

FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: SHA 7273 A

Product name(s): CASINO ROYALE

Chemical active substances:

Boscalid, 267 g/kg

Pyraclostrobin, 67 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: August 2020

MS Finalisation date: August 2021; January 2022

Version history

When	What
August 2021	Finalisation of the assessment by zRMS
September 2021	Applicant update
November 2021	Applicant update
January 2022	Final version after Commenting period

Table of Contents

9	Ecotoxicology (KCP 10).....	6
9.1	Critical GAP and overall conclusions.....	6
9.1.1.1	Overall conclusionsTable Critical GAP and overall conclusions-3 Metabolites of Pyraclostrobin, Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)	15
9.1.1.2	Effects on aquatic organisms (KCP 10.2).....	16
9.1.1.3	Effects on bees (KCP 10.3.1).....	17
9.1.1.4	Effects on arthropods other than bees (KCP 10.3.2)	18
9.1.1.5	Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)	18
9.1.1.6	Effects on non-target terrestrial plants (KCP 10.6)	18
9.1.1.7	Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)	18
9.1.2	Grouping of intended uses for risk assessment.....	18
9.1.3	Consideration of metabolites	19
9.2	Effects on birds (KCP 10.1.1).....	21
9.2.1	Toxicity data	21
9.2.1.1	Justification for new endpoints	22
9.2.2	Risk assessment for spray applications.....	22
9.2.2.1	First-tier assessment (screening/generic focal species)	23
9.2.2.2	Higher-tier risk assessment	35
9.2.2.3	Drinking water exposure.....	47
9.2.2.4	Effects of secondary poisoning.....	48
9.2.2.5	Biomagnification in terrestrial food chains.....	50
9.2.3	Risk assessment for baits, pellets, granules, pills or treated seed	50
9.2.4	Overall conclusions.....	50
9.3	Effects on terrestrial vertebrates other than birds (KCP 10.1.2).....	51
9.3.1	Toxicity data	51
9.3.1.1	Justification for new endpoints	51
9.3.2	Risk assessment for spray applications.....	51
9.3.2.1	First-tier assessment (screening/generic focal species)	52
9.3.2.2	Higher-tier risk assessment	71
9.3.2.3	Drinking water exposure.....	90
9.3.2.4	Effects of secondary poisoning.....	92
9.3.2.5	Biomagnification in terrestrial food chains.....	94
9.3.3	Risk assessment for baits, pellets, granules, pills or treated seed	94
9.3.4	Overall conclusions.....	94
9.4	Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)	95
9.5	Effects on aquatic organisms (KCP 10.2).....	95
9.5.1	Toxicity data	95
9.5.1.1	Justification for new endpoints	98
9.5.2	Risk assessment	98
9.5.3	Overall conclusions.....	177
9.6	Effects on bees (KCP 10.3.1).....	180
9.6.1	Toxicity data	180

9.6.1.1	Justification for new endpoints	181
9.6.2	Risk assessment	181
9.6.2.1	Hazard quotients for bees.....	182
9.6.2.2	Higher-tier risk assessment for bees (tunnel test, field studies).....	182
9.6.3	Effects on bumble bees	183
9.6.4	Effects on solitary bees	183
9.6.5	Overall conclusions.....	183
9.7	Effects on arthropods other than bees (KCP 10.3.2)	183
9.7.1	Toxicity data	183
9.7.1.1	Justification for new endpoints	185
9.7.2	Risk assessment	185
9.7.2.1	Risk assessment for in-field exposure.....	186
9.7.2.2	Risk assessment for off-field exposure	186
9.7.2.3	Additional higher-tier risk assessment.....	189
9.7.2.4	Risk mitigation measures	189
9.7.3	Overall conclusions.....	189
9.8	Effects on non-target soil meso- and macrofauna (KCP 10.4)	189
9.8.1	Toxicity data	189
9.8.1.1	Justification for new endpoints	191
9.8.2	Risk assessment	191
9.8.2.1	First-tier risk assessment.....	191
9.8.2.2	Higher-tier risk assessment.....	193
9.8.3	Overall conclusions.....	194
9.9	Effects on soil microbial activity (KCP 10.5).....	194
9.9.1	Toxicity data	194
9.9.1.1	Justification for new endpoints	196
9.9.2	Risk assessment	197
9.9.3	Overall conclusions.....	198
9.10	Effects on non-target terrestrial plants (KCP 10.6)	198
9.10.1	Toxicity data	198
9.10.1.1	Justification for new endpoints	199
9.10.2	Risk assessment	199
9.10.2.1	Tier-1 risk assessment (based screening data)	199
9.10.2.2	Tier-2 risk assessment (based on dose-response data).....	199
9.10.2.3	Higher-tier risk assessment.....	205
9.10.2.4	Risk mitigation measures	205
9.10.3	Overall conclusions.....	205
9.11	Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)	205
9.12	Monitoring data (KCP 10.8)	205
9.13	Classification and Labelling	205
A 2.1.1	KCP 10.1.1 Effects on birds	212
A 2.1.2	KCP 10.1.2 Effects on terrestrial vertebrates other than birds	219
A 2.1.3	KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians).....	219
A 2.2.1	KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes	220
A 2.2.2	KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms.....	231

A 2.2.3	KCP 10.2.3 Further testing on aquatic organisms	231
A 2.3.1	KCP 10.3.1 Effects on bees	231
A 2.3.2	KCP 10.3.2 Effects on non-target arthropods other than bees.....	247
A 2.4.1	KCP 10.4.1 Earthworms	254
A 2.4.2	KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)	257
A 2.8.1	KCP 10.6.2 Testing on non-target plants.....	269
A 2.8.2	KCP 10.6.3 Extended laboratory studies on non-target plants	275

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, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha	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	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
1	CEU	Sugarbeet	F	Cercospora beticola	Foliar Spray	BBCH 31-39	a) 1-2 b) 1-2	8-10	a) 1.5 b) 3.0	a) 0.4 bos-calid + 0.1 pyraclostrobin b) 0.8 bos-calid + 0.2 pyraclostrobin	300-600	14								
2	CEU	Tomato	F	Phytophthora infestans,	Foliar Spray	When first symptoms are visible BBCH 20-87	a) 1-2 b) 1-2	8-10	a) 1.5 b) 3.0	a) 0.4 bos-calid + 0.1 pyraclostrobin b) 0.8 bos-calid + 0.2 pyraclostrobin	300-600	3								
3	CEU	Tomato	F	Alternaria sp.	Foliar Spray	When first symptoms are visible BBCH 20-87	a) 1-3 b) 1-3	8-10	a) 1.5 b) 4.5	a) 0.4 bos-calid + 0.1 pyraclostrobin b) 1.2 bos-calid + 0.3 pyraclostrobin	300-600	3								
4	CEU	Carrot	F	Septoria apiicola, Cercospora sp, Alternaria sp.	Foliar Spray	When first symptoms are visible BBCH 41-49	a) 1-2 b) 1-2	8-10	a) 1.5 b) 3.0	a) 0.4 bos-calid + 0.1 pyraclostrobin b) 0.8 bos-calid + 0.2 pyraclostrobin	300-600	14								
5	CEU	Onion	F	Puccinia allii	Foliar Spray	When first symptoms are visible BBCH 41-49	a) 1-2 b) 1-2	14	a) 1.5 b) 3.0	a) 0.4 bos-calid + 0.1 pyraclostrobin b) 0.8 bos-calid + 0.2 pyraclostrobin	300-600	14								
Unprotected use in SIGNUM																				

