar beet BBCH 31 – for scenarios D3, D4, R1, R3 - 10 m vfs + 5 m nsb
7. Carrots BBCH 39 – for scenarios D3, R1, R3, R4 - 10 m vfs + 10 m nsb
8. Potato BBCH 14 – for scenarios D3, D4, R1, R3 - 10 m vfs + 5 m nsb
9. Potato BBCH 31 – for scenarios D3, D4, R1, R3 - 10 m vfs + 5 m nsb
10. Leafy vegetables BBCH 14 – for scenarios D3, D4, R1, R3 – 10 m vfs + 10 m nsb and for R4 - 20 m vfs + 10 m nsb
11. Tobacco – for R3 scenario – 10 m vfs + 5 m nsb

12. Orchards BBCH 10 and BBCH 31 – for scenarios D3, D4, D5, R1, R3 – 20 m vfs + 20 m nsb + 75% drift reduction
13. Maize BBCH 14 – for scenarios D3, D4, D5, R1, R3, R4 – 10 m vfs + 10 m nsb
14. Maize BBCH 31 – for scenarios D3, D4, D5, R1, R3, R4 – 10 m vfs + 5 m nsb
15. Sunflower BBCH 14 - for scenarios D5, R1, R3, R4 - 10 m vfs + 10 m nsb
16. Sunflower BBCH 31 - for scenarios D5, R1, R3, R4 - 10 m vfs + 5 m nsb

III. MIXTURE TOXICITY

1. Winter oilseed rape BBCH 14-20 – for scenario R3 - 10 m vfs + 10 m nsb
2. Carrots BBCH 39 – for scenario R4 - 10 m vfs + 10 m nsb
3. Potato BBCH 14 – for scenarios R1, R3 - 10 m vfs + 5 m nsb
4. Potato BBCH 31 – for scenario R3 - 10 m vfs + 5 m nsb
5. Leafy vegetables BBCH 14 – for scenarios R1, R3, R4 – 10 m vfs + 10 m nsb
6. Tobacco – for R3 scenario – 10 m vfs + 5 m nsb
7. Orchards BBCH 10 and BBCH 31 – for scenarios D3, D4, D5, R1, R3, R4 – 20 m vfs + 20 m nsb + 75% drift reduction
8. Maize BBCH 14 – for scenarios R3, R4 – 10 m vfs + 10 m nsb
9. Maize BBCH 31 – for scenarios R3, R4 – 10 m vfs + 5 m nsb
10. Sunflower BBCH 14 - for scenarios R1, R4 - 10 m vfs + 10 m nsb
11. Sunflower BBCH 31 - for scenarios R3, R4 - 10 m vfs + 5 m nsb

9.6 Effects on bees (KCP 10.3.1)

9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out with difenoconazole and azoxystrobin and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on bees of CHR/F/SCORPIO 325 SC were not evaluated as part of the EU assessment of azoxystrobin and difenoconazole. New data submitted with this application are listed in Table below **Błąd! Nie można odnaleźć źródła odwołania.**and summarised in Appendix 2.

Table 9.6-1: Endpoints and effect values relevant for the risk assessment for bees

Species	Substance	Exposure System	Results	Reference
Apis mellifera	Azoxystrobin	Oral	LD50 > 25 µg/bee	EFSA Journal 2010; 8(4):1542
Apis mellifera	Azoxystrobin	Contact	LD50 > 200 µg/bee	EFSA Journal 2010; 8(4):1542

Species	Substance	Exposure System	Results	Reference
Apis mellifera	A13703G	Oral	Oral LD_{50} 516 µg formulated product/bee	dRR of SCORPION 325 SC
Apis mellifera	A13703G	Contact	Contact LD_{50} 1839 µg formulated product/bee	dRR of SCORPION 325 SC
Apis mellifera	difenoconazole	Oral	LD50> 177 µg/bee	EFSA Journal 2011;9(1):1967
Apis mellifera	difenoconazole	Contact	LD50> 100 µg/bee	EFSA Journal 2011;9(1):1967
Bombus spp.	CHR/F/SCORPIO 325 SC	Oral	LD50> 200 µg/bee	E. Kulec-Płoszczyca 2023, Study code: B-37-23
Bombus spp.	CHR/F/SCORPIO 325 SC	Contact	LD50> 200 µg/bee	E. Kulec-Płoszczyca 2023, Study code: B-38-23
Apis mellifera	CHR/F/SCORPIO 325 SC	Chronic oral	LC50>666.7 [mg of test item/kg of diet] LDD50>15.1 [µg of test item/bee/day]	A.Wojciech 2023, Study code: B-39-23
Honey bee larval	CHR/F/SCORPIO 325 SC	Larval	EC_{50}>325.00*[mg of test item/kg of diet] ED_{50}>50.00*[µg of test item/larva] LOED>50.l00[µg of test item/larva] NOED≥50.00[µg of test item/larva]	K. Zaworska 2023, Study code: 0038/0142/E
Higher-tier studies (tunnel test, field studies)				
Not available				
* values determined based on the analysis of the results				

9.6.1.1 Justification for new endpoints

9.6.2 Risk assessment

The evaluation of the risk for bees was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).

To achieve a concise risk assessment, the risk envelope approach is applied.

9.6.2.1 Hazard quotients for bees

Table 9.6-2: First-tier assessment of the risk for bees due to the use of SCORPION 325 SC

Intended use **Active substance** **Application rate (g/ha)**	All intended uses Azoxystrobin 1 x 200		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	25	200	8
Contact toxicity	200		1
Intended use **Active substance** **Application rate (g/ha)**	All intended uses Difenoconazole 1 x 125		
Test design	**LD_{50} (lab.)** (µg/bee	**Single application rate** (g/ha)	**Q_{HO}, Q_{HC}** criterion: $Q_H \leq 50$
Oral toxicity	177	125	0.71
Contact toxicity	100		1.2
Product Application rate (g/ha)	SCORPIO 325 1 x 1110		
Test design	**LD_{50} (lab.)** (µg/bee)	**Single application rate** (g/ha)	**Q_{HO}, Q_{HC}** criterion: $Q_H \leq 50$
Oral toxicity	516	1110	2.15
Contact toxicity	1839		0.60

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.
* The maximum single application rate in g product/ha has been calculated using the single maximum application of 1 L product/ha and a relative density of 1.110 g/ml.

9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

Not relevant.

9.6.3 Effects on bumble bees

Product Application rate (g/ha)	CHR/F/SCORPIO 325 SC 1 x 1110		
Test design	**LD_{50} (lab.)** (µg/bumble bee)	**Single application rate** (g/ha)	**Q_{HO}, Q_{HC}** criterion: $Q_H \leq 50$
Oral toxicity	200	1110	5.55
Contact toxicity	200		5.55

9.6.4 Effects on solitary bees

Not required.

9.6.5 Overall conclusions

All hazard quotients (HQ) are considerably less than 50, indicating that CHR/F/SCORPIO 325 SC applied at the maximum use rate poses low risk to bees.

Review Comments:

The evaluation of the acute risk for bees was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002). The submitted risk assessment, based on laboratory studies, has been accepted. It can therefore be concluded that there will be negligible acute risk associated with the exposure of *Apis mellifera* to CHR/F/SCORPIO 325 SC.

The data requirements in accordance with Commission Regulation (EU) No 284/2013 for the chronic toxicity to adult honeybees and honeybee larvae are fulfilled.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

Studies on the toxicity to non-target arthropods have been carried out with azoxystrobin and difenoconazole and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target arthropods of CHR/F/SCORPIO 325 SC were not evaluated as part of the EU assessment of difenoconazole and azoxystrobin. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.7-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods

Species	Substance	Exposure System	Results	Reference
Typhlodromus pyri (protonymphs)	A13703G	Laboratory test glass plates (2D)	LR_{50} = 1.872 L/ha (2084 g prod/ha)	dRR of SCORPION 325 SC
Aphidius rhopalosiphi (adults)	A13703G	Laboratory test glass plates (2D)	LR_{50} = 2 L/ha (2227 g prod/ha)	dRR of SCORPION 325 SC
Field or semi-field tests				
Not required.				

9.7.1.1 Justification for new endpoints

Not required.

9.7.2 Risk assessment

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

9.7.2.1 Risk assessment for in-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied.

Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of CHR/F/SCORPIO 325 SC

Intended use	All intended uses		
Active substance/product	A13703G		
Application rate (L/ha)	~~1 x 1~~ 2 x 1 L/ha		
MAF	1.7		
Test species Tier I	**LR_{50} (lab.) (L/ha)**	**$PER_{in\text{-}field}$ (L/ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	1.872	1.7	0.91
Aphidius rhopalosiphi	> 2		> 0.85

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment.
Criteria values shown in bold breach the relevant trigger.

* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

9.7.2.2 Risk assessment for off-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied.

Review Comments:

The updated off-field risk assessment performed by the Applicant was not accepted. The endpoints from the studies for A13703G were converted from (m)L/ha to g/ha assuming an unknown RMS density of formulation. Moreover, it should be noted that these are not studies for CHR/F/SCORPIO 325 SC. Therefore, the endpoints should be expressed in accordance with the test reports and compared with the drift factor expressed in mL/ha as was done in the first version of the dRR. zRMS requested that the risk assessment be supplemented with HQ calculation for use in orchards/fruit crops (surrogate crop for energetic plant, forest uses), rather than deleting the assessment entirely. Consequently, the zRMS reinstated the Applicant's original calculations and supplemented them accordingly.

Table 9.7-3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of CHR/F/SCORPIO 325 SC

Intended use **Active substance/product** **Application rate (l/ha)** **MAF** **vdf**	FIELD CROPS CHR/F/SCORPIO 325 SC 2 x 1.0 1.7 10 (Tier 1)				
Test species **Tier I**	**LR_{50} (lab.)** ~~**(g/ha)**~~ **(L/ha)**	**Drift rate**	**$PER_{off\text{-}field}$** ~~**(g/ha)**~~ **(L/ha)**	**CF**	**$HQ_{off\text{-}field}$** **criterion: HQ ≤ 2**
Typhlodromus pyri	1.872	0.0238	0.004	10	0.021
Aphidius rhopalosiphi	2				0.02
Intended use **Active substance/product** **Application rate (l/ha)** **MAF** **vdf**	LEAFY VEGETABLES, ORNAMENTAL PLANTS CHR/F/SCORPIO 325 SC 2 x 1.0 1.7 10 (Tier 1)				
Heigh<50 cm					
Test species Tier I	**LR_{50} (lab.)** ~~**(g/ha)**~~ **(L/ha)**	**Drift rate**	**$PER_{off\text{-}field}$** ~~**(g/ha)**~~ **(L/ha)**	**CF**	**$HQ_{off\text{-}field}$** **criterion: HQ ≤ 2**
Typhlodromus pyri	1.872	0.0238	0.003	10	0.015
Aphidius rhopalosiphi	2				0.014
Heigh>50 cm **Test species** **Tier I**					
Typhlodromus pyri	1.872	0.0723	0.012	10	0.064
Aphidius rhopalosiphi	2				0.06

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

Intended use **Active substance/product** **Application rate (l/ha)** **MAF** **vdf**	FRUIT CROPS EARLY CHR/F/SCORPIO 325 SC 2 x 1.0 1.7 10 (Tier 1)				
Test species Tier I	**LR_{50} (lab.)** **(L/ha)**	**Drift rate**	**$PER_{off\text{-}field}$** **(L/ha)**	**CF**	**$HQ_{off\text{-}field}$** **criterion: HQ ≤ 2**
Typhlodromus pyri	1.872	0.2553	0.0434	10	0.23
Aphidius rhopalosiphi	>2.0				0.22

Intended use	FIELD CROPS

Active substance/product Application rate (l/ha) MAF vdf	CHR-F/SCORPIO 325 SC 2 x 1113 1.3 10 (Tier 1)				
Test species Tier-1	LR$_{50}$ (lab.) (g/ha)	Drift rate	PER$_{in\ field}$ (g/ha)	CF	HQ$_{in\ field}$ criterion: HQ < 2
Typhlodromus pyri	2084	0.0238	4.50	10	0.024
Aphidius rhopalosiphi	2227				0.020
Intended use Active substance/product Application rate (l/ha) MAF vdf	VEGETABLES - ORNAMENTALS CHR-F/SCORPIO 325 SC 2 x 1113 1.3 10 (Tier 1)				
Heigh<50 cm					
Test species Tier-1	LR$_{50}$ (lab.) (g/ha)	Drift rate	PER$_{in\ field}$ (g/ha)	CF	HQ$_{in\ field}$ criterion: HQ < 2
Typhlodromus pyri	2084	0.0238	4.50	10	0.024
Aphidius rhopalosiphi	2227				0.020
Heigh>50 cm					
Test species Tier-1	LR$_{50}$ (lab.) (g/ha)	Drift rate	PER$_{in\ field}$ (g/ha)	CF	HQ$_{in\ field}$ criterion: HQ < 2
Typhlodromus pyri	2084	0.0723	13.68	10	0.065
Aphidius rhopalosiphi	2227				0.006
Intended use Active substance/product Application rate (l/ha) MAF vdf	FRUIT CROPS CHR-F/SCORPIO 325 SC 2 x 1113 1.3 10 (Tier 1)				
Heigh<50 cm					
Test species Tier-1	LR$_{50}$ (lab.) (g/ha)	Drift rate	PER$_{in\ field}$ (g/ha)	CF	HQ$_{in\ field}$ criterion: HQ < 2
Typhlodromus pyri	2084	0.2552	48.30	10	0.232
Aphidius rhopalosiphi	2227				0.217

9.7.2.3 Additional higher-tier risk assessment

Not relevant.

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

All hazard quotients (HQ) are considerably less than 2, indicating that CHR/F/SCORPIO 325 SC applied at the maximum use rate poses no risk to non-target arthropods. No risk mitigation needed.

Review Comments:

Based on the results of the conducted risk assessment, it can be concluded that low risk for non-target arthropods is expected from the use of CHR/F/SCORPIO 325 SC according to the proposed use pattern. No unacceptable effects on non-target arthropods are expected in in-field and off-field habitats.

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

9.8.1 Toxicity data

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with azoxystrobin and difenoconazole and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of CHR/F/SCORPIO 325 SC were not evaluated as part of the EU assessment of azoxystrobin and difenoconazole. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Review Comments:

The risk assessment performed by the Applicant was not accepted as not included relevant toxicity endpoints for both active substance, their metabolites and formulation (e.g. LC_{10}). The following risk assessment for earthworms and other meso- and macroorganisms was performed by zRMS

Table 9.8-1: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)

Species	Substance	Exposure System	Results	Reference
Eisenia fetida	Azoxystrobin YF10537	long term	NOEC 20 mg a.s./kg d.w.soil $NOEC_{corr}$ = 10 mg/kg soil	EFSA Journal 2010; 8(4):1542
Folsomia candida	Azoxystrobin YF10537	long term	NOEC = 50 mg a.s./kg dw soil $NOEC_{corr}$ = 25 mg/kg soil	EFSA Journal 2010; 8(4):1542
Eisenia fetida	A13703G	long term	NOEC 40 mg/kg d.w. soil $NOEC_{corr}$ 20 mg/kg soil	dRR of SCORPIO

Species	Substance	Exposure System	Results	Reference
Eisenia fetida	Difenoconazole	Long term	NOEC = 0.5 mg/kg dry soil $NOEC_{corr}$= 0.25 mg/kg dry soil	EFSA 2014:EN-680 Addendum for confirmatory data 2014 RR of A13703G 2013
Eisenia fetida	CGA205375	Long term	NOEC = 9.6 mg/kg dw $NOEC_{corr}$ = 4.8 mg/kg dw	EFSA 2014:EN-680 Addendum for confirmatory data 2014 RR of A13703G 2013
Eisenia fetida	CGA71019	Long term	NOEC = 1 mg/kg soil	EFSA J 2011; 9 (1): 1967
Folsomia candida	difenoconazole	Chronic 28 days	NOEC 500 mg a.s./kg dw soil $NOEC_{corr}$= 250 mg/kg soil	EFSA Journal 2011;9(1):1967
Folsomia candida	CGA71019	Long term	NOEC = 1.8 mg/kg soil	EFSA Journal 2011;9(1):1967,
Folsomia candida	CGA205375	Long term	NOEC = 2.4 mg/kg soil $NOEC_{corr}$ = 1.2 mg/kg soil	Addendum for confirmatory data 2014 RR of A13703G 2013
Folsomia candida	CHR/F/SCORPIO 325 SC	Chronic 28 days	LC_{10} = 155.1 mg form/kg dw **LC_{10corr} = 77.55 mg form/kg dw** EC_{10} = 193.2 mg form/kg dw NOEC 180.0 mg of the test item/kg dry weight of the artificial soil	P.Pieczka, 2023 Łukasiewicz Study code: G-04-23
Hypoaspis (Geolaelaps) aculeife	CHR/F/SCORPIO 325 SC	14 days	LC_{10} /EC_{10} /NOEC ≥ 1000.0 mg of the test item/kg dry weight of the artificial soil **LC_{10corr} /EC_{10corr} /$NOEC_{corr}$ ≥ 500mg form/kg soil**	A. Wróbel, 2023, Study code: G-05-23
Field studies				
Not required.				
Litter bag test				
Not required.				

* Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002.

9.8.1.1 Justification for new endpoints

Not required.

9.8.2 Risk assessment

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

9.8.2.1 First-tier risk assessment

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3. According to the assessment of environmental-fate data, multi-annual accumulation in soil is considered for azoxystrobin and difenoconazole.
To achieve a concise risk assessment, the risk envelope approach is applied.

Table 9.8-2: First-tier assessment of ~~the acute and~~ chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of CHR/F/SCORPIO 325 SC ~~in sunflower ((worst-case use from GAP table)~~

Intended use	Worst case (all)		
Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Azoxystrobin	10	0.616	16.2
Difenoconazole	0.25	0.3881	**0.64**
1.2.4-triazole (CGA71019)	1.0	0.018	55.6
CGA205375	4.8	0.026	184.6
A13703G	20	1.19	16.8
Chronic effects on other soil macro- and mesofauna - *Folsomia candida*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Azoxistrobin	25	0.616	40.6
Difenoconazole	250	0.3881	644.2
1.2.4-triazole (CGA71019)	1.8	0.018	100
CGA205375	1.2	0.026	46.2
CHR/F/SCORPIO 325 SC	77.55	1.19	65.2
Chronic effects on other soil macro- and mesofauna - *Hypoaspis aculeifer*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
CHR/F/SCORPIO 325 SC	500	1.19	420.2

~~**Intended use**~~			
~~**Acute effects on earthworms**~~			
~~**Product/active substance**~~	~~**LC_{50} (mg/kg dw)**~~	~~**PEC_{soil} (mg/kg dw)**~~	~~**TER_a (criterion TER ≥ 10)**~~
~~Not required~~			

Chronic effects on earthworms					
Product/active substance	**NOEC (mg/kg dw) ***	**PEC_{soil} (mg/kg dw)**		**TER_{lt} (criterion TER ≥ 5)**	
		Single application	Multiple application	Single application	Multiple application
Azoxystrobine	10	0.1600	0.2618	62.5	38.20
A13703G	20			125	76.39
Chronic effects on other soil macro- and mesofauna – *Folsomia candida*					
Product/active substance	**NOEC* (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**		**TER_{lt} (criterion TER ≥ 5)**	
		Single application	Multiple application	Single application	Multiple application
Azoxystrobine	25	0.1600	0.2618	156.25	95.49
Difenoconazole	250			1562.5	954.93
CHR/F/SCORPIO 325 SC	90			562.5	323.77
Chronic effects on other soil macro- and mesofauna – *Hypoaspis aculeifer*					
Product/active substance	**NOEC* (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**		**TER_{lt} (criterion TER ≥ 5)**	
		Single application	Multiple application	Single application	Multiple application
CHR/F/SCORPIO 325 SC	500	0.1600	0.2618	3125	1909.85

Intended use			
Acute effects on earthworms			
Product/active substance	LC50 (mg/kg dw)	PEC_{soil} (mg/kg dw)	TER_{lt} (criterion TER ≥ 10)
Not required			
Chronic effects on earthworms			
Product/active substance	NOEC (mg/kg dw) *	PEC_{soil} (mg/kg dw)	TER_{lt} (criterion TER ≥ 5)
Azoxystrobine	10	0.6160	16.234
A13703G	20	1.10	16.807
Chronic effects on other soil macro- and mesofauna – *Folsomia candida*			
Product/active substance	NOEC* (mg/kg dw)	PEC_{soil} (mg/kg dw)	TER_{lt} (criterion TER ≥ 5)
Azoxystrobine	25	0.6160	40.584
Difenoconazole	250	0.2881	644.164
CHR/F/SCORPIO 325 SC	90	1.10	75.63

Chronic effects on other soil macro- and mesofauna – *Hypoaspis aculeifer*			
Product/active substance	NOEC[a] (mg/kg dwt)	PEC_{soil} (mg/kg dwt)	TER_{lt} (criterion TER ≥ 5)
CHR/F/SCORPIO 325 SC	500	1.19	420.168

9.8.2.2 Higher-tier risk assessment

Not relevant.

Review Comments:

The chronic risk to earthworms from difenoconazole was identified based on Tier 1 assessment. In the fRR of A13703G zRMS - UK, an earthworm field study conducted with a difenoconazole EC formulation was evaluated and accepted. As no dose response or treatment related effects were observed at 450 g a.s/ha, an acceptable chronic risk to earthworms from difenoconazole was concluded.

9.8.3 Overall conclusions

The long-term risk to earthworms and other non-target soil organisms (meso- and macrofauna) was assessed as low for CHR/F/SCORPIO 325 SC in a first-tier risk assessment.

Review Comments:

The long-term risks of CHR/F/SCORPIO 325 SC to soil meso- and macro-organisms were assessed from toxicity exposure ratios between toxicity endpoints and maximum PEC_{soil}. The relevant predicted environmental concentration in soil (PEC_{soil}) for risk assessment covering the proposed use pattern was taken from Part B Section 8 (Environmental Fate).

Safe use of CHR/F/SCORPIO 325 SC was confirmed based on TER_{LT} calculations for formulation, azoxystrobin, difenoconazole (except earthworms), metabolites CGA71019 and CGA205375. An acceptable chronic risk to earthworms from difenoconazole was concluded based on field study.

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

Studies on effects soil microorganisms have been carried out with azoxystrobin and difenoconazole and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on soil microorganisms of CHR/F/SCORPIO 325 SC were not evaluated as part of the EU assessment of azoxystrobin and difenoconazole. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.9-1: Endpoints and effect values relevant for the risk assessment for soil microorganisms

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	R234886	28 d, aerobic type soil	No effect at 1 and 10 mg/kg soil dry weight	EFSA Journal 2010; 8(4):1542
N-mineralisation	R401553	28 d, aerobic type soil	No effect at 0.528 and 2.643 mg test item /kg dry wt soil	EFSA Journal 2010; 8(4):1542
N-mineralisation	R401173	28 d, aerobic type soil	No effect at 0.826 and 4.131 mg test item/kg dry soil	EFSA Journal 2010; 8(4):1542
N-mineralisation	A13703G	28 d, aerobic type soil	<25% after 28 days at 4.44 mg/kg soil d.w	dRR of SCORPION 325 SC
N-mineralisation	difenoconazole	28 d, aerobic type soil	<25% effect at day 28 at 1.67 and 16.7 mg a.s./kg dw soil in silty loam, 60% increase in loamy sand	EFSA Journal 2011;9(1):1967
N-mineralisation	CGA 71019	28 d, aerobic type soil	<25% effect at day 28 at 0.035 and 0.353 mg a.s./kg dw soil	EFSA Journal 2011;9(1):1967
N-mineralisation	CGA 205375	28 d, aerobic type soil	<25% effect at day 28 at 0.09 and 0.22 mg a.s./kg dw soil	EFSA Journal 2011;9(1):1967

9.9.1.1 Justification for new endpoints

Not required.

9.9.2 Risk assessment

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).
The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).
To achieve a concise risk assessment, the risk envelope approach is applied.

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of CHR/F/SCORPIO 325 SC

N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
R234886	10 (at 28 d)	0.111	Yes
R402173	4.131 (at 28 d)	0.030	Yes
R401553	2.643 (at 28 d)	0.093	Yes
Difenoconazole	16.7 (at 28 d)	0.3881	Yes
1.2.4-triazole (CGA71019)	0.353 (at 28 d)	0.018	Yes
CGA205375	0.22 (at 28 d)	0.026	Yes
A13703G	4.44 (at 28 d)	1.19	Yes

~~N-mineralisation~~				
~~Product/active substance~~	~~Max. conc. with effects ≤ 25 % (mg/kg dw)~~	~~PEC_{soil} (mg/kg dw)~~		~~Risk acceptable?~~
		~~Single application~~	~~Multiple applications~~	
~~R234886~~	~~No effect at 1 and 10 mg/kg soil dry weight~~	~~0.0001~~	~~0.0002~~	~~yes~~
~~R401553~~	~~No effect at 0.528 and 2.643 mg test item /kg dry wt soil~~	~~0.0001~~	~~0.0002~~	~~yes~~
~~R402173~~	~~No effect at 0.826 and 4.131 mg test item/kg dry soil~~	~~0.0006~~	~~0.0010~~	~~yes~~
~~SCORPIO~~	~~<25% after 28 days at 14.79 mg/kg soil d.w~~	~~0.325~~	~~0.325~~	~~yes~~
	~~<25% after 28 days at 4.44 mg/kg soil d.w~~			
~~CGA71019~~	~~<25% effect at day 28 at 0.035 and 0.353 mg a.s./kg dw soil~~	~~0.0001~~	~~0.0002~~	~~yes~~
~~CGA205375~~	~~<25% effect at day 28 at 0.09 and 0.22 mg a.s./kg dw soil~~	~~0.0012~~	~~0.0032~~	~~yes~~

9.9.3 Overall conclusions

The Predicted Environmental Concentrations of the formulation CHR/F/SCORPIO 325 SC and its active substance difenoconazole and azoxystrobin in soil are below the concentrations at which no unacceptable effects (< 25%) regarding the soil microbial activity were observed after 28 days or more of exposure, indicating that the proposed use of CHR/F/SCORPIO 325 SC poses an acceptable risk to soil microorganisms.

Review Comments:

The use of CHR/F/SCORPIO 325 SC at the proposed rates poses no unacceptable risk to soil micro-organisms.

9.10 Effects on non-target terrestrial plants (KCP 10.6)

9.10.1 Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with difenoconazole and azoxystrobin and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target terrestrial plants of CHR/F/SCORPIO 325 SC were not evaluated as part of the EU assessment of azoxystrobin and difenoconazole. New data submitted with this application are listed in Appendix 1 summarised in Appendix 2.

Table 9.10-1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants

Species	Substance	Exposure System	Results	Reference
Helianthus annuus *Pisum sativum* *Linum usitatissimum* *Daucus carota* *Avena sativa* *Allium cepa*	CHR/F/SCORPIO 325 SC	vegetative vigour	CHR/F/SCORPIO 325 SC, applied at rates ranging from 51.2 to 2000.0 mL/ha, had no impact on vegetative vigour of sunflower, pea, flax, carrot and oats. Slightly inhibited the process of growth of onion. ER_{50} > 2000 mL/ha ER_{25} = 1015.7 mL/ha EC_{10} = 156.4 mL/ha (onion) NOER = 128 mL/ha (onion)	P.Pieczka, 2023 Study code: G-0623
Helianthus annuus *Pisum sativum* *Linum usitatissimum* *Daucus carota* *Avena sativa* *Allium cepa*	CHR/F/SCORPIO 325 SC	seedling emergence and seedling growth	CHR/F/SCORPIO 325 SC had no impact on seedling emergence and seedling growth of pea, sunflower, flax, carrot and oats. Slightly inhibited the process of growth of onion. ER_{50} > 2000 mL/ha ER_{25} = 1885.97 mL/ha	Gierbuszewska, 2023 Study code: G-08-23

Species	Substance	Exposure System	Results	Reference
			EC_{10} = 765.96 mL/ha (onion) NOER = 800 mL/ha (onion)	
~~*Allium cepa*~~	~~CHR/F/SCORPIO 325 SC~~	~~vegetative vigour~~	~~CHR/F/SCORPIO 325 SC slightly inhibited the process of growth of onion. (Shoot length 128 mL/ha; Plant dry weight 128.0 mL/ha)~~	~~P.Pieczka, 2023 Study code: G-0623~~
~~*Allium cepa*~~	~~CHR/F/SCORPIO 325 SC~~	~~seedling emergence and seedling growth~~	~~CHR/F/SCORPIO 325 SC slightly inhibited the process of growth of onion. (Shoot length 800 mL/ha, Plant dry weight 800 mL/ha)~~	~~Gierbuszewska, 2023 Study code: G-08-23~~

m: monocotyledonous; d: dicotyledonous

9.10.1.1 Justification for new endpoints

Not required.

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

9.10.2.2 Tier-2 risk assessment (based on dose-response data)

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.
To achieve a concise risk assessment, the risk envelope approach is applied.

Table 9.10-2: Assessment of the risk for non-target plants due to the use of CHR/F/SCORPIO 325 SC ~~(drift rate: 2.38%):~~ risk envelope cover in all intended uses.

Intended use **Active substance/product** **Application rate [mL/ha]** **MAF**	Fruit crops early – covers all crops CHR/F/SCORPIO 325 SC 1000 x 1 1		
ER_{50} (mL/ha)	**Drift rate [%]**	**$PER_{off\text{-}field}$ (mL/ha)**	**TER Criterion: TER ≥ 5**
> 2000	29.20	292	6.8
Intended use **Active substance/product** **Application rate [mL/ha]** **MAF**	Fruit crops early – covers: energetic plants, renewals, afforestation, plantations of forest trees CHR/F/SCORPIO 325 SC 1000 x 2 1.7		
ER_{50} (mL/ha)	**Drift rate [%]**	**$PER_{off\text{-}field}$ (mL/ha)**	**TER Criterion: TER ≥ 5**
> 2000	25.53	434.0	**4.6**
Intended use **Active substance/product** **Application rate [mL/ha]** **MAF**	Ornamentals heigh > 50 cm – covers: nursery plants, tobacco CHR/F/SCORPIO 325 SC 1000 x 2 1.7		
ER_{50} (mL/ha)	**Drift rate [%]**	**$PER_{off\text{-}field}$ (mL/ha)**	**TER Criterion: TER ≥ 5**
> 2000	7.23	122.91	16.3

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The TER value for 2-fold application of 1 L/ha considering maximum drift rate (fruit crops, early) is slightly below trigger (4.6). Considering that the maximum tested dose of CHR/F/SCORPIO 325 SC was taken into account in the TER calculations, rather than the actual ER_{50} value, the risk is acceptable.

~~**Intended use**~~ ~~**Active substance/product**~~ ~~**Application rate (L/ha)**~~ ~~**MAF**~~	~~All intended uses~~ ~~CHR/F/SCORPIO 325 SC~~ ~~2 x 1.0~~ ~~1 x 1~~ ~~1.7~~			
~~**Test species**~~	~~**ER_{50} (L/ha)**~~	~~**Drift rate**~~	~~**$PER_{off\text{-}field}$ (L/ha)**~~	~~**TER criterion: TER ≥ 5**~~
~~*Allium cepa*~~ ~~*Pisum sativum*~~ ~~*Triticum aestivum*~~ ~~*Helianthus annuus*~~ ~~*Glycine max*~~ ~~*Linum usitatissimum*~~ ~~*Beta vulgaris*~~ ~~*Daucus carota*~~ ~~*Brassica napus*~~ ~~*Allium cepa*~~ ~~*Cucumis sativus*~~ ~~*Avena sativa*~~	~~0.128~~ ~~2~~	~~0.0238~~	~~0.04~~	~~43.59~~ ~~49.43~~
~~**Drift rate (5m)**~~				

Allium cepa *Pisum sativum* *Triticum aestivum* *Helianthus annuus* *Glycine max* *Linum usitatissimum* *Beta vulgaris* *Daucus carota* *Brassica napus* *Allium cepa* *Cucumis sativus* *Avena sativa*	0.128 2	0.0047	0.008	16 250.31

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

9.10.2.3 Higher-tier risk assessment

Not relevant.

9.10.2.4 Risk mitigation measures

No risk mitigation needed.

9.10.3 Overall conclusions

Based on the predicted rates of CHR/F/SCORPIO 325 SC in off-field areas, the TER values describing the risk for non-target plants following exposure to CHR/F/SCORPIO 325 SC according to the GAP of the formulation CHR/F/SCORPIO 325 SC achieve the acceptability criteria without buffer zone and risk mitigation.

Review Comments:

Based on the risk assessment it can be concluded that the proposed use of CHR/F/SCORPIO 325 SC poses no unacceptable risk to non-target plants, if applied according to the recommended use pattern. Particular precautions to reduce the environmental concentrations resulting from CHR/F/SCORPIO 325 SC applications are not required.

9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Not relevant.

9.12 Monitoring data (KCP 10.8)

Not required.

9.13 Classification and Labelling

In accordance with CLP Regulation and based upon the available aquatic endpoints for CHR/F/SCORPIO 325 SC, the proposed classification and labelling of CHR/F/SCORPIO 325 SC is driven by effects on ~~Daphnia magna (-48h EC50 = 0.035 mg/L for the acute classification).~~

Aquatic acute toxicity Category 1, H 400 Very toxic to aquatic life.

Aquatic chronic toxicity Category 1, H 410 Very toxic to aquatic life with long lasting effects.

Classification:

Aquatic Acute 1, H400

Aquatic Chronic 1, H410

Hazard statement:

Very toxic to aquatic life with long lasting effects - H410

Labelling:

H410 – Very toxic to aquatic life with long lasting effects.

