

DRAFT REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: A12916B

Product name: Amistar Max

Chemical active substances:

Azoxystrobin, 93.5 g/L

Folpet, 500 g/L

Central Zone

Zonal Rapporteur Member State: Germany

NATIONAL ADDENDUM - POLAND

(authorisation)

Applicant: Syngenta

Submission date: June 2024

MS Assessment: 12/08/2024

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When	What
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9 Ecotoxicology (KCP 10)

This is the National Addendum for Poland and should be reviewed in conjunction with the Core Assessment prepared by zRMS Germany.

This National Addendum has been prepared to address specific Polish national requirements and arrangements concerning risk mitigation measures for aquatic organisms as well as Polish comments to the registration report Core Assessment prepared by zRMS.

This document summarises the following sections prepared to meet the national requirements for authorisation in Poland, specifically:

- the aquatic risk assessment with PEC_{sw} values calculated in Part B8 National Addendum,
- the non-target plants risk assessment in accordance with Polish requirements.

Folpet has been included on 1 October 2007 to the Annex I of Directive 91/414/EEC under COMMISSION DIRECTIVE 2007/5/EC of 7 February 2007 amending Council Directive 91/414/EEC. The active substance expiration date is the 31st of July 2020. Currently Folpet is under EU review as part of the AIR3 program.

The selection of endpoints used in the risk assessments reported in the Core Dossier documents is in line with the Folpet endpoints currently approved in EU (EFSA Conclusions, EFSA Journal 2009;7(8) and Commission Review Report - SANCO/10032/2006 –rev 5, 11 July 2008) as finalised in the Standing Committee on the Food Chain and Animal Health on 29 September 2006.

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 sit- uation (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I**	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ syner- gist per ha	Conclusion						
					Method / Kind	Timing / Growth stage of crop & sea- son	Max. num- ber a) per use b) per crop/ season	Min. inter- val between applications (days)	kg or L product/ha a) max. rate per appl. b) max. to- tal 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)																				
25	Poland	Barley [HORVX]	F	<i>Pyrenophora teres</i> [PYRNTE]	Foliar spray	BBCH 30- 59	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/A								
26	Poland	Barley [HORVX]	F	<i>Puccinia hordei</i> [PUCCHD]	Foliar spray	BBCH 30- 59	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/A								
27	Poland	Barley [HORVX]	F	<i>Rhynchosporium secalis</i> [RHYNSE]	Foliar spray	BBCH 30- 59	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/A								
28	Poland	Barley [HORVX]	F	<i>Ramularia collo-cygni</i> [RAMUCC]	Foliar spray	BBCH 30- 59	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/A								
29	Poland	Barley [HORVX]	F	<i>Erysiphe graminis</i> [ERYSGR]	Foliar spray	BBCH 30- 59	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/A								

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 sit- uation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ syner- gist per ha	Conclusion						
					Method / Kind	Timing / Growth stage of crop & sea- son	Max. num- ber a) per use b) per crop/ season	Min. inter- val between applications (days)	kg or L product/ha a) max. rate per appl. b) max. to- tal 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
55	Poland	Oat [AVESA]	F	<i>Puccinia coronata</i> [PUCCCO]	Foliar spray	BBCH 30- 59	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/A								
79	Poland	Wheat [TRZSS]	F	<i>Septoria tritici</i> [SEPTTR]	Foliar spray	BBCH 30- 69	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/A								
80	Poland	Wheat [TRZSS]	F	<i>Puccinia striiformis</i> [PUCCST]	Foliar spray	BBCH 30- 69	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/A								
81	Poland	Wheat [TRZSS]	F	<i>Puccinia recondita</i> [PUCCRE]	Foliar spray	BBCH 30- 69	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/A								
106	Poland	Rye [SECCE]	F	<i>Puccinia recondita</i> [PUCCRE]	Foliar spray	BBCH 30- 69	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/A								
107	Poland	Rye [SECCE]	F	<i>Rhynchosporium secalis</i> [RHYNSE]	Foliar spray	BBCH 30- 69	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/A								
108	Poland	Rye [SECCE]	F	<i>Erysiphe graminis</i> [ERYSGR]	Foliar spray	BBCH 30- 69	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/A								
135	Poland	Triticale [TTLRI]	F	<i>Septoria tritici</i> [SEPTTR]	Foliar spray	BBCH 30- 69	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/A								
136	Poland	Triticale [TTLRI]	F	<i>Puccinia striiformis</i> [PUCCST]	Foliar spray	BBCH 30- 69	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/A								
137	Poland	Triticale [TTLRI]	F	<i>Puccinia recondita</i> [PUCCRE]	Foliar spray	BBCH 30- 69	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/A								