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
6	PL	Cabbage	F	<i>Alternaria</i> , <i>Botrytis cinerea</i>	Spray	BBCH 41-49	a) 1-3 b) 1-3	7	a) 1.0 b) 3.0	a) 0.267 boscalid + 0.067 pyraclostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	600-800	14	Unprotected use in SIGNUM							
7	PL	Tomatoe in greenhouses	G	<i>Botrytis cinerea</i> , <i>Phytophthora infestans</i>	Spray	BBCH 51-85	a) 1-2 b) 1-2	7	a) 2.0 b) 4.0	a) 0.534 boscalid + 0.134 pyraclostrobin b) 1.068 + 0.268 pyraclostrobin	1000	3	Unprotected use in SIGNUM							
8	PL	Strawberry	F	<i>Botrytis cinerea</i> , <i>Ramularia grevilleana</i> <i>Spaerotheca macularis</i> ,	Spray	BBCH 60-81	a) 1-2 b) 1-2	5	a) 1.8 b) 3.6	a) 0.481 boscalid + 0.121 pyraclostrobin b) 0.961 boscalid + 0.241 pyraclostrobin	500-700	3	Unprotected use in SIGNUM							
9	PL	Cherry	F	<i>Monilinia sp.</i>	Spray	BBCH 60-67	a) 1-2 b) 1-2	5	a) 1.0 b) 2.0	a) 0.267 boscalid + 0.067 pyraclostrobin b) 0.534 boscalid + 0.134 pyraclostrobin	500-750	7	Unprotected use in SIGNUM							
10	PL	Raspberry	F	<i>Botrytis cinerea</i> , <i>Didymella applanate</i>	Spray	BBCH 51-90	a) 1-2 b) 1-2	7	a) 1.8 b) 3.6	a) 0.481 boscalid + 0.121 pyraclostrobin b) 0.961 boscalid + 0.241 pyraclostrobin	600-700	3	Unprotected use in SIGNUM							
11	PL	Blackcurrant	F	<i>Drepanopeziza ribis</i> <i>Cronartium ribicola</i>	Spray	BBCH 55-90	a) 1-2 b) 1-2	7-10	a) 1.8 b) 3.6	a) 0.481 boscalid + 0.121 pyra-	600-800	3	Unprotected use in SIGNUM							

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
										clostrobin b) 0.961 boscalid + 0.241 pyra- clostrobin										
Minor uses according to Article 51 (zonal uses)																				

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
12	PL	Beetroot	F	<i>Erysiphe betae</i>	Spray	BBCH 15-49	a) 1-2 b) 1-2	10-14	a) 1.0 b) 2.0	a) 0.267 boscalid + 0.067 pyraclostrobin b) 0.534 boscalid + 0.134 pyraclostrobin	300-600	14								
13	PL	Celery root	F	<i>Sclerotinia sclerotiorum</i>	Spray	BBCH 15-49	a) 1-2 b) 1-2	10-14	a) 1.5 b) 3.0	a) 0.4 boscalid + 0.1 pyraclostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	300-600	14								
14	PL	Parsnip, Parsley	F	<i>Alternaria sp. alternata</i> , <i>Erysiphe heraclei</i>	Spray	BBCH 15-49	a) 1-2 b) 1-2	21-28	a) 0.75 b) 1.5	a) 0.200 boscalid + 0.050 pyraclostrobin b) 0.400 boscalid + 0.100 pyraclostrobin	600-800	14								
15	PL	Radish	F	<i>Botrytis cinerea</i> ,	Spray	BBCH 11-49	a) 1-2 b) 1-2	14-21	a) 1.5 b) 3.0	a) 0.4 boscalid + 0.1 pyraclostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	300-600	14								
16	PL	Radish	F	<i>Rhizoctonia solani</i>	Spray	BBCH 11-12	a) 1 b) 1	NR	a) 1.5 b) 1.5	a) 0.4 boscalid + 0.1 pyraclostrobin b) 0.4 boscalid + 0.1 pyraclostrobin	300-600	14								
17	PL	Horseradish	F	<i>Peronospora sp.</i> <i>Alternaria</i> <i>Erysiphe sp.</i>		BBCH 15-49	a) 1-2 b) 1-2	14-21	a) 1.5 b) 3.0	a) 0.4 boscalid + 0.1 pyraclostrobin b) 0.8 boscalid + 0.2	300-600	14								

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
										pyra- clostrobin										
18	PL	Swedes/rutabagas	F	<i>Peronospora sp.</i> <i>Cercospora beticola</i> <i>Erysiphe sp.</i>	Spray	BBCH 15-49	a) 1-2 b) 1-2	10-14	a) 1.0 b) 2.0	a) 0.267 boscalid + 0.067 pyraclostrobin b) 0.534 boscalid + 0.134 pyraclostrobin	300-600	14								
19	PL	Turnip	F	<i>Botrytis cinerea</i> , <i>Thanatephorus cucumeris</i>	Spray	BBCH 11-49	a) 1-2 b) 1-2	14-21	a) 1.5 b) 3.0	a) 0.4 boscalid + 0.1 pyraclostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	300-600	14								
20	PL	Chicory roots	F	<i>Chicory Alternaria</i> , <i>Chicory Puccinia</i>	Spray	BBCH 13-47	a) 1-2 b) 1-2	14-21	a) 1.5 b) 3.0	a) 0.4 boscalid + 0.1 pyraclostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	300-600	14								
21	PL	Shallot	F	<i>Peronospora destructor</i> <i>Alternaria</i> , <i>Stemphylium</i>	Spray	BBCH 13-48	a) 1-2 b) 1-2	14	a) 1.0 b) 3.0	a) 0.267 boscalid + 0.067 pyraclostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	300-600	14								
22	PL	Onion "seven years old"	F	<i>Puccinia porri</i> <i>Phytophthora porri</i> <i>Alternaria</i> ,	Spray	BBCH 13-47	a) 1-2 b) 1-2	21-28	a) 1.5 b) 3.0	a) 0.4 boscalid + 0.1 pyraclostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	300-600	14								
23	PL	Aubergines/eggplants	G	<i>Botrytis cinerea</i> , <i>Sclerotinia sclerotiorum</i>	Spray	BBCH 12-89	a) 1-2 b) 1-2	7-10	a) 1.5 b) 3.0	a) 0.4 boscalid + 0.1 pyraclostrobin	1000	14								

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
				<i>Leveillula taurica</i>						b) 0.8 boscalid + 0.2 pyraclostrobin										
24	PL	aubergines/eggplants	F	<i>Phytophthora infestans</i> ,	Foliar Spray	When first symptoms are visible BBCH 20-87	a) 1-2 b) 1-2	8-10	a) 1.5 b) 3.0	a) 0.4 boscalid + 0.1 pyraclostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	300-600	3								
25	PL	aubergines/eggplants	F	<i>Alternaria sp.</i>	Foliar Spray	When first symptoms are visible BBCH 20-87	a) 1-3 b) 1-3	8-10	a) 1.5 b) 4.5	a) 0.4 boscalid + 0.1 pyraclostrobin b) 1.2 boscalid + 0.3 pyraclostrobin	300-600	3								
26	PL	Ornamentals in field and greenhouses	F/G	<i>Alternaria</i>	Spray	BBCH 13-47	a) 1-2 b) 1-2	7-14	a) 0.1 b) 0.2	a) 0.0267 boscalid + 0.0067 pyraclostrobin b) 0.0534 boscalid + 0.00134 pyraclostrobin	100	-								
27	PL	Ornamentals in field and greenhouses	F/G	<i>Erysipales</i>	Spray	BBCH 13-47	a) 1-2 b) 1-2	7-14	a) 0.18 b) 0.36	a) 0.0481 boscalid + 0.0121 pyraclostrobin b) 0.0962 boscalid + 0.0242 pyraclostrobin	100	-								
28	PL	Ornamentals in field and greenhouses	F/G	<i>Botrytis cinerea</i> , <i>Sclerotinia sclerotiorum</i> <i>Thanatephorus cucumeris</i>	Spray	BBCH 13-47	a) 1-2 b) 1-2	7-14	a) 0.15 b) 0.3	a) 0.04 boscalid + 0.01 pyraclostrobin b) 0.08 boscalid + 0.02 pyraclostrobin	100	-								
29	PL	Redcurrant,	F	<i>Drepanopeziza ribis</i> ,	Spray	BBCH 55-90	a) 1-2	7-10	a) 1.8	a) 0.4806	600-800	3								

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
		White currant		<i>Drepanopeziza rubric</i> , <i>Botrytis cinerea</i> ,			b) 1-2		b) 3.6	boscalid + 0.1206 pyra- clostrobin b) 0.9612 boscalid + 0.2412 pyra- clostrobin										
30	PL	Salsifies	F	<i>Botrytis cinerea</i> , <i>Sclerotinia scleroti- orum</i> <i>Rhizoctonia</i>	Foliar Spray	When first symptoms are visible BBCH 41-49	a) 1-2 b) 1-2	8-10	a) 1.5 b) 3.0	a) 0.4 bos- calid + 0.1 pyraclostrobin b) 0.8 bos- calid + 0.2 pyra- clostrobin	300-600	14								

* 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

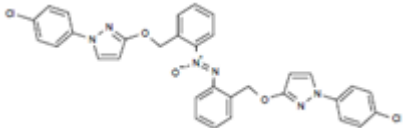
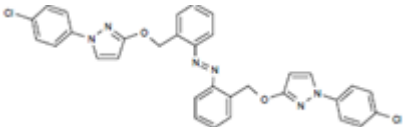
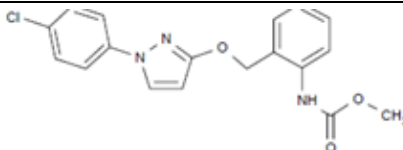
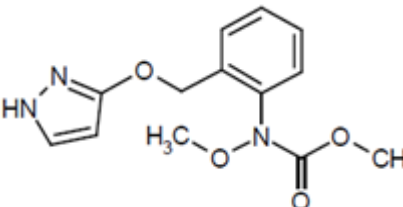
Remarks table:

- (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

zRMS comment:

The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. The changes are introduced directly as text in blue. Not agreed or not relevant information is struck through for transparency.