Pictogram:

GHS09

Signal word:

Warning

Precautionary statement:

~~P273: Avoid release to the environment.~~

P391: Collect spillage.

EUH401: To avoid risks to man and the environment, comply with the instructions for use.

Review Comments:

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to ecotoxicological data is proposed for CHR/F/SCORPIO 325, based on:

Active substances (summation method):

As azoxystrobin and difenoconazole, are classified as H400 and H410 with acute and chronic M factors of 10, according to harmonized classification (ATP 15 and ATP 21):

- Aquatic acute 1 – H400
- Aquatic chronic 1 – H410

Formulation:

- Aquatic acute 1: the acute toxicity endpoints for the formulated product are: EC_{50} = 1.1 mg/l for daphnia and LC_{50} = 1.7 mg/L for fish. As this is >1 mg/L, acute category 1 does not apply to this formulated product.

  It should be noted that the formulation toxicity test for algae was done only for *Pseudokirchneriella subcapitata.* The RACs for both active substances have been derived using endpoints for different algal species (*Pseudokirchneriella subcapitata* for azoxystrobin and *Scenedesmus subspicatus* for difenoconazole). As both species are green algae, the comparison can be considered appropriate. Nevertheless, the most sensitive algal species for azoxystrobin was *Navicula pelliculosa.* No data are available for diatom in LoEP for difenoconazole, and therefore comparison cannot be performed. Therefore, in zRMS opinion, study no. 2033567 cannot be used for product classification and labeling purposes.
- Aquatic chronic 1: No chronic formulation studies were conducted. The algae formulation toxicity study cannot be used for product classification and labeling purposes. Therefore, chronic classification of CHR/F/SCORPIO 325 have to be based on active substances data (summation method).

Therefore, the classification proposed by the Applicant is correct.

Labelling:

Hazard Statement (CLP): H410, very toxic to aquatic life with long lasting effects.
Precautionary statements: P391, P501.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.3.1	K. Zaworska	2023	Honey bee larval toxicity test following repeated exposure of the test item CHR/F/SCORPIO 325 SC according to OECD GD 239 ENV/JM/MONO(2016)34 SORBOLAB Research Laboratory LLC Zaniemyska Street 11 61-029 Poznań, Poland Study code: 0038/0142/E GLP yes Unpublised	N	Chemirol
KCP 10.3.1	A. Wojciech	2023	CHR/F/SCORPIO 325 SC Honeybees (Apis mellifera L.), Chronic Oral Toxicity Test according to the OECD Guideline No. 245 (2017) Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43-200 Pszczyna, Poland Study code: B-39-23 GLP yes Unpublished	N	Chemirol
KCP 10.3.1/2	E. Kulec-Płoszczyca	2023	CHR/F/SCORPIO 325 SC Bumblebees (Bombus spp.), Acute Oral Toxicity Test STUDY CODE: B-37-23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43-200 Pszczyna, Poland	N	Chemirol
KCP 10.3.1	E. Kulec-Płoszczyca	2023	CHR/F/SCORPIO 325 SC Bumblebees (Bombus spp.), Acute Contact Toxicity Test STUDY CODE: B-38-23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43-200 Pszczyna, Poland	N	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.4/1	P. Pieczka	2023	CHR/F/SCORPIO 325 SC Collembolan (*Folsomia candida*) Reproduction Test STUDY CODE: G-04-23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland	N	Chemirol
KCP 10.4/2	A.Wróbel	2003	CHR/F/SCORPIO 325 SC Predatory mite (Hypoaspis (Geolaelaps) aculeifer) reproduction test in soil STUDY CODE: G-05-23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland	N	Chemirol
KCP 10.6/1	P. Pieczka	2023	CHR/F/SCORPIO 325 SC Terrestial Plant Test: Vegetative Vigour Test STUDY CODE: G-06-23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43-200 Pszczyna, Poland	N	Chemirol
KCP 10.6/1/2	A. Gierbuszewska	2023	CHR/F/SCORPIO 325 SC Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test STUDY CODE: G-08-23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Ecotoxicology Research Group Doświadczalna 27, 43 – 200 Pszczyna, Poland	N	Chemirol

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 8.2.1.3/01	xxxxx	2002	R401553 (Azoxystrobin metabolite): Acute toxicity to rainbow trout (*Onchorynchus mykiss*) Syngenta Crop Protection AG, Basel, Switzerland xxxxxxxxxxxxx7252/b 2013675 GLP, not published Syngenta File No SYN501657/0002	Y	SYN
KIIA 8.2.1.3/02	xxxxxx	2002	R402173 (Azoxystrobine metabolite): Acute toxicity to rainbow trout *(Onchorynchus mykiss)* Syngenta Crop Protection AG, Basel, Switzerland xxxxxxxxxxxxxxxxxxxx7338/B, 2013671 GLP, not published Syngenta File No SYN511114/0001	Y	SYN
KIIA 8.3.1.1/01	Bowles A J, Wallace S J	2002a	R401553 (Azoxystrobine metabolite): Acute toxivity to *Daphnia magna* Syngenta Crop Protection AG, Basel, Switzerland Brixham Environmental Laboratory, Brixham, United Kingdom, BL7253/B 2013672 GLP, not published Syngenta File No SYN501657/0003	N	SYN
KIIA 8.3.1.1 /02	Wallace SJ	2002a	R402173 (Azoxystrobin metabolite): Acute toxicity to Daphnia magna Syngenta Crop Protection AG, Basel, Switzerland Brixham Environmental Laboratory, Brixham, United Kingdom, BL7339/B, 2013670 GLP, not published Syngenta File No SYN511114/0002	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 8.4 / 01	Smyth DV, Sankey SA, Kent SJ, Stanley RD	1994	ICIA5504: Toxicity to the Freshwater Diatom Navicula pelliculosa Zeneca Agrochemicals, Jealott‟s Hill, United Kingdom, BL5087/B GLP, not published Syngenta File No ICI5504/0965	N	SYN
KIIA 8.4 / 02	Smyth DV, Kent SJ, Sankey SA, Shearing JM	1994	ICIA5504: Toxicity to the Blue-Green Alga Anabaena flos-aquae Zeneca Agrochemicals, Jealott‟s Hill, United Kingdom , BL5054/B GLP, not published Syngenta File No ICI5504/0967	N	SYN
KIIA 8.4 / 03	Bowles A J, Wallace S J	2002b	R401553 (Azoxystrobin metabolite): Toxicity to the green alga Selenastrum capricornutum Syngenta Crop Protection AG, Basel, Switzerland Brixham Environmental Laboratory, Brixham, United Kingdom, BL7254/B, 2013669 GLP, not published Syngenta File No SYN501657/0004	N	SYN
KIIA 8.4 / 04	Wallace SJ, Woodyer JM	2002	R402173 (Azoxystrobin metabolite): Toxicity to the green alga Selenastrum capricornutum Syngenta Crop Protection AG, Basel, Switzerland Brixham Environmental Laboratory, Brixham, United Kingdom, BL7340/B, 2013668 GLP, not published Syngenta File No SYN511114/0003	~~Y~~ N	SYN
KIIA 8.6	Smyth DV, Sankey SA, Kent SJ, Stanley RD	1994a	ICIA5504: Toxicity to the Duckweed Lemma gibba Zeneca Agrochemicals, Jealott‟s Hill, United Kingdom , BL5000/B GLP, not published Syngenta File No ICI5504/0963	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 8.9.1 / 01	Friedrich S.	2002	Acute toxicity of R234886 to the earthworm Eisenia fetida Syngenta Crop Protection AG, Basel, Switzerland BioChem agrar, Gerichshain, Germany, 2013645, 01 10 48 076 GLP, not published Syngenta File No R234886/0001	N	SYN
KIIA 8.9.1 / 02	Friedrich S.	2008	SYN501657 - Acute toxicity to the earthworm Eisenia fetida Syngenta Crop Protection AG, Basel, Switzerland BioChem agrar, Gerichshain, Germany, 071048052S T003940-07 GLP, not published Syngenta File No SYN501657/0006	¥ N	SYN
KIIA 8.9.1 / 03	Friedrich S.	2008a	SYN501114 - Acute toxicity to the earthworm Eisenia Foetida Syngenta - Jealott‟s Hill International, Bracknell, Berkshire, United Kingdom BioChem agrar, Gerichshain, Germany, 071048051S T003941-07 GLP, not published Syngenta File No SYN501114/0001	¥ N	SYN
KIIA 8.10 / 01	Lemnitzer B	2002	Effects of R234886 (metabolite of Azoxystrobin) on the activity of soil microflora Syngenta Crop Protection AG, Basel, Switzerland BioChem agrar, Gerichshain, Germany, 02 10 35 1001, 2023502 GLP, not published Syngenta File No R234886/0002	N	SYN
KIIA 8.10 / 02	Schulz L.	2008	SYN501657 - Effects on the activity of soil microflora Syngenta - Jealott‟s Hill International, Bracknell, Berkshire, United Kingdom BioChem agrar, Gerichshain, Germany, 071048046C/N T003946-07 GLP, not published Syngenta File No SYN501657/0007	¥ N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 8.10/03	Schulz L.	2008a	SYN501114 - Effects on the activity of soil microflora Syngenta - Jealott‟s Hill International, Bracknell, Berkshire, United Kingdom BioChem agrar, Gerichshain, Germany, 071048045C/N T003947-07 GLP, not published Syngenta File No SYN501114/0002	~~Y~~ N	SYN
KIIA 8.11.1 / 01	Kent SJ, Sankey SA, Grinell AJ	1993	ICIA5504: Acute Toxicity to Mysid Shrimp (Mysidopsis bahia) Zeneca Agrochemicals, Jealott‟s Hill, United Kingdom, BL4785/B GLP, not published Syngenta File No ICI5504/0925	N	SYN
KIIA 8.11.1 / 02	Kent SJ, Sankey SA, Caunter JE, Grinell AJ	1994	ICIA5504: Acute Toxicity to Larvae of the Pacific Oyster (Crassostrea gigas) Zeneca Agrochemicals, Jealott‟s Hill, United Kingdom, BL4842/B GLP, not published Syngenta File No ICI5504/0927	N	SYN
KIIA 8.11.1 / 03	Boeri RL, Magazu JP, Ward TJ	1997	Chronic Toxicity of Azoxystrobin to the Mysid Mysidopsis bahia Zeneca Agrochemicals, Jealott‟s Hill, United Kingdom , 1350-ZE GLP, not published Syngenta File No ICI5504/0952	N	SYN
KIIA 8.11.1 / 04	Smyth DV, Kent SJ, Sankey SA, Johnson PA	1994	ICIA5504: Toxicity to the Marine Alga Skeletonema costatum Zeneca Agrochemicals, Jealott‟s Hill, United Kingdom , BL5053/B GLP, not published Syngenta File No ICI5504/0966	N	SYN
KIIA 8.12	Porch J R, Krueger H O	2002	A Toxicity test to Determine the Effects of Azoxystrobin on Seedling Emergence and Growth of Terrestrial Plants Syngenta Crop Protection AG, Basel Switzerland Wildlife International Ltd., Easton MD, USA, 528-135, 2023574 GLP, not published Syngenta File No ICI5504/1376	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIIA1 10.1.6	xxxxxxxxxx	2005	Avian Acute Oral Toxicity Test for ICI-A-5504 SC xxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx RL143164-AVO-B GLP, not published Syngenta File No ICI5504/2949	Y	SYN
KIIIA1 10.2.3	Cole JFH, Everett CJ Gentle W	2000	Azoxystrobin: An Outdoor Pond Microcosm Study. Zeneca Agrochemicals, Jealott's Hill, United Kingdom, RJ2857B GLP not published Syngenta File No ICI5504/0976	N	SYN
KIIIA1 10.3	Murfitt R.	2008	Review of effect of lower body weight upon wild mammal population dynamics Syngenta – Jealott's Hill International Bracknell, berkshire, United Kingdom. TMJ5073 Not GLP, not published, Syngenta File No N/1184	N	SYN
KIIIA1 10.5.1/01	Taruza S	2001	Azoxystrobin: A Rate-Response laboratory Test to Evaluate the Effects of a 250g/l SC Formulation on the Predatory Mite *Typhlodromus pyri* Syngenta Crop protection AG, Basel, Switzerland Mambo-Tox. Ltd., Southampton, United Kingdom, SYN-01-45 GLP, not published Syngenta File No ICI5504/0006	N	SYN
KIIIA1 10.5.1/02	Stacey D.	2004	Azoxystrobine: A laboratory bioassay of the effect of residues of a 250 g L-1 SC formulation (A12705B) on the parasitic wasp Aphidius rhopalosiphi (Hymenoptera: Braconidae) Syngenta Crop Protection AG, Basel, Switzerland Synegnta, Jealott's Hill United Kingdom RJ3518B GLP, not published Synegnta File No ICI5504/2627	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIIA1 10.5.2/01	Baxter I	2000	Azoxystrobin 250g/l SC (YF10537): An Extended Laboratory Test To Determine Effects on the Parasitoid, *Aphidius rhopalosiphi* Zeneca Agrochemicals, Jealott's Hill, United Kingdom Agrochemical Evaluation Unit, The University Southampton, United Kingdom, ZEN-99-13/C GLP, not published Syngenta File No ICI5504/0880	N	SYN
KIIIA1 10.5.2/03	Philips D	2001	Azoxystrobin: A Tier II Extended Laboratory Test to Evaluate the Effects of an SC Formulation on the Foliar-Dwelling Predator Chrysoperla carnea (Neuroptera, Chrysopidae) Syngenta Crop Protection AG, Basel, Switzerland ZEN-00-12/C GLP, not published Synegnta File No ICI5504/1177	N	SYN
KIIIA1 10.5.2/04	Philips D	2001a	Azoxystrobin: A Tier II Extended Laboratory Test to Evaluate the Effects of High Volume Spray Application Rates of an SC Formulation on the Foliar-Dwelling Predator Chrysoperla carnea (Neuroptera, Chrysopidae) Syngenta Crop Protection AG, Basel, Switzerland ZEN-00-16/C GLP, not published Syngenta File No ICI5504/1179	N	SYN
KIIIA1 10.5.2 /05	Travis A., Gill A.	1998	An Extended Laboratory Study to Evaluate the Effects of Azoxystrobine 25SC on the Green Lacewing Chrysoperla carnea Zeneca Agrochemicals, Jealott's Hill, United Kingdom ER-97-50 GLP, not published Synegnta File No ICI5504/0872	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIIA1 10.5.2/06	Kuhner C	1998	Azoxystrobin 250g/l SC: Acute Toxicity to Ladybird *Coccinnella septempunctata* L. (Coleoptera, Coccinellidae) Zeneca Agrochemicals, Jealott's Hill, United Kingdom 97178/01-NECS/C GLP, not published Syngenta File No ICI5504/0877	N	SYN
KIIIA1 10.5.2/07	Baxter I	2001	Azoxystrobin: A Tier II Extended Laboratory Test to Evaluate the Effects of an SC Formulation on the Ground- Dwelling Preadator *Poecilus cupreus* (Coleoptera, carabidae) Syngenta Crop Protection AG, Basel, Switzerland ZEN-00-13/C GLP, not published Syngenta File No ICI5504/1181	N	SYN
KIIIA1 10.5.2/08	Kling A	2000	Azoxystrobin: An Extended Laboratory Test to Determine the Effects of a 250g/l SC formulation, incorporated into Soil, on the Ground Beetle *Poecilus cupreus* (Coleoptera, carabidae) Zeneca Agrochemicals, Jealott's Hill, United Kingdom GAB Biotechnologie GmbH, Niefern, Germany, 20001035/01-NEPC/C GLP, not published Syngenta File No ICI5504/0882	N	SYN
KIIIA1 10.5.2/09	Austin H.	1998	A Laboratory Study to Evaluate the Effects of Azoxystrobin 25SC on *Pardosa spp.* (Araneae: Lycosidae) Zeneca Agrochemicals, Jealott's Hill, United Kingdom ER-98-22 GLP, not published Syngenta File No ICI5504/0876	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIIAI 10.6.3	Moser T., Rombke J	2000	Azoxystrobin: Reproduction Toxicity of a Azoxystrobin 250g/l SC to the Earthworm Eisenia andrei in an Artificial Soil Test Zeneca Agrochemicals, Jealott‟s Hill, United Kingdom ECT Oekotoxikologie GmbH, Bad Soden am Ts., Germany, F10RR GLP, not published Syngenta File No ICI5504/0903	N	SYN
KIIIA1 10.6.6	Barth M	2001	Azoxystrobin: Toxicity of a 250 g/l SC formulation (YF10537) on the reproduction of the Collembola Folsomia candida Syngenta Crop Protection AG, Basel, Switzerland BioChem agrar, Gerichshain, Germany, 01 10 48 049, 2013722 GLP, not published Syngenta File No ICI5504/1319	N	SYN
KIIIA1 10.6.7	Kollmann S.	2004	A12705A: Litterbag test on decomposition of organic material in the field by soil macro and microorganisms Syngenta Crop Protection AG, Basel, Switzerland Springborn Smithers Laboratories (Europe) AG, Horn, Switzerland, 1047.124.797 2033547 GLP, not published Syngenta File No ICI5504/2319	N	SYN
KIIA 8.1.1/01	xxxxxxx	1998a	21-day acute oral LD50 study with CGA169374 technical in Mallard ducks Novartis Crop protection AG, Basel, Switzerland xxxxxxxxxxxxxxxxxxx GLP Not published Syngenta File No CGA169374/0014	Y	SYN
KIIA 8.1.1/02	xxxxxxxxxx	1993	Acute oral toxicity study with CGA169374 technical in Japanese Quail Novartis Crop Protection AG, Basel, Switzerland xxxxxxxxxxxxxxxx GLP Not Published Syngenta File No CGA169374/0843	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 8.1.2/01	xxxxxxxxx	1998b	11-day acute dietary LC50 study with CGA 169374 in Mallards cudklings Novartis Crop protection AG, Basel, Switzerland xxxxxxxxxxxxx GLP Not published Syngenta File No CGA169374/0290	Y	SYN
KIIA 8.1.2/02	xxxxxx	1988c	9-Day acute dietary LC50 study with CGA 169374 techn. In Bobwhite quail Novartis Crop protection AG, Basel, Switzerland xxxxxxxxxxxx GLP Not published Syngenta File No CGA169374/0332	Y	SYN
KIIA 8.1.2/03	xxxxxx	1983a	A dietary LC50 in the Mallard with CGA 131013. Novartis Crop Protection AG, Basel, Switzerland xxxxxxxxxxxxxxxxx Report No 108-222 Not GLP Not Published Syngenta File No CGA131013/0034	Y	TDMG
KIIA 8.1.2/04	xxxxxxxxx	1983B	A dietary LC50 in the Bobwhite with CGA131013. Novartis Crop Protection AG, Basel, Switzerland xxxxxxxxxxx Report No 108-221 Not GLP Not published Syngenta File No CGA131013/0033	Y	TDMG

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 8.1.3/01	xxxx	1990	CGA 169374 techn.:Toxicity and reproduction study in Mallard ducks Novartis Crop protection AG, Basel, Switzerland xxxxxxxxxxx Report No 88-DR-31 GLP Not Published Syngenta File No CGA169374/0015	Y	SYN
KIIA 8.1.3/02	xxxxx	2000	A reproduction study with the Northern Bobwhite Novartis Crop protection AG, Basel, Switzerland xxxxxxxxxxxxxxReport No 108-427 GLP Not published Syngenta File No CGA169374/2065	Y	SYN
KIIA 10.1/01	Bartlett, D.	2006	Radiolabel study to investigate systemicity Difenoconazole from Dividend seed treatment. Jealotts Hill International, UK report no FP 04 1001 Unpublished Not GLP Syngenta File No CGA169374/2803	N	SYN
KIIA 10.1/02	Kilgour, J	2004	Toxicological relevance of plant metabolote CGA131013. Syngenta Central Toxicology Laboratory UK. Unpublished Not GLP Syngenta File No. CGA131013/0046	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 8.2.1/02	xxxxxxxx	1990a	Acute toxicity of CGA 169374 to Rainbow trout under flow-through conditions Novartis Crop Protection AG, Basel, Switzerland xxxxxxxx Report No 88-5-2663 GLP Not published Syngenta File No CGA169374/0333	Y	SYN
KIIA 8.2.1/03	xxxxxxxx	1988	Acute toxicity of CGA 169374 technical to Bluegill sunfish (lepomis macrochirus) Novartis Crop Protection AG, Basel, Switzerland xxxxxxxx Report No 34834 GLP Not Published Syngenta File No CGA169374/0016	Y	SYN
KIIA 8.2.1/05	xxxxxxxx	1993	Acute toxicity to Sheepshead minnow (cyprinidon variegatus) under Flow Through conditions Novartis Crop Protection AG, Basel, Switzerland xxxxxxxx Report No 93-5-1795 GLP Not Published Syngenta File No CGA169374/0949	Y	SYN
KIIA 8.2.1/06	xxxxxxxx	1983	Report on the test for acute toxicity of CGA 98032 to rainbow trout. Novartis Crop protection AG, Basel, Switzerland xxxxxxxx No 821418 Not GLP Not Published Syngenta File No CGA71019/0024	Y	TDMG
KIIA 8.2.1/07	Swarbrick, R.H	2001a	Acote toxicity to rainbow trout (Oncorhynchus mykiss) Syngenta Crop Protection AG, Basel, Switzerland xxxxxxxx United Kingdom, Report No BL7201/B GLP Not Piblished Syngenta File No CGA205375/0014	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 8.2.2/01	xxxxxxxx	1993a	Report on the prolonged tixicity test of the CGA 169374 tech. to rainbow trout Novartis Crop Protection AG, Basel, Switzerland xxxxxxxx Report No 938152 GLP Not Published Syngenta File No CGA169374/0859	Y	SYN
KIIA 8.2.2/02	xxxxxxxx	2002	1,2,4-Triazole: Juvenile Growth Test on Fish (Oncorhychus mykiss) Syngenta Crop Protection AG, Basel, Switzerland xxxxxxxx GLP Not Published Syngenta File No CGA71019/0052	Y	TDMG
KIIA 8.2.2.1/01	xxxxxxxx	1987b	Toxicity of CGA 169374 TO Fathead minnow (pimephales promelas) embryos and larvae Novartis Crop protection AG, Basel, Switzerland Xxxxxxxx GLP Not Published Syngenta File No CGA169374/0018	Y	SYN
KIIA 8.2.2.1/02	xxxxxxxx	1990b	CGA 169374 techn. Toxicity to fathead minnow (Pimephales promelas) embryos and larvae Novartis Crop protecion AG, Basel Switzerland xxxxxxxx GLP Not Published Syngenta File No CGA169374/0020	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 8.2.3/01	xxxxxxxx	1987	Uptake, depuration and bioconcentration of 14C-CGA 169374 by Bluegill sunfish (lepornis macrochirus) Novartis Crop Protection AG, Basel, Switzerland xxxxxxxx Report No 34837 GLP Not Published Syngenta File No CGA169374/0036	Y	SYN
KIIA 8.2.3/02	xxxxxxxx	1992	Bioconcentration and Elimination of 14C-Residues by Bluegill (Lepomis macrochirus) Exposed to CGA 169374 Novartis Crop Protection AG, Basel, Switzerland xxxxxxxx Not Published Syngenta File No CGA169374/0531	Y	SYN
KIIA 8.2.4/01	Forbis, A.D.	1988a	Acute toxicity of CGA 169374 to Daphnia magna Novartis Crop Protection AG, Basel, Switzerland ABC Analytical Bio-Chemistry Lab. Inc., Columbia, United States, Report No 34835 GLP Not Published Syngenta File No CGA169374/0021	N	SYN
KIIA 8.2.4/02	Surprenant, D.C.	1990c	CGA 169374 techn., Acute toxicity to mysid shrimp (Mysidopsis bahia) under flow-through conditions Novartis Crop Protection AG, Basel, Switzerland Springborn Laboratories Inc., Wareham, United States, Report No SLI-89-2-2936 GLP Not Published Syngenta File No CGA169374/0023	N	SYN
KIIA 8.2.4/03	Surprenant, D.C.	1990d	CGA 169374 techn., Acute toxicity to Eastern oysters (Crassostrea virginica) under flow-through conditions Novartis Crop Protection AG, Basel, Switzerland Springborn Laboratories Inc., Wareham, United States, Report No SLI-89-05-2988 GLP Not Published Syngenta File No CGA169374/0024	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 8.2.4/04	Bell, G.	1995	Fluquinconazole Technical material 100.8% w/w 1,2,4 Triazole: Acute Toxicity to Dapnhnia manga Syngenta Crop Protection AG, Basel, Switzerland Huntingdon Life Scienes Ltd., Huntingdon, United Kingdom, report No ENVIR/95/52 GLP Not Published Syngenta File No CGA169374/2320	N	SYN
KIIA 8.2.4/05	Swarbrick, R.H	2002	Acute toxicity to Daphnia magna Syngenta Crop Protection AG, Basel, Switzerland Brixham Environmental Laboratory, Brixham, United Kingdom, Report No BL7202/B GLP Not Published Syngenta File No CGA205375/0012	~~Y~~ N	SYN
KIIA 8.2.5/01	Forbis, A.D.	1988b	Chronic toxicity of CGA 169374 to Daphnia magna under floow-through test conditions Novartis Crop Protection AG, Basel, Switzerland ABC Analytical Bio-Chemistry Lab, Inc., Columbia, United States, Report No 34836 GLP Not Published Syngenta File No CGA169374/0022	N	SYN
KIIA 8.2.6/01	Rufli, H.	1989	Alga Growth inhibition test of CGA 169374 to Green Algae (Scenedesmus supsicatus) Novartis Crop protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 881699 GLP Not Published Syngenta File No CGA 169374/0026	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 8.2.6/02	Grade, R.	1993b	Report on the growth inhibition test of CGA 169374 tech. to green algae (Scenedesmus subspicatus) Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland, Report No 938153 GLP Not Published Syngenta File No CGA169374/0860	N	SYN
KIIA 8.2.6/03	Palmer, S.J., Kendall, T.Z., Kruger, H.O.	2001	1,2,3-triazole: a 96-hour toxicity test with the freshwater alga (Selenastrum capricornutum) Syngenta Crop Protection AG, Basel, Switzerland Wildlife International Ltd., Easton, MD, United States, report No 528A-101 GLP Not Published Syngenta File No CGA71019/0044	¥ N	TDMG
KIIA 8.2.6/04	Swarbrick, R.H.	2001b	CGA205375: Toxicity to the green alga Selenastrum capricornutum Syngenta Crop Protection, AG, Basel, Switzerland Brixham Environmental Laboratory, Brixham United Kingdom Report No BL7203/B GLP Not Published Syngenta File No CGA205375/0015	¥ N	SYN
KIIA 8.2.7/01	Van, der Kolk J.	1999	Chronic effects on Midge Larvae (Chironomus riparius) in a water/ sediment system Novartis Crop Protection, AG, Basel, Switzerland Springborn Smithers Laboratories (Europe) AG, Horn, Switzerland, Report No 97-192-1008 GLP Not Published Syngenta File No CGA169374/1816	¥ N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 8.2.7/02	Grade, R.	2001	Toxicity test of CGA 211391 (metabolite of CGA 169374) on sediment-dwelling Chironomus riparius (syn. Chironomus thummi) under static conditions Syngenta Crop Protection AG, Basel Switzerland, Report No 2003511 GLP Not Published Syngenta File No CGA211391/0001	~~Y~~ N	SYN
KIIA 8.3.1.1/01	Hoxter, K.A., Jaber, M.	1989	Acute contact toxicity study with the honey bee Novartis Crop protection AG, Basel, Switzerland Wildlife International Ltd., Easton, MD, United States, Report No 108-302A GLP Not Published Syngenta File No CGA169374/0028	N	SYN
KIIA 8.3.1.1/02	Greig-Smith, P.W.	1990	Acute conctact and oral toxicity of CGA 169374 to honeybees Novartis Crop Protection AG, Basel, Switzerland ADAS, Central Science Lab., Tolworth United Kingdom, Report No C89-0370 GLP Not Published Syngenta File No CGA169374/0029	N	SYN
KIIA 8.4.1/01	Suprenant., D.C.	1987c	Fourteen-day toxicity exposing earthworm (eisenia foetida) to CGA169374 Novartis Crop Protection AG, Basel, Switzerland Springborn Laboratories Inc., Wareham United States, report No 87-9-2494 GLP Not Published Syngenta File No CGA169374/0027	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 8.4.1/02	Heimbach, F.	1986	Acute toxicity of 1,2,4-triazole (technical)to earthworms. Novartis Crop Protection AG, Basel,Switzerland Bayer AG, Leverkusen, Germany, ReportNo HBF/RG 59 GLP Not Published Syngenta File N° CGA71019/0021	N	SYN
KIIA 8.4.1/03	Bätscher, R	2002	Acute Toxicity of CGA 205375 (Metabolite of CGA 169374) to the Earthworm Eisenia fetida in a 14-day TestSyngenta Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, Report No 812092 GLP Not Published Syngenta File N° CGA205375/0011	~~Y~~ N	SYN
KIIA 8.4.2/03	Ehlers, H.A.	2000	Effects of 1,2,4-triazole on reproduction and growth of Earthworms Eisenia fetida(Savigny 1826) in artificial soil Novartis Crop Protection AG, Basel,Switzerland IBACON GmbH, Rossdorf, Germany,Report No 7781022 GLP Not Published Syngenta File N° CGA64250/4385	~~Y~~ N	TDMG
KIIA 8.4.2/01	Coulson, M	2006	Re-analysis of CGA169374 Sub-lethalEarthworm Study [CGA169374/1926].Jealotts Hill International Report. UnpublishedNot GLP Syngenta File No. CGA169374/2812	N	SYN
KIIA 8.5/01	Ellgehausen, H.	1990	The effects of CGA 169374 on the activityof soil microbes Novartis Crop Protection AG, Basel,Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 17-90 GLP Not Published Syngenta File N° CGA169374/0289	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 8.5/02	Grade, R.	2000	The effect of CGA 169374 tech. on the growth of soil fungi on soil-maltextract-agar-plates Novartis Crop Protection AG, Basel,Switzerland, Report No 203636 GLP Not Published Syngenta File N° CGA169374/2042	~~Y~~ N	SYN
KIIA 8.5/03	Völkel, W.	2000	The effects of CGA 71019 on soilrespiration and nitrification Novartis Crop Protection AG, Basel,Switzerland RCC Ltd., Itingen, Switzerland, Report No 763367 GLP Not Published Syngenta File N° CGA71019/0042	~~Y~~ N	TDMG
KIIA 8.5/04	Seyfried, B	2002	The Effects of CGA 205375 (Metabolite ofCGA 169374) on Soil Respiration and Nutrification Syngenta Crop Protection AG, Basel,Switzerland RCC Ltd., Itingen, Switzerland, Report No 808176 GLP Not Published Syngenta File N° CGA205375/0019	~~Y~~ N	SYN
KIIA 8.6/01	Meister, A	2002	Effects of CGA 169374 on Reproductionof the Collembola Folsomia candida in Artificial Soil Syngenta Crop Protection AG, Basel,Switzerland IBACON GmbH, Rossdorf, Germany,Report No 8491016 GLP Not Published Syngenta File N° CGA169374/2202	~~Y~~ N	SYN
KIIA 8.6/02	Moser, Th. and Scheffczyk A.	2002	1,2,4-Triazole: Acute and ReproductionToxicity to the Collembolan species Folsomia candida Syngenta Crop Protection AG, Basel,Switzerland ECT Oekotoxikologie GmbH, Bad Sodenam Ts., Germany, Report No P31CR GLP Not Published Syngenta File N° CGA71019/0053	~~Y~~ N	TDMG