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 situ- ation (crop destination / purpose of crop)	F, Fn, Fpn G, Gpn or I **	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ syner- gist per ha	Conclusion						
					Method / Kind	Timing / Growth stage of crop & sea- son	Max. num- ber a) per use b) per crop/ season	Min. inter- val between applications (days)	kg or L product/ha a) max. rate per appl. b) max. to- tal 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
138	Poland	Triticale [TTLRI]	F	<i>Erysiphe graminis</i> [ERYSGR]	Foliar spray	BBCH 30- 69	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/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)																				
	None																			
Minor uses according to Article 51 (zonal uses)																				
172	Poland	Rye, spring [SECCS]	F	<i>Puccinia recondita</i> [PUCCRE]	Foliar spray	BBCH 30- 69	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/A								
173	Poland	Rye, spring [SECCS]	F	<i>Rhynchosporium secalis</i> [RHYNSE]	Foliar spray	BBCH 30- 69	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/A								
174	Poland	Rye, spring [SECCS]	F	<i>Erysiphe graminis</i> [ERYSGR]	Foliar spray	BBCH 30- 69	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/A								
175	Poland	Triticale, spring [TTLRI]	F	<i>Puccinia striiformis</i> [PUCCST]	Foliar spray	BBCH 30- 69	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/A								
176	Poland	Durum wheat [TRZDX]	F	<i>Septoria tritici</i> [SEPTTR]	Foliar spray	BBCH 30- 69	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/A								
177	Poland	Durum wheat [TRZDX]	F	<i>Puccinia striiformis</i> [PUCCST]	Foliar spray	BBCH 30- 69	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/A								
178	Poland	Durum wheat [TRZDX]	F	<i>Puccinia recondita</i> [PUCCRE]	Foliar spray	BBCH 30- 69	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/A								

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 situ- ation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ syner- gist per ha	Conclusion						
					Method / Kind	Timing / Growth stage of crop & sea- son	Max. num- ber a) per use b) per crop/ season	Min. inter- val between applications (days)	kg or L product/ha a) max. rate per appl. b) max. to- tal 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
179	Poland	Grasses (orna- mental & for seed production)	F	<i>Septoria spp</i> [SEPTSP]	Foliar spray	BBCH 30- 59	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/A								
180	Poland	Grasses (orna- mental & for seed production)	F	<i>Puccinia spp</i> [PUCCSP]	Foliar spray	BBCH 30- 59	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/A								
181	Poland	Energy crop - Miskanthus	F	<i>Septoria spp</i> [SEPTSP]	Foliar spray	BBCH 30- 59	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/A								
182	Poland	Energy crop - Miskanthus	F	<i>Puccinia spp</i> [PUCCSP]	Foliar spray	BBCH 30- 59	a) 1 b) 1	NA	a) 1.5 b) 1.5	a) 140 + 750 b) 140 + 750	100 - 400	N/A								
Minor uses according to Article 51 (interzonal uses)																				
	None																			

* 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:	<ul style="list-style-type: none">(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 (<i>e.g.</i> 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 <u>and</u> 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
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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)

Birds

Please refer to core assessment.

Mammals

Please refer to core assessment.

9.1.1.2 Please refer to core assessment.

9.1.1.3 Effects on aquatic organisms (KCP 10.2)

The PEC/RAC ratios calculated for scenarios D3, D4 and R1 characteristic for Poland, using worst-case PEC_{SW} values for azoxystrobin and folpet are less than the trigger value of 1, indicating that the risk to aquatic organisms is acceptable following the proposed mitigation:

winter cereals:

- ~~5m vegetated buffer zone + 75% drift reduction OR~~
- ~~10m vegetated buffer zone + 50% drift reduction OR~~
- 20m vegetated buffer zone;

spring cereals:

- ~~10m vegetated buffer zone + 75% drift reduction OR~~
- 20m vegetated buffer zone + 50% drift reduction.

9.1.1.4 Effects on bees (KCP 10.3.1)

Please refer to core assessment.

9.1.1.5 Effects on arthropods other than bees (KCP 10.3.2)

Please refer to core assessment.

9.1.1.6 Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil

microbial activity (KCP 10.5)

Soil meso- and macrofauna

Please refer to core assessment.

Soil micro-organisms

Please refer to core assessment.

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

The risk of A12916B to non-target terrestrial plants was assessed from toxicity exposure ratios (TERs) using the formulation toxicity data from a screening study and the maximum off-field predicted environmental residues (PERs). The risk to non-target terrestrial plants in off-crop areas is acceptable following use of A12916B according to the proposed use pattern.

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

Please refer to core assessment.

9.1.2 Grouping of intended uses for risk assessment

Table 9.1-2: Critical use pattern of A12916B grouped according to crop group

Grouping according to criterion			
Group	Intended uses	Relevant use parameters for grouping	Relevant parameter or value for sorting
1	Cereals	Winter cereals BBCH 30-69 Application rate: 1 x 1.5 L A12916B/ha - 140 g azoxystrobin/ha - 750 g folpet/ha	Relevant parameter for all areas of the risk assessment
		Spring cereals BBCH 30-69 Application rate: 1 x 1.5 L A12916B/ha - 140 g azoxystrobin/ha - 750 g folpet/ha	

9.1.3 Consideration of metabolites

Please refer to core assessment.

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Please refer to core assessment.

9.2.1.1 Justification for new endpoints

Please refer to core assessment.

9.2.2 Risk assessment for spray applications

Please refer to core assessment.

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

Please refer to core assessment.

9.2.2.2 Higher-tier risk assessment

Please refer to core assessment.

9.2.2.3 Drinking water exposure

Please refer to core assessment.

9.2.2.4 Effects of secondary poisoning

Please refer to core assessment.

9.2.2.5 Biomagnification in terrestrial food chains

Please refer to core assessment.

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

Please refer to core assessment.

9.2.4 Overall conclusions

Please refer to core assessment.

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

9.3.1 Toxicity data

Please refer to core assessment.