9.1.1.1 Overall conclusions Table 9.1-3: Metabolites of Pyraclostrobin

9.1.1.2	Molar mass	Chemical structure	Maximum occurrence in compartments	Risk assessment required?
BF 500-6	611.5		Soil: max. 31 % after 120 d Sediment : 6.5 % after 61 d	Yes, for non-target soil meso- and macrofauna and soil microbial activity
BF 500-7	595.5		Soil: max. 13 % after 62 d Sediment: 6.3% after 61 d	Yes, for non-target soil meso- and macrofauna and soil microbial activity
BF 500-3	357.8		Soil: max. 95.8 % after 7 d (tolyl-label), anaerobic conditions Water: 2.3% after 61 d Sediment: 65.7 % after 14 d (river system)	No
BF 500-11	277.3		Water/photolysis study: 44.5 % after 21 d (tolyl label)	Yes, for aquatic organisms

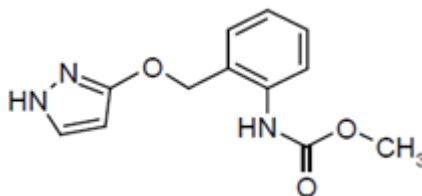
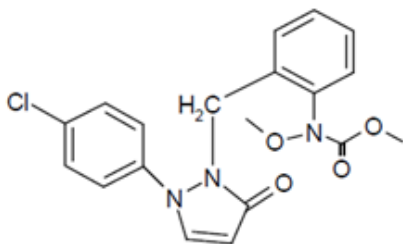
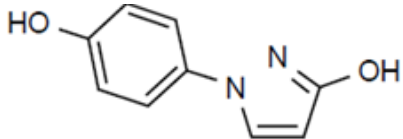
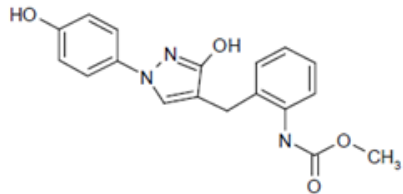
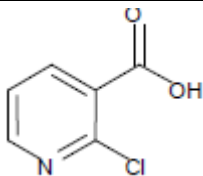
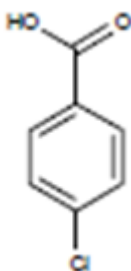
9.1.1.2	Molar mass	Chemical structure	Maximum occurrence in compartments	Risk assessment required?
BF 500-13	247.3		Water/photolysis study: 16.8 % after 6 d (tolyl label)	Yes, for aquatic organisms
BF 500-14	387.8		Water/photolysis study: 20.7 % after 3 h (Cholo-phenyl label)	Yes, for aquatic organisms
BF 500-15	176.2		Water/photolysis study: 26.6 % after 1 day (Chloro-phenyl label)	No
500 M 58	-339.3		Water/photolysis study: 22.7 % after 6 h (chloro-phenyl label)	No

Table 9.1-3 Metabolites of Boscalid

Metabolite	Molar mass	Chemical structure	Maximum occurrence in compartments	Risk assessment required?
M510F47	157.6		Soil: anaerobic conditions. 2.6 % after 3 d, 6 % after 62 d, 5.9 % after 90 d, 6.7 % after 120 d	No

Metabolite	Molar mass	Chemical structure	Maximum occurrence in compartments	Risk assessment required?
M510F64	156.56		Sediment: under outdoor condit. 7.3 % after 7 d 9 % after 14 d 9.4 % after 30 d 1.9 % after 120 d	No

9.1.1.3 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

Fruiting vegetables, bush and cane fruit, leafy vegetables and strawberry

According to the screening assessment, all the TER_a and TER_{lt} values for the active substance Pyraclostrobin are greater than the Annex VI trigger of 10 and 5, respectively. After screening assessment for active substance Boscalid, the TER_a value are greater than the trigger of 10, indicating that Casino Royale presents no unacceptable acute risk to birds. However, according to the first-tier assessment, TER_{lt} values are lower than the Annex VI trigger of 5 for frugivorous bird "crow" and frugivorous bird "Starling" (fruiting vegetables), frugivorous bird "blackcap" and small insectivorous bird "warbler" (bush and cane fruit), medium herbivorous/granivorous bird "pigeon" (leafy vegetables) and frugivorous bird "starling" (strawberries), indicating that Casino Royale presents an unacceptable long-term risk to birds. A refinement of the risk was done by refining of RUD, diet type, deposition factor and MAF, and the TER values were above the trigger showing no risk. Therefore, the acute and long-term risk to birds after the application of Casino Royale according to the GAP is considered acceptable

Sugar beet, root and stem vegetables, bulbs and onion like crops, cherry and ornamentals

According to the screening and first-tier assessments, all the TER_a and TER_{lt} values for active substances Pyraclostrobin and Boscalid are greater than the Annex VI trigger of 10 and 5, respectively, indicating that Casino Royale presents no unacceptable acute and long-term risk to birds according to the intended uses on sugar beet, root and stem vegetables, bulbs and onion like crops, cherry and ornamentals.

Pyraclostrobin has been shown to have the potential for bioaccumulation, however, there is no risk to earthworm and fish-eating birds according to the intended uses of Casino Royale.

• Mammals

Sugar beet, cherry and ornamentals

According to the screening and first-tier assessments, all the TER_a and TER_{lt} values for active substances Pyraclostrobin and Boscalid are greater than the Annex VI trigger of 10 and 5, respectively, indicating that Casino Royale presents no unacceptable acute and long-term risk to mammals according to the intended uses on sugar beet, cherry and ornamentals.

Fruiting vegetables and leafy vegetables

According to the screening assessments, all the TER_a values for the active substance Pyraclostrobin and Boscalid are greater than the Annex VI trigger of 10. After first-tier assessment for active substance Pyraclostrobin and Boscalid, some TER_{it} values are lower than the Annex VI trigger of 5, for small herbivorous mammal "vole" in both active substance and frugivorous mammal "rat" for Pyraclostrobin in fruiting vegetables, indicating that Casino Royale presents an unacceptable long-term risk to mammals. A refinement of the risk was done by refining of RUD and DF, and the TER values were above the trigger showing no risk. Therefore, the acute and long-term risk to mammals after the application of Casino Royale according to the GAP is considered acceptable.

Bush and cane fruits, root and stem vegetables, bulbs and onion like crops and strawberry

According to the screening assessments, all the TER_a values for the active substance Pyraclostrobin and Boscalid are greater than the Annex VI trigger of 10. After first-tier assessment for active substance Pyraclostrobin, the TER_{it} values are lower than the Annex VI trigger of 5 for small herbivorous mammal "vole", indicating that Casino Royale presents an unacceptable long-term risk to mammals. A refinement of the risk was done by refining of RUD and DF, and the TER values were above the trigger showing no risk. Therefore, the acute and long-term risk to mammals after the application of Casino Royale according to the GAP is considered acceptable.

Pyraclostrobin has been shown to have the potential for bioaccumulation, however, there is no risk to earthworm and fish-eating mammals according to the intended uses of Casino Royale.

It should be noted, that if any of refinement option for birds and mammals is not accepted by some MSs, they should conclude this issue on MS level.

The refinement of the combined risk assessment for vole should be considered at MSs level.