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 8.6/03	Balluff, M.	2004	CGA169374 (Difenconazole): A toxicity test to determine the effects on seedling emergence and growth of three species ofplants Syngenta Crop Protection AG, Basel,Switzerland GAB Biotechnologie GmbH, Niefern, Germany, Report No 20033067/S1-FGSEGLP Not Published Syngenta File N° CGA169374/2423	~~Y~~ N	SYN
KIIA 8.7/01	Grade, R.	1997	Report on the test for activated sludgerespiration inhibition of CGA 169374Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel,Switzerland, Report No 973535 GLP Not Published Syngenta File N° CGA169374/1422	N	SYN
KCP 9.5.3	Bowles, A Maynard, S.	2003	Bowles, A and Maynard, S. (2003). Difenoconazole/Azoxystrobin 125/200 g l^{-1} SC formulation (A13703G): Acute toxicity to *Daphnia magna*. Brixham environmental laboratory, UK. Lot No./Lot no. : J6474/028 GLP: Yes	N	Syngenta
KCP 9.5.3	Maynard, S.	2003	Difenoconazole/Azoxystrobin 125/200 g l^{-1} SC formulation (A13703G): Toxicity to the green alga *Selenastrum capricornutum*. Brixham environmental laboratory, UK. Lot No./Batch No: J6474/028 GLP: Yes	N	Syngenta
KCP 9.5.3	Bowles, A Maynard, S.	2003	Bowles, A and Maynard, S. (2003). Difenoconazole/Azoxystrobin 125/200 g l^{-1} SC formulation (A13703G): Acute toxicity to *Daphnia magna*. Brixham environmental laboratory, UK. Lot No./Lot no. : J6474/028 GLP: Yes	N	Syngenta
KCP 10.3.1/1	Bocksch S.	2003	ZA5504 / CGA169374 (azoxystrobin / difenoconazole): Acute toxicity of a 200 / 125 g/L SC formulation (A13703G) to the honeybee, Apis mellifera L. in the laboratory Syngenta Crop Protection AG, Basel, Switzerland GAB Biotechnologie GmbH, Niefern, Germany, 20031268/01-BLEU GLP, not published Syngenta File No ICI5504/2072	~~Y~~ N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIIA2 10.1.3/01	Gallagher, S.P., Beavers, J.B.	1999	A-9142 G A test for avoidance of treatedwheat seed with the rock dove (Columba livia) Novartis Crop Protection AG, Basel,Switzerland Wildlife International Ltd., Easton, MD,United States, Report No 108-416 GLP Not Published Syngenta File N° CGA169374/1947	N	SYN
KIIIA 10.1/01	Bartlett, D	2006	Radiolabel study to investigate systemicity of Difenoconazole fromDividend seed treatment. Jealotts Hill International, UK reportno. FP 04 1001 Unpublished.Not GLP Syngenta File No CGA169374/2803	N	SYN
KIIIA 10.1/02	Murfitt, R	2006	Investigation of Crop Seedling ShootWeights at Differing Timings after Emergence Jealotts Hill International, UK Report.Unpublished Not GLP Syngenta File No N/1048	N	SYN
KIIIA2 10.2.1/02	Gries, Th.	1999b	Acute Toxicity test of CGA 169374 FS 30(A9142 G) to daphnids (Daphnia magna) under static conditions Novartis Crop Protection AG, Basel,Switzerland Springborn Smithers Laboratories (Europe) AG, Horn, Switzerland, ReportNo 1047.062.110 GLP Not Published Syngenta File N° CGA169374/1908	N	SYN
KIIIA2 10.2.1/03	Gries, Th.	1999c	Toxicity test of CGA 169374 FS 30 (A9142 G) to the freshwater algae Pseudokirchneriella subcapitata Novartis Crop Protection AG, Basel,Switzerland Springborn Smithers Laboratories (Europe) AG, Horn, Switzerland, ReportNo 1047.062.430 GLP Not Published Syngenta File N° CGA169374/1906	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIIA2 10.5.1/01	Kleiner, R.	2000	Acute dose-response toxicity of CGA 169374 EC250 (A-7402 G) to the cerealaphid parasitoid Aphidius rhopalosiphi (Destefani-Perez) under laboratory conditions Novartis Crop Protection AG, Basel,Switzerland BioChem GmbH, Cunnersdorf, Germany,Report No 99 10 48 083 GLP Not Published Syngenta File N° CGA169374/2095	N	SYN
KIIIA2 10.5.1/02	Kleiner, R.	2001	Acute dose-response toxicity of CGA169374 EC 250 (A-7402 G) to the predatory mite Typhlodromus pyri (SCHEUTEN) under laboratory conditionsSyngenta Crop Protection AG, Basel, Switzerland BioChem GmbH, Cunnersdorf, Germany,Report No 99 10 48 084 GLP Not Published Syngenta File N° CGA169374/2131	N	SYN
KIIIA2 10.5.1/03	Grimm, C.	1999a	Acute toxicity test of CGA 169374 FS 30 (A-9142 G) to the rove beetle Aleochara bilineata Gyll. (Coleoptera, Staphylinidae)Novartis Crop Protection AG, Basel, Switzerland, Report No 982924 GLP Not Published Syngenta File N° CGA169374/1959	N	SYN
KIIIA2 10.5.1/04	Grimm, C.	1999b	Acute toxicity test of CGA 169374 FS 30 (A-9142 G) to the predatory ground beetlePoecilus cupreus L. (Coleoptera: Carabidae) Novartis Crop Protection AG, Basel,Switzerland, Report No 982923 GLP Not Published Syngenta File N° CGA169374/1960	N	SYN
KIIIA2 10.5.1/05	Reber, B.	1999	Acute toxicity of CGA 169374 FS 30 (A 9142 G) to larvae of the predatory ground beetle Poecilus cupreus L. (Coleoptera:carabidae) Novartis Crop Protection AG, Basel, Switzerland, Report No 991501 GLP Not Published Syngenta File No CGA169374/1975	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIIA2 10.6.1.2/01	Friedrish, S	2002	Sublethal toxicity of CGA169374 FS 030 (A-9142 G) to the eartworm Eisenia fetida Syngenta Crop Protection AG, Basel, Swizterland BioChem agrar, Gerichshain, Germany, Report No 021048036 GLP Not Published Syngenta File No CGA169374/2242	N	SYN
KIIIA2 10.6.2/01	Meister, A. and Schwiening S.	2002	Effects of A7402G on the Decomposition of Organic Material enclosed in Litter Bags in the field Syngenta Crop protection AG, Basel, Switzerland IBACON GmbH, Roosdorf, Germany, Report No 8381081 GLP Not Published Syngenta File No CGA169374/2228	N	SYN
KIIIA 10.1/03	Kilgour, J	2004	Toxicological relevance of plant metabolite CGA131013 Syngenta Central Toxicology Laboratory, UK. Unpublished. Not GLP. Syngenta File No. CGA131013/0046	N	SYN
KIIIA1 10.2.1/03	xxxxxxxx	1991	Toxizitat von CGD 96 430 F fur Regenbogenforellen Salmo gairdnerii (21 Tage) Novartis Crop Protection AG, Basel, Switzerland xxxxxxxx No 01/91/299 Not GLP Not Published Syngenta File No CGA169374/0762	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIIA1 10.2.1/04	Voigt, H.	1990b	Toxizitat von CGD 96 430 F auf Wasserflohe (Dapnhnia magna) (48 H) Novartis Crop protection AG, Basel, Switzerland Oekolimna, Burgwedel, Germany, Report No 07/90/217 GLP Not Published Syngenta File No CGA169374/0759	N	SYN
KIIIA1 10.2.1/07	Peters, A.	1992	CGA 169374 Toxizitat von CGD 96430 F auf Scenedesmus subspicatus CHODAT (96 h) Novartis Crop Protection AG, Basel, Switzerland Oekolimna, Burgwedel, Germany, Report No N/A Not Published Syngenta File No CGA169374/0630	N	SYN
KIIIA1 10.2.1/09	Neumann, Ch.	1997	Acute toxicity test of CGA 169374 EC 250 (A-7402 G) on sediment-dwelling larvar of Chironomus reparium (syn. Chrionomus thummi) under static conditions Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report 953501 GLP Not Published Syngenta File No CGA169374/1359	N	SYN
KIIIA1 10.2.1/01	xxxxxxxx	2004	Difenoconazole 250 EC formulation (A7402T): Acute toxicity to rainbow trout (Oncorhynchus mykiss) in a 96-hour static test. xxxxxxxx No. 853035 Not published GLP Syngenta File No. CGA169374/2554	Y	SYN

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
KIIIA 10.2.1/02	Volz, E	2004	Difenoconazole 250 EC formulation (A7402T): Acote toxicity to Daphnia magna n a 48 hour immobilization test. RCC Ltd. Switzerland Report No. 853039 Not published GLP Syngenta File No. CGA169374/2552	N	SYN
KIIIA 10.2.1/03	Volz, E	2004	Difenoconazole 250 EC formulation (A7402T): A 72 hour algal growth inhibition test with *Scenedesmus subspicatus* RCC Ltd. Switzerland Report No. 853037 Not published GLP Syngenta File No. CGA169374/2553	N	SYN
KIIIA1 10.4.3/01	Decker, U.	1993	Testing for the toxicity of CGD 96430 F toforaging honey bees, (apis mellifera L.) under semi-field (tent) conditions Novartis Crop Protection AG, Basel,Switzerland RCC Ltd., Itingen, Switzerland, Report No 323436 GLP Not Published Syngenta File N° CGA169374/1272	N	SYN
KCP 10.4/2	T. Schmidt	2003	CGA 169374 (Difenoconazole) / ZA 5504 (Azoxystrobin): Acute toxicity of a 125 / 200 g/L SC formulation (A13703G) to the earthworm *Eisenia fetida* in a 14-day test in artificial soil. RCC Ltd, Switzerland. Study no: 850140. Sponsor: Syngenta. Study no: 2033572	N	SYN
	Schulz, L.	2010	Azoxystrobin/Difenoconazole SC (A13703G) – Effects on the Activity of Soil Microflora. BioChem agrar GmbH, Germany. Study number 10 10 48 007 C/N. Sponsor: Syngenta. February 2010	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIIA1 10.5.1/01	Kleiner, R.	2000a	Acute dose-reposone toxicity of CGA 169374 EC250 (A-7402 G) to the cereal aphid parasitoid Aphidius rhopalosiphi (Destefani-Perez) under laboratory conditions Novartis Crop Protection AG, Basel, Switzerland BioChem GmbH, Cunnersdorf, Germany, Report No 99 10 48 083 GLP Not Published Syngenta File No CGA169374/2059	N	SYN
KIIIA1 10.5.1/02	Nienstedt, K.M.	1999a	CGA 169374 EC 250 (A-7402 G): laboratory acute toxicity test with the parasitic wasp, Aphidius rhopalosiphi (Gymenoptera: aphidiidae) Novartis Crop Protection AG, Basel, Switzerland Springborn Smithers Laboratories (Europe) AG, Horn, Switzerland, Report No 1047.035.270 GLP Not Published Syngenta File No CGA169374/1963	N	SYN
KIIIA1 10.5.1/05	Longley, M.	2001b	A semi-field study to evaluate the effects of fresh and aged residues of CGA 169374 EC250 (A7402 G) on the Parasitic Wasp Trichogramma cacoeciae (Hymenoptera, Trichogrammatidae) Syngenta Crop Protection AG, Basel, Switzerland Ecotox, Ltd., Tavistock, Devon, United Kingdom, Report No ER-00-kcb141 GLP Not Published Syngenta File No CGA1699374/2105	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIIA1 10.5.1/06	Kleiner, R.	2001	Acute dose-response toxicity of CGA 169374 EC 250 (A-7402 G) to the predatory mite Typhlodromus pyri (SCHEUTEN) under laboratory conditions Syngenta Crop Protection AG, Basel, Switzerland BioChem GmbH, Cunnersdorf, Germany, Report No 99 10 48 084 GLP Not Published Syngenta File No CGA169374/2131	N	SYN
KIIIA1 10.5.1/07	Nienstedt,K.M.	1999b	CGA 169374 EC 250 (A-7402 G): laboratory acute toxicity test with the predacious mite Typhlodromus pyri Scheuten (Acari: phytoseiidae) Novartis Crop Protection AG, Basel,Switzerland Springborn Smithers Laboratories (Europe) AG, Horn, Switzerland, ReportNo 1047.035.268 GLP Not Published Syngenta File N° CGA169374/1978	N	SYN
KIIIA1 10.5.1/08	Grimm, C.	1999	Toxicity of CGA 169374 EC 250 (A-7402 G) to the predacious mite Typhlodromus pyri Scheuten (Acari: Phytoseiidae) underextended laboratory conditions Novartis Crop Protection AG, Basel,Switzerland, Report No 983929 GLP Not Published Syngenta File N° CGA169374/1981	N	SYN
KIIIA1 10.5.1/09	Kleiner, R.	2000b	The effects of A-7402 G (Bardos Neu, 250g/l difenoconazole) on the green lacewing Chrysoperla carnea Steph. under laboratory conditions Novartis Crop Protection AG, Basel,Switzerland BioChem GmbH, Cunnersdorf, Germany,Report No 99 10 48 055 GLP Not Published Syngenta File N° CGA169374/2040	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIIA1 10.5.1/10	Walker, H.M.	2001	Difenoconazole: A Tier II laboratory studyto determine the effects of a 250 g l-1 EC formulation (A 7402 G) on the green lacewing, Chrysoperla carnea (Neuroptera:Chrysopidae) Syngenta Crop Protection AG, Basel,Switzerland Ecotox, Ltd., Tavistock, Devon, UnitedKingdom, Report No ER-01-HMA430 GLP Not Published Syngenta File N° CGA169374/2205	N	SYN
KIIIA1 10.5.1/11	Engelhard,E.K.	1997b	CGA 169374 EC 250 (A-7402 G): semi- field toxicity test with the seven-spotted lady beetle, Coccinella septempunctata L.(Coleoptera: coccinellidae) Novartis Crop Protection AG, Basel,Switzerland Springborn Smithers Laboratories (Europe) AG, Horn, Switzerland, ReportNo 97-198-1047 GLP Not Published Syngenta File N° CGA169374/1463	N	SYN
KIIIA1 10.5.1/12	Longley, M.	2001c	A Semi-field study to evaluate the effectsof fresh & aged residued of CGA 169374EC 250 (A 7402 G) on the Hoverfly, Episyrphus balteatus (Diptera. Syrphidae)Syngenta Crop Protection AG, Basel, Switzerland Ecotox, Ltd., Tavistock, Devon, UnitedKingdom, Report No ER-00-KCB139 GLP Not Published Syngenta File N° CGA169374/2132	N	SYN
KIIIA1 10.5.1/13	Reber, B.	1999a	Toxicity of CGA 169374 EC 250 (A-7402 G) to the predator Orius laevigatus Fiber (Heteroptera: Anthocoridae) under extended laboratory conditions Novartis Crop Protection AG, Basel,Switzerland, Report No 983928 GLP Not Published Syngenta File N° CGA169374/1965	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIIA1 10.5.1/14	Kleiner, R.	1999	The effects of A-7402 G (Bardos Neu, 250g/l difenoconazole) on the spider Pardosa spp. under laboratory conditions Novartis Crop Protection AG, Basel,Switzerland BioChem GmbH, Cunnersdorf, Germany,Report No 99 10 48 054 GLP Not Published Syngenta File N° CGA169374/2041	N	SYN
KIIIA1 10.5.1/15	Reber, B.	1999b	Acute toxicity of CGA 169374 EC 250 (A-7402 G) to the predatory ground beetle Poecilus cupreus L. (Coleoptera: Carabidae) Novartis Crop Protection AG, Basel,Switzerland, Report No 993512 GLP Not Published Syngenta File N° CGA169374/1964	N	SYN
KIIIA1 10.5.1/16	Müther, J.	2000a	A field study to evaluate the effects ofCGA 169374 EC 250 (A 7402 G) on Predatory mites in an apple orchard in ItalySyngenta Crop Protection AG, Basel, Switzerland GAB Biotechnologie GmbH, Niefern, Germany, Report No 20001049/I1-NFTpGLP Not Published Syngenta File N° CGA169374/2097	N	SYN
KIIIA1 10.5.1/17	Müther, J.	2000b	A field study to evaluate the effects ofCGA 169374 EC 250 (A 7402 G) on Predatory Mites in an apple orchard inGermany Syngenta Crop Protection AG, Basel,Switzerland GAB Biotechnologie GmbH, Niefern, Germany, Report No 20001049/G1-NFTpGLP Not Published Syngenta File N° CGA169374/2096	N	SYN
KIIIA1 10.6.1.1/01	Thun, S.	1993	Acute Toxicity in Earthworm according toOECD 207 Test Article: "CGD 96430 F" Novartis Crop Protection AG, Basel, Switzerland IBR Forschungs GmbH, Hannover, Germany, Report No 80-91-0423-06-90GLP Not Published Syngenta File N° CGA169374/0763	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIIA1 10.6.1.2/01	Nienstedt,K.M.	2001	A chronic toxicity and reproduction test exposing the earthworm Eisenia fetida toCGA 169374 250 EC (A-7402 G) in OECD artificial soil Syngenta Crop Protection AG, Basel,Switzerland Springborn Smithers Laboratories (Europe) AG, Horn, Switzerland, ReportNo 1047.100.631 GLP Not Published Syngenta File N° CGA169374/2140	N	SYN
KIIIA 10.6.1.2/01	Friedrich, S	2003	CGA169374/azoxystrobin: Sublethal toxicity of a 125/200 g/L SC formulation(A13703G) to the earthworm *Eisenia fetida* in artificial soil. Biochem agrar GmbH, Germany(Syngenta Report No. 2033574) Not published GLP Syngenta File No. ICI5504/2144	N	SYN
KIIIA 10.6.1.2/02	Friedrich, S	2003	CGA169374/paclobutrazol: Sublethal toxicity of a 250/125 g/L SC formulation(A14049A) to the earthworm *Eisenia andrei*. Biochem agrar GmbH, Germany(Syngenta Report No. 2033722) Not published GLP Syngenta File No. PP333/0729	N	SYN
KIIIA1 10.7.1/01	Maas, G.	1990	Effects on soil microflora activity Novartis Crop Protection AG, Basel,Switzerland Labor für Bodenuntersuchungen UF, Braunschweig, Germany, Report No N/ANot GLP Not Published Syngenta File N° CGA169374/0767	N	SYN
KIIIA1 10.8/01	Wälder, L.	2000	Herbicide profiling test to evaluate the phytotoxicity of CGA 169374 250 EC (A-7402 G) to terrestrial non-target higher plants Novartis Crop Protection AG, Basel,Switzerland, Report No 15 GLP Not Published Syngenta File N° CGA169374/2029	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
	Bruehl C., Pinch	2003	CGA169374 (difenoconazole) / ZA5504 (azoxystrobin): Tier1 standard laboratory bioassay of the effects of fresh residues of a 125/200 g/L SC formulation (A13703G) on the predatory mite Typhlodromus pyri (Acari, Phytoseiidae) Syngenta Crop Protection AG, Basel, Switzerland Syngenta, Jealott's Hill, United Kingdom, RJ3444B GLP, not published Syngenta File No ICI5504/2098	N	Syngenta
	Stacey D.	2003	CGA169374 (difenoconazole) / ZA5504 (azoxystrobin): Tier I standard laboratory bioassay of the effects of fresh residues of a 125/200 g/L SC formulation (A13703G) on the parasitic wasp *Aphidius rhopalosiphi* Syngenta Crop Protection AG, Basel, Switzerland Syngenta, Jealott's Hill, United Kingdom, RJ3438B GLP, not published Syngenta File No ICI5504/2162	N	Syngenta
	Stevens J.	2011	Azoxystrobin/difenoconazole SC (A13703G) - A rate response extended laboratory bioassay of the effects of fresh residues on the parasitic wasp *Aphidius rhopalosiphi* (Hymenoptera, Braconidae) Syngenta Crop Protection AG, Basel, Switzerland Mambo-Tox Ltd., Southampton, United Kingdom, SYN-11-30 GLP, not published Syngenta File No A13703G_10490	N	Syngenta

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

Appendix 2 Detailed evaluation of the new studies

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

Not required.

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

A 2.2 KCP 10.2 Effects on aquatic organisms

A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

Study 1

Comments of zRMS:	The study has been previously evaluated in the Core Assessment for A137003G by zRMS - UK and it has been considered acceptable. Based on nominal concentrations, the 96-hour LC_{50} value was 1.7 mg formulation/L. The 96-hour NOEC was 1.0 mg formulation/L.

XXX . (2003). Difenoconazole/Azoxystrobin 125/200 g l^{-1} SC formulation (A13703G): Acute toxicity to rainbow trout (*Oncorhynchus mykiss*). Brixham environmental laboratory, UK. Sponsor: Syngenta. Report no. 2033568 December 2003.

Test material:	
Test item	Difenoconazole/Azoxystrobin 125/200 g/l SC formulation (A13703G)
Purity	129 g/L difenoconazole 191 g/L azoxystrobin
Description	Yellow liquid
Lot No./Batch No	J6474/028
Test system:	
Organism (Species)	Rainbow trout (*Oncorhynchus mykiss*) No mortality occurred during the 7 day acclimatisation period prior to test initiation.
Study Type	Acute
GLP Status	Yes
Guidelines followed	OECD 203 (1992)
Duration of study	96 hours (4 days)
Test conditions	Static
Parameters measured	Survival, abnormal behaviour.
Observation intervals	3, 24, 48, 72 and 96 hours
Weight range of fish	1.77-2.95 g weight (average weight 2.25 g)
Range of fish length	50-57 mm length (average length 54mm). Guideline states total length of fish 5.0 ±1 .0 cm.
Test medium	Dechlorionated tap water Loading rate <1 g/l.
Test chamber	Glass test vessels (400mm x 280mm x 280mm, maximum capacity of 31 L) containing 20 L of test media. Test vessels were slightly aerated during the test period.
No. of holding days before dosing	Held at laboratory for at least 12 days prior to test.
Number of fish per dose group	7
Number of fish per control group	7
Feeding	None during the test and for 24 hours before test initiation.
Test concentrations:	
Nominal concentrations	Nominal: 0 (control- dechlorinated tap water), 0.56, 1.0, 1.8, 3.2, 5.6 mg formulation/L Equivalent to: Azoxystrobin-0.096, 0.17, 0.31, 0.55, 0.96 mg/L
Analytical verification:	Gas chromatography at 0 and 96 hours for azoxystrobin. LOQ for azoxystrobin-0.087 mg/l
Environmental conditions:	
Temperature	15 ± 1°C (guideline states between 13-17 °C)
Photoperiod	16 h light: 8 hours dark
Dissolved Oxygen concentration	9.22-10.07 mg/l (92-100% of the air saturation value)
pH	7.30-7.66 (guideline states between 6.0-8.5 mg/L)
Water hardness	48.7 mg/L (guideline states between 10-250 mg/L)

Methodology

A 96-hour static test was performed with nominal concentrations of 0 (control- dechlorinated tap water), 0.56, 1.0, 1.8, 3.2, 5.6 mg formulation/L. Test fish were held at the laboratory for at least 12 days prior to test. Seven fish were then selected at random and allocated into test vessels. The treatments were not replicated. Test solutions were prepared by the addition of a known amount of the formulation directly to the dilution water. The solutions were clear and colourless.

Fish were not fed throughout the test. Observations for mortality and sub-lethal responses were made at approximately 3, 24, 48, 72, and 96 hours.
Temperature, pH, and dissolved oxygen concentration were measured daily for each test chamber. Hourly temperature measurements were also recorded using an electronic recording system. The test media was aerated during the test.
Analytical verification of concentrations of azoxystrobin took place at 0 and 96 hours. Samples were taken from the centre of the test vessels.

Results

Concentrations of Azoxystrobin were not within 80-120% of the nominal (98-159%). Results were based on nominal concentrations.

Nominal conc of formulation ($mg\ l^{-1}$)	Nominal conc of azoxystrobin[b] ($mg\ l^{-1}$)	Measured concentration of azoxystrobin ($mg\ l^{-1}$)				Mean measured conc over the test duration[c] ($mg\ l^{-1}$)	Mean measured conc as percentage of nominal conc
		0 hour	% of nominal	96 hour	% of nominal		
Dilution water control	-	<0.087	-	<0.020	-	<0.087	-
0.56	0.096	0.15	156	0.094	98	0.12	125
1.0	0.17	0.27[d]	159	0.20[e]	118	0.24	141
1.8	0.31	0.37	119	0.33	106	0.35	113
3.2	0.55	0.57	104	0.54	98	0.56	102
5.6	0.96	1.0	104	1.0	104	1.0	104

Table 1- Effects of A13703G on mortality and sub lethal effects

Treatment (mg/L)	No. of fish	Cumulative mortality					
Nominal		3-h	24-h	48-h	72-h	96-hr	Total (%)
Control	7	0	0	0	0	0	0
0.56	7	0	0	0	0	0	0
1.0	7	0	0 (c)	0 (c)	0 (e)	0 (ce)	0
1.8	7	0 (abcd)	0 (bcd)	1 (bd)	2 (bcf)	4(c)	57
3.2	7	7	7	7	7	7	100
5.6	7	7	7	7	7	7	100

Sub-lethal effects affected more than 30% of the test population.
a-ceased swimming
b-loss of balance
c-dark discoloured
d-slow respiration
e-sounding
f-weak

Table 2- Toxicity values of A13703G

Time point (hours)	LC_{50} (mg/L)	NOEC (mg/L)
96 hours	1.7 (1.2-2.4)	1.0

Conclusions
There was no mortality among control animals during the course of the study. Therefore, control animals satisfied test acceptability criteria for survival (i.e., ≥90%) as stated in the OECD 203 guideline. Dissolved oxygen did not fall below 60% of the air saturation.
Based on nominal concentrations, the 96-hour LC_{50} value was 1.7 mg formulation/L. The 96-hour NOEC was 1.0 m formulation/L.

Study 2

Comments of zRMS:	The study has been previously evaluated in the Core Assessment for A137003G by zRMS - UK and it has been considered acceptable. Based on nominal concentrations, the 48-hour EC_{50} value was 1.1 mg formulation/L. The 48-hour NOEC was 0.63 mg formulation/L.

Bowles, A and Maynard, S. (2003). Difenoconazole/Azoxystrobin 125/200 g l^{-1} SC formulation (A13703G): Acute toxicity to *Daphnia magna*. Brixham environmental laboratory, UK. Sponsor: Syngenta. Report no. 2033569. December 2003.

Test material

Test item:	Difenoconazole/Azoxystrobin 125/200 g/l SC formulation (A13703G)
Purity:	129 g/L difenoconazole 191 g/L azoxystrobin
Description:	Yellow liquid
Lot No./Lot no. :	J6474/028

Test system

Organism (Species):	Female water flea (*Daphnia magna*)
Study Type:	Acute
GLP Status:	GLP
Guidelines followed:	OECD 202 (2004)
Duration of study:	48 hours
Test conditions:	Static
Parameters measured:	Immobility
Observation intervals:	24 and 48 hours
Age range of water fleas at test initiation:	<24 hours old (not first brood progeny)
Test medium:	Reconstituted water (Elendt M4), aerated for 2 hours before use.
Test concentrations (Nominal):	0 (control- reconstituted water medium), 0.078, 0.16, 0.31, 0.63, 1.3, 2.5, 5.0 and 10 mg formulation/L. Equivalent to 0.013, 0.027, 0.053, 0.11, 0.22, 0.43, 0.86 and 1.7 mg azoxystrobin/L
Analytical confirmation of test concentrations:	Gas chromatography At test initiation (0 h) and at test termination (48 h) for azoxystrobin. LOQ for azoxystrobin-0.0016 mg/l
Number of water fleas per dose group:	20 individuals divided into 4 replicates with 5 animals per test vessel.
Number of water fleas per control group:	20 individuals divided into 4 replicates with 5 animals per test vessel.
Feeding:	None

Test vessels:	Glass beakers of 250 ml, each vessel contained 200 ml of test solution providing a depth of 60 mm. Beakers were covered with loose fitting glass lids. Positions of the beakers within the test area was randomly allocated. No aeration to test vessels.
Environmental conditions:	Temperature: 20 ± 1°C (guideline states 18-22 °C, each test vessel constant within ± 1°C) Photoperiod: 16 hour light:8 hour dark (guideline states 16:8) Dissolved Oxygen concentration: ≥ 3 mg/L (9.0-9.2 mg/L) pH: 7.86-7.99 (guideline states 6-9, should not vary by more than 1.5 units in any one test) Water hardness: 247 mg/L (guideline states 140-250 mg/l)
Reference item:	Potassium dichromate tested at least twice a year, no results provided for last test.

Methodology

A 48 hour definitive test was performed at nominal concentrations of 0 (control- reconstituted water medium), 0.078, 0.16, 0.31, 0.63, 1.3, 2.5, 5.0 and 10 mg formulation/L. Test vessels were 250 mL glass beakers containing 200 mL of medium. Vessels were covered to avoid evaporation. A stock solution was prepared by adding a specified amount of the test item to the test water. From this solution, aliquots were taken and diluted to obtain the desired test concentrations. All test concentrations were clear and colourless. Test media was prepared just before introduction of the daphnids. Five neonates (<24-hours old) were added randomly to each of four replicate test chambers per treatment at test initiation. The daphnids were observed for immobility and sub-lethal effects at approximately 24 and 48 hours after test initiation.

The concentrations of azoxystrobin were analysed at 0 and 48 hours.

Dissolved oxygen concentration and pH were determined in each treatment group replicate at test initiation and termination. Temperature was determined daily, hourly measurements were also recorded using an electronic recording system.

Results

Concentrations of Azoxystrobin were not within 80-120% of the nominal (100-126%). Results were based on nominal concentrations.

Nominal conc of formulation ($mg\ l^{-1}$)	Nominal conc of azoxystrobin[b] ($mg\ l^{-1}$)	Measured concentration of azoxystrobin ($mg\ l^{-1}$)				Mean measured conc over the test duration[c] ($mg\ l^{-1}$)	Mean measured conc as percentage of nominal conc
		0 hour	% of nominal	48 hour	% of nominal		
Dilution water control	-	<0.0016	-	<0.0016	-	<0.0016	-
0.078	0.013	0.015	115	0.015	115	0.015	115
0.16	0.027	0.034[d]	126	0.033[e]	122	0.034	126
0.31	0.053	0.062	117	0.060	113	0.061	115
0.63	0.11	-[f]	-	0.11	100	0.11	100
1.3	0.22	0.27	123	0.24	109	0.26	118
2.5	0.43	0.47	109	0.46	107	0.47	109
5.0	0.86	0.93	108	0.92	107	0.93	108
10	1.7	1.7	100	1.8	106	1.8	106

Table 1: Effect of A13703G on immobility

Nominal concentration (mg/l)	No. of water fleas	Cumulative percent immobile	
		24-h	48-h
0 (control)	20	0	0
0.078	20	0	5
0.16	20	0	0
0.31	20	0	0
0.63	20	5	5
1.3	20	45	70
2.5	20	45	95
5.0	20	100	100
10	20	100	100

Table 2- Toxicity values of A13703G

Time point (hours)	Nominal EC_{50} (mg formulation/L)	Nominal NOEC (mg formulation/L)
48 hours	1.1 (0.82-1.6)	0.63

Conclusions

The test acceptability criteria were met for this study. Immobilization in the control treatments were 0%, below the acceptability limit of 10%. The dissolved oxygen concentration at the end of the test was ≥3 mg/l in the control and test vessels.
Based on nominal concentrations, the 48-hour EC_{50} value was 1.1 mg formulation/L. The 48-hour NOEC was 0.63 mg formulation/L.

Study 3

Comments of zRMS:	The study has been previously evaluated in the Core Assessment for A137003G by zRMS - UK and it has been considered acceptable.

Maynard, S. (2003). Difenoconazole/Azoxystrobin 125/200 g l^{-1} SC formulation (A13703G): Toxicity to the green alga *Selenastrum capricornutum*. Brixham environmental laboratory, UK. Sponsor: Syngenta. Report no. 2033567. December 2003.

Test material

Test item:	Difenoconazole/Azoxystrobin 125/200 g/l SC formulation (A13703G)
Purity:	129 g/L difenoconazole 191 g/L azoxystrobin
Description:	Yellow liquid
Lot No./Batch No. :	J6474/028

Test system

Organism (*Species*):	Green algae *Selenastrum capricornutum* (now known as *P.subcapitata*) ATCC 22662
Study Type:	laboratory study assessing algae growth-static
GLP Status:	GLP
Guidelines followed:	OECD 201 (1984), EPA OPPTS 850.5400.

Duration of study:	96 hrs
Parameters measured:	Area under the growth curve and growth rate
Environmental conditions:	pH:7.38-9.94 (maximum increase of 2.5 units in the control observed over the test duration- guideline states that it should not deviate by more than 1 unit during the test) Temperature: 24 ± 2°C Photoperiod: 24 hr day light Light intensity (range): 4400 lux Continuous shaking at 100 rpm
Observation intervals:	0, 24, 48, 72 and 96 hours
Test concentrations:	Nominal: 0 (control- test media with algae), 0.12, 0.23, 0.47, 0.94, 1.9, 3.8, 7.5 and 15 mg formulation/L Equivalent to 0.021, 0.039, 0.081, 0.16, 0.33, 0.65, 1.3 and 2.6 mg azoxystrobin/L
Age of inoculum	3 day old
Initial cell density	0.992 x 10^4 cells/ml
Test media	US EPA medium
No. of control replicates	6
No. of test concentration replicates	3
Test vessels:	Glass conical flasks 250ml capacity closed with foam bungs. Each flask contained 100 ml test solution.
Analytical verification:	Method: Gas chromatography Samples taken: Test initiation (0) and termination (96 hrs) for azoxystrobin. LOQ-0.011 mg/L for azoxystrobin

Methodology

A definitive test was conducted at nominal concentrations of 0 (control- test media with algae), 0.12, 0.23, 0.47, 0.94, 1.9, 3.8, 7.5 and 15 mg formulation /L. The exposure vessels were 250 mL conical flasks containing 100 mL of the test solution. Each test substance treatment was replicated three times, the control was replicated 6 times. One blank vessel (without algae) was also set up for the control and each test concentration. The test solution was prepared by dissolving the test item into test water to produce a stock solution. Volumes of this stock solution were added to test water in order to prepare the test concentrations. Test media was prepared just before the start of the test and was clear and colourless. At test initiation, each replicate of each test substance treatments and the controls were inoculated with an algal pre-culture, containing approximately 9920 cells/mL.

At the beginning of the test and every 24 hours, cell density was measured by electronic particle counting. Analytical verification for azoxystrobin was conducted before the start and at the end of the test in all test concentrations.

pH was measured at test initiation and termination. All test flasks were incubated, the temperature of the incubator was measured daily. Light intensity was measured once during the test.

Results

Concentrations of azoxystrobin were not within 80-120% of the nominal (97-125%). The results of this test were based on nominal concentrations.