9.3.1.1 Justification for new endpoints

Please refer to core assessment.

9.3.2 Risk assessment for spray applications

Please refer to core assessment.

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

Please refer to core assessment.

9.3.2.2 Higher-tier risk assessment

Please refer to core assessment.

9.3.2.3 Drinking water exposure

Please refer to core assessment.

9.3.2.4 Effects of secondary poisoning

Please refer to core assessment.

9.3.2.5 Biomagnification in terrestrial food chains

Please refer to core assessment.

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

Please refer to core assessment.

9.3.4 Overall conclusions

Please refer to core assessment.

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

Please refer to core assessment.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Please refer to core assessment.

9.5.1.1 Justification for new endpoints

Please refer to core assessment.

9.5.2 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 and 2 PEC_{SW} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios for active substances and their metabolites are presented in the Core Assessment. No further calculations for active substances and their metabolites at Step 1 and 2 are required.

The global maximum FOCUS Step 3 and 4 PEC_{SW} for scenarios D3, D4 and R1 that are relevant for Poland and PEC/RAC ratios are presented in the tables below. Step 4 modelling was performed with exposure mitigation options: buffer strips (D scenarios), vegetated buffer strips VFSmod (R scenarios) and spray-drift reducing nozzles. The regulatory acceptable concentrations (RAC) for aquatic organisms used for risk assessment have been agreed and accepted in the Core Assessment.

The mixture toxicity assessment included in the Core Assessment full covers the risk arising from the application of A12916B in winter and spring cereals. No further risk assessment is needed.

Azoxystrobin

Table 9.5-1: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on the maximum FOCUS Step 3 calculations for the use of A12916B on winter cereals

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Aquatic mac- rophyte	Sed. dwell. prolonged		Sed. dwell. pro- longed
RAC (µg/L)		4.7	14.7	0.55	0.954	6.3	320	80		2 300 µg/kg
FOCUS Scenario	PEC _{gl-max} (µg/L)								PEC _{gl-max} (µg/kg)	
Step 3 – winter cereals – Option 1										
D3 Ditch	0.8863	0.19	0.06	1.61	0.93	0.14	0.00	0.01	0.4184	0.00
D4 Pond	0.2486	0.05	0.02	0.45	0.26	0.04	0.00	0.00	1.660	0.00
D4 Stream	0.6563	0.14	0.04	1.19	0.69	0.10	0.00	0.01	0.6244	0.00
R1 Pond	0.1001	0.02	0.01	0.18	0.10	0.02	0.00	0.00	0.09943	0.00
R1 Stream	0.9054	0.19	0.06	1.65	0.95	0.14	0.00	0.01	0.4283	0.00
Step 3 – winter cereals – Option 2										
D3 Ditch	0.8863	0.19	0.06	1.61	0.93	0.14	0.00	0.01	0.4185	0.00
D4 Pond	0.2461	0.05	0.02	0.45	0.26	0.04	0.00	0.00	1.676	0.00
D4 Stream	0.6563	0.14	0.04	1.19	0.69	0.10	0.00	0.01	0.6293	0.00
R1 Pond	0.09682	0.02	0.01	0.18	0.10	0.02	0.00	0.00	0.6125	0.00
R1 Stream	0.9054	0.19	0.06	1.65	0.95	0.14	0.00	0.01	0.4293	0.00

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

For winter cereals, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (acute toxicity to invertebrates) in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies.

Table 9.5-2: Aquatic organisms: higher-tier risk assessment for acceptability of risk (PEC/RAC < 1) for azoxystrobin incorporating exposure mitigation options for the use of A12916B on winter cereals

Intended use		winter cereals					
Active substance		azoxystrobin					
Application rate (g/ha)		1 × 140					
		Option 1			Option 2		
Nozzle reduction	Vegetative strip (m)	5 VFSmod	10 VFSmod	20 VFSmod	5 VFSmod	10 VFSmod	20 VFSmod
	No spray buffer (m)	5	10	20	5	10	20
None	D3 Ditch	0.2403	0.1274	0.06618	0.2403	0.1274	0.06618
50 %		0.1201	0.06371	0.03310	0.1201	0.06371	0.03310
75 %		0.06007	0.03185	0.01654	0.06007	0.03185	0.01654
90 %		0.02402	0.01274	0.006615	0.02402	0.01274	0.006615
None	D4 Pond	0.2481	0.2473	0.2465	0.2457	0.2449	0.2443
50 %		0.2466	0.2461	0.2457	0.2443	0.2439	0.2436
75 %		0.2458	0.2455	0.2453	0.2436	0.2434	0.2433
90 %		0.2453	0.2452	0.2451	0.2432	0.2432	0.2431
None	D4 Stream	0.2770	0.2770	0.2770	0.2770	0.2770	0.2770
50 %		0.2770	0.2770	0.2770	0.2770	0.2770	0.2770
75 %		0.2770	0.2770	0.2770	0.2770	0.2770	0.2770
90 %		0.2770	0.2770	0.2770	0.2770	0.2770	0.2770
None	R1 Pond	0.02645	0.01902	0.01270	0.02645	0.01902	0.01270
50 %		0.01364	0.009507	0.006348	0.01323	0.009507	0.006348
75 %		0.01018	0.004753	0.003173	0.009854	0.004753	0.003173
90 %		0.008123	0.001901	0.001269	0.007917	0.001901	0.001269
None	R1 Stream	0.2133	0.1131	0.05878	0.2133	0.1131	0.05878