~~In addition the combined long risk assessment for mammals could be further considered at MSs level for the following scenarios:~~

- ~~– Fruiting vegetables: BBCH 10–49 Small herbivorous mammal "vole". Grass + cereals. 100% grass~~
- ~~– Fruiting vegetables: BBCH > 50 Small herbivorous mammal "vole". Grass + cereals. 100% grass~~
- ~~– Bush & cane fruit BBCH ≥ 40 Small herbivorous mammal "vole". Grass + cereals. 100% grass~~
- ~~– Root & stem vegetables BBCH ≥ 40: Small herbivorous mammal "vole". Grass + cereals. 100% grassy~~
- ~~– Leafy vegetables BBCH 40–49 Small herbivorous mammal "vole". Grass + cereals. 100% grass~~
- ~~– Orchards Application crop directed BBCH ≥ 40 Small herbivorous mammal "vole". Grass + cereals. 100% grass~~
- ~~– Strawberries BBCH ≥ 40: Small herbivorous mammal "vole". Grass + cereals. 100% grass~~
- ~~– Ornamentals: Ornamentals BBCH 40–49 and BBCH > 50 Small insectivorous mammal "vole"~~

9.1.1.4 Effects on aquatic organisms (KCP 10.2)

Pyraclostrobin

After the refinement, an acceptable risk was obtained with the following mitigation measures:

- Sugar beet: no-spray buffer zone of 5 m
- Fruiting vegetables and potato: no-spray buffer zone of 5m
- Root vegetables: no-spray buffer zone of 5m
- Bulb vegetables: no-spray buffer zone of 5m
- Leafy vegetables: no-spray buffer zone of 10m
- Apple (early application): no-spray buffer zone of 40m OR no-spray buffer zone of 30m + 50% nozzles OR no-spray buffer zone of 20m + 75% nozzles OR no-spray buffer zone of 15m + 90% nozzles
- Vines (late application): no-spray buffer zone of 20m OR no-spray buffer zone of 15m + 50% nozzles OR no-spray buffer zone of 10m + 75% nozzles OR no-spray buffer zone of 5m + 90% nozzles

Metabolites of Pyraclostrobin

For all intended uses, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms. Therefore, no further assessment is necessary.

Boscalid

An acceptable risk was obtained with the following mitigation measures:

- Leafy vegetables: no-spray buffer zone of 5m with 5m vegetative strip.
- Apple early application: no-spray buffer zone of 15m OR no-spray buffer zone of 5m + 50% of nozzle reduction.

However, the PEC/RAC ratio values calculated were still above the trigger of 1 for D6 2nd ditch in bulb vegetables and D6 ditch scenario in leafy vegetables for multiple application. However, D6 scenario is not relevant for CEU countries.

Conclusions

Sugar beet, Fruiting vegetables and potato, Root vegetables and Bulb vegetables – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 5 m to surface water bodies.

Leafy vegetables – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 10 m with 5m vegetative strip to surface water bodies.

Apple (early application) – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 40 m to surface water bodies OR respect an unsprayed buffer zone of 30 m to surface water bodies with 50% of nozzles reduction OR respect an unsprayed buffer zone of 20 m to surface water bodies with 75% of nozzles reduction OR respect an unsprayed buffer zone of 15 m to surface water bodies with 90% of nozzles reduction.

Vines (late application) – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 20 m to surface water bodies OR respect an unsprayed buffer zone of 15 m to surface water bodies with 50% of nozzles reduction OR respect an unsprayed buffer zone of 10 m to surface water bodies with 75% of nozzles reduction OR respect an unsprayed buffer zone of 5 m to surface water bodies with 90% of nozzles reduction.

After this refinement, an acceptable risk was obtained for **the worst case scenario for each uses for both substances** with the following mitigation measures:

- Sugar beet: no-spray buffer zone of 10 m
- Fruiting vegetables and potato: no-spray buffer zone of 10 m
- Root vegetables: no-spray buffer zone of 10 m
- Bulb vegetables: no-spray buffer zone of 10 m
- Leafy vegetables: no-spray buffer zone of 10 m including **5 meter vegetative buffer strip**
- Apple (early application): no-spray buffer zone of 40 m OR no-spray buffer zone of 30 m + 50% nozzles OR no-spray buffer zone of 20 m + 75% nozzles OR no-spray buffer zone of 15 m + 90% nozzles
- Vines (late application): no-spray buffer zone of 20 m OR no-spray buffer zone of 15 m + 50% nozzles OR no-spray buffer zone of 10 m + 75% nozzles OR no-spray buffer zone of 5 m + 90% nozzles

The final risk mitigation measures should be considered at MSs level depend on relevant scenarios for each countries.

9.1.1.5 Toxicity data

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

Effects on aquatic organisms of Pyraclostrobin 6.7% Boscalid 26.7% WG were not evaluated as part of the EU assessment of Pyraclostrobin and Boscalid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

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

Species	Substance	Exposure System	Results	Reference
<i>Oncorhynchus mykiss</i>	Pyraclostrobin	96 h, s	LC ₅₀ = 0.006 mg a.s./L	SANCO/1420/2001-Final
<i>Oncorhynchus mykiss</i>	BF 500-13	96 h, s	LC ₅₀ > 50 - < 100 mg a.s./L	SANCO/1420/2001-Final
<i>Oncorhynchus mykiss</i>	BF 500-14	96 h, s	LC ₅₀ > 39 - < 83 mg a.s./L	SANCO/1420/2001-Final
<i>Oncorhynchus mykiss</i>	BF 500-11	96 h, s	LC ₅₀ > 100 mg a.s./L	SANCO/1420/2001-Final
<i>Oncorhynchus mykiss</i>	Pyraclostrobin	28 d, f	NOEC = 0.005 mg a.s./L	SANCO/1420/2001-Final
<i>Oncorhynchus mykiss</i>	Pyraclostrobin	98 d, ELS	NOEC = 0.002 mg a.s./L	SANCO/1420/2001-Final
<i>Daphnia magna</i>	Pyraclostrobin	48 h, s	EC ₅₀ = 0.016 mg a.s./L	SANCO/1420/2001-Final
<i>Daphnia magna</i>	BF 500-13	48 h, s	EC ₅₀ > 100 mg a.s./L	SANCO/1420/2001-Final
<i>Daphnia magna</i>	BF 500-14	48 h, s	EC ₅₀ = 61 mg a.s./L	SANCO/1420/2001-Final
<i>Daphnia magna</i>	BF 500-11	48 h, s	EC ₅₀ > 100 mg a.s./L	SANCO/1420/2001-Final
<i>Daphnia magna</i>	Pyraclostrobin	21 d, ss	NOEC = 0.004 mg a.s./L	SANCO/1420/2001-Final
<i>Chironomus riparius</i>	Pyraclostrobin	28 d, s	NOEC = 0.04 mg a.s./L EC ₂₀ > 100 mg a.s./kg	SANCO/1420/2001-Final
<i>Pseudokirchneriella subcapitata</i>	Pyraclostrobin	72 h, s	E _r C ₅₀ > 0.843 mg a.s./L E _b C ₅₀ = 0.152 mg a.s./L	SANCO/1420/2001-Final

Species	Substance	Exposure System	Results	Reference
<i>Pseudokirchneriella subcapitata</i>	BF 500-13	72 h, s	E_rC₅₀ > 100 mg a.s./L E _b C ₅₀ = 66 mg a.s./L	SANCO/1420/2001-Final
<i>Pseudokirchneriella subcapitata</i>	BF 500-14	72 h, s	E_rC₅₀ > 100 mg a.s./L E _b C ₅₀ = 46 mg a.s./L	SANCO/1420/2001-Final
<i>Pseudokirchneriella subcapitata</i>	BF 500-11	72 h, s	E _r C ₅₀ > 100 mg a.s./L	SANCO/1420/2001-Final
<i>Lemna gibba</i>	Not required			SANCO/1420/2001-Final
Higher-tier studies (micro- or mesocosm studies)				
Aquatic mesocosm in a large number of different species (approximately 260 taxa) in outdoor conditions for the representative formulation BAS 500 00 F (247.8 g as/L). Results: NOEC 8 µg a.s./L LOEC 24 µg a.s./L EAC ≥ 8 µg a.s./L				

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

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

Species	Substance	Exposure System	Results	Reference
<i>Oncorhynchus mykiss</i>	Boscalid	96 h, s	EC ₅₀ = 2.7 mg a.s./L	SANCO/3919 /2007-rev. 5
<i>Oncorhynchus mykiss</i>	Boscalid	97 d, f	NOEC = 0.125 mg a.s./L	SANCO/3919 /2007-rev. 5
<i>Daphnia magna</i>	Boscalid	48 h, s	EC ₅₀ = 5.33 mg a.s./L	SANCO/3919 /2007-rev. 5
<i>Daphnia magna</i>	Boscalid	21 d, ss	NOEC = 1.31 mg a.s./L	SANCO/3919 /2007-rev. 5
<i>Chironomus riparius</i>	Boscalid	28 d, s	NOEC = 1 mg a.s./L	SANCO/3919 /2007-rev. 5
<i>Pseudokirchneriella subcapitata</i>	Boscalid	96 h, s	EC ₅₀ = 1.34 mg a.s./L	SANCO/3919 /2007-rev. 5
Higher-tier studies (micro- or mesocosm studies)				

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.