Table 1: Percentage inhibition of cell density, area under the growth curve and growth rate after 96-hours

Nominal concentration (mg formulation/L)	Cell density#	% Inhibition (as compared to the control)	
		Mean area under the growth curve 96 hours	Mean growth rate 96 hours
0	392	-	-
0.12	386	3.0	-

Nominal concentration (mg formulation/L)	Cell density#	% Inhibition (as compared to the control)	
		Mean area under the growth curve 96 hours	Mean growth rate 96 hours
0.23	383	7.0	-
0.47	267	39*	6*
0.94	162	63*	15*
1.9	67.1	83*	29*
3.8	17.0	95*	52*
7.5	5.74	98*	71*
15	2.43	99*	85*

*mean value is significantly different from the control (p=0.05)
x 10,000

Table 2: Effects of A13703G on algal growth based on nominal concentrations

Endpoint	Area under the growth curve	Growth rate
72 hour EC_{50}	0.587 (0.552-0.623)	3.09 (3.01-3.18)
72 hour NOEC	0.12	0.23
96 hour EC_{50}	0.687 (0.656-0.717)	3.9 (3.81-3.98)
96 hour NOEC	0.23	0.23

Conclusions
The test acceptability criteria were met for this study. The cell concentration in the control cultures increase by a factor of at least 16 within the three days.
The lowest NOEC for area under the growth curve and growth rate was at 72 hours-0.12 mg/L.
The E_bC_{50} at 72 hours is 0.587 mg formulation/L.
The E_rC_{50} at 72 hours is 3.09 mg formulation/L.

A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

A 2.3 KCP 10.3 Effects on arthropods

A 2.3.1 KCP 10.3.1 Effects on bees

A 2.3.1.1 KCP 10.3.1.1 Acute toxicity to bees

A 2.3.1.1.1 KCP 10.3.1.1. Acute oral toxicity to bees and bumblebees.

Study 1:

Comments of zRMS:	The study has been previously evaluated in the Core Assessment for A137003G by zRMS - UK and it has been considered acceptable. The 48 hour LD_{50} for honeybees exposed to A13703G in an acute oral and contact test was 516 and 1839 µg product/bee, respectively.

Bocksch (2003). ZA5504 / CGA169374 (azoxystrobin / difenoconazole): Acute toxicity of a 200 / 125 g/L SC formulation (A13703G) to the honeybee, *Apis mellifera* L. in the laboratory. GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, Niefern-Öschelbronn, Germany. Study code:20031268/01-BLEU. Sponsor: Syngenta. Study number 2033573. November 2003.

Test item

Test Item:	A13703G
Purity:	Difenoconazole (125 g/L) Azoxystrobin (200 g/L)
Description:	Liquid, beige yellow
Lot No./Batch No. :	J6474/028

Test system

Organism (Species):	Honey bee (*Apis mellifera*)
Study Type:	Acute oral and contact
GLP Status:	GLP
Guidelines followed:	OECD 213 and 214 (1998)
Study design:	Definitive test for acute contact and oral. Duration of both was 72 h.
Information on bee colony (health etc):	Worker bees; collected randomly from the outer combs of the colony the day before the test.
Observations	Assessment of mortality and sub lethal effects after 4, 24, 48 and 72 hours.
Test concentrations:	Contact test: 0 (control-tap water), 125, 250, 500, 1000 and 2000 µg A13703G/bee. Oral test: 0 (control-50% sucrose solution), 125, 250, 500, 1000 and 2000 µg A13703G/bee.
No of replicates (test substance and control)	Oral: 5 replicates (10 bees in each- total of 50 bees) Contact: 5 replicates (10 bees in each- total of 50 bees)
Feeding method:	Contact- After application of the test substance, bees were provided with a continuous supply of 50% sucrose solution. Oral- Bees were fed with 50% w/v aqueous sucrose solution containing the test item for 6 hours. When the test solution was completely consumed, the treated feeding tubes were replaced with tubes containing untreated 50% sucrose solution for the remainder of the study.
Environmental conditions:	Temperature: 23-28 °C Relative humidity: 42-74 % Photoperiod: 24 h darkness, observations made under neon light.
Test unit:	Cages made of high grade steel (width 10 cm; depth 5.5 cm; height 8.5 cm). The front of the cages were equipped with a transparent window so that the bees could be observed. The bottom of the cages consisted of perforated steel, which guaranteed sufficient air supply for the test insects. Test cages were lined with filter paper.

Reference substance:	Perfekthion BAS 152 11 I (a.s dimethoate 400 g/l). Oral- 0.10, 0.17, 0.26 and 0.36 µg test item/bee Contact-0.10, 0.15, 0.23 and 0.30 µg test item/bee

Methodology

Contact study:
A definitive test consisting of a tap water control and concentrations of 125, 250, 500, 1000 and 2000 µg A13703G/bee. The test item was dissolved in tap water. For the contact toxicity test, treatments consisted of five replicates of the treatment dose and control, with 10 honeybees per replicate (total 50 bees). Bees were lightly anaesthetised with CO_2 and were dosed by topical application of a 2 µL droplet of dosing solution to the thorax of each bee. According to practical experience and to guarantee a good penetration of the test solution, the application was carried out ventrally. After application, the bees were returned to the test cages and fed with a 50% sucrose solution *ad libitum*.
Oral study:
A definitive test consisting of a 50% sucrose solution control and concentrations of 125, 250, 500, 1000 and 2000 µg A13703G/bee. The test item was dissolved in tap water to make a stock solution. Final doses were achieved by mixing an amount of the stock solution with 50% sucrose solution. 20 µL contained the required amount of test item per bee although 25 µL was provided. All bees were starved for 2 hours prior to the beginning of the test. Treatments consisted of five replicates for the treatment dose and control, with 10 honeybees per replicate (total 50 bees). Each cage was provided with 250ul of test substance. It is assumed that due to the honeybees' behaviour of sharing the food, that each honeybee consumes the same dose. The test item was left in the cages for 6 hours, after this time the amount of test solution consumed by each replicate was determined by weighing the feeders (eppendorf cups) before and after feeding. When all the test material had been consumed, feeding tubes were replaced by tubes containing untreated 50% sucrose solution.

Assessments for mortalities and sub lethal effects were carried out at 4, 2, 48 and 72 hours after treatment in both tests.
Temperature and humidity were monitored throughout and the test was conducted in the dark.

Results

Contact toxicity

No behavioural abnormalities were observed during the test.

Table 1:Acute contact toxicity

Nominal test concentration (µg test item/bee)	Mean cumulative mortality (%)			
	4 hours	24 hours	48 hours	72 hours
0 (Control)	0	0	0	0
125	0	0	0	0
250	0	0	0	0
500	2.0	2.0	2.0	2.0
1000	0	6.0	8.0	10.0
2000	0	40.0	54.0	58.0
LD_{50}	1839 µg test item/bee (1583-2277)			

Oral toxicity

No behavioural abnormalities were observed during the test.

Table 2:Acute oral toxicity

Nominal test concentration (µg test item/bee)	Mean cumulative mortality (%)			
	4 hours	24 hours	48 hours	72 hours
0 (Control)	0	0	0	0
125	0	4.0	4.0	4.0
250	0	14.0	16.0	16.0
500	0	34.0	48.0	48.0
1000	4.0	68.0	74.0	74.0
2000	10.0	86.3	90.2	94.1
LD_{50}	516 µg test item/bee (452-590)			

The 24-hour contact and oral LD_{50} values for dimethoate technical were 0.21 and 0.13 µg/bee, respectively.

Conclusions

All validity criteria were met for this study. Oral and contact control mortality was <15%. In the positive toxic reference studies the effect levels indicated that the honeybees were responding normally within the test system.

The 48 hour LD_{50} for honeybees exposed to A13703G in an acute oral and contact test was 516 and 1839 µg product/bee, respectively.

Study 2:

Comments of zRMS:	The study was conducted to OECD guideline 247 and according to the principles of GLP. No significant deviations to the guideline were noted. The study is considered to be reliable.

Reference:	KCP 10.3/02
Report	CHR/F/SCORPIO 325 SC Bumblebees (Bombus spp.), Acute Oral Toxicity Test, El. Kulec-Płoszczyca, Study code: B-37-23
Guideline(s):	to the OECD Guideline for Testing of Chemicals No. 247 (2017)
Deviations:	~~No~~ Yes - According to the OECD Guideline No. 247 it is recommended to use plastic syringes for the test item administration. However, in the experiment they were replaced by calibrated glass pipettes.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No
Validity criteria	Mortality of the control group was 2.0% at the end of the test (criterion: ≤ 10%)

Mortality in the toxic reference item group (dimethoate) at the end of the test was 96.6% (criterion: ≥ 50%)

Summary

The study was conducted to determine the acute oral toxicity of CHR/F/SCORPIO 325 SC to bumblebees (Bombus spp.) with a laboratory method and to demonstrate, that the median lethal dose, i.e. the LD50 at the end of exposure, is higher than the dose used in the test (limit test). One dose of the test item, i.e. 200.0 µg test item/bumblebee, plus the control and one dose of the reference item were used. The design of the definitive test was selected on the basis of non-GLP preliminary range-finding test results.

The bumblebees were exposed to the test item distributed in a 50% aqueous sucrose solution. The insects were selected for the exposure in terms of their sizes. The treated diet was provided in calibrated pipettes. Each pipette contained 40 µL of the sucrose solution with the test item at the tested dose. The insects were kept individually in isolators.

The sensitivity of the test bumblebees was verified using a reference item, i.e. dimethoate at the dose of 4.0 µg/bumblebee.

The insects were observed for mortality and other signs of toxicity 4, 24 and 48 hours after the test/ reference item administration. The acute oral toxicity test finished after the 48-hour observation.

Materials and methods

Test item:	CHR/F/SCORPIO 325 SC content: 205.89 g/L of azoxystrobin (CAS: 131860-33-8) 125.41 g/L of difenoconazole (CAS: 119446-68-3) batch no.: CHR12/23 production date: 22.02.2023 expiry date: 22.02.2026
Biological test system:	species: bumblebee, Bombus spp. source: Koppert Polska sp. z o.o. (a commercial supplier) age: adult worker bumblebees
Experimental design:	− a control (50% sucrose solution w/v) number of replicates: 50; number of insects: 1 insect/replicate; − test item: number of doses: 1, number of replicates: 50; number of insects: 1 insect/replicate; − the reference item: number of doses: 1, number of replicates: 30; number of insects: 1 insect/replicat
Dose of test item:	200.0 µg test item/bumblebee
Dose of the reference item:	4.0 µg/bumblebee
Exposure duration:	48 hours place: a dark room

Test conditions:

	temperature: 24.5 – 25.5 (required: 25 ± 2°C) relative air humidity: 55 – 56% (required: 60 ± 20%) place: a dark climate room
Endpoints:	− bumblebee mortality after 48 hours of exposure, − LD_{50} after 48 hours of exposure
Statistical method:	Chi2 rx2- Contingency Test

Results:
The median lethal doses (LD_{50}/24 h, LD_{50}/48 h) are higher than the dose used in the test, i.e. > 200.0 µg test item/bumblebee, i.e. > 37.10 µg of azoxystrobin + 22.60 µg of difenoconazole /bumblebee.

Dose		**Number of tested bumble-bees [no.]**	**Mortality after 48 h**		**LD_{50}/48 h**	
Test item [µg/ bumblebee]	**Active ingredients [µg a.i. / bumblebee]**		**[no.]**	**[%]**	**[µg/ Bumble-bee]**	**Active ingredients [µg a.i. / bumblebee]**
Control		50	1	**2.0**	**> 200.0**	> 37.10 µg of azoxystrobin + 22.60 µg of difenoconazole
200.0	37.10 µg of azoxystrobin + 22.60 µg of difenoconazole	50	2	**2.0[a]**		
Reference item: dimethoate						
Dose [µg/ bumblebee]	**4.0**	30	29	**96.6[a]**	**100.0**	

[a]: mortality corrected according to the formula of Abbott [9]

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees and bumblebees.

Comments of zRMS:	The study was conducted to OECD guideline 246 and according to the principles of GLP. No significant deviations to the guideline were noted. The study is considered to be reliable.

Reference:	KCP 10.3
Report	CHR/F/SCORPIO 325 SC Bumblebees (Bombus spp.), Acute Contact Toxicity Test, El. Kulec-Płoszczyca, Study code: B-38-23
Guideline(s):	to the OECD Guideline for Testing of Chemicals No. 246 (2017)
Deviations:	~~No~~ Yes - Anesthesia with carbon dioxide or chilling was replaced with mechanical immobilisation
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No
Validity criteria	The following validity criteria were met: Mortality of the control groups was 0.0% at the end of the test (criterion: ≤ 10%) Mortality in the toxic reference item group (dimethoate) at the end of the test was 100.0% (criterion: ≥ 50%)

Material and methods:

Test item:	CHR/F/SCORPIO 325 SC content: 205.89 g/L of azoxystrobin (CAS: 131860-33-8) 125.41 g/L of difenoconazole (CAS: 119446-68-3) batch no.: CHR12/23 production date: 22.02.2023 expiry date: 22.06.2026
Biological test system:	species: bumblebee, Bombus spp. source: Koppert Polska sp.zo.o (a commercial supplier) age: adult worker bumblebees
Experimental design:	-control with surfactant (distilled water with 1% of Triton® X-100) number of replicates:10 number of insects: 1 insect/replicate - test item with surfactant: number of doses: 1 number of replicates: 50 number of insects: 1 insect/replicate - test item with surfactant: number of doses: 1, number of replicates: 50; number of insects: 1 insect/replicate – the reference item with surfactant: number of doses: 1,

	number of replicates: 30; number of insects: 1 insect/replicate
Dose of test item	200.0 µg test item/bumblebee
Dose of reference item:	10.0 µg/bumblebe
Exposure duration:	48 hours
Test conditions:	temperature: 24.5 – 25.5˚C relative humidity: 55 – 56% place: a dark climate room
Statistical method:	not conducted due to the lack of mortality
Endpoints:	− bumblebee mortality after 48 hours of exposure, − LD_{50} after 48 hours of exposure

Summary:

The study was conducted to determine the acute contact toxicity of CHR/F/SCORPIO 325 SC to bumblebees (Bombus spp.) with a laboratory method and to demonstrate, that the median lethal dose, i.e. the LD50 at the end of exposure, is higher than the dose used in the test (limit test). One dose of the test item, i.e. 200.0 µg test item/bumblebee, plus the control with surfactant and one dose of the reference item with surfactant were used. The design of the definitive test was selected on the basis of the non-GLP preliminary range finding test results.

The bumblebees were exposed to the test item diluted in 1% water solution of surfactant Triton(R) X-100 and applied to the dorsal part of the thorax, using a microapplicator. The volume was 2 µL/bumblebee.

The insects were selected for the exposure in terms of their sizes. After that, the insects were kept individually in isolators.

The sensitivity of the test bumblebees was verified using a reference item, i.e. dimethoate (applied in 1% water-solution of surfactant) at the dose of 10.0 µg/bumblebee.

The insects were observed for mortality and other signs of toxicity 4, 24 and 48 hours after the test/ reference item administration. The acute contact toxicity test finished after the 48-hour observation

Results:

The median lethal doses (LD_{50}/24 h, LD_{50}/48 h) are higher than the dose used in the test, i.e. > 200.0 µg test item/bumblebee, i.e. > 37.10 µg of azoxystrobin + 22.60 µg of difenoconazole /bumblebee.

Dose		Number of tested bumble-bees [no.]	Mortality after 48 h		LD_{50}/48 h	
Test item [µg/ bumblebee]	Active ingredients [µg a.i. / bumblebee]		[no.]	[%]	[µg/ bumblebee]	Active ingredients [µg a.i. / bumblebee]
Control + 1% surfactant		50	0	0.0	> 200.0	> 37.10 µg of azoxystrobin + 22.60 µg of difenoconazole
200.0	37.10 µg of azoxystrobin + 22.60 µg of difenoconazole	50	0	0.0		
Reference item: dimethoate						
Dose [µg/bumble bee]	10.0	30	30	100.0	–	

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

Comments of zRMS:	The study was conducted to OECD guideline 245 and according to the principles of GLP. No deviations to the guideline were noted. The study is considered to be valid.

Study 1:

Reference:	KCP 9.6
Report	CHR/F/SCORPIO 325 SC Honeybees (Apis mellifera L.), Chronic Oral Toxicity Test, Wojciech A., 2023, Study code: B-39-23
Guideline(s):	OECD Guideline No. 245 (2017)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No
Validity criteria:	The following validity criteria were met during the test: − At the end of the experiment average mortality of the control groups was 0.0% (criterion: it must not exceed 15%) − After 10 days of exposure corrected mortality of the honeybees exposed to the reference item at the concentration of 0.8 mg/kg (0.024 µg/bee/day) was 100% (criterion: it must be ≥ 50% on day 10 of exposure).

Summary:
The mortality of honeybees exposed to CHR/F/SCORPIO 325 SC was investigated during 10-days chronic oral toxicity test.

The design of the definitive test was selected on the basis of the preliminary range-finding non-GLP test

results. One dose of the test item was used (limit test). The nominal concentration of the test item was 666.7 mg of test item/kg of diet (corresponding to the nominal dose of 20.0 µg of test item/30 mg of diet/day).

Daily dose, consumed by the bees in the group treated with the test item at the nominal concentration of 666.7 mg/kg (20 µg/30 mg/day) was 15.1 µg of test item/bee/day (dietary dose). Daily dose was calculated on the basis of average consumption of a treated 50% sucrose solution and the nominal dose used for the treatment.

Each group of bees (5 replicates/group; 10 bees/replicate) was fed with 2 mL of a 50% sucrose solution containing the test item at the concentration of 666.7 mg/kg or 50% sucrose solution alone (control group) for 10 days.

Dimethoate, which is a recommended reference item, was used to verify the sensitivity of the bees and the precision of the test procedure. The group treated with the reference item (3 replicates per 10 bees) was fed with 2 mL of a 50% sucrose solution containing reference item at the nominal concentration of 0.8 mg of reference item/kg of diet (corresponding to the nominal dose of 0.024 µg of reference item/30 mg of diet). Daily weighed feeders were used. During the experiment, the insects were caged in groups of 10. Daily dose, consumed by the bees in the group treated with the reference item at the nominal concentration of 0.8 mg/kg (0.024 µg/30 mg/day) was 0.017 µg of reference item /bee/day (dietary dose).

The insects were observed for mortality and behavioral abnormalities (signs of intoxication) at daily intervals up to 10 days of exposure.

Average consumption of a 50% sucrose solution in the control group was 26.58 mg of diet/bee/day. Average consumption in the group treated with the test item at the concentration of 666.7 mg/kg was 22.58 mg of treated diet/bee/day. Average consumption of a 50% sucrose solution containing the reference item at the concentration of 0.8 mg/kg was 21.79 mg of treated diet/bee/day.

The concentrations of azoxystrobin and difenoconazole were chemically determined using the validated high performance liquid chromatographic method with DAD detection. Fresh samples of the test item concentration and the control were chemically analyzed at test initiation and at the end of the maximum storage period (i.e. after 4 days). At exposure initiation, in the fresh sample of the test item of 666.7 mg/kg, the determined concentration of azoxystrobin was 93.0% of nominal concentration and the determined

Material and methods:

Test item:	CHR/F/SCORPIO 325 SC content: 205.89 g/L of azoxystrobin (CAS No. 131860-33-8) 125.41 g/L of difenoconazole (CAS No. 119446-68-3) batch no.: CHR12/23 production date: 22.02.2023 expiry date: 22.02.2026
Biological test system:	species: the honeybee, Apis mellifera L.; strain: carnica, source: an apiary at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna; age: freshly emerged worker honeybees (max. 2 days old) from the same queen-right colony
Experimental design:	-the test item: number of concentrations: 1 and the control

	number of replicates: 5 number of insects: 10 bees/replicate - the reference item: number of concentrations: 1 number of replicates: 3 number of insects: 10 bees/replicate exposure duration: 10 days
Nominal concentration of the test item:	666.7 mg/kg
Nominal dose of the test item:	20.0 µg/bee/day
Test item dietary dose:	15.1 µg/bee/day
Nominal concentration of the reference item (dimethoate):	0.8 mg/kg
Nominal dose of the reference item (dimethoate):	0.024 µg/bee/day
Reference item dietary dose:	0.017 µg/bee/day
Test conditions:	temperature: 32.9 – 35.0°C; relative humidity: 50.4 – 66.3%;
Statistical method:	statistical analysis was not needed due the lack of mortality
Endpoints:	honeybee mortality after 10 days of exposure

Results:

The validity criterion concerning mortality was met, because mortality in the control was 0.0% after 10 days of exposure [1]. The percentage of mortality of the honeybees exposed to the test item, at the concentration of 666.7 mg/kg (dietary dose 15.1 µg of test item/bee/day) at exposure termination (after 10 days), was 0.0%. On the basis of the obtained mortality results the LC50 is higher than 666.7 mg/kg, and the LDD50 value is higher than 15.1 µg of test item/bee/day. The validity criterion concerning mortality of the honeybees exposed to the reference item, dimethoate was met, because mortality was equal to 100% after 10 days of exposure. The results obtained in the reference item group showed that the insects were sensitive to dimethoate

The effects of CHR/F/SCORPIO 325 SC on mortality of honeybees are summarized below:

Nominal test item concentration/ dose		Ingested[a] dose	Number of tested bees	Total mortality		LC_{50}	LDD_{50}
[µg of test item/30 mg of diet/day] [µg of test item/bee/day]	[mg of test item/kg of diet]	[µg of test item/bee/day]	[no]	No.	[%]	[mg of test item/kg of diet]	[µg of test item/bee/day]
CHR/F/SCORPIO 325 SC							
0.0 (Control)			50	0	**0.0**	**> 666.7**	**> 15.1**
20.0	**666.7**	**15.1**	50	0	**0.0**		
Dimethoate (reference item)							
0.024	**0.8**	**0.017**	30	30	**100.0**	not determined	

[a]: ingested doses (dietary doses) were calculated on the basis of the concentrations of the test item / reference item and average sucrose solution consumption

A 2.3.1.3 KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

Study 1

Comments of zRMS:	The study was conducted to OECD guideline 239 and according to the principles of GLP. No significant deviations to the guideline were noted. The study is considered to be valid.

Reference: KCP 9.6

Report: Honey bee larval toxicity test following repeated exposure of the test item CHR/F/SCORPIO 325 SC, Zaworska K., Study code: 0038/0142/E

Guideline(s): OECD GD 239 ENV/JM/MONO(2016)34

Deviations: ~~No~~ Yes
Deviations from the Study plan and OECD GD 239 ENV/JM/MONO(2016)34 guideline were found:
1. During the definitive test the decrease in temperature during larval stage (to 33.3°C) and pre-pupal stage (to 32.5°C) and decrease in humidity during larval stage (to 79.8 % RH) and pre-pupal stage (74.7% RH) and increase in humidity during pre-pupal stage (to 95.6 %RH). Requirements: temperature: 34.5±0.5°C, humidity: larvae 95±5% RH, pre-pupae 80±5% RH, pupae/imago 50-80% RH.
3. During range-finding test decrease in temperature during larval stage (to 32.3°C) and pupal/imago stage (to 32.9°C) and in humidity during larval stage (to 80.7 % RH), pre-pupal stage (to 69.6%RH) and pupal/imago stage (to 35.6 % RH). Requirements: temperature: 34.5±0.5°C, humidity: larvae 95±5% RH, pre-pupae 80±5% RH, pupae/imago 50-80% RH
Deviations from the Study plan were found:

	2. In the stability test the temperature increased to maximum 8.5°C. Requirements: temperature: 6.0±2.0°C The above deviations did not affect the test result. The study met the validity criteria.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No
Validity criteria:	The study met the validity criteria (acc. to OECD GD 239 ENV/JM/MONO(2016)34): – larval mortality in control on days 3-8 was 8.3% in replicate 1 and replicate 2 and 0.0% in replicate 3, (required: ≤15%), -the adults emergence rate in control on day 22 was 83.3% in replicate 1 and replicate 3 and 75.0% in replicate 2 (required: ≥70%), - for dimethoate as reference item, the larval mortality on day 8 was 100.00% (required: ≥50%)

Summary

The assessment test of the test item CHR/F/SCORPIO 325 SC toxicity on honey bee larvae (Apis mellifera L.) was conducted in accordance with the OECD GD 239 ENV/JM/MONO(2016)34 Guideline. During the test, the impact on the successive stages of development of the honey bee, resulting from the repeated exposure of the larval stage to the test item, were determined. The aim of the study was to determine the concentration of the test item causing the mortality of 50% of the population in the test (EC50 value) and the dose of the test item causing the mortality of 50% of the population after 22 days (ED50 value). The values of NOEC/NOED and LOEC/LOED, EC10/ED10 and EC20/ED20 were determined for emerged adults (survival) on the 22nd day of the study

The definitive test:

Test design	tested concentrations and control groups consisted of 36 larvae i.e. 12 larvae from 3 different colonies (breedings) located on the plate
Test equipment	48-well breeding plates with queen-cell cups placed in the dissector and placed in incubator; from day 15 of the test – transparent plastic boxes placed in test room
Exposition time	4 days (from day 3 to day 6)
Duration of the test	22 days
Tested concentrations (doses)	– control (0.00 mg of test item/kg of diet), corresponding to 0.00 µg of test item/larva (0.00 g of test item/L of deionized water) -0.45 mg of test item/kg of diet, corresponding to 0.07 µg of test item/larva (0.03 g of test item/L of deionized water

	- 1.34 mg of test item/kg of diet, corresponding to 0.21 µg of test item/larva (0.10 g of test item/L of deionized water) - 4.01 mg of test item/kg of diet, corresponding to 0.62 µg of test item/larva (0.31 g of test item/L of deionized water) - 12.04 mg of test item/kg of diet, corresponding to 1.85 µg of test item/larva (0.93 g of test item/L of deionized water) -36.11 mg of test item/kg of diet, corresponding to 5.56 µg of test item/larva (2.78 g of test item/L of deionized water) -108.33 mg of test item/kg of diet, corresponding to 16.67 µg of test item/larva (8.33 g of test item/L of deionized water) -325.00 mg of test item/kg of diet, corresponding to 50.00 µg of test item/larva (25.00 g of test item/L of deionized water) -48 mg of reference item/kg of diet, corresponding to 7.39 µg/larva (0.528 g of reference item/L of deionized water
Test conditions	– for larval stage (day 1-8): average temperature 34.3°C (min. 33.3°C, max. 34.5°C) average relative humidity 94.4% (min. 79.8%, max. 95.6%) darkness – for pre-pupal stage (day 8-15): average temperature 34.4°C (min. 32.5°C, max. 35.0°C average relative humidity 76.0% (min. 74.7%, max. 95.6%) darkness - for pupal/imago stage (day 15-22): average temperature 34.4°C (min. 34.0°C, max. 34.4°C) average relative humidity 74.3% (min. 73.3%, max. 75.1%) darkness [1]The deviations from Study plan and OECD GD 239 ENV/JM/MONO(2016)34 guideline were found. The deviations are described in details in point 6.

Final results:

In course of the study, the test item showed statistically significant effect on larval mortality in concentrations range 108.33 mg of the test item/kg of diet – 325.00 mg of the test item/kg of diet. The test item showed no statistically significant effect on emergence of adult honey bees in concentrations range 0.45 mg of the test item/kg of diet – 650.00 mg of the test item/kg of diet. The final results of the study are presented in Table 1.

Emergence results			
Parameter	**Concentration [mg of test item/kg of diet]**	**Parameter**	**Dose [µg of test item/larva]**
EC_{10}	4.17	**ED_{10}**	0.65
EC_{20}	63.82	**ED_{20}**	9.82
EC_{50}	>325.00*	**ED_{50}**	>50.00*

EC_{10} test item concentration causing effect on 10% population
EC_{20} test item concentration causing effect on 20% population
EC_{50} test item concentration causing effect on 50% population
ED_{10} test item dose causing effect on 10% population
ED_{20} test item dose causing effect on 20% population
ED_{50} test item dose causing effect on 50% population
* values determined based on the analysis of the results

Pupal mortality results						
Concentration [mg of test item/kg of diet]	Time [day]					
	15		22			
	Mortality [%]	Statistical significance*)	Mortality [%]	Statistical significance*)	LOEC	NOEC
					[mg of test item/kg of diet]	
Control	5.9	not applicable	14.7	not applicable	>325.00	≥325.00
0.45	9.1	-	18.2	-		
1.34	3.2	-	16.1	-		
4.01	9.7	-	12.9	-		
12.04	0.0	-	7.1	-		
36.11	0.0	-	3.7	-		
108.33	8.0	-	16.0	-		
325.00	4.3	-	13.0	-		

- statistically insignificant
NOEC the highest test item concentration not causing statistically significant differences in relations to the control
LOEC the lowest test item concentration causing statistically significant differences in relations to the control
*) values calculated using ToxRat Professional using Fisher test after Bonferroni-Holm correction with significance level p=0.05
**) values determined based on the analysis of the results

Emergence results							
Concentration [mg of test item/kg of diet]	Dose [µg of test item/larva]	Time [day]					
		22					
		Mortality [%]	Statistical significance*)	LOED	NOED	LOEC	NOEC
				[µg of test item/larva]		[mg of test item/kg of diet]	
Control	Control	19.4	not applicable	>50.00	≥50.00	>325.00	≥325.00
0.45	0.07	25.0	-				
1.34	0.21	27.8	-				
4.01	0.62	25.0	-				
12.04	1.85	27.8	-				
36.11	5.56	27.8	-				
108.33	16.67	41.7	-				
325.00	50.00	44.4	-				

- statistically insignificant
+ statistically significant
*) values calculated using ToxRat Professional using Fisher test after Bonferroni-Holm correction with significance level p=0.05
**) values determined based on the analysis of the results
NOEC the highest test item concentration not causing statistically significant differences in relations to the control
LOEC the lowest test item concentration causing statistically significant differences in relations to the control
NOED the highest test item dose not causing statistically significant differences in relations to the control
LOED the lowest test item dose causing statistically significant differences in relations to the control

Table 1. Final results of the study

Larval mortality results				
Concentration [mg of test item/kg of diet]	Time [day]			
	8			
	Mortality [%]	Statistical significance*)	LOEC	NOEC
			[mg of test item/kg of diet]	
Control	5.6	not applicable	108.33	36.11
0.45	8.3	-		
1.34	13.9	-		
4.01	13.9	-		
12.04	22.2	-		
36.11	25.0	-		
108.33	30.6	+		
325.00	36.1	+		
Concentration [mg of reference item/kg of diet]	Time [day]			
	8			
	Mortality [%]	Statistical significance*)	LOEC	NOEC
			[mg of reference item/kg of diet]	
48.00	100.00	+	not applicable	

- statistically insignificant
+ statistically significant
NOEC the highest test item concentration not causing statistically significant differences in relations to the control
LOEC the lowest test item concentration causing statistically significant differences in relations to the control
*) values calculated using ToxRat Professional using Fisher's Test after Bonferroni-Holm correction with significance level p=0.05
**) values determined based on the analysis of the results

~~A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects~~

Study 1

Comments of zRMS:	The study has been previously evaluated in the Core Assessment for A137003G by zRMS - UK and it has been considered acceptable. 48 hour LR_{50} of A13703G to the mortality of *A. rhopalosiphi* was >2000 ml/ha.

Stacey, D. (2003). CGA169374 (difenoconazole)/ZA5504 (azoxystrobin): Tier I standard laboratory bioassay of the effects of fresh residues of a 125/200g/L SC formulation (A3703G) on the parasitic wasp *Aphidius rhopalosiphi* (Hymenoptera, Braconidae). Syngenta. Report no: RJ3438B. Study number: 2033571. December 2003

Test system

Test item:	A13703G
Purity:	Difenoconazole (125 g/L, analysed 129 g/L) Azoxystrobin (200 g/L, analysed 191 g/L)
Description:	Liquid, beige yellow

Lot No./Batch No. :	J6474/028

Organism (Species):	Parasitic wasp, *Aphidius rhopalosiphi*
Age/Life stage at dosing	<48 hours
Host species	*Rhopalosiphum padi* (cereal aphid)
Study Type:	Test duration was 13 days. Exposed for 48 hours to dried residues on glass plates. Mortality assessed over 48 hours. Parasitation period of 24 hours. Fecundity then assessed over a further 10 days.
GLP Status:	GLP
Guidelines followed:	Mead-Briggs *et al.*, (2000)
Parameters observed:	Mortality and fecundity.
Observation intervals:	Mortality was assessed after 2, 24 and 48 hours. Fecundity assessed at the end of 10 days (termination).
Test units	Exposure 2 treated glass plates (10 cm x 10 cm) which were fitted to a square frame made from stainless steel (2cm high). Holes were drilled though the frame to provide ventilation. One hole at the bottom of the cage was connected to a water bath with a cotton wick, this supplied water to the wasps. All units were attached by tubing to air pumps which maintain air movement within the units. Fecundity- Untreated pots) with barley seedlings infested with >50 host aphids (*Rhopalosiphum padi*) were enclosed within a ventilated clear plastic, cylindrical cage. The soil surface was covered with a thin layer of light-coloured sand to aid observations.
Number of replicates	4 replicates (each containing 7 female and 3 males- 40 wasps in total) for the control, test concentrations and toxic reference Fecundity- 10 replicates per test concentration and control- 1 female per test unit.
Test concentrations:	0 (deionised water control), 51.2, 128, 320, 800 and 2000 ml product/ha in 200L deionised water/ha
Environmental conditions:	Temperature: mean 21.3 °C (short deviation of >22°C) Relative Humidity: mean 67.5% (short deviation of humidity <60%) Photoperiod: 16 hour light:8 hours dark (2730 lux for exposure and 7980 lux for fecundity period) Feeding: Before the test the wasps were fed with honey: tap water solution (1: 3, v: v) and during the test wasps were fed with honey: tap-water solution (1:1; v: v) applied to cotton wool, but were not fed during the 24 h parasitisation period.
Reference substance:	Dimethoate 400 g/L (37.7% w/w) applied at a rate of 0.5 ml formulation/ha.