50 %		0.1066	0.05654	0.02937	0.1066	0.05654	0.02937
75 %		0.05331	0.02828	0.01469	0.05331	0.02828	0.01469
90 %		0.05126	0.01131	0.005875	0.05126	0.01131	0.005875
RAC (µg/L)							
0.55		PEC/RAC ratio					
None	D3 Ditch	0.437	0.232	0.120	0.437	0.232	0.120
50 %		0.218	0.116	0.060	0.218	0.116	0.060
75 %		0.109	0.058	0.030	0.109	0.058	0.030
90 %		0.044	0.023	0.012	0.044	0.023	0.012
None	D4 Pond	0.451	0.450	0.448	0.447	0.445	0.444
50 %		0.448	0.447	0.447	0.444	0.443	0.443
75 %		0.447	0.446	0.446	0.443	0.443	0.442
90 %		0.446	0.446	0.446	0.442	0.442	0.442
None	D4 Stream	0.504	0.504	0.504	0.504	0.504	0.504
50 %		0.504	0.504	0.504	0.504	0.504	0.504
75 %		0.504	0.504	0.504	0.504	0.504	0.504
90 %		0.504	0.504	0.504	0.504	0.504	0.504
None	R1 Pond	0.048	0.035	0.023	0.048	0.035	0.023
50 %		0.025	0.017	0.012	0.024	0.017	0.012
75 %		0.019	0.009	0.006	0.018	0.009	0.006
90 %		0.015	0.003	0.002	0.014	0.003	0.002
None	R1 Stream	0.388	0.206	0.107	0.388	0.206	0.107
50 %		0.194	0.103	0.053	0.194	0.103	0.053
75 %		0.097	0.051	0.027	0.097	0.051	0.027
90 %		0.093	0.021	0.011	0.093	0.021	0.011

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

Table 9.5-3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for azoxystrobin for each organism group based on the maximum FOCUS Step 3 calculations for the use of A12916B on spring cereals

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae	Aquatic mac- rophyte	Sed. dwell. prolonged		Sed. dwell. pro- longed
RAC (µg/L)		4.7	14.7	0.55	0.954	6.3	320	80		2 300 µg/kg
FOCUS Scenario	PEC _{gl-max} (µg/L)								PEC _{gl-max} (µg/kg)	
Step 3 – spring cereals – Option 1										
D3 Ditch	0.8873	0.19	0.06	1.61	0.93	0.14	0.00	0.01	0.4501	0.00
D4 Pond	0.2887	0.06	0.02	0.52	0.30	0.05	0.00	0.00	1.921	0.00
D4 Stream	0.7259	0.15	0.05	1.32	0.76	0.12	0.00	0.01	0.7152	0.00
R1 ^a Pond	0.2852	0.06	0.02	0.52	0.30	0.05	0.00	0.00	1.491	0.00
R1 ^a Stream	1.661	0.35	0.11	3.02	1.74	0.26	0.01	0.02	1.496	0.00
Step 3 – spring cereals – Option 2										
D3 Ditch	0.8873	0.19	0.06	1.61	0.93	0.14	0.00	0.01	0.4502	0.00
D4 Pond	0.2854	0.06	0.02	0.52	0.30	0.05	0.00	0.00	1.937	0.00
D4 Stream	0.7259	0.15	0.05	1.32	0.76	0.12	0.00	0.01	0.7249	0.00
R1 ^a Pond	0.2789	0.06	0.02	0.51	0.29	0.04	0.00	0.00	1.470	0.00
R1 ^a Stream	1.661	0.35	0.11	3.02	1.74	0.26	0.01	0.02	1.497	0.00

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; ^a worst-case spring cereals, ^b D4 Pond spring cereals worst case

^amaize as a surrogate scenario

For spring cereals, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (acute and chronic toxicity to invertebrates) in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies.

Table 9.5-4: Aquatic organisms: higher-tier risk assessment for acceptability of risk (PEC/RAC < 1) for azoxystrobin incorporating exposure mitigation options for the use of A12916B on spring cereals

Intended use		spring cereals					
Active substance		azoxystrobin					
Application rate (g/ha)		1 × 140					
		Option 1			Option 2		
Nozzle reduction	Vegetative strip (m)	5 VFSmod	10 VFSmod	20 VFSmod	5 VFSmod	10 VFSmod	20 VFSmod
	No spray buffer (m)	5	10	20	5	10	20
None	D3 Ditch	0.2405	0.1275	0.06625	0.2405	0.1275	0.06625
50 %		0.1202	0.06378	0.03314	0.1202	0.06378	0.03314
75 %		0.06013	0.03188	0.01656	0.06013	0.03188	0.01656
90 %		0.02404	0.01275	0.006622	0.02404	0.01275	0.006622
None	D4 Pond	0.2880	0.2867	0.2856	0.2848	0.2838	0.2828
50 %		0.2857	0.2850	0.2845	0.2829	0.2824	0.2819
75 %		0.2845	0.2842	0.2839	0.2819	0.2817	0.2814
90 %		0.2839	0.2837	0.2836	0.2813	0.2812	0.2811
None	D4 Stream	0.3233	0.3233	0.3233	0.3233	0.3233	0.3233
50 %		0.3233	0.3233	0.3233	0.3233	0.3233	0.3233
75 %		0.3233	0.3233	0.3233	0.3233	0.3233	0.3233
90 %		0.3233	0.3233	0.3233	0.3233	0.3233	0.3233
None	R1 ^a Pond	0.06787	0.02961	0.01270	0.06820	0.03557	0.01270
50 %		0.05928	0.02342	0.006348	0.05807	0.02307	0.006348
75 %		0.05499	0.02035	0.003174	0.05398	0.02014	0.003174
90 %		0.05242	0.01852	0.001269	0.05154	0.01840	0.001269
None	R1 ^a Stream	0.2841	0.1136	0.05904	0.5091	0.5091	0.05904