Table 9.5-3: Endpoints and effect values relevant for the risk assessment for aquatic organisms – CASINO ROYALE

Species	Substance	Exposure System	Results	Reference
<i>Oncorhynchus mykiss</i>	CASINO ROYALE	96 h, ss	LC ₅₀ = 0.054 mg f.p./L ^{nom}	KCP 10.2.1-01 xxx. 2018 W/140/17
<i>Daphnia magna</i>	CASINO ROYALE	48 h, s	EC ₅₀ = 0.254 mg f.p./L ^{nom}	KCP 10.2.1-02 Kulec-Płoszczyca, E., 2018 W/142/17
<i>Pseudokirchneriella subcapitata</i>	CASINO ROYALE	96 h, s	E _r C ₅₀ = 28.75 mg f.p./L ^{nom} E _y C ₅₀ = 2.74 mg f.p./L ^{nom}	KCP 10.2.1-03 Kulec-Płoszczyca, E., 2018 W/141/17
<i>Lemna gibba</i>	CASINO ROYALE	7d, ss	<u>Fronde number:</u> E _r C ₅₀ = 79.56 mg f.p./L ^{nom} E _y C ₅₀ = 17.25 mg f.p./L ^{nom} <u>Dry weight:</u> E _r C ₅₀ = 167.26 mg f.p./L ^{nom} E _y C ₅₀ = 12.15 mg f.p./L ^{nom}	KCP 10.2.1-04 Kulec-Płoszczyca, E., 2018 W/143/17

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

9.1.1.7 Justification for new endpoints

There is not deviation from the EU agreed endpoints.

9.1.2 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, 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.

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.

PYRACLOSTROBIN

Table 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pyraclostrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in sugar beet (single/multiple application)

Group	Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species	<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Endpoint (µg/L)		LC ₅₀ 6	NOEC 2	EC ₅₀ 16	NOEC 4	E _r C ₅₀ 843	NOEC 40
AF		100	10	100	10	10	10
RAC (µg/L)		0.06	0.2	0.16	0.4	84.3	4
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
	3.52/7.04	58.67/117.33	17.60/35.20	22.00/44.00	8.800/17.600	0.042/0.084	0.880/ 1.760
Step 2							
S/N-Europe	0.92/0.89	15.333/14.833	4.600/4.450	5.750/5.563	2.300/2.225	0.011/0.011	0.230/0.223
Step 3							
D3/ditch	0.524/0.456	8.733/7.600	2.620/2.280	3.275/2.850	1.310/1.140	0.006/0.005	0.131/0.114
D4/pond	0.021/0.031	0.350/0.517	0.105/0.155	0.131/0.194	0.053/0.078	0.000/0.000	0.005/0.008
D4/stream	0.422/0.363	7.033/6.050	2.110/1.815	2.638/2.269	1.055/0.908	0.005/0.004	0.106/0.091
R1/pond	0.028/0.058	0.467/0.967	0.140/0.290	0.175/0.363	0.070/0.145	0.000/0.001	0.007/0.015
R1/stream	0.364/0.314	6.067/5.233	1.820/1.570	2.275/1.963	0.910/0.785	0.004/0.004	0.091/0.079
R3/stream	0.511/0.442	8.517/7.367	2.555/2.210	3.194/2.763	1.278/1.105	0.006/0.005	0.128/0.111

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 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pyraclostrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in tomato and eggplant (fruiting vegetables and potato, BBCH 12 as worst case) (single/multiple application)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀ 6	NOEC 2	EC ₅₀ 16	NOEC 4	E _r C ₅₀ 843	NOEC 40
AF		100	10	100	10	10	10
RAC (µg/L)		0.06	0.2	0.16	0.4	84.3	4
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
	3.52/10.57	58.67/176.17	17.60/52.85	22.00/66.06	8.80/26.43	0.042/0.125	0.880/2.643
Step 2							
S-Europe	0.92/2.05	15.333/34.167	4.600/10.25	5.750/12.813	2.300/5.125	0.011/0.024	0.230/0.513
N-Europe	0.92/1.12	15.333/18.667	4.600/5.600	5.750/7.000	2.300/2.800	0.011/0.013	0.230/0.280
Step 3							
D3/ditch	0.525/0.382	8.750/6.367	2.625/1.910	3.281/2.388	1.313/0.955	0.006/0.005	0.131/0.096
D4/pond	0.021/0.031	0.350/0.517	0.105/0.155	0.131/0.194	0.053/0.078	0.000/0.000	0.005/0.008
D4/stream	0.447/0.323	7.450/5.383	2.235/1.615	2.794/2.019	1.118/0.808	0.005/0.004	0.112/0.081
D6/ditch	0.624/0.459	10.400/7.650	3.120/2.295	3.900/2.869	1.560/1.148	0.007/0.005	0.156/0.115
R1/pond	0.021/0.043	0.350/0.717	0.105/0.215	0.131/0.269	0.053/0.108	0.000/0.001	0.005/0.011
R1/stream	0.357/0.263	5.950/4.383	1.785/1.315	2.231/1.644	0.893/0.658	0.004/0.003	0.089/0.066
R2/stream	0.553/0.407	9.217/6.783	2.765/2.035	3.456/2.544	1.383/1.018	0.007/0.005	0.138/0.102
R3/stream	0.589/0.429	9.817/7.150	2.945/2.145	3.681/2.681	1.473/1.073	0.007/0.005	0.147/0.107
R4/stream	0.418/0.314	6.967/5.233	2.090/1.570	2.613/1.963	1.045/0.785	0.005/0.004	0.105/0.079

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 Pyraclostrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in carrots, beetroot, celery root, radish, horseradish, swedes, turnip, chicory roots and salsifies (root vegetables, BBCH 11 as worst case) (single/multiple application)

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀	NOEC	EC ₅₀	NOEC	E _r C ₅₀	NOEC
AF		6	2	16	4	843	40
RAC (µg/L)		100	10	100	10	10	10
RAC (µg/L)		0.06	0.2	0.16	0.4	84.3	4
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
	3.52/7.04	58.67/117.3	17.60/35.20	22.00/44.00	8.800/17.60	0.042/0.084	0.880/ 1.760
Step 2							
S-Europe	0.92/1.50	15.33/25.00	4.600/7.500	5.750/9.375	2.300/3.750	0.011/0.018	0.230/0.375
N-Europe	0.92/0.89	15.33/14.83	4.600/4.450	5.750/5.563	2.300/2.225	0.011/0.011	0.230/0.223
Step 3							
D3/ditch	0.634/0.555	10.57/9.250	3.170/2.775	3.963/3.469	1.585/1.388	0.008/0.007	0.159/0.139
D6/ditch	0.633/0.557	10.55/9.283	3.165/2.785	3.956/3.481	1.583/1.393	0.008/0.007	0.158/0.139
R1/pond	0.025/0.040	0.417/0.667	0.125/0.200	0.156/0.250	0.063/0.100	0.000/0.000	0.006/0.010
R1/stream	0.418/0.361	6.967/6.017	2.090/1.805	2.613/2.256	1.045/0.903	0.005/0.004	0.105/0.090
R2 1 st /stream	0.552/0.478	9.200/7.967	2.760/2.390	3.450/2.988	1.380/1.195	0.007/0.006	0.138/0.120
R2 2 nd /stream	0.562/0.486	9.367/8.100	2.810/2.430	3.513/3.038	1.405/1.215	0.007/0.006	0.141/0.122
R3/stream	0.587/0.508	9.783/8.467	2.935/2.540	3.669/3.175	1.468/1.270	0.007/0.006	0.147/0.127
R4/stream	0.413/0.360	6.883/6.000	2.065/1.800	2.581/2.250	1.033/0.900	0.005/0.004	0.103/0.090