Methodology
Exposure
A tier I, dose-response toxicity study on the parasitoid wasp, *Aphidius rhopalosiphi* was conducted in the

laboratory. The test organisms were exposed for 48 hours to an untreated control and to fresh, dried residues of A13703G on glass slides at nominal rates of 0 (deionised water control), 51.2, 128, 320, 800 and 2000 ml product/ha in 200L deionised water/ha. A positive reference treatment of a dimethoate formulation was also included at a concentration of 0.5 ml formulation/ha. All treatments were applied in an application volume equivalent to 200 L/ha water. Four replicates of 10 wasps were tested for each treatment group, control and reference substance. The test item was applied to glass plates using a track sprayer to simulate field application. Glass plates were left to dry before individuals were added approximately 1 hour later.
Assessments for adult wasp mortality were carried out approximately 2, 24 and 48 hours after the start of the exposure phase.
If after the exposure phase, the effects on mortality were ≤50% (corrected mortality) then the fecundity phase of the test was set up. 10 female wasps from the control and each test concentration were individually added to test units containing barley seedlings infested with aphids. The female wasps were left in these units for a further 24 hours, after which they were removed. The remaining aphids were maintained for 10 days and then the parasitised aphids (aphid mummies) per female wasp were counted.

Temperature and humidity were monitored continuously.

Statistics

For statistical analysis of mortality data a probit model was fitted by a technique called maximum likelihood in which the binomial distribution of the data is taken into account. For fecundity, an analysis of variance was carried out. This was then followed by a Dunnett's two-sided t-test.

Results

Table 1: Effects of A13703G on the survival and fecundity of *A. rhopalosiphi*

Test concentrations (ml/ha)	**% mortality after 48 hr**	**Mean mummies per female**	**% difference in reproduction compared to control**
Control	0 **Abbott corrected % mortality**	17.0	-
51.2	5	9.2	-45.9
128	0	8.9	-47.6
320	10	8.7	-48.8
800	7.5	21.2	+24.7
2000	2.5	7.0	-58.8
Toxic Reference	100	-	-

Conclusions
Validity criteria for this study were met. The control mortality was ≤13% after 48 hours of exposure. The mean number of mummies produced in the control per female during the fecundity assessment was ≥ 5 (17.0). There were no more than two female wasps in the control group that produced 0 mummies.

Mortality in the reference substance was 100% (corrected mortality) after 48 hours, as this was >50%, the validity criteria was met.
Under worst case laboratory conditions the 48 hour LR_{50} of A13703G to the mortality of *A. rhopalosiphi* was >2000 ml/ha.
There were no statistically significant effects of the test item on reproduction up to 2000 ml/ha (ER_{50} >

3000 ml/ha). The highest test concentration did have effects on fecundity >50% compared to the control but this difference was not statistically significant.

Study 2

Comments of zRMS:	The study has been previously evaluated in the Core Assessment for A137003G by zRMS - UK and it has been considered acceptable. 7-day LR_{50} of A13703G on *Typhlodromus pyri* was 1872 ml/ha

Brühl C & Pinch C (2003). CGA169374 (difenoconazole)/ZA5504 (azoxystrobin): Tier I standard laboratory bioassay of the effects of fresh residues of a 125/200 g/L SC formulation (A13703G) on the predatory mite *Typhlodromus pyri* (Acari: Phytoseiidae). Syngenta. Report no RJ3444B. Study no. 2033570. December 2003.

Test system

Test item:	A13703G
Purity:	Difenoconazole (125 g/L, analysed 129 g/L) Azoxystrobin (200 g/L, analysed 191 g/L)
Description:	Liquid, beige yellow
Lot No./Batch No. :	J6474/028

Organism (Species):	Predatory mite, *Typhlodromus pyri*
Age/Life stage at dosing	Protonymphs (<24 hours old).
Study Type:	Tier 1 laboratory study, glass plates for mortality. Duration of 7 days for mortality assessment and 7 days for reproductive capacity assessment.
GLP Status:	GLP
Guidelines followed:	Brumel *et al* (2000), Candolfi *et al* (2001)
Parameters observed:	Mortality and reproductive capacity
Observation intervals:	Mortality was assessed at day 3 and 7. Reproductive capacity assessed on day 10, 13 and 14.
Test units	The test unit was a petri dish (diameter 14 cm). Foam rubber was placed into this dish and soaked in tap water. Filter paper was then put on top of the foam rubber. Two cover slides were then placed on top of the filter paper, their longitudinal sides touching each other. The slides were fixed together using sticky tape. By capillary force, the thin slit between the cover slides was filled with water which served as drinking water for the mites. The test arena (13 cm^2) was limited by a barrier of glue. The petri dishes were covered with a lid containing a hole covered with fine mesh netting.
Number of replicates	3 replicates each with 20 protonymph mites for the control, test concentrations and the reference item.
Test concentrations:	0 (deionised water control), 80, 400, 800, 1600 and 3200 ml product/ha in 200L deionised water/ha
Environmental conditions:	Temperature: 24.4-25.4 °C Relative Humidity: 39.9-81% Photoperiod: 16 hour light:8 hours dark (1570 lux) Feeding: Pollen of walnut and apple provided before and during the test. Food was given every 3-4 days. Water provided *ad libitum*.
Reference substance:	400 g/l Dimethoate (43.2% w/w) applied at a rate of 15

	ml product/ha in 200 L deionised water/ha.

Methodology

A tier I, dose-response toxicity study on the predatory mite *Typhlodromus pyri* was conducted in the laboratory. The test organisms were exposed for 7 days to an untreated control and to fresh, dried residues of A13703G on glass slides at nominal rates of 80, 400, 800, 1600 and 3200 ml product/ha in 200L deionised water/ha. A positive reference treatment of a dimethoate formulation was also included at a rate of 15.0 ml/ha. Three replicates were tested for each treatment group, with 20 protonymph mites in each replicate, selected randomly. All treatments were applied using a track sprayer, in an application volume equivalent to 200 L/ha water. The time between spray application and the addition of mites was <2 hours. Pollen of walnut and apple was provided every 3-4 days as a food source.

Survival of the mites was assessed after 3 and 7 days. The percent mortality of the mites in each vessel was calculated and corrected according to the control (Abbott), included all observations of dead, trapped and missing mites. A mean per treatment was then calculated.

On day 7, the number of males and females were counted and any eggs, larvae or juveniles present were removed from the arena and therefore did not count towards the fecundity assessments. If after the exposure period, the sex-ratio of males to female's is more than 5 females: 1 male then males from other replicates of the same treatment group can be added until the correct ratio is reached. From day 7-14, 3 assessments of fecundity took place (day 10, 13 and 14). The number of eggs and juveniles were counted (per female) and removed from the test units. The mean cumulative number of eggs produced per female over the fecundity period was calculated.

Temperature and relative humidity were monitored continuously.

Statistics

The LR_{50} was determined by fitting a probit model to the mortality data. For the fecundity phase an analysis of variance was performed in order to determine a pooled estimate of residual error variance. The response for each treatment was then compared with the control using a two-sided Dunnett's test.

Results

Table 1: Effects of A13703G on the survival of *Typhlodromus pyri*

Test concentrations (ml/ha)	Mean corrected[1] % mortality after 7 days	Eggs/female	Effect on reproduction (%)
Control	0	9.88	-
80	0	11.24	-13.75
400	25.00	10.47	-5.99
800	40.00	11.06	-11.91
1600	50.00	2.76	72.04*
3200	51.67	1.19	87.91*
Toxic Reference	100	-	-

[1] Abbott (1925).
*significantly different compared to the control (Dunnett's test)

Conclusions

The validity criteria applied to this study were met, the water control treatment mortality was <20% at 7

days (0%). Control fecundity also achieved >4 eggs per female over the fecundity period (9.88 eggs/female). In addition, the positive reference treatment, dimethoate, achieved 100% corrected mortality, indicating that the mites were responding as expected in the test system.
Under worst case laboratory conditions the 7-day LR_{50} of A13703G on *Typhlodromus pyri* was 1872 ml/ha (95% confidence limit of 1179-4126 ml/ha). Fecundity was statistically significantly affected at the test rates of 1600 and 3200 mL product/ha compared to the control. Therefore the NOEL for fecundity was 800 ml/ha.

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna

~~A 2.4.1 KCP 10.4.1 Earthworms~~

Study 1

Comments of zRMS:	Study not required.

Schmidt, T (2003). CGA 169374 (Difenoconazole) / ZA 5504 (Azoxystrobin): Acute toxicity of a 125 / 200 g/L SC formulation (A13703G) to the earthworm *Eisenia fetida* in a 14-day test in artificial soil. RCC Ltd, Switzerland. Study no: 850140. Sponsor: Syngenta. Study no: 2033572. December 2003.

Test material

Test Item:	A13703G
Purity:	Difenoconazole (125 g/l, analysed 129 g/l) Azoxystrobin (200 g/l, analysed 191 g/l)
Description:	Liquid- yellow, beige
Batch No.	J6474/028

Test system

Organism (Species):	Earthworm (*Eisenia fetida*). Adult worms were used of about 6 months old with clitellum (weight ranged from 349-412 mg/earthworm).
Study Type:	14 day acute earthworm study
GLP Status:	Yes
Guidelines followed:	OECD Guideline 207
Parameters observed:	Assessment of the mortality, behaviour and biomass change. Mortality and sub lethal effects observed after 7 and 14 days. Biomass effects observed after 14 days.
Test item and control replicates:	4 replicates, consisting of 10 individuals per replicate (40 individuals per treatment)
Test Concentrations:	0 (control- purified water), 10, 50, 250, 750 and 1500 mg

	product/kg soil dry weight.
Soil Parameters	Artificial soil according to OECD 207. Soil details were as follows: 10% Sphagnum-peat, air-dried and finely ground 20% Kaolin clay 70% sand 0.5% calcium carbonate pH at initiation: 6.1 pH at termination: 5.8-6.0 Water content at initiation: 35% of soil dry weight Water content at termination: 33-34% of soil dry weight
Test unit:	1 litre glass vessel (diameter 10cm, height 14 cm) covered by glass lids to prevent evaporation.
Environmental Conditions:	Temperature: 18.4-19.9°C Light Intensity: continuous illumination (520-580 lux)
Reference Item:	2-Chloroacetamide tested as a positive control once a year. In the most recent test (December, 2003), the reference item demonstrated the suitability of the test species and experimental conditions as the LC50 was within the range of values determined from reference tests over the last eight years (LC50 19 mg/kg soil)

Methodology

A definitive test was performed at test concentrations of: 0 (control- purified water), 10, 50, 250, 750 and 1500 mg product/kg soil dry weight. A stock solution of the highest test solution was produced by diluting a specified amount of the test item in purified water. Amounts of this stock solution were then further diluted with purified water before being added to 556 g dry weight of artificial soil for each replicate. This was mixed in a laboratory mixer to ensure homogeneity. During mixing, additional purified water was added in order to achieve the soil moisture water content of 35%. 556g dry weight of this soil was then added to each test concentration replicate before the earthworms were introduced on top of the soil. Test units were a 1 litre glass vessel, diameter 10cm, height 14 cm. Adult earthworms were given approximately 1 day to acclimatise to test conditions before initiation (this was carried out in the artificial soil). 4 replicates were used per test concentration with 10 worms in each (giving a total of 40 individuals per treatment group). Assessment of worm mortality and behavioural effects was assessed at after 7 and 14 days, measurement of mean fresh weight change as a sub-lethal parameter was measured at initiation and after 14 days.

Temperature was continuously monitored. pH and water content were determined at test initiation and termination.

Statistics

Statistically significant changes in body weight compared to the control were determined using the Williams t-test.

Results

After 7 day, one worm was observed moving unusually slowly at the highest test concentration of 1500 mg/kg d.w. soil.

Body weight changes were not statistically significantly different compared to the control up to and including 50mg test item/kg soil. At 250 mg/kg soil and above, body weight was statistically significantly different from the control.

Table 1: Effects of A13703G on earthworm survival and biomass

Test concentrations (mg/kg)	% mortality after 14 days	Biomass fresh weight change after 14 days (%)
Control	0	-7
10	0	-8
50	0	-8
250	0	-10*
750	5	-14*
1500	5	-16*

*Statistically significantly different from the control (Williams test, one sided, α=0.05)

Conclusions

All validity criteria of the test were met. Mortality in the control group did not exceed 10% (0%) and average loss of biomass in the control group was less than 20% (-7%). The results of the positive toxic reference item indicate that the laboratory conditions were adequate and had not changed over time. In a 14-day toxicity study with A13703G to earthworms (*Eisenia fetida*) the 14-day LC_{50} was determined to be >1500 mg /kg soil dry weight. The NOEC for effects on weight was determined to be 50 mg/kg soil d.w.

Study 2

Comments of zRMS:	The study was conducted to the guideline and according to the principles of GLP. All validity criterions were met. The study is considered to be reliable and suitable for the risk assessment.

Reference: KCP. 10.4

Report: Pieczka, P. (2023). CHR/F/SCORPIO 325 SC, Collembolan (Folsomia candida) Reproduction Test, according to the OECD Guideline No. 232 (2016), Study code: G-04-23. Sponsor: Chemirol, July 2023

Guideline(s): OECD Guideline No. 232 (2016)

Deviations: Deviation from the OECD Guideline No. 232 (2016): at the end of the test the soil moisture content was determined by drying small sample of the artificial soil in 105°C instead of weighing the test vessels as it is mentioned in OECD Guideline No. 232 (2016) (3.6.6). The deviation did not affect the results of the study.

GLP: Yes

Acceptability:

Duplication: No
(if vertebrate study)

Validity criteria: Deviation from the OECD Guideline No. 232 (2016) – at the end of the test the soil moisture content was determined by drying small sample of the artificial soil in 105°C instead of weighing the test vessels as it is mentioned in OECD Guideline No. 232 (2016) (3.6.6). The deviation did not affect the results of the study

Summary:

The aims of the study were to assess the impact of CHR/F/SCORPIO 325 SC on reproduction of the collembolans, Folsomia candida and to determine the EC10, EC20, EC50, and NOEC. Ten concentrations of the test item were used. These were 5.6, 10.0, 18.0, 32.0, 56.0, 100.0, 180.0, 320.0, 560.0, and 1000.0 mg of the test item/kg of dry weight of the artificial soil. Each concentration was divided into four replicates. There was also an untreated control group divided into eight replicates. The test item in form of aqueous suspension was mixed with the artificial soil. The control artificial soil was mixed with deionized water alone. The exposure period lasted 28 days. After that, the collembolans were extracted from the artificial soil. The numbers of adults and juveniles were determined separately.

Materials and methods:

Test item:	CHR/F/SCORPIO 325 SC batch no.: CHR12/23
Active substances:	azoxystrobin – 205.89 g/L difenoconazole – 125.41 g/L
Artificial soil:	5% sphagnum peat, 20% kaolin clay, 74.88% air-dried industrial sand and 0.12% calcium carbonate
Test organism:	the collembolan, Folsomia candida obtained from a standard laboratory culture at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna, Laboratory of Soil Organisms Toxicology. The collembolans used in the study were between 9 and 12 days old.
Test design:	test duration: 28 days number of replicates: 4 replicates / concentration + 8 replicates / control; number of collembolans: 10 / replicate
Concentrations of the test item:	a control, 5.6, 10.0, 18.0, 32.0, 56.0, 100.0, 180.0, 320.0, 560.0, and 1000.0 mg of the test item/kg of dry weight of the artificial soil
Test conditions:	temperature: 19.8 – 21.8°C; pH at the beginning of the test: 5.70 – 5.81; pH at the end of the test: 5.73 – 5.78; soil moisture content at the beginning of the test: 17.1 – 18.1% (46.4 – 49.1 % of the maximum water holding capacity); soil moisture content at the end of the test: 15.8 – 17.0% (42.9 – 46.1% of the maximum water holding capacity); lighting: 16 h light and 8h dark; light intensity at the beginning of the experiment: 668.3 – 679.7 lux; light intensity at the end of the experiment:

698.3 – 713.1 lux

Statistical analysis: EC10, EC20, EC50 – Probit analysis using linear max. likelihood regression LC10, LC20, LC50 – Probit analysis using linear max. likelihood regression NOEC (number of juveniles): - Shapiro-Wilk's Test on Normal Distribution, - Levene's Test on Variance Homogeneity (with Residuals), - Trend analysis by Contrasts (Monotonicity of Concentration/Response), - Williams Multiple Sequential t-test Procedure, NOEC (survival): - Qualitative Trend Analysis by Contrasts (Monotonicity of Concentration/Response) – Tarone's Test Procedure – Step-down Cochran-Armitage Test Procedure

Endpoints: EC10, EC20, EC50, NOEC LC10, LC20, LC50, NOEC

Results:

After the application of the test item at the concentrations ranging from 5.6 to 1000.0 mg/kg dry weight of the artificial soil, the mortality of adults ranged from 12.5 to 35.0%. As for the control group, it was equal to 11.3%. The endpoint values showing the impact of the test item on the survival of adult collembolans are presented in the Table given below.

Endpoint	Value [mg test item/kg dry weight of the artificial soil]	Value [mg of azoxystrobin/kg dry weight of the artificial soil]	Value [mg of difenoconazole/kg dry weight of the artificial soil]
LC_{10}	155.1 (76.0 – 299.2)	28.8 (14.1 – 55.5)	17.5 (8.6 – 33.8)
LC_{20}	679.2 (344.3 – >1000.0)	126.0 (63.9 – >185.5)	76.7 (38.9 – >113.0)
LC_{50}	>1000.0	>185.5	>113.0
NOEC	180.0	33.4	20.3

After the exposure of collembolans to the test item at the concentrations ranging from 5.6 to 1000.0 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 75.8 – 767.3 per replicate. As for the control group, the number of juveniles was equal 685.3 per replicate. The endpoint values showing the impact of the test item on reproduction of Folsomia candida are presented in the Table

given below.

Endpoint	Value [mg test item/kg dry weight of the artificial soil]	Value [mg of azoxystrobin/kg dry weight of the artificial soil]	Value [mg of difenoconazole/kg dry weight of the artificial soil]
EC_{10}	193.2 (151.8 – 228.9)	35.8 (28.2 – 42.5)	21.8 (17.2 – 25.9)
EC_{20}	264.8 (222.4 – 301.1)	49.1 (41.3 – 55.9)	29.9 (25.1 – 34.0)
EC_{50}	484.1 (440.5 – 533.1)	89.8 (81.7 – 98.9)	54.7 (49.8 – 60.2)
NOEC	180.0	33.4	20.3

Study 3

Comments of zRMS:	The study was conducted to the guideline and according to the principles of GLP. All validity criterions were met. The study is considered to be reliable and suitable for the risk assessment.

Reference:	KCP 10.4.1
Report	**Wróbel, A. (2023). CHR/F/SCORPIO 325 SC, Predatory mite (Hypoaspis (Geolaelaps) aculeifer) reproduction in soil, according to the OECD Guideline No. 226 (2016), Study code: G-05-23, Sponsor: Chemirol, 2023**
Guideline(s):	OECD Guideline No. 222 (2016)
Deviations:	Yes *The deviation from the SOP/G/122*: As it is indicated in the SOP/G/122, the amount of calcium carbonate to adjust the pH should be in the range from 0.04 to 0.055%. In the study, the needed amount of calcium carbonate was equal to 0.15%, therefore it is a deviation from the SOP/G/122. According to the OECD Guideline the amount of $CaCO_3$ should be less than 1.0%. The applied quantity of the calcium carbonate in the study was in line with OECD assumptions. The deviation did not affect the results of the study
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No
Validity criteria	The results are considered valid because the following criteria were satisfied in the control: mean adult mortality: 10.0% (criterion: ≤ 20%), the mean number of juveniles per vessel at the end of the test: 128.5 (criterion: ≥ 50

juveniles at the end of the test), the coefficient of variation for the number of juveniles: 18.8% (criterion: ≤ 30%)

Summary

The aims of the study were to assess the impact of CHR/F/SCORPIO 325 SC on reproduction of the predatory mite, Hypoaspis (Geolaelaps) aculeifer and to determine the EC10, EC20, EC50, and NOEC.

Ten concentrations of the test item were used. These included: 5.6, 10.0 18.0, 32.0, 56.0, 100.0, 180.0, 320.0, 560.0 and 1000.0 mg/kg dry weight of the artificial soil. Each concentration was divided into four replicates. There was also an untreated control group divided into eight replicates. The test item in the form of water suspension was mixed with the artificial soil. The control artificial soil was mixed with deionized water alone. The exposure period lasted 14 days. After that, the mites were extracted from the artificial soil (48-hour extraction). The numbers of adults and juveniles were determined separately.

Materials and methods:

Test item:	CHR/F/SCORPIO 325 batch number: CHR12/23
Active substances:	azoxystrobin – 205.89 g/L difenoconazole – 125.41 g/L (Appendix No. 1)
Artificial soil:	5% sphagnum peat, 20% kaolin clay, and 74.825% air-dried industrial sand, 0.175% calcium carbonate
Test system:	the predatory mites, Hypoaspis (Geolaelaps) aculeifer (adult female mites from a synchronized culture) obtained from a standard laboratory culture at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna, Ecotoxicology Research Group, Laboratory of Soil Organisms Toxicology. The mites were introduced 7 – 14 days after becoming adult.
Test design:	exposure time: 14 days number of replicates: 4 replicates / concentration + 8 replicates / control; number of mites: 10 mites / replicate, a control, 5.6, 10.0, 18.0, 32.0, 56.0, 100.0, 180.0, 320.0,
Concentrations of the test item:	560.0 and 1000.0 mg test item/kg dry weight of the artificial soil
Test conditions:	temperature: 19.8 – 21.6°C pH at the beginning of the test: 6.30 – 6.41 pH at the end of the test: 6.04 – 6.32 soil moisture content at the beginning of the test: 18.1 – 18.8% (45.7 – 47.5% of the

	maximum water holding capacity) soil moisture content in the middle of the test: 17.9 – 18.9% (45.2 – 47.7% of the maximum water holding capacity) soil moisture content at the end of the test: 17.4 – 18.3% (43.9 – 46.2% of the maximum water holding capacity) light-dark cycle: 16 h light and 8 h dark light intensity at the beginning of the test: 599.3 – 714.5 lux light intensity at end of the test: 659.8 – 671.1 lux
Statistical analysis:	EC10, EC20, EC50 – logit analysis using linear max. likelihood regression. LC10, LC20, LC50 – probit analysis using linear max. likelihood regression. NOEC: - offspring number – Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Dunnett's Multiple t-test Procedure. - survival – Step-down Cochran-Armitage Test Procedure
Endpoints:	EC10, EC20, EC50, NOEC LC10, LC20, LC50, NOEC

Results

Mortality of the predatory mites exposed to the test item at the concentrations ranging from 5.6 to 1000.0 mg/kg dry weight of the artificial soil was between 0.0% and 12.5%. Mortality of the control group was equal to 10.0%. After the application of the test item at the concentrations ranging from 5.6 to 1000.0 mg/kg dry weight of the artificial soil the mean number of juveniles was between 122.3 and 168.0 per replicate. The mean number of juveniles in the control group was equal to 128.5 per replicate.

Concentration [mg/kg dry weight of the artificial soil]	Adult mites			Number of juveniles (mean)
	Number of tested mites	Dead mites after 14 days of exposure		
		No.	%	
control	80	8	10.0	128.5
5.6	40	3	7.5	126.0
10.0	40	5	12.5	150.5
18.0	40	2	5.0	157.8
32.0	40	4	10.0	168.0
56.0	40	0	0.0	160.0
100.0	40	5	12.5	135.5
180.0	40	3	7.5	149.3
320.0	40	0	0.0	140.0
560.0	40	1	2.5	154.5
1000.0	40	2	5.0	122.3

Endpoint values – the impact of the test item on reproduction and on mortality of the predatory mites (Hypoaspis aculeifer)

Endpoint	Value [mg of the test item/kg dry weight of the artificial soil]	Value [mg of azoxystrobin/kg dry weight of the artificial soil]	Value [mg of difenoconazole/kg dry weight of the artificial soil]
EC_{10}	> 1000.0	> 185.5	> 113.0
EC_{20}	> 1000.0	> 185.5	> 113.0
EC_{50}	> 1000.0	> 185.5	> 113.0
NOEC (reproduction)	≥ 1000.0	≥ 185.5	≥ 113.0
LC_{10}	> 1000.0	> 185.5	> 113.0
LC_{20}	> 1000.0	> 185.5	> 113.0
LC_{50}	> 1000.0	> 185.5	> 113.0
NOEC (survival)	≥ 1000.0	≥ 185.5	≥ 113.0

Study 4

Comments of zRMS:	The study has been previously evaluated in the Core Assessment for A137003G by zRMS - UK and it has been considered acceptable. zRMS-UK comments: The study is considered to be acceptable and hence suitable for use in risk assessment. However the RMS notes that a 23.3% reduction in reproduction was observed at the highest test concentration of 50 mg/kg soil.As this could potentially be biologically relevant the RMS proposed a **NOEC of 40 mg/kg soil**.

Reference:	KCP 10.4
Report	Friedrich, S (2010). Azoxystrobin/difenoconazole SC (A13703G) - Sublethal Toxicity to the Earthworm *Eisenia fetida* in Artificial Soil with 5 % Peat. BioChem agrar, Germany. IBACON, Germany. Study number 10 10 48 062 S. Sponsor: Syngenta. October 2010.
Guideline(s):	OECD Guideline No. 222 (2004)
Deviations:	
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No
Validity criteria	The validity criteria for the control group were met: • Adult mortality after 4 weeks: ≤ 10 % (2.5 %) • Number of juveniles per replicate:≥ 30 (72 – 113) • Coefficient of variation for reproduction: ≤ 30 % (17.1 %) The validity criteria for the solvent control group were met: • Adult mortality after 4 weeks: ≤ 10 % (3.8 %) • Number of juveniles per replicate: ≥ 30 (68 – 115) • Coefficient of variation for reproduction: ≤ 30 % (17.9 %)

Summary

Worms were assessed for mortality, sub lethal (behavioural) effects and biomass change after 28 days of exposure. Following this assessment, the adult worms were removed and the test substrate was returned to the respective test vessels. The test substrate was incubated for a further 28 days (day 56) under the same test conditions to allow juvenile worms to grow. At day 56 the juveniles were removed from the soil, counted, and reproduction effects assessed.

Ten concentrations of the test item were used. These included Control (deionised water), 25, 30, 35, 40, 50 mg/kg dry substrate.
Each concentration was divided : 4 (10 earthworms in each) for each test concentrations and 8 (10 earthworms in each) for the control.

Materials and methods:

Test item:	A13703G
Lot No:	Difenoconazole (125 g/l, analysed 125 g/l 11.3% w/w) Azoxystrobin (200 g/l, analysed 202 g/l, 18.2% w/w
Artificial soil:	Artificial soil according to OECD 222, with a reduced peat content of 5%: 5% Sphagnum peat, air-dried and finely ground. 20% Kaolin clay 74.7% quartz sand 0.5% calcium carbonate. pH (initiation)- 5.80-6.08 (guideline requirement 6.0 ± 0.5) pH (termination)-5.63-5.69 (guideline requirement 6.0 ± 0.5) Maximum water holding capacity = 43% of the substrate dry weight Water content at initiation: 24.9-25.1% of soil dry weight (57.9-58.4% of the maximum water holding capacity) Water content at termination: 24.8-25.0% of soil dry weight (57.7-58.1% of the maximum water holding capacity)
Test system:	Earthworm (*Eisenia fetida*). Adult worms with clitellum, weight range 307-467 mg. All individuals used were approximately 3 months old
Test design:	exposure time: 56 days number of replicates: 4 (10 earthworms in each) for each test concentrations. 8 (10 earthworms in each) for the control.
Test concentrations:	Control (deionised water), 25, 30, 35, 40, 50 mg/kg dry substrate.
Environmental conditions:	Temperature: 18-22°C Light Intensity: 16 hr light: 8 hr dark. Continuous (750 lux)
Statistical analysis:	Statistically significant effects were determined using Fishers exact binomial test and Dunnett's t-test ($p \leq 0.05$)
Endpoints:	EC50, NOEC

Results

Nominal concentration of formulation (mg/kg dry soil)	Mean adult mortality after 28 days (%)	Mean change in adult body weight, day 0 to 28 (%)	Mean number of juveniles per replicate	Reduction in juvenile production (%)
Control	0	24.6	75.6 (CV 16.7)	-
25	0	24.8	80.3	-6.1
30	2.5	25.0	73.0	3.5
35	0	21.6	79.3	-4.8
40	2.5	22.2	68.8	9.1
50	2.5	20.6	58.0	23.3

Conclusions

All validity criteria were met for this study. Mortality in the control group was <10% (0%), the rate of production of juveniles was ≥30 per control replicate and the coefficient of variance of reproduction in the control was <30 (16.7).

None of the body weight changes in the test concentrations were statistically significant and therefore the NOEC was 50 mg/kg soil.

Juvenile production was not reduced by more than 50%, relative to the control at the highest test concentration. Therefore the NOEC was determined to be 50 mg/kg. No effects on mortality were observed after 28 days and therefore the NOEC for mortality was determined to be 50 mg/kg.

The EC50 for reproduction was determined to be >50 mg/ kg soil.

~~A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects~~

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

Comments of zRMS:	The study has been previously evaluated in the Core Assessment for A137003G by zRMS - UK and it has been considered acceptable. zRMS-UK comments: <u>Conclusion on post treatment results</u> In conclusion, the zRMS supports the applicant's conclusion that there are no effects of the test item on the total numbers or biomass of earthworms in this study. The overall pattern across juveniles/adults/species is consistent in that there is no clear dose response or treatment effect. It is noted that for some groups (i.e. tanylobous juveniles), the results were uncertainty due to unclear reference item effects most likely due to low numbers.

Hamberger, A (2015). Difenoconazole EC (A7402T) - A Field Study to Investigate Effects on the Earthworm Fauna in Southern Germany. Eurofins, Germany. Sponsor: Syngenta. Report no: S14-01431. December 2015.

Test material

Test Item:	Difenoconazole EC formulation (A7402T)
Purity:	Difenoconazole nominal 250 g/L, 23.2% w/w analysed: 265 g/L, 24.8% w/w
Description:	Yellow liquid
Batch No.	SMO2B511

Test system

Organism (Species):	Naturally occurring earthworm populations
Study Type:	Field study (12 months)
Year of study:	April 2014- May 2015
GLP Status:	Yes
Guidelines followed:	ISO 11268-3 (1999), ISO 23611-1 (2006), Kula *et al* (2006)
Test site:	<table><tr><td>**Location**</td><td colspan="2">Bodelshausen</td></tr><tr><td>**Region / Federal State**</td><td colspan="2">Baden-Württemberg</td></tr><tr><td>**Country**</td><td colspan="2">Germany</td></tr><tr><td>**Meters above sea level**</td><td colspan="2">489 m</td></tr><tr><td>**GPS coordinates of field site corners**</td><td>**North**</td><td>**East**</td></tr><tr><td>**Corner**</td><td>48°40'70.05''</td><td>08°99'29.40''</td></tr></table> The history of the field was known, in regards to crops and fertilisers/pesticides applications. The field had a cultivation history of winter wheat in 2010, maize in 2012 and winter wheat in 2012. Previous applied pesticides include propoxycarbazone, metsulfuron methyl, carfentazon ethyl, prothioconazole, spiroxamine, beta-cyfluthrin, MCPA and fluroxpyr in 2011. Foramsulfuron, iodosulfuron-methyl-natrium, isozadifen-ethyl, terbuthylazin and bromoxynil in 2012. Propoxycarbazone, metsulfuron methyl, carfentazon ethyl, trinexapac-ethyl, isopyrazum, epoxiconazole, chlorthalonil and picoxystrobin in 2013. Fertilisers were applied each year. A grass/clover mixture was drilled before application (14th April). Irrigation: Irrigation took place after application in order to ensure earthworm exposure to the test item. Irrigation was carried out from 8 days before application to 27 days after application.

TABLE 9 Timing and Amount of Water by Irrigation and Rainfall

Timing		Irrigation (mm)	Rainfall (mm) *
16 April 2014	8 DBA	5.2	0.0
17 April 2014	7 DBA	10.5	0.0
18 April 2014	6 DBA	-	4.8
19 April 2014	5 DBA	-	1.6
20 April 2014	4 DBA	-	0.0
21 April 2014	3 DBA	-	1.6
22 April 2014	2 DBA	8.9	0.2
23 April 2014	1 DBA	4.9	0.0
24 April 2014	**0 DAA**	**7.8**	0.2
25 April 2014	1 DAA	9.6	0.0
26 April 2014	2 DAA	-	0.0
27 April 2014	3 DAA	-	14.2
28 April 2014	4 DAA	-	0.2
29 April 2014	5 DAA	5.0	6.4
30 April 2014	6 DAA	-	24.2
01 May 2014	7 DAA	-	4.4
02 May 2014	8 DAA	-	0.4
03 May 2014	9 DAA	-	0.0
04 May 2014	10 DAA	-	0.2
05 May 2014	11 DAA	5.0	0.0
06 May 2014	12 DAA	-	6.0
07 May 2014	13 DAA	-	9.4
08 May 2014	14 DAA	-	2.2
09 May 2014	15 DAA	-	5.8
10 May 2014	16 DAA	-	0.2
11 May 2014	17 DAA	-	4.6
12 May 2014	18 DAA	-	3.2
13 May 2014	19 DAA	-	10.0
14 May 2014	20 DAA	-	1.8
15 May 2014	21 DAA	-	1.0
16 May 2014	22 DAA	4.9	2.4
17 May 2014	23 DAA	-	0.0
18 May 2014	24 DAA	-	0.0
19 May 2014	25 DAA	-	0.0
20 May 2014	26 DAA	-	0.0
21 May 2014	27 DAA	5.8	0.0

* measured by the weather station at the field site, DBA = days before application, DAA = days after application

Soil characterisation: A soil sample was prepared from 10 soil cores taken across the site in the guard rows.