50 %		0.2841	0.08395	0.02951	0.2841	0.08395	0.02951
75 %		0.2841	0.08395	0.01475	0.2841	0.08395	0.01475
90 %		0.2841	0.08395	0.005902	0.2841	0.08395	0.005902
RAC (µg/L)							
0.55		PEC/RAC ratio					
None	D3 Ditch	0.437	0.232	0.120	0.437	0.232	0.120
50 %		0.219	0.116	0.060	0.219	0.116	0.060
75 %		0.109	0.058	0.030	0.109	0.058	0.030
90 %		0.044	0.023	0.012	0.044	0.023	0.012
None	D4 Pond	0.524	0.521	0.519	0.518	0.516	0.514
50 %		0.519	0.518	0.517	0.514	0.513	0.513
75 %		0.517	0.517	0.516	0.513	0.512	0.512
90 %		0.516	0.516	0.516	0.511	0.511	0.511
None	D4 Stream	0.588	0.588	0.588	0.588	0.588	0.588
50 %		0.588	0.588	0.588	0.588	0.588	0.588
75 %		0.588	0.588	0.588	0.588	0.588	0.588
90 %		0.588	0.588	0.588	0.588	0.588	0.588
None	R1 ^a Pond	0.123	0.054	0.023	0.124	0.065	0.023
50 %		0.108	0.043	0.012	0.106	0.042	0.012
75 %		0.100	0.037	0.006	0.098	0.037	0.006
90 %		0.095	0.034	0.002	0.094	0.033	0.002
None	R1 ^a Stream	0.517	0.207	0.107	0.926	0.926	0.107
50 %		0.517	0.153	0.054	0.517	0.153	0.054
75 %		0.517	0.153	0.027	0.517	0.153	0.027
90 %		0.517	0.153	0.011	0.517	0.153	0.011

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
^amaize as a surrogate scenario

Folpet

Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for folpet for each organism group based on FOCUS Step 3 calculations for the use of A12916B on winter cereals

Group		Fish acute (Tier 2a, flow through)	Fish chronic (Tier 1, flow through)	Inverteb. acute	Algae
RAC (µg/L)		0.36	0.881	5	> 1 000
FOCUS Scenario	PEC _{gl-max} (µg/L) ^a				
Step 3 – winter cereals – Option 1					
D3 Ditch	4.751	13.20	5.39	0.95	0.00
D4 Pond	0.1639	0.46	0.19	0.03	0.00
D4 Stream	3.509	9.75	3.98	0.70	0.00
R1 Pond	0.1640	0.46	0.19	0.03	0.00
R1 Stream	3.130	8.69	3.55	0.63	0.00
Step 3 – winter cereals – Option 2					
D3 Ditch	4.751	13.20	5.39	0.95	0.00
D4 Pond	0.1639	0.46	0.19	0.03	0.00
D4 Stream	3.509	9.75	3.98	0.70	0.00
R1 Pond	0.1640	0.46	0.19	0.03	0.00
R1 Stream	3.130	8.69	3.55	0.63	0.00

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

For winter cereals, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (acute and chronic toxicity to fishes) in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies.

Table 9.5-6: Aquatic organisms: higher-tier risk assessment for acceptability of risk (PEC/RAC < 1) for folpet incorporating exposure mitigation options for the use of A12916B on winter cereals

Intended use		winter cereals					
Active substance		folpet					
Application rate (g/ha)		1 × 750					
		Option 1			Option 2		
Nozzle reduction	Vegetative strip (m)	5 VFSmod	10 VFSmod	20 VFSmod	5 VFSmod	10 VFSmod	20 VFSmod
	No spray buffer (m)	5	10	20	5	10	20
None	D3 Ditch	1.288	0.6831	0.3550	1.288	0.6831	0.3550
50 %		0.6440	0.3415	0.1775	0.6440	0.3415	0.1775
75 %		0.3220	0.1708	0.08872	0.3220	0.1708	0.08872
90 %		0.1288	0.06831	0.03550	0.1288	0.06831	0.03550
None	D4 Pond	0.1419	0.1020	0.06809	0.1419	0.1020	0.06809
50 %		0.07091	0.05099	0.03404	0.07091	0.05099	0.03404
75 %		0.03546	0.02549	0.01702	0.03546	0.02549	0.01702
90 %		0.01419	0.01020	0.006809	0.01419	0.01020	0.006809
None	D4 Stream	1.282	0.6800	0.3534	1.282	0.6800	0.3534
50 %		0.6410	0.3400	0.1766	0.6410	0.3400	0.1766
75 %		0.3204	0.1700	0.08832	0.3204	0.1700	0.08832
90 %		0.1282	0.06800	0.03534	0.1282	0.06800	0.03534
None	R1 Pond	0.1419	0.1020	0.06810	0.1419	0.1020	0.06810
50 %		0.07093	0.05100	0.03405	0.07093	0.05100	0.03405
75 %		0.03546	0.02550	0.01702	0.03546	0.02550	0.01702
90 %		0.01419	0.01020	0.006810	0.01419	0.01020	0.006810
None	R1 Stream	1.144	0.6066	0.3152	1.144	0.6066	0.3152