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 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pyraclostrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in onion, shallot, onion “seven years old and ornamentals (bulb vegetables, BBCH 13 as worst case) (single/multiple application)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀ 6	NOEC 2	EC ₅₀ 16	NOEC 4	E _r C ₅₀ 843	NOEC 40
AF		100	10	100	10	10	10
RAC (µg/L)		0.06	0.2	0.16	0.4	84.3	4
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
	3.52/7.04	58.67/117.33	17.60/35.20	22.00/44.00	8.800/17.60	0.042/0.084	0.880/ 1.760
Step 2							
S-Europe	0.97/1.79	16.17/29.83	4.850/8.950	6.063/11.19	2.425/4.475	0.012/0.021	0.243/0.448
N-Europe	0.92/0.98	15.33/16.33	4.600/4.900	5.750/6.125	2.300/2.450	0.011/0.012	0.230/0.245
Step 3							
D3/ditch	0.643/0.556	10.72/9.267	3.215/2.780	4.019/3.475	1.608/1.390	0.008/0.007	0.161/0.139
D4/pond	0.022/0.030	0.367/0.500	0.110/0.150	0.138/0.188	0.055/0.075	0.000/0.000	0.006/0.008
D4/stream	0.479/0.415	7.983/6.917	2.395/2.075	2.994/2.594	1.198/1.038	0.006/0.005	0.120/0.104
D6 1 st /ditch	0.638/0.598	10.63/9.967	3.190/2.990	3.988/3.738	1.595/1.495	0.008/0.007	0.160/0.150
D6 2 nd /ditch	0.639/0.558	10.65/9.300	3.195/2.790	3.994/3.488	1.598/1.395	0.008/0.007	0.160/0.140
R1/pond	0.023/0.039	0.383/0.650	0.115/0.195	0.144/0.244	0.058/0.098	0.000/0.000	0.006/0.010
R1/stream	0.411/0.355	6.850/5.917	2.055/1.775	2.569/2.219	1.028/0.888	0.005/0.004	0.103/0.089
R2/stream	0.553/0.479	9.217/7.983	2.765/2.395	3.456/2.994	1.383/1.198	0.007/0.006	0.138/0.120
R3/stream	0.587/0.510	9.783/8.500	2.935/2.550	3.669/3.188	1.468/1.275	0.007/0.006	0.147/0.128
R4/stream	0.415/0.359	6.917/5.983	2.075/1.795	2.594/2.244	1.038/0.898	0.005/0.004	0.104/0.090

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 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pyraclostrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in cabbage, strawberry, parsnip and parsley (leafy vegetables, BBCH 15 as worst case) (single/multiple application)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀ 6	NOEC 2	EC ₅₀ 16	NOEC 4	E _r C ₅₀ 843	NOEC 40
AF		100	10	100	10	10	10
RAC (µg/L)		0.06	0.2	0.16	0.4	84.3	4
FOCUS Sce- nario	PEC _{gl-max} (µg/L)						
Step 1							
	3.52/7.04	58.67/117.3	17.60/35.20	22.00/44.00	8.800/17.60	0.042/0.084	0.880/1.760
Step 2							
S-Europe	0.92/1.55	15.33/25.83	4.600/7.750	5.750/9.688	2.300/3.875	0.011/0.018	0.230/0.388
N-Europe	0.92/0.90	15.33/15.00	4.600/4.500	5.750/5.625	2.300/2.250	0.011/0.011	0.230/0.225
Step 3							
D3 1 st /ditch	0.768/0.673	12.80/11.22	3.840/3.365	4.800/4.206	1.920/1.683	0.009/0.008	0.192/0.168
D3 2 nd /ditch	0.764/0.669	12.73/11.15	3.820/3.345	4.775/4.181	1.910/1.673	0.009/0.008	0.191/0.167
D4/pond	0.026/0.036	0.433/0.600	0.130/0.180	0.163/0.225	0.065/0.090	0.000/0.000	0.007/0.009
D4/stream	0.571/0.505	9.517/8.417	2.855/2.525	3.569/3.156	1.428/1.263	0.007/0.006	0.143/0.126
D6/ditch	0.757/0.668	12.62/11.13	3.785/3.340	4.731/4.175	1.893/1.670	0.009/0.008	0.189/0.167
R1 1 st /pond	0.028/0.049	0.467/0.817	0.140/0.245	0.175/0.306	0.070/0.123	0.000/0.001	0.007/0.012
R1 2 nd /pond	0.030/0.059	0.500/0.983	0.150/0.295	0.188/0.369	0.075/0.148	0.000/0.001	0.008/0.015
R1 1 st /stream	0.500/0.433	8.333/7.217	2.500/2.165	3.125/2.706	1.250/1.083	0.006/0.005	0.125/0.108
R1 2 nd /stream	0.507/0.439	8.450/7.317	2.535/2.195	3.169/2.744	1.268/1.098	0.006/0.005	0.127/0.110
R2 1 st /stream	0.670/0.579	11.17/9.650	3.350/2.895	4.188/3.619	1.675/1.448	0.008/0.007	0.168/0.145
R2 2 nd /stream	0.680/0.588	11.33/9.800	3.400/2.940	4.250/3.675	1.700/1.470	0.008/0.007	0.170/0.147
R3 1 st /stream	0.715/0.618	11.92/10.30	3.575/3.090	4.469/3.863	1.788/1.545	0.008/0.007	0.179/0.155
R3 2 nd /stream	0.715/0.619	11.92/10.32	3.575/3.095	4.469/3.869	1.788/1.548	0.008/0.007	0.179/0.155
R4 1 st /stream	0.507/0.438	8.450/7.300	2.535/2.190	3.169/2.738	1.268/1.095	0.006/0.005	0.127/0.110
R4 2 nd /stream	0.505/0.439	8.417/7.317	2.525/2.195	3.156/2.744	1.263/1.098	0.006/0.005	0.126/0.110

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 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pyraclostrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in cherry (apple early application as worst case, BBCH 60) (single/multiple application)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀ 6	NOEC 2	EC ₅₀ 16	NOEC 4	E _r C ₅₀ 843	NOEC 40
AF		100	10	100	10	10	10
RAC (µg/L)		0.06	0.2	0.16	0.4	84.3	4
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
	8.26/16.53	137.7/275.5	41.30/82.65	51.63/103.31	20.65/41.33	0.098/0.196	2.065/4.133
Step 2							
S/N-Europe	6.52/6.32	108.7/105.3	32.60/31.60	40.75/39.50	16.30/15.80	0.077/0.075	1.630/1.580
Step 3							
D3/ditch	5.221/4.153	87.02/69.22	26.11/20.77	32.63/25.96	13.05/10.38	0.062/0.049	1.305/1.038
D4/pond	0.317/0.501	5.283/8.350	1.585/2.505	1.981/3.131	0.793/1.253	0.004/0.006	0.079/0.125
D4/stream	5.534/4.733	92.23/78.88	27.67/23.67	34.59/29.58	13.84/11.83	0.066/0.056	1.384/1.183
D5/pond	0.317/0.474	5.283/7.900	1.585/2.370	1.981/2.963	0.793/1.185	0.004/0.006	0.079/0.119
D5/stream	5.977/5.107	99.62/85.12	29.89/25.54	37.36/31.92	14.94/12.77	0.071/0.061	1.494/1.277
R1/pond	0.316/0.468	5.267/7.800	1.580/2.340	1.975/2.925	0.790/1.170	0.004/0.006	0.079/0.117
R1/stream	4.241/3.620	70.68/60.33	21.21/18.10	26.51/22.63	10.60/9.050	0.050/0.043	1.060/0.905
R2/stream	5.684/4.853	94.73/80.88	28.42/24.27	35.53/30.33	14.21/12.13	0.067/0.058	1.421/1.213
R3/stream	5.935/5.103	98.92/85.05	29.68/25.52	37.09/31.89	14.84/12.76	0.070/0.061	1.484/1.276
R4/stream	4.145/3.620	69.08/60.33	20.73/18.10	25.91/22.63	10.36/9.050	0.049/0.043	1.036/0.905