TABLE 12 Summary of Soil Characterisation Data

pH ($CaCl_2$)	7.60
Total organic carbon *	2.42 %
Total carbon *	2.77 %
Organic matter (calculated TOC x 1.72)*	4.16 %
CEC [mval Ba/100 g dry weight]	26
Sand (2000 to ≥ 50 µm) *	11.7 %
Silt (50 to ≥ 2 µm) *	70.2 %
Clay (< 2 µm) *	18.1 %
Soil texture (USDA)	silt loam
Water holding capacity [g/100 g dry weight]	58

* refer to dry matter

Time of year:	April 2014-May 2015
Sampling:	Plots 12 plots (12.0 m x 12.0 m) in the field. Each plot was surrounded by at least a 5m guard row between the plots. Plots were randomised. Earthworms were sampled from 4 50 cm x 50 cm sampling areas per plot per occasion. Monitoring took place on 4, 100 cm x 100 cm areas which were situated between the sampling areas. The minimum distance from these areas to the border of the sampling

areas was 2m.

FIGURE 4 Trial Design

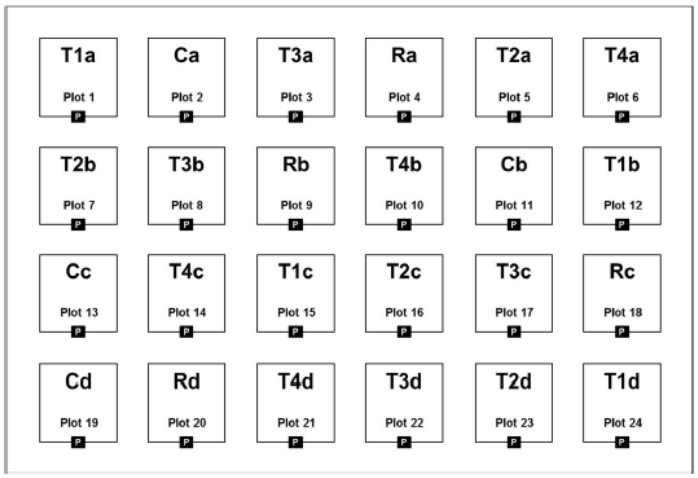
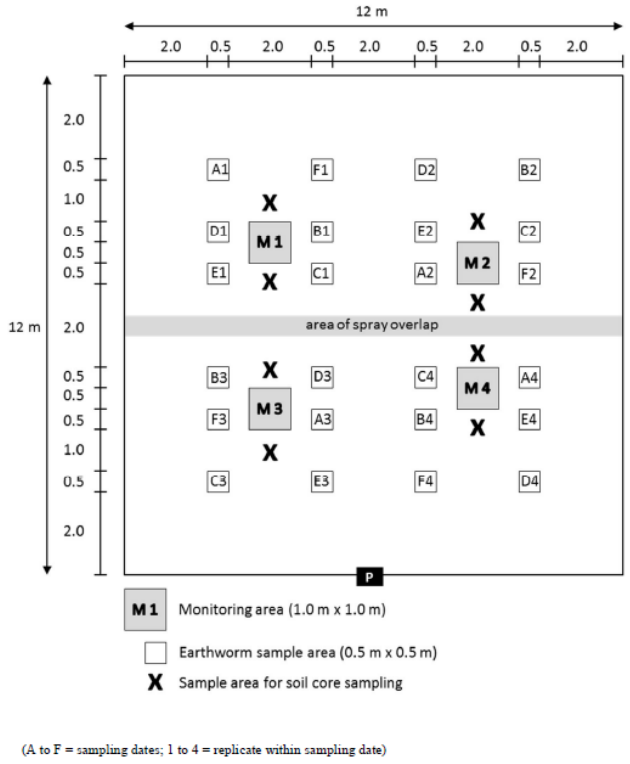


FIGURE 5 12.0 m x 12.0 m Plot Showing the Positions of Individual Sample and Monitoring Areas



(A to F = sampling dates; 1 to 4 = replicate within sampling date)

Earthworm extraction

On each sampling occasion for each treatment, 16 samples were taken in total from the 4 sampling points. In each sample area, the soil was excavated with a spade to a depth of 20 cm. The excavated soil was placed in plastic buckets and hand sorted to carefully check for earthworms. Earthworms were placed in containers with water covering their bases. A 0.2% formaldehyde solution (rate of 20 L/m^2) was also applied to the excavated hole. The duration of the extraction was 30-40 minutes.

At the end of sampling, the worms were placed in 80% alcohol. Earthworms were identified down to species level and were weighed.

Soil deposition

Sampling was performed on the day of application in the treatment replicates and the

<table>
<tr><td></td><td>control.
Top soil (0-10cm) was collected from outside the plots several days before application. This was sun dried and sieved. On the day of application, this soil was evenly distributed in aluminium foil trays. Four trays were placed across a plot. The soil in the trays was at the same level as the soil surface of the plot. After application, the soil in these 4 trays was combined, frozen and analysed for residues.</td></tr>
<tr><td>Application of the test item:</td><td>Application was performed during high earthworm activity. Application was to bare soil via a boom sprayer on the 24th April 2015. The spray volume was 300 L/ha. The boom sprayer was calibrated before application. Deviation was <5%.</td></tr>
<tr><td>Analytical verification:</td><td>Spray solution samples were taken before and after spraying but were not analysed.
Soil deposition samples from the day of application were analysed (HPLC-MS/MS).</td></tr>
<tr><td>Parameters observed:</td><td><u>Pre-treatment (15 days before application)</u>
Sampling of the natural populations was conducted in order to determine the density, diversity and homogeneity of the earthworm populations at the site before treatment. It was determined that the site selected contained representatives of all the major earthworm groups which are recommended in the guideline.
<u>Post-treatment</u>
Abundance and biomass of earthworms was assessed at approximately 1 (29 DAA-23rd May 2014), 4 (95 DAA-28th July 2014) 6 (182 DAA- 23rd October 2014), 9 (312 DAA- 02nd March 2015) and 12 months (383 DAA- 12th May 2015). Daily monitoring of surface density counts of alive, affected and dead earthworms within 10 days after application. Only earthworms on the soil surface were assessed. Four visual observations per plot were carried out in separate monitoring areas (see sampling plot detail above).</td></tr>
<tr><td>Test item and control replicates:</td><td>4 replicates per treatment. 4 samples per replicate.</td></tr>
<tr><td>Test Concentrations:</td><td>Control (tap water), 0.6 L/ha, 1.0 L/ha, 1.4 L/ha and 1.8 L/ha.
Equivalent to 150 g a.s/ha, 250 g a.s/ha, 350 g a.s/ha and 450 g a.s/ha (based on nominal concentrations).</td></tr>
<tr><td>Environmental conditions:</td><td>Ambient temperature, air humidity, soil moisture and soil temperature were recorded with portable devices. These data were GLP recorded.
Climatic data was also recorded continuously by a weather station. Weather data cannot be considered full GLP.</td></tr>
<tr><td>Environmental Conditions:</td><td><u>At application</u>
<table>
<tr><th>Treatment group</th><th>Air temperature (°C)</th><th>Air humidity (%)</th><th>Wind speed (m/s)</th><th>Cloud cover (%)</th><th>Ground cover (%)</th><th>Soil temperature (°C)</th><th>Soil condition</th></tr>
<tr><td>Control</td><td>16.1-18.5</td><td>62.2-64.9</td><td>1.2-2.2</td><td>0</td><td>0</td><td>10.1-11.4</td><td>moist</td></tr>
<tr><td>0.6 L/ha</td><td>19.1-20.8</td><td>54.8-60.3</td><td>1.8-2.5</td><td>20</td><td>0</td><td>12.6-13.5</td><td>moist</td></tr>
<tr><td>1.0 L/ha</td><td>21.4-22.6</td><td>49.4-55.9</td><td>0.8-1.3</td><td>20-25</td><td>0</td><td>13.9-14.6</td><td>moist</td></tr>
<tr><td>1.4 L/ha</td><td>19.9-21.4</td><td>50.1-53.2</td><td>2.2-2.6</td><td>30-45</td><td>0</td><td>14.8-15.5</td><td>moist</td></tr>
<tr><td>1.8 L/ha</td><td>19.6-20.3</td><td>48.2-50.2</td><td>0.9-2.4</td><td>80-85</td><td>0</td><td>14.5-15.2</td><td>moist</td></tr>
<tr><td>Toxic reference</td><td>21.0-21.8</td><td>44.9-47.6</td><td>2.2-2.6</td><td>75-85</td><td>0</td><td>14.7-14.9</td><td>moist</td></tr>
</table>
<u>After application</u></td></tr>
</table>

TABLE 15 Monthly Values of Air Temperature, Soil Temperature, Precipitation, Soil Humidity, Relative Air Humidity, Wind Speed and Radiation at the Field Site at Bodelshausen, Germany

Month[A]	Mean air temp.	Max. air temp.	Min. air temp	Soil temp. 5 cm	Soil temp. 20 cm	Precipitation	Soil humidity 5 cm	Soil humidity 20 cm	Relative air humidity	Wind speed	Radiation
	°C	°C	°C	°C	°C	mm	volume %	volume %	%	m/s	W/m²
April 2014	10.4	22.5	-2.6	9.4	11.6	58.8	39.3	36.7	76.9	2.6	151.7
May 2014	11.9	27.6	1.3	11.6	13.9	99.2	42.6	45.7	81.6	3.6	198.2
June 2014	16.4	34.8	3.4	16.6	19.4	44.0	30.8	32.2	75.3	1.8	249.7
July 2014	17.9	33.6	5.9	16.6	18.7	206.0	38.4	37.7	83.4	2.0	193.2
August 2014	15.7	27.2	4.6	16.1	16.9	92.4	37.4	35.8	83.6	2.5	161.4
September 2014	14.1	25.4	1.2	14.6	15.2	82.8	39.8	39.3	88.4	1.4	118.8
October 2014	12.1	25.3	0.0	12.1	12.4	77.2	39.7	39.2	88.7	2.1	92.6
November 2014	6.7	19.1	-1.0	7.7	7.2	46.8	44.2	41.6	92.9	1.1	71.1
December 2014	3.0	14.0	-11.4	4.1	4.0	33.6	45.3	44.2	92.2	5.4	23.8
January 2015	1.9	14.0	-5.5	2.0	2.0	63.6	46.4	44.5	91.7	5.2	32.6
February 2015	-0.6	12.0	-11.9	0.4	0.5	20.6	45.8	43.3	90.2	3.6	69.2
March 2015	5.3	18.5	-5.4	4.0	5.1	34.4	42.7	43.7	79.2	4.9	118.8
April 2015	8.9	24.8	-4.7	7.3	8.6	52.2	37.0	39.7	72.1	4.2	180.3
May 2015	13.2	28.2	0.6	11.0	12.4	106.6	38.7	39.3	79.7	2.7	180.1

[A] monthly mean values (air temperature, soil temperatures, soil humidity, air humidity, wind speed, radiation), monthly maximum and minimum values (air temperature) and total monthly values (precipitation)

Reference Item:	Carbendazim (10,000 g/ha)

Statistics

One of the assumptions of the analysis is that the variances in earthworm counts/weights between plots in different treatment groups are equal. This assumption is generally acceptable for earthworm weights but not for earthworm counts, where treatment groups with larger mean counts tend to have larger variances, and vice versa. Therefore prior to analysis both pre- and post-treatment counts were transformed onto a log10 (count + 1) scale. This transformation is commonly used to correct for the specific form of heterogeneity of variance observed in count data.

An analysis of variance (ANOVA) was performed on the transformed pre-treatment counts and untransformed pre-treatment weights. Each treatment was compared to the control using a two sided Dunnett's t-test at the 5% significance level.

An analysis of covariance (ANCOVA) was performed on the transformed post-treatment counts using the transformed pre-treatment counts as a covariate. An ANCOVA was also performed on the untransformed post-treatment weighs using the untransformed pre-treatment weights as a covariate These analyses were followed by significance tests (in particular F tests) at the 5% significance level to determine whether the pre-treatment counts/weights influenced the post-treatment counts/weighs. If the covariate was found to be significant an analysis of covariance was selected, whereas if the covariate was found to be non-significant an analysis of variance was selected. For both counts and weights, the pooled estimate of residual error variance obtained from the selected form of analysis (ANOVA or ANCOVA) was used to compare each treatment to the control using a two-sided Dunnett's t-test at the 5 % significance level.

Results

Ten different taxa of earthworm were observed and identified throughout the study. For juvenile worms that were difficult to identify, a distinction between tanylobous and epilobous was made.

List of identified taxa

Genus	Species	Adult/Juvenile	Ecological Group
Aporrectodea	*caliginosa*	adult	Endogeic
Allolobophora	*chlorotica*	adult	Endogeic
Aporrectodea	*longa*	adult	Anecic
Aporrectodea	*rosea*	adult	Endogeic
Lumbricus	*castaneus*	adult	Epigeic
Lumbricus	*terrestris*	adult	Anecic
Octolasium	*lacteum*	adult	Endogeic
Murchieona	*minuscula*	adult	Endogeic
Tanylobous	spp.	juvenile	-
Epilobous	spp.	juvenile	-
Tanylobous	spp.	front ends	-
Epilobous	spp.	front ends	-

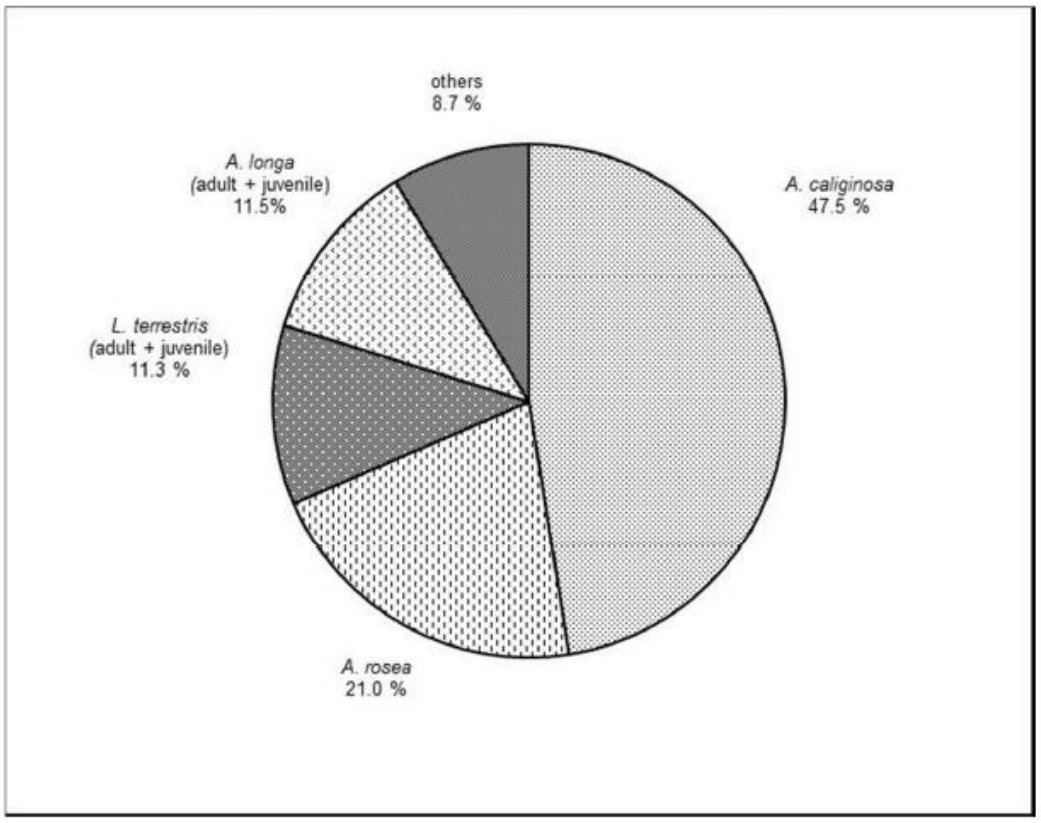
Pre-treatment

The mean earthworm abundance in the control at sampling point 1 (pre-treatment sampling, 15 days before application) was 167 earthworms/m^2.

The initial adult earthworm population before application was characterised as 0.4% epigeic, 81.8% endogeic and 17.8% anecic earthworms.

FIGURE 8 Adult Earthworm Species Distribution

(Percentage of number of adult earthworms including *L. terrestris* juveniles and *A. longa* juveniles across all plots at trial start)



The dominant endogeic species at the start of the test was *Aporrectodea caliginosa* (47.9 earthworms/m^2, 29% of total earthworms, 50.5% of adult earthworms) followed by *Aporrectodea rosea* (21.2 earthworm/m^2, 12.8% of total earthworms and 22.4% of adult earthworms). The dominant anecic species were *Aporrectodea longa* (including juveniles: 11.6 earthworms/m^2, 7.0% of total earthworms and 11.5% of adult earthworms) and *Lumbricus terrestris* (including juveniles: 11.4 earthworms/m^2, 6.9% of total earthworms and 11.3% of adult earthworms). The adult: juvenile ratio was 1.5 (60% adults).

Post-treatment

Earthworm abundance

Mean earthworm abundance (earthworms/m^2) in control plots	
29 DAA (sampling point 2)	188
95 DAA (sampling point 3)	293

182 DAA (sampling point 4)	609
312 DAA (sampling point 5)	591
383 DAA (sampling point 6)	553

DAA- days after application

Test concentrations

Total abundance per plot was calculated prior to any statistical analysis. No significant reductions in total earthworm numbers were found in any treatment group. No statistically significant reductions were observed for any of the dominant species.

Changes of earthworm abundance for the test item (A7402T) treatment 1

Treatment	**A7402T (0.6 L product/ha)**				
species / group	**change (%) [a)]**				
	29 DAA	**95 DAA**	**182 DAA**	**312 DAA**	**383 DAA**
A. caliginosa	+17.4	-25.6	+22.4	-1.8	+2.4
A. longa	+0.7	-47.3	-39.1	-34.0	+12.1
A. rosea	-20.6	-2.6	-4.7	-29.6	+22.5
L. terrestris	-25.2	-51.0	+10.0	+22.2	-27.2
Total adult	+7.4	-17.9	-7.7	-28.7	+9.9
Tanylobous juvenile	+38.0	+13.5	+2.6	+6.6	+14.6
Epilobous juvenile	-29.1	-35.6	-2.6	+10.3	-6.0
Total earthworms	**-8.2**	**-23.0**	**-5.4**	**-6.6**	**+0.2**

a) negative values indicate decrease in earthworm abundance compared to the control
positive values indicate increase in earthworm abundance compared to the control

Changes of earthworm abundance for the test item (A7402T) treatment 2

Treatment	**A7402T (1.0 L product/ha)**				
species / group	**change (%) [a)]**				
	29 DAA	**95 DAA**	**182 DAA**	**312 DAA**	**383 DAA**
A. caliginosa	+67.7	+10.6	+5.3	+9.8	-20.7
A. longa	+2.9	-6.8	-4.7	+7.4	+37.5
A. rosea	+40.9	+6.5	+12.7	-18.3	+20.8
L. terrestris	+14.2	-15.9	+10.5	+10.3	+15.3
Total adult	+36.9	-0.6	-7.3	-19.9	+2.8
Tanylobous juvenile	+111.4	-6.9	-7.4	-5.2	-11.1
Epilobous juvenile	-6.4	-32.2	+0.7	-25.6	-14.5
Total earthworms	**+19.3**	**-16.0**	**-3.7**	**-22.9**	**-9.1**

a) negative values indicate decrease in earthworm abundance compared to the control
positive values indicate increase in earthworm abundance compared to the control

Changes of earthworm abundance for the test item (A7402T) treatment 3

Treatment	A7402T (1.4 L product/ha)				
species / group	change (%) [a)]				
	29 DAA	95 DAA	182 DAA	312 DAA	383 DAA
A. caliginosa	+63.6	+48.6	+22.6	+10.7	-7.0
A. longa	+2.1	+45.5	+16.3	-30.6	-16.0
A. rosea	+17.4	+13.1	-9.4	+14.1	-3.8
L. terrestris	-20.5	-19.3	+1.3	+7.5	-28.7
Total adult	+42.6	+26.9	-3.8	-10.8	-8.3
Tanylobous juvenile	+250.1	+33.0	-10.4	+4.6	-19.5
Epilobous juvenile	-26.4	-2.9	+11.3	+16.3	-23.1
Total earthworms	**+15.3**	**+15.1**	**+2.5**	**+3.9**	**-19.5**

a) negative values indicate decrease in earthworm abundance compared to the control
positive values indicate increase in earthworm abundance compared to the control

Changes of earthworm abundance for the test item (A7402T) treatment 4

Treatment	A7402T (1.8 L product/ha)				
species / group	change (%) [a)]				
	29 DAA	95 DAA	182 DAA	312 DAA	383 DAA
A. caliginosa	+27.6	+1.3	-4.9	+8.5	-7.4
A. longa	+33.4	-4.1	-26.0	-2.1	-25.5
A. rosea	+1.2	-15.0	-18.6	-28.7	+10.5
L. terrestris	-40.5	+2.0	+3.9	-24.1	-9.9
Total adult	+20.3	-0.3	-13.4	-19.9	+2.4
Tanylobous juvenile	+119.0	-9.7	-20.7	-9.4	-12.4
Epilobous juvenile	-17.4	-14.6	-5.8	+15.2	-16.0
Total earthworms	**+4.8**	**-8.1**	**-10.3**	**-3.2**	**-11.9**

a) negative values indicate decrease in earthworm abundance compared to the control
positive values indicate increase in earthworm abundance compared to the control

Changes in earthworm abundance in the toxic reference item treatment

Treatment	10 000 g carbendazim/ha				
species / group	change (%)[a)]				
	29 DAA	95 DAA	182 DAA	312 DAA	383 DAA
A. caliginosa	-93.3 *	-98.3 *	+27.6	+29.5	+0.1
A. longa	-89.1 *	-89.9 *	-31.8	-11.3	+142.8
A. rosea	-82.0 *	-91.7 *	-70.2 *	-54.4	-13.5
L. terrestris	-69.0 *	-67.8 *	-54.2	-49.6	-33.2
Total adult	-83.5 *	-90.0 *	-35.0 *	-27.0	-2.2
Tanylobous juvenile	+83.8	-60.9	-30.6	-21.6	-50.6 *
Epilobous juvenile	-82.6 *	-81.9 *	-71.9 *	-69.5 *	-80.4 *
Total earthworms	**-82.0 ***	**-83.7 ***	**-56.1 ***	**-47.5 ***	**-57.3 ***

* significantly different from control ($p \leq 0.05$)

a) negative values indicate decrease in earthworm abundance compared to the control
positive values indicate increase in earthworm abundance compared to the control

Earthworm biomass

Total biomass per plot was calculated prior to any statistical analysis. No significant reductions in total earthworm biomass were found on any of the assessment days. No other significant reductions of groupings or single species biomass occurred.

Changes of earthworm biomass for the test item (A7402T) treatment 1

Treatment	A7402T (0.6 L product/ha)				
species / group	change (%) [a)]				
	29 DAA	95 DAA	182 DAA	312 DAA	383 DAA
A. caliginosa	+21.7	-25.5	+8.4	+3.6	-1.2
A. longa	+4.4	-18.5	-7.4	-21.1	-8.9
A. rosea	-29.2	-9.0	-10.3	-34.3	+5.5
L. terrestris	-22.9	-44.0	+13.3	+38.4	-14.4
Total adult	-1.5	-34.8	+3.6	+3.4	+1.2
Tanylobous juvenile	+59.3	+23.0	+7.6	-2.9	+1.3
Epilobous juvenile	-42.1	-43.7	-4.8	-2.4	+1.7
Total earthworms	**-3.8**	**-33.9**	**-0.4**	**+1.1**	**+1.9**

a) negative values indicate decrease in earthworm biomass compared to the control
positive values indicate increase in earthworm biomass compared to the control

Changes of earthworm biomass for the test item (A7402T) treatment 2

Treatment	**A7402T (1.0 L product/ha)**				
species / group	**change (%) [a)]**				
	29 DAA	**95 DAA**	**182 DAA**	**312 DAA**	**383 DAA**
A. caliginosa	+50.2	+8.8	-9.3	+15.4	-1.8
A. longa	-21.3	-15.7	+28.4	+4.4	+4.8
A. rosea	+39.2	-8.4	+11.2	-13.9	+8.3
L. terrestris	+16.0	-13.4	+3.4	+7.7	+37.6
Total adult	+30.5	-16.9	+7.3	-0.1	+30.3
Tanylobous juvenile	+5.5	-13.4	+1.0	+6.9	-4.2
Epilobous juvenile	-31.3	-32.8	-4.0	-12.9	-6.3
Total earthworms	**+23.4**	**-18.3**	**-0.2**	**-1.1**	**+10.9**

a) negative values indicate decrease in earthworm biomass compared to the control
positive values indicate increase in earthworm biomass compared to the control

Changes of earthworm biomass for the test item (A7402T) treatment 3

Treatment	**A7402T (1.4 L product/ha)**				
species / group	**change (%) [a)]**				
	29 DAA	**95 DAA**	**182 DAA**	**312 DAA**	**383 DAA**
A. caliginosa	+59.9	+56.0	+4.1	+14.1	-16.7
A. longa	+15.2	+65.7 *	+32.4	-25.5	-33.6
A. rosea	+12.7	+8.8	-10.9	+4.9	-18.7
L. terrestris	-15.2	-19.5	-2.1	+7.2	-12.9
Total adult	+13.3	+3.6	+2.3	-9.0	-13.4
Tanylobous juvenile	+156.0	+53.6	-7.3	+13.8	-16.2
Epilobous juvenile	-40.2	+6.0	+12.3	+3.7	-10.9
Total earthworms	**+10.3**	**+5.5**	**+1.6**	**-0.7**	**-13.8**

* significantly different from control ($p \leq 0.05$)
a) negative values indicate decrease in earthworm biomass compared to the control
positive values indicate increase in earthworm biomass compared to the control

Changes of earthworm biomass for the test item (A7402T) treatment 4

Treatment	A7402T (1.8 L product/ha)				
species / group	change (%) [a)]				
	29 DAA	95 DAA	182 DAA	312 DAA	383 DAA
A. caliginosa	+36.9	+12.6	-13.0	+5.3	-18.9
A. longa	+30.9	+10.9	-19.7	+7.3	-42.9
A. rosea	+7.5	-22.1	-16.3	-26.8	-0.7
L. terrestris	-32.0	+0.6	+6.0	-7.9	+1.7
Total adult	-8.0	+2.3	-5.1	-8.4	-2.3
Tanylobous juvenile	+180.7	-24.3	-21.5	+1.5	-6.5
Epilobous juvenile	-56.4 *	-19.4	-5.6	+1.8	-5.9
Total earthworms	**-12.3**	**-0.8**	**-7.5**	**-5.5**	**-5.6**

* significantly different from control ($p \leq 0.05$)
a) negative values indicate decrease in earthworm biomass compared to the control
positive values indicate increase in earthworm biomass compared to the control

Changes in earthworm biomass in the toxic reference item treatment

Treatment	10 000 g carbendazim/ha				
species / group	change (%)[a)]				
	29 DAA	95 DAA	182 DAA	312 DAA	383 DAA
A. caliginosa	-100.0 *	-100.0 *	+18.5	+47.5	+10.2
A. longa	-93.7	-72.9 *	+0.2	-8.2	+54.4
A. rosea	-85.1 *	-84.7 *	-65.5 *	-41.3	-9.3
L. terrestris	-62.3 *	-69.7 *	-62.1	-37.9	-32.3
Total adult	-63.5 *	-75.8 *	-35.2	-22.3	+0.9
Tanylobous juvenile	+61.4	-78.3	+3.4	+7.2	-5.3
Epilobous juvenile	-83.8 *	-84.7 *	-45.8	-50.6	-64.6 *
Total earthworms	**-61.1 ***	**-76.6 ***	**-35.6 ***	**-20.4**	**-14.9**

* significantly different from control ($p \leq 0.05$)
a) negative values indicate decrease in earthworm biomass compared to the control
positive values indicate increase in earthworm biomass compared to the control

Surface monitoring

Surface monitoring after application showed that there was no effect on earthworms caused by the test item. No dead earthworms were found on the soil surface during the first 10 days in any treatment group.

Soil residue analysis

Soil deposition samples for the control and test concentrations were analysed for difenoconazole residues. In the control plot samples, residues were below LOD (0.003 mg/kg).

Mean residues of test item A7402T

Treatment	Replicate	Difenoconazole [mg/kg dry weight]	Mean [mg/kg dry weight]	Expected of nominal a.i.[mg/kg dry weight]	% of target rate (based on nominal a.i.)	Mean
T1 0.6 L/ha	a	0.848	0.692	0.834	101.7	83.0
	b	0.630			75.5	
	c	0.646			77.5	
	d	0.644			77.2	
T2 1.0 L/ha	a	0.983	1.038	1.391	70.7	74.6
	b	1.02			73.3	
	c	1.05			75.5	
	d	1.10			79.1	
T3 1.4 L/ha	a	1.64	1.688	1.947	84.2	86.6
	b	1.75			89.9	
	c	1.70			87.3	
	d	1.66			85.3	
T4 1.8 L/ha	a	2.21	2.240	2.503	88.3	89.5
	b	2.26			90.3	
	c	2.40			95.9	
	d	2.09			83.5	

Conclusions

Authors conclude: Validity criteria were met due to the high earthworm abundance, the presence of key species and the homogeneity in abundance. The effect of the toxic reference item demonstrated the sensitivity of the population. No statistically significant reduction in the total numbers of earthworms (or number of a single species) was observed at any test concentrations tested.

~~A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)~~

~~**Study 1**~~

~~**Stacey, D. (2003). CGA169374 (difenoconazole)/ZA5504 (azoxystrobin): Tier I standard laboratory bioassay of the effects of fresh residues of a 125/200g/L SC formulation (A3703G) on the parasitic wasp *Aphidius rhopalosiphi* (Hymenoptera, Braconidae). Syngenta. Report no: RJ3438B. Study number: 2033571. December 2003**~~

~~**Test system**~~

~~Test item:~~	~~A13703G~~
~~Purity:~~	~~Difenoconazole (125 g/L, analysed 129 g/L)~~

	Azoxystrobin (200 g/L, analysed 191 g/L)
Description:	Liquid, beige yellow
Lot No./Batch No. :	J6474/028

Organism (Species):	Parasitic wasp, *Aphidius rhopalosiphi*
Age/Life stage at dosing	<48 hours
Host species	*Rhopalosiphum padi* (cereal aphid)
Study Type:	Test duration was 13 days. Exposed for 48 hours to dried residues on glass plates. Mortality assessed over 48 hours. Parasitation period of 24 hours. Fecundity then assessed over a further 10 days.
GLP Status:	GLP
Guidelines followed:	Mead-Briggs *et al*., (2000)
Parameters observed:	Mortality and fecundity.
Observation intervals:	Mortality was assessed after 2, 24 and 48 hours. Fecundity assessed at the end of 10 days (termination).
Test units	Exposure 2 treated glass plates (10 cm x 10 cm) which were fitted to a square frame made from stainless steel (2cm high). Holes were drilled though the frame to provide ventilation. One hole at the bottom of the cage was connected to a water bath with a cotton wick, this supplied water to the wasps. All units were attached by tubing to air pumps which maintain air movement within the units. Fecundity- Untreated pots) with barley seedlings infested with >50 host aphids (*Rhopalosiphum padi*) were enclosed within a ventilated clear plastic, cylindrical cage. The soil surface was covered with a thin layer of light- coloured sand to aid observations.
Number of replicates	4 replicates (each containing 7 female and 3 males- 40 wasps in total) for the control, test concentrations and toxic reference Fecundity- 10 replicates per test concentration and control- 1 female per test unit.
Test concentrations:	0 (deionised water control), 51.2, 128, 320, 800 and 2000 ml product/ha in 200L deionised water/ha
Environmental conditions:	Temperature: mean 21.3 °C (short deviation of >22°C) Relative Humidity: mean 67.5% (short deviation of humidity <60%) Photoperiod: 16 hour light:8 hours dark (2730 lux for exposure and 7980 lux for fecundity period) Feeding: Before the test the wasps were fed with honey: tap water solution (1: 3, v: v) and during the test wasps were fed with honey: tap-water solution (1:1; v: v) applied to cotton wool, but were not fed during the 24 h parasitisation period.
Reference substance:	Dimethoate 400 g/L (37.7% w/w) applied at a rate of 0.5 ml formulation/ha.

Methodology

Exposure

A tier I, dose response toxicity study on the parasitoid wasp, *Aphidius rhopalosiphi* was conducted in the laboratory. The test organisms were exposed for 48 hours to an untreated control and to fresh, dried residues of A13703G on glass slides at nominal rates of 0 (deionised water control), 51.2, 128, 320, 800 and 2000 ml product/ha in 200L deionised water/ha. A positive reference treatment of a dimethoate formulation was also included at a concentration of 0.5 ml formulation/ha. All treatments were applied in an application volume equivalent to 200 L/ha water. Four replicates of 10 wasps were tested for each treatment group, control and reference substance. The test item was applied to glass plates using a track sprayer to simulate field application. Glass plates were left to dry before individuals were added approximately 1 hour later.

Assessments for adult wasp mortality were carried out approximately 2, 24 and 48 hours after the start of the exposure phase.

If after the exposure phase, the effects on mortality were ≤50% (corrected mortality) then the fecundity phase of the test was set up. 10 female wasps from the control and each test concentration were individually added to test units containing barley seedlings infested with aphids. The female wasps were left in these units for a further 24 hours, after which they were removed. The remaining aphids were maintained for 10 days and then the parasitised aphids (aphid mummies) per female wasp were counted.