50 %		0.5718	0.3033	0.1576	0.5718	0.3033	0.1576
75 %		0.2858	0.1516	0.07878	0.2858	0.1516	0.07878
90 %		0.1144	0.06066	0.03152	0.1144	0.06066	0.03152
RAC (µg/L)							
0.36		PEC/RAC ratio					
None	D3 Ditch	3.578	1.898	0.986	3.578	1.898	0.986
50 %		1.789	0.949	0.493	1.789	0.949	0.493
75 %		0.894	0.474	0.246	0.894	0.474	0.246
90 %		0.358	0.190	0.099	0.358	0.190	0.099
None	D4 Pond	0.394	0.283	0.189	0.394	0.283	0.189
50 %		0.197	0.142	0.095	0.197	0.142	0.095
75 %		0.099	0.071	0.047	0.099	0.071	0.047
90 %		0.039	0.028	0.019	0.039	0.028	0.019
None	D4 Stream	3.561	1.889	0.982	3.561	1.889	0.982
50 %		1.781	0.944	0.491	1.781	0.944	0.491
75 %		0.890	0.472	0.245	0.89	0.472	0.245
90 %		0.356	0.189	0.098	0.356	0.189	0.098
None	R1 Pond	0.394	0.283	0.189	0.394	0.283	0.189
50 %		0.197	0.142	0.095	0.197	0.142	0.095
75 %		0.099	0.071	0.047	0.099	0.071	0.047
90 %		0.039	0.028	0.019	0.039	0.028	0.019
None	R1 Stream	3.178	1.685	0.876	3.178	1.685	0.876
50 %		1.588	0.843	0.438	1.588	0.843	0.438
75 %		0.794	0.421	0.219	0.794	0.421	0.219
90 %		0.318	0.169	0.088	0.318	0.169	0.088

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

Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for folpet for each organism group based on FOCUS Step 3 calculations for the use of A12916B on spring cereals

Group		Fish acute (Tier 2a, flow through)	Fish chronic (Tier 1, flow through)	Inverteb. acute	Algae
RAC (µg/L)		0.36	0.881	5	> 1 000
FOCUS Scenario	PEC _{gl-max} (µg/L)				
Step 3 – spring cereals – Option 1					
D3 Ditch	4.756	13.21	5.40	0.95	0.00
D4 Pond	0.1640	0.46	0.19	0.03	0.00
D4 Stream	3.888	10.80	4.41	0.78	0.00
R1 ^a Pond	0.5234	1.45	0.59	0.10	0.00
R1 ^a Stream	3.547	9.85	4.03	0.71	0.00
Step 3 – spring cereals – Option 2					
D3 Ditch	4.756	13.21	5.40	0.95	0.00
D4 Pond	0.1640	0.46	0.19	0.03	0.00
D4 Stream	3.888	10.80	4.41	0.78	0.00
R1 ^a Pond	0.1588	0.44	0.18	0.03	0.00
R1 ^a Stream	2.741	7.61	3.11	0.55	0.00

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

^amaize as a surrogate scenario

For spring cereals, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (acute and chronic toxicity to fishes) in several FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies.

Table 9.5-8: Aquatic organisms: higher-tier risk assessment for acceptability of risk (PEC/RAC < 1) for folpet incorporating exposure mitigation options for the use of A12916B on spring cereals

Intended use		spring cereals					
Active substance		folpet					
Application rate (g/ha)		1 × 750					
		Option 1			Option 2		
Nozzle reduction	Vegetative strip (m)	5 VFSmod	10 VFSmod	20 VFSmod	5 VFSmod	10 VFSmod	20 VFSmod
	No spray buffer (m)	5	10	20	5	10	20
None	D3 Ditch	1.289	0.6838	0.3554	1.289	0.6838	0.3554
50 %		0.6447	0.3419	0.1777	0.6447	0.3419	0.1777
75 %		0.3224	0.1710	0.08882	0.3224	0.1710	0.08882
90 %		0.1289	0.06838	0.03554	0.1289	0.06838	0.03554
None	D4 Pond	0.1420	0.1020	0.06813	0.1420	0.1020	0.06813
50 %		0.07096	0.05102	0.03406	0.07096	0.05102	0.03406
75 %		0.03548	0.02551	0.01703	0.03548	0.02551	0.01703
90 %		0.01420	0.01020	0.006813	0.01420	0.01020	0.006813
None	D4 Stream	1.421	0.7535	0.3916	1.421	0.7535	0.3916
50 %		0.7103	0.3768	0.1957	0.7103	0.3768	0.1957
75 %		0.3550	0.1883	0.09786	0.3550	0.1883	0.09786
90 %		0.1421	0.07535	0.03916	0.1421	0.07535	0.03916
None	R1 ^a Pond	0.1704	0.1020	0.06811	0.1419	0.1020	0.06811
50 %		0.1185	0.05101	0.03405	0.07094	0.05101	0.03405
75 %		0.09255	0.02571	0.01703	0.03547	0.02550	0.01703
90 %		0.07699	0.01444	0.006811	0.01419	0.01020	0.006811
None	R1 ^a Stream	1.149	0.6093	0.3166	1.149	0.6093	0.3166