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 9.5-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pyraclostrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in raspberry, blackcurrant, ornamentals, redcurrant and white currant (vines and apple late application as worst case, BBCH 61)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀ 6	NOEC 2	EC ₅₀ 16	NOEC 4	E _r C ₅₀ 843	NOEC 40
AF		100	10	100	10	10	10
RAC (µg/L)		0.06	0.2	0.16	0.4	84.3	4
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
	6.39/12.77	106.5/212.8	31.95/63.85	39.94/79.81	15.98/31.93	0.076/0.151	1.598/3.193
Step 2							
S/N-Europe	3.24/3.17	54.00/52.83	16.20/15.85	20.25/19.81	8.100/7.925	0.038/0.038	0.810/0.793
Step 3							
D3/ditch	2.067/1.836	34.45/30.60	10.34/9.180	12.92/11.48	5.168/4.590	0.025/0.022	0.517/0.459
D4/pond	0.074/0.117	1.233/1.950	0.370/0.585	0.463/0.731	0.185/0.293	0.001/0.001	0.019/0.029
D4/stream	1.988/1.757	33.13/29.28	9.940/8.785	12.43/10.98	4.970/4.393	0.024/0.021	0.497/0.439
D6/ditch	2.064/1.861	34.40/31.02	10.32/9.305	12.90/11.63	5.160/4.653	0.024/0.022	0.516/0.465
R1/pond	0.074/0.103	1.233/1.717	0.370/0.515	0.463/0.644	0.185/0.258	0.001/0.001	0.019/0.026
R1/stream	1.519/1.340	25.32/22.33	7.595/6.700	9.494/8.375	3.798/3.350	0.018/0.016	0.380/0.335
R2/stream	2.042/1.801	34.03/30.02	10.21/9.005	12.76/11.26	5.105/4.503	0.024/0.021	0.511/0.450
R3/stream	2.139/1.894	35.65/31.57	10.70/9.470	13.37/11.84	5.348/4.735	0.025/0.022	0.535/0.474
R4/stream	1.523/1.344	25.38/22.40	7.615/6.720	9.519/8.400	3.808/3.360	0.018/0.016	0.381/0.336

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

zRMS comment:

The PEC_{sw}/RAC ratio for a.s.- pyraclostrobin for most scenarios for acute/chronic fish and aquatic invertebrates organism risk assessment are above trigger of 1 indicating needs for further refinement with Higher Tier assessment.

The lowest RAC is 0.06 µg/L for acute fish was considered further in the refined risk assessment.

METABOLITES OF PYRACLOSTROBIN

Table 9.5-11: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-11 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in sugarbeet (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 100000	EC ₅₀ 100000	E _r C ₅₀ 100000
AF		100	100	10
RAC (µg/L)		1000	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	10.88/21.77	0.011/0.022	0.011/0.022	0.001/0.002
Step 2				
S-Europe	1.17/2.14	0.001/0.002	0.001/0.002	<0.001/<0.001

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 9.5-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-11 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in tomato and eggplant (fruiting vegetables, BBCH 12 as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 100000	EC ₅₀ 100000	E _r C ₅₀ 100000
AF		100	100	10
RAC (µg/L)		1000	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	10.88/32.65	0.011/0.033	0.011/0.033	0.001/0.003
Step 2				
S-Europe	3.22/8.19	0.003/0.008	0.003/0.008	<0.001/0.001

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 9.5-13: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-11 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in carrots, beetroot, celery root, radish, horseradish, swedes, turnip, chicory roots and salsifies (root vegetables, BBCH 11 as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 100000	EC ₅₀ 100000	ErC ₅₀ 100000
AF		100	100	10
RAC (µg/L)		1000	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	10.88/21.77	0.011/0.022	0.011/0.022	0.001/0.002
Step 2				
S-Europe	3.22/5.94	0.003/0.006	0.003/0.006	<0.001/0.001

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 9.5-14: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-11 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in onion, shallot, onion “seven years old and ornamentals (bulb vegetables, BBCH 13 as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 100000	EC ₅₀ 100000	ErC ₅₀ 100000
AF		100	100	10
RAC (µg/L)		1000	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	10.88/21.77	0.011/0.022	0.011/0.022	0.001/0.002
Step 2				
S-Europe	3.81/7.09	0.004/0.007	0.004/0.007	<0.001/0.001

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 9.5-15: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-11 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in cabbage, strawberry, parsnip and parsley (leafy vegetables, BBCH 15 as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 100000	EC ₅₀ 100000	E _r C ₅₀ 100000
AF		100	100	10
RAC (µg/L)		1000	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	10.88/21.77	0.011/0.022	0.011/0.022	0.001/0.002
Step 2				
S-Europe	3.22/6.10	0.003/0.006	0.003/0.006	<0.001/0.001

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 9.5-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-11 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in cherry (apple early application as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 100000	EC ₅₀ 100000	E _r C ₅₀ 100000
AF		100	100	10
RAC (µg/L)		1000	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	9.17/18.34	0.009/0.018	0.009/0.018	0.001/0.002
Step 2				
S-Europe	2.98/5.35	0.003/0.005	0.003/0.005	<0.001/0.001

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 9.5-17: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-11 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in raspberry, blackcurrant, ornamentals, redcurrant and white currant (vines late application as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 100000	EC ₅₀ 100000	E _r C ₅₀ 100000
AF		100	100	10
RAC (µg/L)		1000	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	13.85/27.69	0.014/0.028	0.014/0.028	0.001/0.003
Step 2				
S-Europe	2.45/4.47	0.002/0.004	0.002/0.004	<0.001/<0.001

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 9.5-18: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-13 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in sugar beet (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 50000	EC ₅₀ 100000	E _r C ₅₀ >100000
AF		100	100	10
RAC (µg/L)		500	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	3.66/7.33	0.007/0.015	0.004/0.007	<0.001/0.001
Step 2				
S-Europe	0.39/0.72	0.001/0.001	<0.001/0.001	<0.001/<0.001

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 9.5-19: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-13 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in tomato and eggplant (fruiting vegetables, BBCH 12 as worst case) (fruiting vegetables) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 50000	EC ₅₀ 100000	ErC ₅₀ >100000
AF		100	100	10
RAC (µg/L)		500	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	3.66/10.99	0.007/0.022	0.004/0.011	<0.001/0.001
Step 2				
S-Europe	1.09/2.76	0.002/0.006	0.001/0.003	<0.001/<0.001

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 9.5-20: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-13 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in carrots, beetroot, celery root, radish, horseradish, swedes, turnip, chicory roots and salsifies (root vegetables, BBCH 11 as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 50000	EC ₅₀ 100000	ErC ₅₀ >100000
AF		100	100	10
RAC (µg/L)		500	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	3.66/7.33	0.007/0.015	0.004/0.007	<0.001/0.001
Step 2				
S-Europe	1.09/2.00	0.002/0.004	0.001/0.002	<0.001/<0.001

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 9.5-21: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-13 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in onion, shallot, onion “seven years old and ornamentals (bulb vegetables, BBCH 13 as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 50000	EC ₅₀ 100000	ErC ₅₀ >100000
AF		100	100	10
RAC (µg/L)		500	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	3.66/7.33	0.007/0.015	0.004/0.007	<0.001/0.001
Step 2				
S-Europe	1.28/2.39	0.003/0.005	0.001/0.002	<0.001/<0.001

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 9.5-22: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-13 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in cabbage, strawberry, parsnip and parsley (leafy vegetables, BBCH 15 as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 50000	EC ₅₀ 100000	ErC ₅₀ >100000
AF		100	100	10
RAC (µg/L)		500	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	3.66/7.33	0.007/0.015	0.004/0.007	<0.001/0.001
Step 2				
S-Europe	1.09/2.05	0.002/0.004	0.001/0.002	<0.001/<0.001

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 9.5-23: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-13 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in cherry (apple early application as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 50000	EC ₅₀ 100000	ErC ₅₀ >100000
AF		100	100	10
RAC (µg/L)		500	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	3.09/6.18	0.006/0.012	0.003/0.006	<0.001/0.001
Step 2				
S-Europe	1.00/1.80	0.002/0.004	0.001/0.002	<0.001/<0.001

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 9.5-24: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-13 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in raspberry, blackcurrant, ornamentals, redcurrant and white currant (vines late application as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 50000	EC ₅₀ 100000	ErC ₅₀ >100000
AF		100	100	10
RAC (µg/L)		500	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	4.66/9.32	0.009/0.019	0.005/0.009	<0.001/0.001
Step 2				
S-Europe	0.82/1.49	0.002/0.003	0.001/0.001	<0.001/<0.001