Temperature and humidity were monitored continuously.

Statistics

For statistical analysis of mortality data a probit model was fitted by a technique called maximum likelihood in which the binomial distribution of the data is taken into account. For fecundity, an analysis of variance was carried out. This was then followed by a Dunnett's two-sided t-test.

Results

Table 1: Effects of A13703G on the survival and fecundity of *A. rhopalosiphi*

Test concentrations (ml/ha)	**% mortality after 48 hr**	**Mean mummies per female**	**% difference in reproduction compared to control**
Control	0	17.0	-
	Abbott corrected % mortality		
51.2	5	9.2	-45.9
128	0	8.9	-47.6
320	10	8.7	-48.8
800	7.5	21.2	+24.7
2000	2.5	7.0	-58.8

Test concentrations (ml/ha)	% mortality after 48 hr	Mean mummies per female	% difference in reproduction compared to control
Toxic Reference	100	-	-

Conclusions

Validity criteria for this study were met. The control mortality was ≤13% after 48 hours of exposure. The mean number of mummies produced in the control per female during the fecundity assessment was ≥ 5 (17.0). There were no more than two female wasps in the control group that produced 0 mummies.

Mortality in the reference substance was 100% (corrected mortality) after 48 hours, as this was >50%, the validity criteria was met.

Under worst case laboratory conditions the 48 hour LR_{50} of A13703G to the mortality of *A. rhopalosiphi* was >2000 ml/ha.

There were no statistically significant effects of the test item on reproduction up to 2000 ml/ha (ER_{50} > 3000 ml/ha). The highest test concentration did have effects on fecundity >50% compared to the control but this difference was not statistically significant.

Study 2

Brühl C & Pinch C (2003). CGA169374 (difenoconazole)/ZA5504 (azoxystrobin): Tier I standard laboratory bioassay of the effects of fresh residues of a 125/200 g/L SC formulation (A13703G) on the predatory mite *Typhlodromus pyri* (Acari: Phytoseiidae). Syngenta. Report no RJ3444B. Study no. 2033570. December 2003.

Test system

Test item:	A13703G
Purity:	Difenoconazole (125 g/L, analysed 129 g/L) Azoxystrobin (200 g/L, analysed 191 g/L)
Description:	Liquid, beige yellow
Lot No./Batch No. :	J6474/028

Organism (Species):	Predatory mite, *Typhlodromus pyri*
Age/Life stage at dosing	Protonymphs (<24 hours old).
Study Type:	Tier 1 laboratory study, glass plates for mortality. Duration of 7 days for mortality assessment and 7 days for reproductive capacity assessment.
GLP Status:	GLP
Guidelines followed:	Brumel *et al* (2000), Candolfi *et al* (2001)
Parameters observed:	Mortality and reproductive capacity

Observation intervals:	Mortality was assessed at day 3 and 7. Reproductive capacity assessed on day 10, 13 and 14.
Test units	The test unit was a petri dish (diameter 14 cm). Foam rubber was placed into this dish and soaked in tap water. Filter paper was then put on top of the foam rubber. Two cover slides were then placed on top of the filter paper, their longitudinal sides touching each other. The slides were fixed together using sticky tape. By capillary force, the thin slit between the cover slides was filled with water which served as drinking water for the mites. The test arena (13 cm^2) was limited by a barrier of glue. The petri dishes were covered with a lid containing a hole covered with fine mesh netting.
Number of replicates	3 replicates each with 20 protonymph mites for the control, test concentrations and the reference item.
Test concentrations:	0 (deionised water control), 80, 400, 800, 1600 and 3200 ml product/ha in 200L deionised water/ha
Environmental conditions:	Temperature: 24.4-25.4 °C Relative Humidity: 39.9-81% Photoperiod: 16 hour light:8 hours dark (1570 lux) Feeding: Pollen of walnut and apple provided before and during the test. Food was given every 3-4 days. Water provided *ad libitum*.
Reference substance:	400 g/l Dimethoate (43.2% w/w) applied at a rate of 15 ml product/ha in 200 L deionised water/ha.

Methodology

A tier I, dose response toxicity study on the predatory mite *Typhlodromus pyri* was conducted in the laboratory. The test organisms were exposed for 7 days to an untreated control and to fresh, dried residues of A13703G on glass slides at nominal rates of 80, 400, 800, 1600 and 3200 ml product/ha in 200L deionised water/ha. A positive reference treatment of a dimethoate formulation was also included at a rate of 15.0 ml/ha. Three replicates were tested for each treatment group, with 20 protonymph mites in each replicate, selected randomly. All treatments were applied using a track sprayer, in an application volume equivalent to 200 L/ha water. The time between spray application and the addition of mites was <2 hours. Pollen of walnut and apple was provided every 3-4 days as a food source.

Survival of the mites was assessed after 3 and 7 days. The percent mortality of the mites in each vessel was calculated and corrected according to the control (Abbott), included all observations of dead, trapped and missing mites. A mean per treatment was then calculated.

On day 7, the number of males and females were counted and any eggs, larvae or juveniles present were removed from the arena and therefore did not count towards the fecundity assessments. If after the exposure period, the sex ratio of males to female's is more than 5 females: 1 male then males from other replicates of the same treatment group can be added until the correct ratio is reached. From day 7-14, 3 assessments of fecundity took place (day 10, 13 and 14). The number of eggs and juveniles were counted (per female) and removed from the test units. The mean cumulative number of eggs produced per female over the fecundity period was calculated.

Temperature and relative humidity were monitored continuously.

Statistics

The LR_{50} was determined by fitting a probit model to the mortality data. For the fecundity phase an analysis of variance was performed in order to determine a pooled estimate of residual error variance. The response for each treatment was then compared with the control using a two-sided Dunnett's test.

Results

Table 1: Effects of A13703G on the survival of *Typhlodromus pyri*

Test concentrations (ml/ha)	Mean corrected[1] % mortality after 7 days	Eggs/female	Effect on reproduction (%)
Control	0	9.88	-
80	0	11.24	-13.75
400	25.00	10.47	-5.99
800	40.00	11.06	-11.91
1600	50.00	2.76	72.04*
3200	51.67	1.19	87.91*
Toxic Reference	100	-	-

[1] Abbott (1925).
*significantly different compared to the control (Dunnett's test)

Conclusions

The validity criteria applied to this study were met, the water control treatment mortality was <20% at 7 days (0%). Control fecundity also achieved >4 eggs per female over the fecundity period (9.88 eggs/female). In addition, the positive reference treatment, dimethoate, achieved 100% corrected mortality, indicating that the mites were responding as expected in the test system.

Under worst case laboratory conditions the 7-day LR_{50} of A13703G on *Typhlodromus pyri* was 1872 ml/ha (95% confidence limit of 1179-4126 ml/ha). Fecundity was statistically significantly affected at the test rates of 1600 and 3200 mL product/ha compared to the control. Therefore the NOEL for fecundity was 800 ml/ha.

A 2.4.2.1 KCP 10.4.2.1 Species level testing

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

Comments of zRMS:	The study has been previously evaluated in the Core Assessment for A137003G by zRMS - UK and it has been considered acceptable. zRMS-UK comments: The soil nitrate formation rate was calculated using both an incremental approach (i.e. between successive sampling intervals) and for the whole period of the test (0-28 days). Between days 14 and 28, the deviation from the control was 9.2 and 27.7% at 4.44 and 14.79 mg/kg dry soil, respectively. For the whole study period (0-28 days), the deviations from the control were -13.3 and -9.5% at 4.44 and 14.79 mg/kg dry soil, respectively. As the variation is > 25% in the 14.79 mg/kg dry soil concentration, the length of the study should have been extended and therefore the nitrogen study at this concentration is not considered to be acceptable by the zRMS. However it can be concluded that at 4.44 mg/kg dry soil after 28 days, <25% effects on nitrogen transformation rate were observed.

Reference:	KCP 10.5
Report	**Schulz, L. (2010)** Azoxystrobin/Difenoconazole SC (A13703G) – Effects on the Activity of Soil Microflora. BioChem agrar GmbH, Germany. Study number 10 10 48 007 C/N. Sponsor: Syngenta. February 2010
Guideline(s):	OECD guidelines 216 and 217 (2000).
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Methodology

In a soil microflora laboratory study, the effects of A13703G on nitrogen and carbon transformation were investigated in a loamy sand soil. A13703G was applied to the soil at nominal concentrations of 4.44 and 14.79 mg/kg soil d.w. Three replicate batches were treated and incubated for each test. The control consisted of soil treated with deionised water.
At test initiation pH, soil moisture, water holding capacity (WHC) and microbial biomass were determined. The test item was mixed with deionised water and then subsequently mixed into the soil using a hand stirrer. Additional water was added in order to achieve approximately 45% WHC at test initiation in each replicate. Water content was monitored and adjusted weekly (to the required range of 40-50% WHC) through the test if required. pH was also determined at test termination on day 28.

Soil nitrogen transformation

Three replicates of 200g soil dry weight for each test concentration and the control. These replicates of soil were enriched with lucerne meal (5 g/kg soil d.w- equivalent to 1.0 g per 200 g soil d.w). One additional soil sample (without lucerne) was used to determine the initial NH4-N- and NO3-N- content. Samples were incubated in glass flasks (500 ml) with screw caps lids which prevented loss of moisture but also permitted air exchange.

At day 0 (within 3 hours of test substance addition) and after 7, 14 and 28 days, samples were removed for determination of ammonium, nitrate and nitrite-nitrogen content. Soil extracts were prepared by taking 10g (dry weight equivalent) soil and extracting in 50ml 1M KCl, the extraction process took 60 minutes. The supernatant was centrifuged then frozen at -20°C. Analysis was performed using a continuous flow analysis system by comparison of the test item treated soil with a non-treated control soil.

Soil microflora respiration

Three replicates of 1000g of soil (dry weight) were used for each test concentration and the control. Each soil replicate was added to a steel 4 L vessel. Each vessel had a lid to prevent moisture loss but permit air exchange.

At day 0 (within 3 hours of test substance addition) and after 7, 14 and 28 days, 100g samples of soil were removed for determination of microbial respiration. Soil respiration was determined after the addition of glucose to the soil, the optimal glucose concentration was determined before test initiation to be 0.4%. The respiration of micro-organisms leads to O_2 consumption and formation of CO_2 which is absorbed in an NaOH solution. The absorption of CO_2 causes low-pressure in a reaction flask, which is in turn compensated with O_2 delivered by a respirometer. The respirometer determines the cumulative oxygen production which corresponds to the O_2 consumption by the microorganisms. This was measured over 12 hours for each sample.

Results

Table 1: Effects of A13703G on the Nitrate content in loamy sand soil

Treatment (mg formulation/kg soil d.w)	Mean nitrogen transformation (mg NO_3-N/kg soil d.w) (% inhibition in comparison to the control)			
	Day 0	Day 7	Day 14	Day 28
Control	16.6	33.5	36.8	45.9
4.44	17.0 (2.4)	38.0 (13.2)	42.0 (14.1)*	50.3 (9.5)
14.79	16.5 (-1.0)	41.4 (23.6)*	42.2 (14.8)*	48.8 (6.3)

Negative values (-) = % nitrate was below the control value.

*statistically significantly different from the control (Student t-test, $p \leq 0.05$)

The soil nitrate content increased in the control and all test concentration groups over the course of the study (between day 0 and 28). The % inhibition from the control after 28 days was < 25%.

Table 2: Effects of A13703G on oxygen consumption rate i.e. carbon transformation rate in soil.

Treatment (mg/kg soil d.w)	O_2 consumption (mg/kg soil d.w/h) (% inhibition compared to control)			
	Day 0	Day 7	Day 14	Day 28
Control	14.37	13.54	11.61	12.52
4.44	14.41 (0.3)	13.42 (-0.8)	11.70 (0.8)	12.55 (0.2)
14.79	14.26 (-0.8)	13.47 (-0.5)	10.81 (-6.9)*	11.53 (-7.9)*

*statistically significantly different from the control (Student t-test, $p \leq 0.05$)

Exposure to A13703G at both test concentrations, did not give rise to inhibition in oxygen consumption (compared to the control) of greater than 25% after 28 days.

Conclusions

The coefficient of variation in the control replicates did not deviate more than 15% (6.1% and 2.8% deviation being the maximum for the nitrogen and carbon tests, respectively).

The soil carbon and nitrogen transformation rates were within the trigger value of ±25% set by OECD guidelines 216 and 217 at day 28. The study report concluded that A13703G had no impact on carbon or nitrogen transformation when applied up to and including 14.79 mg/kg soil dry weight.

In the most recent test with the positive reference substance, dinoterb caused carbon transformation effects of -28.8%, -42.1% and -46.9% at the concentrations of 6.80, 16.00 and 27.00 mg/kg soil d.w respectively. This demonstrates the sensitivity of the test system. The study report also stated that in the most recent test with the positive reference substance, dinoterb caused nitrogen transformation effects of 18.8%, 37.9% and 48.3% at the concentrations of 6.80, 16.00 and 27.00 mg/kg soil d.w respectively.

A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.6.1 KCP 10.6.1 Summary of screening data

A 2.6.2 KCP 10.6.2 Testing on non-target plants

Comments of zRMS:	The study was conducted to the guideline and according to the principles of GLP. All validity criterions were met. The study is considered to be reliable and suitable for the risk assessment.

Reference:

Report CHR/F/SCORPIO 325 SC, Terrestial Plant Test: Vegetative Vigour Test, Study code: G-06-23, P. Pieczka, 2023

Guideline(s): according to the OECD Guideline No. 227 (2006)

Deviations: ~~No~~ Yes. According to OECD Guideline No. 227 (2006), the light intensity should be 350 ± 50 µE/m2 /s, however these values are recommended for

	tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 231.4 – 297.8 µE/m2 /s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. The deviation did not affect the results of the experiment.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No
Validity criteria	On the basis of the obtained results, it was stated that the following validity criteria of the study aimed at evaluating the impact of CHR/F/SCORPIO 325 SC on vegetative vigour of terrestrial plants were met: - the seedling emergence of plants (validity criterion: at least 70%) was as follows: 90.5 – 95.2 – sunflower, 88.1 – 92.9 – pea, 92.5 – 100.0 – flax, 92.5 – 97.5 – carrot, 90.0 – 97.5 – onion, 90.0 – 97.5 – oats, - the mean plant survival of the control was 100% for all tested species (validity criterion: at least 90%) - the control plants did not exhibit any visible phytotoxic symptoms, - environmental conditions for all plants belonging to the same species were identical.

Summary:

The study, aimed at evaluating the effect of CHR/F/SCORPIO 325 SC on vegetative vigour of 6 terrestrial plants, was conducted on 4 dicotyledonous and 2 monocotyledonous species. Seeds of the test plant species were sown in plastic pots (6 seeds/pot for sunflower, pea; 10 seeds/pot for flax, carrot, onion and oats). The plants were grown to the 2- to 4- true leaf stage. Then, some of them were removed. As a result, the number of plants per pot as well as the total number of plants per rate were:
- sunflower: 3 plants/pot – 21 plants/application rate (7 pots/application rate);
- pea: 3 plants/pot – 21 plants/application rate (7 pots/application rate);
- flax: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate);
- carrot: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate);
- onion: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate),
- oats: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate).

The pot is defined as a replicate. The test item was sprayed onto the plants. For each species, five application rates were used. Untreated control group was conducted simultaneously. The experiment was conducted in a plant growth room where suitable environmental conditions for each test species were provided. During the experiment, the plants were observed for visual phytotoxicity and mortality (7, 14 and 21 days after the test item application). The exposure period finished 21 days after the spraying. At the end of the exposure, the number of surviving plants was counted. Next, the plants were cut down, and the lengths of their shoots were determined. Finally, they were dried at 60ºC to a constant weight and weighed.

The results concerning the shoot length, the dry weight, and the number of plants at the end of the experiment were statistically analyzed to determine the ER10, ER25, ER50 and NOER.

Additionally, the ER50 was determined for visual phytotoxicity effects, basis on the results after 21 days

of the experiment.

Material and methods:

~~The study coded as G-06-23 [SOP/OG/2] was performed according to the OECD Guideline for the Testing of Chemicals No. 227 (2006): "Terrestrial Plant Test: Vegetative Vigour Test" [1], the Standard Operating Procedure SOP/G/70: "Terrestrial Plant Test: Vegetative Vigour Test" and the Study Plan.~~

~~**Name:**~~	~~CHR/F/SCORPIO 325 SC~~
~~**Batch number:**~~	~~CHR12/23~~
~~**CAS number of active substances:**~~	~~azoxystrobin: 131860-33-8 [12] difenoconazole: 119446-68-3 [13]~~
~~**Production date:**~~	~~22.02.2023~~
~~**Expiry date:**~~	~~22.02.2023~~
~~**Appearance:**~~	~~Liquid~~
~~**Formulation:**~~	~~SC (suspension concentrate)~~
~~**Active substances:**~~	~~azoxystrobin – 205.89 g/L difenoconazole – 125.41 g/~~
~~**Density (20 °C)**~~	~~1.11 g/mL~~
~~**Storage conditions**~~	~~19.3 – 20.3°C [SOP/G/114~~
~~**Crtificate of Analysis:**~~	~~no. 223031401102 from 23.03.2023 (Appendix No. 1)~~

~~The test item in a plastic bottle was delivered on March 03, 2023. The sample was taken from the Test item collection point at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna on May 04, 2023 [SOP/OG/1]. The Sponsor is responsible for specifying the identity, purity, and stability of the test item.~~

Test item:	CHR/F/SCORPIO 325 batch number: CHR12/23
Active substance:	azoxystrobin – 205.89 g/L; difenoconazole – 125.41 g/
Test species:	sunflower (Helianthus annuus), pea (Pisum sativum), flax (Linum usitatissimum), carrot (Daucus carota) onion (Allium cepa), oats (Avena sativa)
Soil:	Sandy loam
Study design:	number of rates: 5 + control; number of replicates/rate: 7 (sunflower, pea), 4 (flax, carrot, onion, oats). The total number of plants per application rate: 21 (sunflower, pea) or 20 (flax, carrot, onion, oats)
Exposure termination:	21 days after spraying

Application rates:	51.2, 128.0, 320.0, 800.0, 2000.0 mL/ha; in case of each species, there was one untreated control group; volume of deionized water used to prepare application rates corresponded to 300 L spraying liquid/ha.
Test conditions:	temperature: 19.4 – 23.9°C, humidity: 48.8 – 75.3%, lighting: 16 h light : 8 h dark; light intensity: 231.4 – 297.8 µE/m2 /s; carbon dioxide concentration: 337 – 362 ppm
Statistical analysis:	Because no change in mortality of plants was to be observed, no computations in plant number have been performed for all tested plants species. In order to determine ER10, ER25, ER50 the following test were used: shoot length: Probit analysis using linear max. likelihood regression, 3-param. Normal CDF shoot dry weight: Probit analysis using linear max. likelihood regression, 3-param. Normal CDF, ER50 (plant damages) - Probit analysis using linear max. likelihood regression, 3-param. Normal CDF; In order to determine the NOER values, the following tests were used: - for the shoot length: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Non-parametric Trend analysis by Contrasts (Monotonicity of Rate/Response), Trend analysis by Contrasts (Monotonicity of Rate/Response), Step-down Jonckheere-Terpstra Test Procedure, Williams Multiple Sequential t-test Procedure, Dunnett`s Multiple test Procedure, - for the plant shoot dry weight: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Non-parametric Trend analysis by Contrasts (Monotonicity of Rate/Response), Trend analysis by Contrasts (Monotonicity of Rate/Response), Step-down Jonckheere-Terpstra Test Procedure, Williams Multiple Sequential t-test Procedure, Dunnett`s Multiple t-test Procedure

Test system

Six plant species were used. These were sunflower (Helianthus annuus), pea (Pisum sativum), flax (Linum usitatissimum), carrot (Daucus carota), onion (Allium cepa) and oats (Avena sativa) . The test species were selected from the list given in the OECD Guideline No. 227 [1]. Before the experiment started, seeds had been kept under dry conditions, at ambient temperature, and with no access to light. The seed viability had also been examined [SOP/G/124]. The general characteristics of the test species is presented below.

I. Class: Dicotyledonae

▪ Sunflower (Helianthus annuus),
- family: Asteraceae (Compositae),
- variety: ogrodowy
- source: „PlantiCo-Hodowla i Nasiennictwo Ogrodnicze Zielonki" Sp. z o.o., Zielonki Parcele, ul. Parkowa 1A, 05-082 Stare Babice, Poland
- batch no.: PL014/32/83/SO94
- seed viability: 97%

▪ Pea (Pisum sativum),
- family: Fabaceae (Leguminosae)
- variety: PEGAZ
- source: PNOS w Ożarowie Mazowieckim Sp. z o.o., Żeromskiego 3, 05- 850, Ożarów Mazowiecki, Poland
- batch no. PL014/32/17672/2004/A
- seed viability: 98%.

Flax (Linum usitatissimum),
- family: Linaceae,
- source: Planta sp. z o.o. w Tarnowie
- batch no. 12/63/115
- seed viability: 92%

▪ Carrot (Daucus carota),
- family: Apiaceae (Umbelliferae)
- variety: Amsterdam
- source: BROS Sp. z o.o. sp. k., Karpia 24, 61-619 Poznań, Poland
- batch no: PL630/12/210/L441/A
- seed viability: 83%

II. Class: Monocotyledonae

▪ Onion (Allium cepa),
- family: Liliaceae (Amarylladaceae)
- - variety: siedmiolatka
- - source: Vilmorin Garden Sp. z o.o., ul. Szkolna 30, 62-064 Plewiska, Poland
- - batch no: p.1-0051-90042-01 ST
- - seed viability: 92%

▪ Oats (Avena sativa),
- family: Poaceae (Gramineae)
- variety: Romulus
- source: "DANKO" Hodowla Roślin Sp. z o.o., Zakład Hodowli Roślin oddział Choryń, Choryń 27, 64-

000 Kościan, Poland
- harvest year: 2022
- seed viability: 91%

3.3. Soil

Agricultural soil was used. The soil was taken from a place belonging to the Łukasiewicz Research Network - Institute of Industrial Organic Chemistry Branch Pszczyna (49˚ 59', 780 N; 18˚55', 190 E). The site chosen for soil collection had not been treated with any plant protection products or organic and inorganic fertilisers. The soil was collected from a depth of 20 cm. It was sieved to 2 mm particle size to homogenize it and remove coarse particles [SOP/G/74]. The required physical and chemical parameters of the soil were determined. Their values and the determination methods are shown in Table 1. The soil texture (point 1) was determined beyond GLP at the Institute for Ecology of Industrial Areas in Katowice, whereas the remaining parameters by the Łukasiewicz Research Network - Institute of Industrial Organic Chemistry Branch Pszczyna. On the basis of the soil texture, it was concluded that it was a sandy loam [7]. The soil was subjected to evaporation to reduce the effect of soil pathogens.

3.4. Course of the experiment

3.4.1. Soil preparation

In cultivation of flax, carrot, onion and oats 136 mL of deionized water was added to 2688 g of the soil (i.e. 2400 g dry weight); for sunflower and pea 238 mL of deionized water was added to 4704 g of the soil (i.e. 4200 g dry weight) [6], [SOP/G/24, SOP/G/120]. The dry weight content of the soil was 89.3% [SOP/G/11, SOP/G/106]. The aim was to obtain the final soil moisture content about 50% of the maximum water holding capacity. Thereafter, the soil was distributed to plastic pots. Each pot contained about 706 g of the soil (i.e. 600 g dry weight), [SOP/G/120].

3.4.2. Seed sowing

Seeds of the test plant species were sown in plastic pots (pot's diameter – 15 cm, pot's surface area – about 177 cm2) containing the test soil. There were 10 seeds in each pot for flax, carrot, onion and oats and 6 seeds in each pot for sunflower and pea. The replicate is defined as a pot. The plants were grown to the 2- to 4- true leaf stage. Then, some of them were removed. As a result, the number of plants per pot as well as the total number of plants per application rate was: - sunflower: 3 plants/pot – 21 plants/application rate (7 pots/application rate); - pea: 3 plants/pot – 21 plants/application rate (7 pots/application rate); - flax: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate); - carrot: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate); - onion: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate), - oats: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate). Next, the test item was sprayed onto the plants with calibrated spraying equipment [SOP/G/75]. The pots were placed on trays. To prevent bias, random assignment of the test and the control pots is recommended. They were rearranged once a week.

3.4.3. Application rates

The following application rates of the test item were used for all test species: 51.2, 128.0, 320.0, 800.0, 2000.0 mL/ha. In case of each species, there was one untreated control group. A separation factor was 2.5. The rates of the test item was selected on the basis of the maximum recommended single rate, i.e. 1000.0 mL/ha. The maximum recommended rate is applied two times per season, therefore the maximum rate in the study was equal to 2000 mL/ha. The volume of deionised water used to prepare the tested application rates corresponded to 300 L of spraying liquid/ha.

3.4.4. Preparation of the test suspensions

To prepare a stock suspension which corresponded to the highest application rate, 7.4 g of the test item was mixed with deionized water [SOP/G/11, SOP/G/121]. The volume was made up to 1000 mL. The quantity of the test item and deionized water used to prepare the stock suspension corresponded to 300 L spraying liquid/ha. The remaining test suspensions were prepared by diluting the stock suspension (Table 4). The stock suspension and the test suspensions (dilutions of the stock suspension) were prepared on the application day.

3.4.5. Chemical analysis

The concentrations of azoxystrobin and difenoconazole in water were determined with a validated analytical method [SOP/C/323]. The process of validation involved the range of linearity of the analytical graph, the regression residual (di), selectivity and specificity, precision, matrix effect, accuracy, stability stock solution and limit of quantification and detection. All test suspensions (application rates) as well as the control sample were subjected to chemical analysis in order to confirm the correct preparation of the tested aqueous suspensions. The volume of all samples was equal to 100 mL. A description of the analytical method and the results of the determination of azoxystrobin and difenoconazole in the test suspensions are presented in Appendix No. 2 to the Final Report. Basis on the results of the analytical measurements (Table 7 and 8 of the Appendix No. 2) it was proved, that the test aqueous suspensions were prepared correctly.

3.4.6. Application method

The test item was sprayed onto the soil using a suitable spraying chamber [SOP/G/75]. The spraying chamber works as a pressure sprayer which makes it possible to apply traditional nozzles used in plant protection. Before the test item was applied, the spraying equipment had been calibrated using deionised water in order to select a suitable nozzle providing the most appropriate way of application under the conditions of specified pressure and working quickness. Tables 2 and 3 present the technical characteristics of the spraying chamber and a description of the calibration process.

3.4.7. Conditions of the experiment

The experiment was conducted in a special room where suitable environmental conditions for each species were provided. The air temperature and humidity were constantly measured [SOP/G/114]. The light intensity was controlled at the beginning and at the end of the experiment [SOP/G/85]. The CO2 concentration in the air was also determined [SOP/G/101]. The conditions of the experiment are shown in Table 5. Appropriate soil nutrients were supplemented to maintain good plant vigour (fertilizer: “Florovit” at the concentration of 2.5 mL/L). Top watering (30 mL/pot) was used

3.4.8. Observations

The exposure period finished 21 days after the application of the test item (22.06.2023 – 15.07.2023). The plants were observed for visual phytotoxicity and mortality 7, 14 and 21 days after the spraying. At the end of the exposure period, the number of plants was determined. Next, they were cut down, measured, dried to a constant weight at 60°C [SOP/G/106] and weighed [SOP/G/11].

3.5. Analysis of the results

On the basis of the obtained results, the following values were calculated:

ER_{10} (effective rate) – the rate of the test item that results in a 10% reduction in vegetative vigour of the test plants.

ER_{25} (effective rate) – the rate of the test item that results in a 25% reduction in vegetative vigour of the test plants.

ER_{50} (effective rate) – the rate of the test item that results in a 50% reduction in vegetative vigour of the test plants.

Due to the lack of mortality of plants during the exposure period, no computations have been performed for the plant number at the end of the experiment for all tested plant species.

The ER_{10}, ER_{25} and ER_{50} values were determined by the following tests:
- shoot length: Probit analysis using linear max. likelihood regression, 3-param. Normal CDF
- shoot dry weight: Probit analysis using linear max. likelihood regression, 3-param. Normal CDF, NOER (no observed effect rate) – the highest rate at which the test item is observed to have no effects on vegetative vigour. In order to determine the NOER values, the following tests were used:

- for the shoot length: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Non-parametric Trend analysis by Contrasts (Monotonicity of Rate/Response), Trend analysis by Contrasts (Monotonicity of Rate/Response), Step-down Jonckheere-Terpstra Test Procedure, Williams Multiple Sequential t-test Procedure, Dunnett`s Multiple t-test Procedure;
- for the plant shoot dry weight: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Non-parametric Trend analysis by Contrasts (Monotonicity of Rate/Response), Trend analysis by Contrasts (Monotonicity of Rate/Response), Step-down Jonckheere-Terpstra Test Procedure, Williams Multiple Sequential t-test Procedure, Dunnett`s Multiple t-test Procedure.

Additionally, basis on the results after 21 days of the experiment for visual phytotoxicity effects, the ER_{50} values were determined using the: Probit analysis using linear max. likelihood regression, 3-param. Normal CDF.

The ER_{10}, ER_{25}, ER_{50} and NOER values were determined using the ToxRat Professional 3.3.0 computer software [11], [SOP/G/80] [Appendix No. 3]. The all ER_{10}, ER_{25}, ER_{50} and NOER values were expressed in mL of the test item/ha and g of the active substances/ha [SOP/OG/7]

4. RESULTS

4.1. Sunflower (Helianthus annuus)

After the application of the test item at the rates ranging from 51.2 to 2000.0 mL/ha the mortality of plants was not observed (Table 6). After the application of the test item at the rates ranging from 51.2 to 2000.0 mL/ha, the sunflower shoot length was between 90.8 and 93.8% of the control shoot length (Table 7). The rate – effect scatter plot showing the influence of the test item on the plant shoot length at the end of the experiment is presented in Figure 1. After the application of the test item at the rates ranging from 51.2 to 2000.0 mL/ha, the sunflower shoot dry weight was between 87.9 and 112.3% of the control shoot dry weight (Table 8). The rate – effect scatter plot showing the influence of the test item on the plant dry weight at the end of the experiment is presented in Figure 2. After 21 days of exposure period the plant damages were not observed at the rates between 51.2 and 2000.0 mL/ha (Table 9). The rate – effect scatter plot showing the influence of the test item on the plant damages at the end of the experiment is presented in Figure 3.

The ER_{10}, ER_{25}, ER_{50}, and NOER values expressed as mL of the test item/ha are presented in Table 30.

The ER_{10}, ER_{25}, ER_{50}, and NOER values expressed as g of azoxystrobin/ha are presented in Table 32.

The ER_{10}, ER_{25}, ER_{50}, and NOER values expressed as g of difenoconazole/ha are presented in Table 34.

4.2. Pea (Pisum sativum)

After the application of the test item at the rates equal to 51.2 and 2000.0 mL/ha the mortality of plants was not observed (Table 10). After the application of the test item at the rates ranging from 51.2 to 2000.0 mL/ha, the pea shoot length was between 94.5 and 112.3 % of the control shoot length (Table 11). The rate – effect scatter plot showing the influence of the test item on the plant shoot length at the end of the experiment is presented in Figure 4. After the application of the test item at the rates ranging from 51.2 to 2000.0 mL/ha, the pea shoot dry weight was between 91.6 and 117.3% of the control shoot dry weight (Table 12). The rate – effect scatter plot showing the influence of the test item on the plant dry weight at the end of the experiment is presented in Figure 5. After 21 days of exposure period at the rates between 51.2 and 2000.0 mL/ha the plant damages were not observed (Table 13). The rate – effect scatter plot showing the influence of the test item on the plant damages at the end of the experiment is presented in Figure 6.

The ER_{10}, ER_{25}, ER_{50}, and NOER values expressed as mL of the test item/ha are presented in Table 30.

The ER_{10}, ER_{25}, ER_{50}, and NOER values expressed as g of azoxystrobin/ha are presented in Table 32.

The ER_{10}, ER_{25}, ER_{50}, and NOER values expressed as g of difenoconazole/ha are presented in Table 34.

4.3. Flax (Linum usitatissimum)

After the application of the test item at the rates between 51.2 and 2000.0 mL/ha the mortality of plants was not observed (Table 14).
After the application of the test item at the rates ranging from 51.2 to 2000.0 mL/ha, the flax shoot length was between 96.3 and 101.3% of the control shoot length (Table 15).
The rate – effect scatter plot showing the influence of the test item on the plant shoot length at the end of the experiment is presented in Figure 7.

After the application of the test item at the rates ranging from 51.2 to 2000.0 mL/ha, the flax shoot dry weight was between 92.1 and 111.5% of the control shoot dry weight (Table 16). The rate – effect scatter plot showing the influence of the test item on the plant dry weight at the end of the experiment is presented in Figure 8. After 21 days of exposure period at the rates between 51.2 and 2000.0 mL/ha the plant damages were not observed (Table 17). The rate – effect scatter plot showing the influence of the test item on the plant damages at the end of the experiment is presented in Figure 9.

The ER_{10}, ER_{25}, ER_{50}, and NOER values expressed as mL of the test item/ha are presented in Table 30.

The ER_{10}, ER_{25}, ER_{50}, and NOER values expressed as g of azoxystrobin/ha are presented in Table 32.

The ER_{10}, ER_{25}, ER_{50}, and NOER values expressed as g of difenoconazole/ha are presented in Table 34.