50 %		0.6306	0.3047	0.1583	0.5744	0.3047	0.1583
75 %		0.6306	0.1523	0.07914	0.4795	0.1523	0.07914
90 %		0.6306	0.07011	0.03166	0.4795	0.06093	0.03166
RAC (µg/L)							
0.36		PEC/RAC ratio					
None	D3 Ditch	3.581	1.899	0.987	3.581	1.899	0.987
50 %		1.791	0.950	0.494	1.791	0.950	0.494
75 %		0.896	0.475	0.247	0.896	0.475	0.247
90 %		0.358	0.190	0.099	0.358	0.190	0.099
None	D4 Pond	0.394	0.283	0.189	0.394	0.283	0.189
50 %		0.197	0.142	0.095	0.197	0.142	0.095
75 %		0.099	0.071	0.047	0.099	0.071	0.047
90 %		0.039	0.028	0.019	0.039	0.028	0.019
None	D4 Stream	3.947	2.093	1.088	3.947	2.093	1.088
50 %		1.973	1.047	0.544	1.973	1.047	0.544
75 %		0.986	0.523	0.272	0.986	0.523	0.272
90 %		0.395	0.209	0.109	0.395	0.209	0.109
None	R1 ^a Pond	0.473	0.283	0.189	0.394	0.283	0.189
50 %		0.329	0.142	0.095	0.197	0.142	0.095
75 %		0.257	0.071	0.047	0.099	0.071	0.047
90 %		0.214	0.040	0.019	0.039	0.028	0.019
None	R1 ^a Stream	3.192	1.693	0.879	3.192	1.693	0.879
50 %		1.752	0.846	0.440	1.596	0.846	0.440
75 %		1.752	0.423	0.220	1.332	0.423	0.220
90 %		1.752	0.195	0.088	1.332	0.169	0.088

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
^amaize as a surrogate scenario

9.5.3 Overall conclusions

The PEC/RAC ratios calculated for scenarios D3, D4 and R1 characteristic for Poland, using worst-case PEC_{sw} values for azoxystrobin and folpet are less than the trigger value of 1, indicating that the risk to aquatic organisms is acceptable following the proposed mitigation:

winter cereals:

- 5m vegetated buffer zone + 75% drift reduction OR
- 10m vegetated buffer zone + 50% drift reduction OR
- 20m vegetated buffer zone;

spring cereals:

- 10m vegetated buffer zone + 75% drift reduction OR
- 20m vegetated buffer zone + 50% drift reduction.

Review Comments:

A12916B

The risk assessment for A12916B was accepted in the Core dossier and the PEC/RAC ratio is below 1 when **10 m buffer zone** is applied. No further risk assessment is needed.

The mixture toxicity assessment included in the Core Assessment full covers the risk arising from the application of A12916B in winter and spring cereals. Based on the RQ_{mix} calculation and taking into account the scenarios relevant for Poland, **20 m buffer zone and 20 m vegetated buffer zone** is required. No further risk assessment is needed.

Metabolites of active substances

The risk assessment for metabolites was accepted in the Core dossier without risk mitigation measures. No further risk assessment is needed.

Azoxystrobin

The risk assessment was based on the endpoints accepted in the Core dossier and the PEC_{sw} values assessed and accepted in the National Addendum Part B8 for Poland.

All PEC/RAC ratios, for winter and spring cereals are below 1 in all FOCUS Step 4 scenarios (relevant for Poland D3, D4 and R1) when **5 m buffer zone and 5 m vegetated buffer zone** is applied.

Folpet

The risk assessment was based on the endpoints accepted in the Core dossier and the PEC_{sw} values assessed and accepted in the National Addendum Part B8 for Poland.

All PEC/RAC ratios for winter cereals are below 1 in all FOCUS Step 4 scenarios (relevant for Poland D3, D4 and R1) when

- **20 m buffer zone and 20 m vegetated buffer zone** or
- **10 m buffer zone and 10 m vegetated buffer zone and 50 % nozzle reduction** or
- **5 m buffer zone and 5 m vegetated buffer zone and 75% nozzle reduction** is applied.

All PEC/RAC ratios for spring cereals are below 1 in all FOCUS Step 4 scenarios (relevant for Poland D3, D4 and R1) when

- **20 m buffer zone and 20 m vegetated buffer zone and 50% nozzle reduction** or
- **10 m buffer zone and 10 m vegetated buffer zone and 75 % nozzle reduction** is applied.

Conclusion

According to the performed risk assessment there is no potential of risk for aquatic organisms resulting

from acute and long-term exposure to active substances following use of A12916B in compliance with proposed GAP when the risk mitigation measures were applied:

for the intended use in winter cereals

- 20m vegetated buffer zone;

for the intended use in spring cereals

- 20m vegetated buffer zone + 50% drift reduction.

9.6 Effects on bees (KCP 10.3.1)

9.6.1 Toxicity data

Please refer to core assessment.