4.4. Carrot (Daucus carota)

After the application of the test item at the rates between 51.2 and 2000.0 mL/ha the mortality of plants was not observed (Table 18). After the application of the test item at the rates ranging from 51.2 to 2000.0 mL/ha, the carrot shoot length was between 94.8 and 100.1% of the control shoot length (Table 19). The rate – effect curve showing the influence of the test item on the plant shoot length at the end of the experiment is presented in Figure 10. After the application of the test item at the rates ranging from 51.2 to 2000.0 mL/ha, the carrot shoot dry weight was between 90.1 and 110.4% of the control shoot dry weight (Table 20). The rate – effect scatter plot showing the influence of the test item on the shoot dry weight at the end of the experiment is presented in Figure 11. After 21 days of exposure period at the rates between 51.2 and 2000.0 mL/ha the plant damages were not observed (Table 21). The rate – effect scatter plot showing the influence of the test item on the plant damages at the end of the experiment is

presented in Figure 12.

The ER_{10}, ER_{25}, ER_{50}, and NOER values expressed as mL of the test item/ha are presented in Table 31.

The ER_{10}, ER_{25}, ER_{50}, and NOER values expressed as g of azoxystrobin/ha are presented in Table 33.

The ER_{10}, ER_{25}, ER_{50}, and NOER values expressed as g of difenoconazole/ha are presented in Table 35.

4.5. Onion (Allium cepa)

After the application of the test item at the rates between 51.2 and 2000.0 mL/ha the mortality of plants was not observed (Table 22). After the application of the test item at the rates ranging from 51.2 to 2000.0 mL/ha, the onion shoot length was between 81.1 and 93.0% of the control shoot length (Table 23). The rate – effect curve showing the influence of the test item on the plant shoot length at the end of the experiment is presented in Figure 13. After the application of the test item at the rates ranging from 51.2 to 2000.0 mL/ha, the onion shoot dry weight was between 67.8 and 95.6% of the control shoot dry weight (Table 24). The rate – effect curve showing the influence of the test item on the shoot dry weight at the end of the experiment is presented in Figure 14. After 21 days of exposure period the plant damages were observed at the rates between 800.0 and 2000.0 mL/ha and they were ranging from 12.5 to 15.0%. The occurrence of individual symptoms and the percentage of plant damages are presented in Table 25. The rate – effect curve showing the influence of the test item on the plant damages at the end of the experiment is presented in Figure 15.

The ER_{10}, ER_{25}, ER_{50}, and NOER values expressed as mL of the test item/ha are presented in Table 31.

The ER_{10}, ER_{25}, ER_{50}, and NOER values expressed as g of azoxystrobin/ha are presented in Table 33.

The ER_{10}, ER_{25}, ER_{50}, and NOER values expressed as g of difenoconazole/ha are presented in Table 35.

4.6. Oats (Avena sativa)

After the application of the test item at the rates between 51.2 and 2000.0 mL/ha the mortality of plants was not observed (Table 26). After the application of the test item at the rates ranging from 51.2 to 2000.0 mL/ha, the oats shoot length was between 100.8 and 1107.5% of the control shoot length (Table 27). The rate – effect curve showing the influence of the test item on the plant shoot length at the end of the experiment is presented in Figure 16. After the application of the test item at the rates ranging from 51.2 to 2000.0 mL/ha, the oats shoot dry weight was between 100.2 and 127.5% of the control shoot dry weight (Table 28). The rate – effect curve showing the influence of the test item on the shoot dry weight at the end of the experiment is presented in Figure 17. After 21 days of exposure period at the rates between 51.2 and 2000.0 mL/ha the plant damages were not observed (Table 29). The rate – effect curve showing the influence of CHR/F/SCORPIO 325 SC Terrestrial Plant Test: Vegetative Vigour Test Study code: G-06-23 REPORT Page 34 of 112 the test item on the plant damages at the end of the experiment is presented in Figure 18.

The ER_{10}, ER_{25}, ER_{50}, and NOER values expressed as mL of the test item/ha are presented in Table 31.

The ER_{10}, ER_{25}, ER_{50}, and NOER values expressed as g of azoxystrobin/ha are presented in Table 33.

The ER_{10}, ER_{25}, ER_{50}, and NOER values expressed as g of difenoconazole/ha are presented in Table 35.

5. CONCLUSIONS

The test item, i.e. CHR/F/SCORPIO 325 SC, applied at rates ranging from 51.2 to 2000.0 mL/ha, had no impact on vegetative vigour of sunflower, pea, flax, carrot and oats. Slight effect was noticed in cultivation of onion. On the basis of NOER, ER10, ER25 and ER50 values determined from the plant

number at the end of the experiment it was proved that the test item did not inhibit the process of growth of all testes plant species. On the basis of NOER, ER10, ER25 and ER50 values determined from the shoot length it was proved that the test item slightly inhibited the process of growth of onion. On the basis of NOER, ER10, ER25 and ER50 values determined from the dry shoot weight it was proved that the test item slightly inhibited the process of growth of onion. During the experiment the phytotoxic symptoms of the test item were noticed in cultivation of onion.

6. VALIDITY CRITERIA

On the basis of the obtained results, it was stated that the following validity criteria of the study aimed at evaluating the impact of CHR/F/SCORPIO 325 SC on vegetative vigour of terrestrial plants were met:

- the seedling emergence of plants (validity criterion: at least 70%) was as follows:

90.5 – 95.2 – sunflower,
88.1 – 92.9 – pea,
92.5 – 100.0 – flax,
92.5 – 97.5 – carrot,
90.0 – 97.5 – onion,
90.0 – 97.5 – oats

- the mean plant survival of the control was 100% for all tested species (validity criterion: at least 90%), - the control plants did not exhibit any visible phytotoxic symptoms, - environmental conditions for all plants belonging to the same species were identical.

7. DEVIATIONS IN THE STUDY

Deviation from OECD Guideline No. 227:

According to OECD Guideline No. 227 (2006), the light intensity should be 350 ± 50µE/m2 /s, however these values are recommended for tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 231.4 – 297.8 µE/m2 /s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. The deviation did not affect the results of the experiment.

~~KCP 10.6.3 Extended laboratory studies on non-target plants~~

~~A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)~~

~~A 2.8 KCP 10.8 Monitoring data~~

Comments of zRMS:	The study was conducted to the guideline and according to the principles of GLP. All validity criterions were met. The study is considered to be reliable and suitable for the risk assessment.

Reference: KCP 10.6

Report **Gierbuszewska, A (2006)** CHR/F/SCORPIO 325 SC Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test, according to the OECD Guideline No. 208 (2006), STUDY CODE: G-08-23, PUH Chemirol Sp. z

o.o. August 2023

Guideline(s):	OECD Guideline No. 208 (2006)
Deviations:	Yes Deviation from OECD Guideline No. 208: According to OECD Guideline No. 208 (2006), the light intensity should be 350 ± 50µE/m2 /s. However, these values are recommended for tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 200.3 and 247.2 µE/m2 /s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. The deviations did not affect results of the study.
GLP:	Yes
Acceptability:	
Duplication (if vertebrate study)	No
Validity criteria	On the basis of the obtained results, it was stated that the following validity criteria of the study aimed at evaluating the impact of CHR/F/SCORPIO 325 SC on seedling emergence and seedling growth of terrestrial plants were met: - the seedling emergence in the control (validity criterion: at least 70%) was as follows: 100.0% – pea, 90.5% – sunflower, 90.0% – flax, 75.0% – carrot, 85.0% – onion, 85.0% – oats, - the mean survival of the emerged control seedlings of all testes species was 100.0% (validity criterion: 90%); - the control seedlings did not exhibit any visible phytotoxic effects; - environmental conditions for all plants of the same species were identical.

SUMMARY

The study, aimed at evaluating the effect CHR/F/SCORPIO 325 SC on seedling emergence and seedling growth of 6 terrestrial plants, was conducted on 4 dicotyledonous and 2 monocotyledonous species. The test item was sprayed onto the soil surface. There was also a concurrent control group. Seeds of the test plant species were sown in plastic pots. There were 5 (flax, carrot, onion and oats) or 3 (pea and sunflower) seeds/pot. The experiment was conducted in a special room. Suitable environmental conditions for each test species were provided. During the experiment, the plants were observed for emergence (every day to the emergence of 50% of the control seedlings and after then every 1 – 3 days) and visual phytotoxicity (after 7 and 14 days after the emergence of 50% of the control seedlings). The exposure period finished 14 days after the emergence of 50% of the control seedlings. At the end of the exposure, the number of surviving plants was determined. Next, the plants were cut down, measured, dried to a constant weight at 60ºC, and weighed. The results concerning the emergence, the shoot length,

and the dry weight were statistically analyzed in order to determine the ER10, ER25, ER50, and NOER. Additionally, the ER50 was determined for visual phytotoxicity effects, basis on the results obtained at the end exposure period.

MATERIALS AND METHODS

The study was performed according to the OECD Guideline for the Testing of Chemicals No. 208 (2006): "Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test" [1], the Study Plan and the Standard Operating Procedure SOP/G/42: "Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test".

~~**Name:**~~	~~CHR/F/SCORPIO 325 SC~~
~~**Batch number:**~~	~~CHR12/23~~
~~**CAS number of active substances:**~~	~~azoxystrobin: 131860-33-8 [12] difenoconazole: 119446-68-3 [13]~~
~~**Production date:**~~	~~22.02.2023~~
~~**Expiry date:**~~	~~not determined by the Sponsor~~
~~**Appearance:**~~	~~Liquid~~
~~**Formulation:**~~	~~SC (suspension concentrate)~~
~~**Active substances:**~~	~~azoxystrobin – 205.89 g/L difenoconazole – 125.41 g/~~
~~**Density (20 °C)**~~	~~1.11 g/mL~~
~~**Storage conditions**~~	~~10 – 30°C [SOP/OG/1, SOP/PB/1]~~
~~**Certificate of Analysis:**~~	~~23.03.2023 (Appendix No. 1)~~

Test item:	CHR/F/SCORPIO 325 SC batch number: CHR12/23
Active substance:	azoxystrobin: 205.89 g/L difenoconazole: 125.41 g/L
Test species:	pea (Pisum sativum), sunflower (Helianthus annuus), flax (Linum usitatissimum) carrot (Daucus carota), onion (Allium cepa), oats (Avena sativa)
Soil:	Sandy loam
Study design:	number of rates: 5 + control; number of replicates/rate: 7 (pea and sunflower), 4 (flax, carrot, onion and oats). The total number of seeds per application rate: 21 (pea and sunflower) or 20 (flax, carrot, onion and oats)
Exposure termination:	14 days after the emergence of 50% of the control seedlings;

Application rates: a control, 51.2, 128.0, 320.0, 800.0, 2000.0 mL/ha

Volume of deionized water: volume of deionized water used to prepare the highest rate corre sponded to 300 L spraying liquid/ha

Test conditions: temperature: 16.6 – 23.8°C, humidity: 46.7 – 87.5%, lighting: 16 h light : 8 h dark; light intensity: 65.82 – 147.8 µE/m2 /s; carbon dioxide concentration: 366 – 381 ppm;

Statistical analysis: The ER_{10}, ER_{25} and ER_{50} values for the final number of plants - probit analysis usisng linerar max likelihood regression (all test species)

The ER_{10}, ER_{25} and ER_{50} values for shoot length were determined with probit analysis using linear max likelihood regression (pea, cabbage, onion, corn) or logit analysis using linear max likelihood regression (flax, carrot) .

The ER_{10}, ER_{25} and ER_{50} values for shoot dry weight were determined with with probit analysis using linear max likelihood regression (pea, cabbage, flax, carrot) or logit analysis using linear max likelihood regression (onion, corn) .

Additionally, the ER_{50} was determined for visual phytotoxicity effects, basis on the results obtained at the end exposure period. The probit analysis using linear max likelihood regression (all test species).

NOER (no observed effect rate) – the highest rate at which the test item is observed to have no effects on seedling emergence and seedling growth.

In order to determine the NOER values, the following tests were used:

The final number of plants: Fisher's Exact Test with Bonferroni Correction.

The shoot length: Shapiro-Wilk's Test on Normal Distribution, Bartlett's Test Procedure on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test or Dunnett's Multiple t-test Procedure (onion).

The plant dry weight: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure.

The test item in a plastic vessel was delivered on March 03, 2023. The sample of the test item was taken from the Test item collection point at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna on May 04, 2023 [SOP/OG/1]. The Sponsor is responsible for specifying the identity, purity, and stability of the test item

Test system

Six plant species belonging to different taxonomic families were used. These were pea (Pisum sativum), sunflower (Helianthus annuus), flax (Linum usitatissimum), carrot (Daucus carota), onion (Allium cepa), oats (Avena sativa). The test species were selected from the list given in the OECD Guideline No. 208 [1]. Before the experiment started, seeds had been kept under dry conditions, at ambient temperature, and

with no access to light. The seed viability had also been examined [SOP/G/124]. The general characteristics of the test species is presented below

Class: Dicotyledonae

▪ Pea (Pisum sativum),
- family: Fabaceae (Leguminosae)
- variety: sześciotygodniowy - source: PNOS w Ożarowie Mazowieckim Sp. z o.o., Żeromskiego 3, 05 – 850 Ożarów Mazowiecki, Poland
- batch no. PL014/32/17672/2041/A
- seed viability: 90%.

▪ Sunflower (Helianthus annuus),
- family: Asteraceae (Compositae),
- variety: ogrodowy
- source: „PlantiCo-Hodowla i Nasiennictwo Ogrodnicze Zielonki" Sp. z o.o., Zielonki Parcele, ul. Parkowa 1A, 05 – 082 Stare Babice, Poland
- batch no.: PL014/32/83/S094
- seed viability: 97%

▪ Flax (Linum usitatissimum),
- family: Linaceae,
- source: Planta Sp. z o.o., Wyszyńskiego 16a, 33 – 100 Tarnów, Poland - entrepreneur No.: 12/63/115
- seed viability: 92%.

▪ Carrot (Daucus carota),
- family: Apiaceae (Umbelliferae)
- variety: Amsterdam - source: BROS Sp. z o.o. sp. k., Karpia 24, 61 – 619 Poznań, Poland - batch no: PL630/12/210/L441/A
- seed viability: 83%

Class: Monocotyledonae

▪ Onion (Allium cepa),
- family: Liliaceae (Amarylladaceae)
- variety: siedmiolatka
- source: Vilmorin Garden Sp. z o.o., Szkolna 30, 62 – 064 Plewiska, Poland - batch no: p.1-0051-90042-01
- seed viability: 92%

▪ Oats (Avena sativa),
- family: Poaceae (Gramineae)
- variety: Romulus
- source: "DANKO" Hodowla Roślin Sp. z o.o., Zakład Hodowli Roślin Oddział Choryń, Choryń 27, 64 – 000 Kościan, Poland - harvest year: 2022
- seed viability: 91%

Soil

Agricultural soil was used in the study. The soil was collected from the place belonging to the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna (49˚ 59', 780 N; 18˚55', 190 E) where no plant protection products or organic and inorganic fertilizers had been used. The soil was collected from a depth of 20 cm. It was manually cleared of large objects, e.g. plant residuals or stones, and sieved to 2 mm particle size

[SOP/G/74]. The required physical and chemical parameters of the soil were determined. The results and the assessment methods are shown in Table 1. The soil texture (point 1) was assessed beyond GLP by the Institute for Ecology of Industrial Areas in Katowice, whereas the parameters numerated in points 2 – 6 were assessed by the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna. The soil texture showed it was a sandy loam [7]. The soil was subjected to evaporation to reduce the effect of soil pathogens.

Soil preparation

In cultivation of flax, carrot, onion and oats 181 mL of deionized water was added to 2643 g of the soil/rate (i.e. 2400 g dry weight/rate). For pea and sunflower 317 mL of deionized water was added to 4626 g of the soil/rate (i.e. 4200 g dry weight/rate) [5], [SOP/G/120]. The soil dry weight content was 90.8% [SOP/G/11, SOP/G/24, SOP/G/106]. The aim was to obtain the final soil moisture content about 50% of the maximum water holding capacity. Thereafter, the soil was distributed to plastic pots. Each pot contained about 706 g of the soil (i.e. 600 g dry weight), [SOP/G/120].

Seed sowing

Seeds of the test plant species were sown in plastic pots (pot's diameter – 15 cm, pot's surface area – about 177 cm2) containing the soil which had been prepared previously. All seeds of each species belonged to the same size class. There were the following numer of seeds in each pot:
- pea: 3 seeds/pot – 21 seeds/application rate (7 pots/rate);
- sunflower: 3 seeds/pot – 21 seeds/application rate (7 pots/rate);
- flax: 5 seeds/pot – 20 seeds/application rate (4 pots/rate);
- carrot: 5 seeds/pot – 20 seeds/application rate (4 pots/rate);
- onion: 5 seeds/pot – 20 seeds/application rate (4 pots/rate);
- oats: 5 seeds/pot – 20 seeds/application rate (4 pots/rate).

A pot was defined as the replicate. Next, the test item was sprayed onto the soil surface with calibrated spraying equipment [SOP/G/75]. The pots were placed on trays. To prevent bias, random assignment of the test and the control pots is recommended. They were rearranged once a week.

Application rates

Five rates of the test item were used in the experiment: 51.2, 128.0, 320.0, 800.0, 2000.0 mL/ha In case of each species, there was one untreated control group. The rates of the test item were selected on the basis of the maximum recommended rate, i.e. 2000.0 mL/ha. The maximum recommended rate is applied one time per season. The volume of deionised water used to prepare the test item at the highest rate corresponded to 300 L of spraying liquid/ha.

Preparation of the test suspensions

To prepare a stock suspension which corresponded to the highest application rate, 7.4 g of the test item was mixed with deionized water [SOP/G/11, SOP/G/121]. The volume was made up to 1000 mL. The quantity of the test item and deionized water used to prepare the stock suspension corresponded to 300 L spraying liquid/ha. The remaining test suspensions were prepared by diluting the stock suspension (Table 4). The stock suspension and the test suspensions (dilutions of the stock suspension) were prepared on the application day.

Chemical analysis

The concentrations of azoxystrobin and difenoconazole in water were determined with a validated analytical method [SOP/C/323]. The process of validation involved the range of linearity of the analytical graph, the regression residual (di), selectivity and specificity, precision, matrix effect, accuracy, stability stock solution and limit of quantification and detection. All test suspensions (application rates) as well as the control sample were subjected to chemical analysis in order to confirm the correct preparation of the tested aqueous suspensions. The volume of samples was equal to 100 mL for rates: 51.2; 128.0; 320.0; 800.0; 2000.0 mL/ha and for the control. A description of the analytical method and the results of the determination of azoxystrobin and difenoconazole in the test suspensions are presented in Appendix No. 2 to the Final Report. Basis on the results of the analytical measurements (Tables 7 and 8 of the Appendix No. 2) it was proved, that the test aqueous suspensions were prepared correctly.

Application method

The test item was sprayed onto the soil using a suitable spraying chamber [SOP/G/75]. The spraying chamber works as a pressure sprayer which makes it possible to apply traditional nozzles used in plant protection. Before the test item was applied, the spraying equipment had been calibrated using deionised water in order to select a suitable nozzle providing the most appropriate way of application under the conditions of specified pressure and working quickness. Tables 2 and 3 present the technical characteristics of the spraying chamber and a description of the calibration process.

Conditions of the experiment

The experiment was conducted in a special room where suitable environmental conditions were provided. Air temperature and humidity were constantly monitored [SOP/G/114]. The light intensity was measured at the beginning and at the end of the experiment [SOP/G/85]. The CO2 concentration in the air was also determined [SOP/G/101]. The conditions of the experiment are shown in Table 5. Appropriate soil nutrients were supplemented to maintain good plant vigour (fertilizer: “Florovit” at the concentration of 2.5 mL/L). Top watering (30 mL/pot) was used.

Observations

The experiment finished 14 days after the emergence of 50% of the control seedlings. During the experiment, the plants were observed for emergence (every day and then every 2 – 3 days) and visual days after the emergence of 50% of the control seedlings). At the end of the experiment, the plants were counted, cut down, measured, dried to a constant weight at 60°C [SOP/G/106, SOP/G/81], and weighed [SOP/G/11, SOP/G/125].

Analysis of the results

On the basis of the obtained results, the following values were calculated:
ER_{10} (effective rate) – the rate of the test item that results in a 10% reduction in seedling emergence and seedling growth of the test plants.
ER_{25} (effective rate) – the rate of the test item that results in a 25% reduction in seedling emergence and seedling growth of the test plants.
ER_{50} (effective rate) – the rate of the test item that results in a 50% reduction in seedling emergence and seedling growth of the test plants.

The ER_{10}, ER_{25} and ER_{50} values for: - the final number of plants: probit analysis using linear max. likelihood regression; - shoot length: probit analysis using linear max. likelihood regression, 3-param. normal CDF; - dry weight: probit analysis using linear max. likelihood regression, logit analysis using linear max. likelihood regression.

NOER (no observed effect rate) – the highest rate at which the test item is observed to have no effects on seedling emergence and seedling growth.

In order to determine the **NOER** values, the following tests were used:

- for the plant number at the end of the experiment the following tests were used: Qualitative Trend Analysis by Contrasts (Monotonicity of Rate/Response), Tarone's Test Procedure, Multiple Sequentially-rejective Fisher Test After Bonferroni-Holm, Fisher's Exact Binomial Test with Bonferroni Correction;

- for the shoot length: Shapiro-Wilk´s Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Trend analysis by Contrasts (Monotonicity of Rate/Response), Williams Multiple Sequential t-test Procedure, Multiple Sequentially rejective Welsh-t-test After Bonferroni-Holm, Dunnett's Multiple t-test Procedure;

- for the plant dry weight: Shapiro-Wilk´s Test on Normal Distribution, Levene´s Test on Variance Homogeneity (with Residuals), Trend analysis by Contrasts (Monotonicity of Rate/Response), Williams Multiple Sequential t-test Procedure, Non-parametric Trend analysis by Contrasts (Monotonicity of Rate/Response), Step-down Jonckheere-Terpstra Test Procedure.

Additionally, the ER_{50} was determined for visual phytotoxicity effects, basis on the results obtained at the end exposure period. The probit analysis using linear max. likelihood regression was used.

The ER_{10}, ER_{25}, ER_{50} and NOER values were determined using the ToxRat Professional 3.3.0 computer software [10] [SOP/G/80, SOP/OG/7] [Appendix No. 3]. The all ER_{10}, ER_{25}, ER_{50} and NOER values were expressed in mL of the test item/ha and g of the active substances/ha.

RESULTS

Pea *(Pisum sativum)*

After the application of the test item at the rates between 51.2 and 2000.0 mL/ha, seedling emergence of plants was not delayed when compared with the control. The death of plants was not observed (Table 6). At the control group 100% of plants emerged. At the rates ranging from 51.2 to 2000.0 mL/ha, total number of plants at the end of the experiment was between 85.7 and 100.0% in comparison to the control group (Table 7). After the application of the test item at the rates ranging from 51.2 to 2000.0 mL/ha, the pea shoot length was between 100.3 and 108.8% of the control shoot length (Table 8). The rate – effect curve showing the influence of the test item on the shoot length at the end of the experiment is presented in Figure 1. After the application of the test item at the rates ranging from 51.2 to 2000.0 mL/ha, the pea shoot weight was between 113.6 and 125.3% of the control shoot weight (Table 9). The rate – effect curve showing the influence of the test item on the shoot dry weight at the end of the experiment is presented in Figure 2. At the end of the exposure period the plant damages were not observed at the rates between 51.2 and 2000.0 mL/ha. The occurrence of individual symptoms and the percentage of plant damages are presented in

Table 10. The rate – effect curve showing the influence of the test item on the plant damages at the end of the experiment is presented in Figure 3. The ER10, ER25, ER50, and NOER values expressed as mL of the test item/ha are presented in Table 36. The ER10, ER25, ER50, and NOER values expressed as g of azoxystrobin/ha are presented in Table 38. The ER10, ER25, ER50, and NOER values expressed as g of difenoconazole/ha are presented in Table 40.

Sunflower *(Helianthus annuus)*

After the application of the test item at the rates between 51.2 and 2000.0 mL/ha, seedling emergence of sunflower was not delayed when compared with the control. The death of plants was not observed (Table 11). At the control group, 90.5% of plants emerged. At the rates ranging from 51.2 to 2000.0 mL/ha, total number of plants at the end of the experiment was ranging from 94.7 to 105.3% in comparison to the control group (Table 12). The rate – effect curve showing the influence of the test item on the seedling emergence at the end of the experiment is presented in Figure 4. After the application of the test item at the ranging from 51.2 to 2000.0 mL/ha, the sunflower shoot length was between 82.8 and 101.8% of the control shoot length (Table 13). The rate – effect curve showing the influence of the test item on the shoot length at the end of the experiment is presented in Figure 5. After the application of the test item at the rates ranging from 51.2 to 2000.0 mL/ha, the sunflower shoot weight was between 90.5 and 107.8% of the control shoot weight (Table 14). At the end of the exposure period the plant damages were not observed at the rates between 51.2 and 2000.0 mL/ha. The occurrence of individual symptoms and the percentage of plant damages are presented in Table 15. The rate – effect curve showing the influence of the test item on the plant damages at the end of the experiment is presented in Figure 6. The ER10, ER25, ER50, and NOER values expressed as mL of the test item/ha are presented in Table 36. The ER10, ER25, ER50, and NOER values expressed as g of azoxystrobin/ha are presented in Table 38. The ER10, ER25, ER50, and NOER values expressed as g of difenoconazole/ha are presented in Table 40.

Flax *(Linum usitatissimum)*

After the application of the test item at the rates between 51.2 and 2000.0 mL/ha, seedling emergence of flax was not delayed when compared with the control. The death of plants was not observed (Table 16). At the control group 90% of plants emerged. At the rates ranging from 51.2 to 2000.0 mL/ha, total number of plants at the end of the experiment was between 94.4 and 105.6% in comparison to the control group (Table 17). After the application of the test item at the rates ranging from 51.2 to 2000.0 mL/ha, the flax shoot length was between 110.5 and 117.3% of the control shoot length (Table 18). The rate – effect curve showing the influence of the test item on the shoot length at the end of the experiment is presented in Figure 7. After the application of the test item at the rates ranging from 51.2 to 2000.0 mL/ha, the flax shoot weight was between 104.5 and 137.9% of the control shoot weight (Table 19). The rate – effect curve showing the influence of the test item on the shoot dry weight at the end of the experiment is presented in Figure 8. At the end of the exposure period the plant damages were not observed at the rates between and 51.2 and 2000.0 mL/ha. The occurrence of individual symptoms and the percentage of plant damages are presented in Table 20. The rate – effect curve showing the influence of the test item on the plant damages at the end of the experiment is presented in Figure 9. The ER10, ER25, ER50, and NOER values expressed as mL of the test item/ha are presented in Table 36. The ER10, ER25, ER50, and NOER values expressed as g of azoxystrobin/ha are presented in Table 38. The ER10, ER25, ER50, and NOER values expressed as g of difenoconazole/ha are presented in Table 40.

Carrot *(Daucus carota)*

After the application of the test item at the rates between 51.2 and 128.0 mL/ha seedling emergence of carrot was not delayed when compared with the control. After the application of the test item at the rates between 320.0 and 2000.0 mL/ha seedling emergence of carrot was delayed by one day (320.0 and 2000.0 mL/ha) and two days (800.0 mL/ha) when compared with the control. The death of plants was not observed (Table 21). At the control group 75% of plants emerged. At the rates ranging from 51.2 to 2000.0 mL/ha, total number of plants at the end of the experiment was between 93.3 and 120.0% in comparison to the control group (Table 22). After the application of the test item at the rates ranging from 51.2 to 2000.0 mL/ha, the carrot shoot length was between 93.8 and 105.0% of the control shoot length (Table 23). The rate – effect curve showing the influence of the test item on the shoot length at the end of the experiment is presented in Figure 10. After the application of the test item at the rates ranging from 51.2 to 2000.0 mL/ha, the carrot shoot weight was between 106.2 and 140.7% of the control shoot weight (Table 24). The rate – effect curve showing the influence of the test item on the shoot dry weight at the end of the experiment is presented in Figure 11. At the end of the exposure period the plant damages were not observed at the rates ranging from 51.2 to 2000.0 mL/ha. The occurrence of individual symptoms and the percentage of plant damages are presented in Table 25. The rate – effect curve showing the influence of the test item on the plant damages at the end of the experiment is presented in Figure 12. The ER10, ER25, ER50, and NOER values expressed as mL of the test item/ha are presented in Table 37. The ER10, ER25, ER50, and NOER values expressed as g of azoxystrobin/ha are presented in Table 39. The ER10, ER25, ER50, and NOER values expressed as g of difenoconazole/ha are presented in Table 41.

Onion *(Allium cepa)*

After the application of the test item at the rates between 51.2 and 320.0 mL/ha seedling emergence of onion was not delayed when compared with the control. After the application of the test item at the rates 800.0 and 2000.0 mL/ha seedling emergence of onion was delayed by one day when compared with the control. The death of plants was not observed (Table 26). At the control group 85% of plants emerged. At the rates ranging from 51.2 to 2000.0 mL/ha, total number of plants at the end of the experiment was between 105.9. and 111.8% in comparison to the control group (Table 27). The rate – effect curve showing the influence of the test item on the seedling emergence at the end of the experiment is presented in Figure 13. After the application of the test item at the rates ranging from 51.2 to 2000.0 mL/ha, the onion shoot length was between 88.1 and 110.4% of the control shoot length (Table 28). The rate – effect curve showing the influence of the test item on the shoot length at the end of the experiment is presented in Figure 14. After the application of the test item at the rates ranging from 51.2 to 2000.0 mL/ha, the onion shoot weight was between 74.5 and 106.2% of the control shoot weight (Table 29). The rate – effect curve showing the influence of the test item on the shoot dry weight at the end of the experiment is presented in Figure 15. At the end of the exposure period the plant damages were not observed at the rates between 51.2 and 2000.0 mL/ha (Table 30). The rate – effect curve showing the influence of the test item on the plant damages at the end of the experiment is presented in Figure 16. The ER10, ER25, ER50, and NOER values expressed as mL of the test item/ha are presented in Table 37. The ER10, ER25, ER50, and NOER values expressed as g of azoxystrobin/ha are presented in Table 39. The ER10, ER25, ER50, and NOER values expressed as g of difenoconazole/ha are presented in Table 41.

Oats (*Avena sativa)*

After the application of the test item at the rates between 51.2 and 2000.0 mL/ha, seedling emergence of oats was not delayed when compared with the control. The death of plants was not observed (Table 31). At the control group 85% of plants emerged. At the rates ranging from 51.2 to 2000.0 mL/ha, total number of plants at the end of the experiment was between

111.8 and 117.6% in comparison to the control group (Table 32). The rate – effect curve showing the influence of the test item on the seedling emergence at the end of the experiment is presented in Figure 17. After the application of the test item at the rates ranging from 51.2 to 2000.0 mL/ha, the oats shoot length was between 99.5 and 108.8% of the control shoot length (Table 33). The rate – effect curve showing the influence of the test item on the shoot length at the end of the experiment is presented in Figure 18. After the application of the test item at the rates ranging from 51.2 to 2000.0 mL/ha, the oats shoot weight was between 78.7 and 131.6% of the control shoot weight (Table 34). The rate – effect curve showing the influence of the test item on the shoot dry weight at the end of the experiment is presented in Figure 19. At the end of the exposure period the plant damages were not observed at the rates ranging from 51.2 to 2000.0 mL/ha (Table 35). The rate – effect curve showing the influence of the test item on the plant damages at the end of the experiment is presented in Figure 20. The ER10, ER25, ER50, and NOER values expressed as mL of the test item/ha are presented in Table 37. The ER10, ER25, ER50, and NOER values expressed as g of azoxystrobin/ha are presented in Table 39. The ER10, ER25, ER50, and NOER values expressed as g of difenoconazole/ha are presented in Table 41.

CONCLUSIONS

On the basis of the obtained results it was proved that the test item i.e. CHR/F/SCORPIO 325 SC had no impact on seedling emergence and seedling growth of pea, sunflower, flax, carrot and oats. It has an impact on seedling emergence and seedling growth of onion. The delayed emergence of plants in comparison to the control group was observed in cultivation of carrot and onion. The death of plants was not noticed in cultivation of all tested plants. On the basis of NOER, ER_{10}, ER_{25} and ER_{50} values determined from the plant number it was proved that the test item did not inhibit the seedling emergence and the process of growth of all tested plants. On the basis of NOER, ER_{10}, ER_{25} and ER_{50} values determined from the shoot length it was proved that the test item inhibited the process of growth of onion. On the basis of NOER, ER_{10}, ER_{25} and ER_{50} values determined from the dry shoot weight it was proved that the test item inhibited the process of growth of onion. During the experiment the phytotoxic symptoms of the test item were not noticed in cultivation of all tested plants.

VALIDITY CRITERIA

On the basis of the obtained results, it was stated that the following validity criteria of the study aimed at evaluating the impact of CHR/F/SCORPIO 325 SC on seedling emergence and seedling growth of terrestrial plants were met: - the seedling emergence in the control (validity criterion: at least 70%) was as follows:
100.0% – pea,
90.5% – sunflower,
90.0% – flax,
75.0% – carrot,
85.0% – onion,
85.0% – oats,
- the mean survival of the emerged control seedlings of all testes species was 100.0% (validity criterion: 90%);
- the control seedlings did not exhibit any visible phytotoxic effects;
- environmental conditions for all plants of the same species were identical

DEVIATIONS IN THE STUDY

According to OECD Guideline No. 208 (2006), the light intensity should be 350 ± 50µE/m2 /s. However, these values are recommended for tests conducted in greenhouses. The

experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 200.3 and 247.2 µE/m2 /s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. The deviations did not affect results of the study