9.6.1.1 Justification for new endpoints

Please refer to core assessment.

9.6.2 Risk assessment

Please refer to core assessment.

9.6.2.1 Hazard quotients for bees

Please refer to core assessment.

9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

Please refer to core assessment.

9.6.3 Effects on bumble bees

Please refer to core assessment.

9.6.4 Effects on solitary bees

Please refer to core assessment.

9.6.5 Overall conclusions

Please refer to core assessment.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

Please refer to core assessment.

9.7.1.1 Justification for new endpoints

Please refer to core assessment.

9.7.2 Risk assessment

Please refer to core assessment.

9.7.2.1 Risk assessment for in-field exposure

Please refer to core assessment.

9.7.2.2 Risk assessment for off-field exposure

Please refer to core assessment.

9.7.2.3 Additional higher-tier risk assessment

Please refer to core assessment.

9.7.2.4 Risk mitigation measures

Please refer to core assessment.

9.7.3 Overall conclusions

Please refer to core assessment.

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

9.8.1 Toxicity data

Please refer to core assessment.

9.8.1.1 Justification for new endpoints

Please refer to core assessment.

9.8.2 Risk assessment

Please refer to core assessment.

9.8.2.1 First-tier risk assessment

Please refer to core assessment.

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

Please refer to core assessment.

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

Please refer to core assessment.

9.9.1.1 Justification for new endpoints

Please refer to core assessment.

9.9.2 Risk assessment

Please refer to core assessment.

9.9.3 Overall conclusions

Please refer to core assessment.

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

9.10.1 Toxicity data

Please refer to core assessment.

9.10.1.1 Justification for new endpoints

Please refer to core assessment.

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

The risk assessment for use in cereals is conducted based on the maximum use rate of 1 x 1500 mL A12916B/ha.

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.

Table 9.10-1: Assessment of the risk for non-target plants due to the use of A12916B in cereals

Intended use		cereals		
Active substance/product		A12916B		
Application rate (ml/ha)		1 × 1500		
MAF		1		
Test species	ER₅₀ (ml/ha)	Drift rate (%)	PER_{off-field} (ml/ha)	TER criterion: TER ≥ 5

<i>Allium cepa</i> m <i>Avena fatua</i> m <i>Glycine max</i> d <i>Beta vulgaris</i> d <i>Brassica napus</i> d <i>Cucumis sativus</i> d	> 3200	2.77	41.55	>77.02
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MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

m: monocotyledonous; d: dicotyledonous

9.10.2.2 Tier-2 risk assessment (based on dose-response data)

Not relevant.

9.10.2.3 Higher-tier risk assessment

Not relevant.

9.10.2.4 Risk mitigation measures

No risk mitigation needed. Overall conclusions

The risk of A12916B to non-target terrestrial plants was assessed from toxicity exposure ratios (TERs) using the formulation toxicity data from a screening study and the maximum off-field predicted environmental residues (PERs). The risk to non-target terrestrial plants in off-crop areas is acceptable following use of A12916B according to the proposed use pattern.

Review Comments:

The risk assessment was performed based on the endpoint for formulation accepted in the Core dossier and the maximum application rate.

The TER value is above the trigger value of 5.

Conclusion

No unacceptable risk to non-target terrestrial plants is expected following the application of A12916B according to the proposed use pattern.

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

Please refer to core assessment.

9.12 Monitoring data (KCP 10.8)

Please refer to core assessment.

9.13 Classification and Labelling

Please refer to core assessment.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on – A12916B (KCP)

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
-	-	-	-	-	-

List of data submitted by the applicant and relied on – Azoxystrobin (KCA1)

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
-	-	-	-	-	-

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
-	-	-	-	-	-

Syngenta is not the notifier for approval of the active substance folpet and appropriate letters of access are included in this submission. Syngenta reached agreement with the data owner to access the studies necessary for this evaluation. Please, refer to the Data owner for further details.

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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

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

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 10.3.1.1.1	Acute oral toxicity to bees
A 2.3.1.1.2	KCP 10.3.1.1.2	Acute contact toxicity to bees
A 2.3.1.2	KCP 10.3.1.2.	Chronic toxicity to bees
A 2.3.1.3	KCP 10.3.1.3	Effects on honey bee development and other honey bee life stages
A 2.3.1.4	KCP 10.3.1.4	Sub-lethal effects
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 2.3.2	KCP 10.3.2	Effects on non-target arthropods other than bees
A 2.3.2.1	KCP 10.3.2.1	Standard laboratory testing for non-target arthropods
A 2.3.2.2	KCP 10.3.2.2	Extended laboratory testing, aged residue studies with non-target arthropods
A 2.3.2.3	KCP 10.3.2.3	Semi-field studies with non-target arthropods
A 2.3.2.4	KCP 10.3.2.4	Field studies with non-target arthropods
A 2.3.2.5	KCP 10.3.2.5	Other routes of exposure for non-target arthropods
A 2.4	KCP 10.4	Effects on non-target soil meso- and macrofauna
A 2.4.1	KCP 10.4.1	Earthworms
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
A 2.4.2	KCP 10.4.2	Effects on non-target soil meso- and macrofauna (other than earthworms)
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
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
A 2.6.3	KCP 10.6.3	Extended laboratory studies on non-target plants
A 2.6.4	KCP 10.6.4	Semi-field and field tests 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