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 9.5-25: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-14 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in sugar beet (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 39000	EC ₅₀ 61000	E _r C ₅₀ 100000
AF		100	100	10
RAC (µg/L)		390	610	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	7.08/14.16	0.018/0.036	0.012/0.023	0.001/0.001
Step 2				
S-Europe	0.76/1.39	0.002/0.004	0.001/0.002	<0.001/<0.001

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 9.5-26: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-14 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in tomato and eggplant (fruiting vegetables, BBCH 12 as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 39000	EC ₅₀ 61000	E _r C ₅₀ 100000
AF		100	100	10
RAC (µg/L)		390	610	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	7.08/21.24	0.018/0.054	0.012/0.035	0.001/0.002
Step 2				
S-Europe	2.10/5.33	0.005/0.014	0.003/0.009	<0.001/0.001

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 9.5-27: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-14 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in carrots, beetroot, celery root, radish, horseradish, swedes, turnip, chicory roots and salsifies (root vegetables, BBCH 11 as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 39000	EC ₅₀ 61000	ErC ₅₀ 100000
AF		100	100	10
RAC (µg/L)		390	610	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	7.08/14.16	0.018/0.036	0.012/0.023	0.001/0.001
Step 2				
S-Europe	2.10/3.86	0.005/0.010	0.003/0.006	<0.001/<0.001

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 9.5-28: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-14 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in onion, shallot, onion “seven years old” and ornamentals (bulb vegetables, BBCH 13 as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 39000	EC ₅₀ 61000	ErC ₅₀ 100000
AF		100	100	10
RAC (µg/L)		390	610	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	7.08/14.16	0.018/0.036	0.012/0.023	0.001/0.001
Step 2				
S-Europe	2.48/4.61	0.006/0.012	0.004/0.008	<0.001/<0.001

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 9.5-29: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-14 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in cabbage, strawberry, parsnip and parsley (leafy vegetables, BBCH 15 as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 39000	EC ₅₀ 61000	ErC ₅₀ 100000
AF		100	100	10
RAC (µg/L)		390	610	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	7.08/14.16	0.018/0.036	0.012/0.023	0.001/0.001
Step 2				
S-Europe	2.10/3.97	0.005/0.010	0.003/0.007	<0.001/<0.001

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 9.5-30: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-14 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in cherry (apple early application as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 39000	EC ₅₀ 61000	ErC ₅₀ 100000
AF		100	100	10
RAC (µg/L)		390	610	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	5.97/11.93	0.015/0.031	0.010/0.020	0.001/0.001
Step 2				
S-Europe	1.94/3.48	0.005/0.009	0.003/0.006	<0.001/<0.001

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 9.5-31: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-14 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in raspberry, blackcurrant, ornamentals, redcurrant and white currant (vines late application as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 39000	EC ₅₀ 61000	E _r C ₅₀ 100000
AF		100	100	10
RAC (µg/L)		390	610	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	9.01/18.02	0.023/0.046	0.015/0.030	0.001/0.002
Step 2				
S-Europe	1.59/2.91	0.004/0.007	0.003/0.005	<0.001/<0.001

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

zRMS comment:

The PEC_{sw}/RAC ratio for metabolites of pyraclostrobin are below trigger of 1 indicating an acceptable risk assessment for aquatic organism.

BOSCALID

Table 9.5-32: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in sugarbeet (single/multiple application)

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		EC ₅₀ 2700	NOEC 125	EC ₅₀ 5330	NOEC 1310	EC ₅₀ 1340	NOEC 1000
AF		100	10	100	10	10	10
RAC (µg/L)		27	12.5	53.3	131	134	100
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
	70.68/141.35	2.618/5.235	5.654/11.308	1.326/2.652	0.540/1.079	0.527/1.055	0.707/1.414
Step 2							
S-Europe	8.16/15.64	0.302/0.579	0.653/ 1.251	0.153/0.293	0.062/0.119	0.061/0.117	0.082/0.156
N-Europe	6.18/11.72	0.229/0.434	0.494/0.938	0.116/0.220	0.047/0.089	0.046/0.087	0.062/0.117
Step 3							
D3/ditch	-/1.823	-/0.068	-/0.146	-/0.034	-/0.014	-/0.014	-/0.018
D4/pond	-/3.306	-/0.122	-/0.264	-/0.062	-/0.025	-/0.025	-/0.033
D4/stream	-/4.412	-/0.163	-/0.353	-/0.083	-/0.034	-/0.033	-/0.044
R1/pond	-/1.395	-/0.052	-/0.112	-/0.026	-/0.011	-/0.010	-/0.014
R1/stream	-/4.679	-/0.173	-/0.374	-/0.088	-/0.036	-/0.035	-/0.047
R3/stream	-/5.472	-/0.203	-/0.438	-/0.103	-/0.042	-/0.041	-/0.055

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

zRMS comments:

The PEC/RAC ratio for a.s.- boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in sugarbeet (single/multiple application) was below 1 indicated acceptable risk .

Table 9.5-33: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in tomato and eggplant (fruiting vegetables and potato, BBCH 12 as worst case) (single/multiple application)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		EC ₅₀ 2700	NOEC 125	EC ₅₀ 5330	NOEC 1310	EC ₅₀ 1340	NOEC 1000
AF		100	10	100	10	10	10
RAC (µg/L)		27	12.5	53.3	131	134	100
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
	70.68/212.03	2.618/7.853	5.654/16.962	1.326/3.978	0.540/ 1.619	0.527/ 1.582	0.707/ 2.120
Step 2							
S-Europe	22.04/62.78	0.816/ 2.325	1.763/5.022	0.414/ 1.178	0.168/0.479	0.164/0.469	0.220/0.628
N-Europe	12.13/33.81	0.449/ 1.252	0.970/ 2.705	0.228/0.634	0.093/0.258	0.091/0.252	0.121/0.338
Step 3							
D3/ditch	2.099/1.528	0.078/0.057	0.168/0.122	0.039/0.029	0.016/0.012	0.016/0.011	0.021/0.015
D4/pond	1.795/6.843	0.066/0.253	0.144/0.547	0.034/0.128	0.014/0.052	0.013/0.051	0.018/0.068
D4/stream	2.237/7.616	0.083/0.282	0.179/0.609	0.042/0.143	0.017/0.058	0.017/0.057	0.022/0.076
D6/ditch	2.556/7.344	0.095/0.272	0.204/0.588	0.048/0.138	0.020/0.056	0.019/0.055	0.026/0.073
R1/pond	0.389/1.011	0.014/0.037	0.031/0.081	0.007/0.019	0.003/0.008	0.003/0.008	0.004/0.010
R1/stream	3.383/8.229	0.125/0.305	0.271/0.658	0.063/0.154	0.026/0.063	0.025/0.061	0.034/0.082
R2/stream	2.213/2.794	0.082/0.103	0.177/0.224	0.042/0.052	0.017/0.021	0.017/0.021	0.022/0.028
R3/stream	4.144/9.703	0.153/0.359	0.332/0.776	0.078/0.182	0.032/0.074	0.031/0.072	0.041/0.097
R4/stream	6.441/-	0.239/-	0.515/-	0.121/-	0.049/-	0.048/-	0.064/-

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

zRMS comments:

The PEC/RAC ratio for a.s.-boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in tomato and eggplant (fruiting vegetables and potato, BBCH 12 as worst case) (single/multiple application) was below 1 indicated acceptable risk.

Table 9.5-34: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in carrots, beetroot, celery root, radish, horseradish, swedes, turnip, chicory roots and salsifies (root vegetables, BBCH 11 as worst case) (single/multiple application)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		EC ₅₀	NOEC	EC ₅₀	NOEC	EC ₅₀	NOEC
AF		2700	125	5330	1310	1340	1000
RAC (µg/L)		100	10	100	10	10	10
RAC (µg/L)		27	12.5	53.3	131	134	100
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
	70.68/141.35	2.618/5.235	5.654/11.308	1.326/2.652	0.540/ 1.079	0.527/ 1.055	0.707/ 1.414
Step 2							
S-Europe	22.04/43.04	0.816/ 1.594	1.763/3.443	0.414/0.808	0.168/0.329	0.164/0.321	0.220/0.430
N-Europe	12.13/23.47	0.449/0.869	0.970/ 1.878	0.228/0.440	0.093/0.179	0.091/0.175	0.121/0.235
Step 3							
D3/ditch	2.537/2.221	0.094/0.082	0.203/0.178	0.048/0.042	0.019/0.017	0.019/0.017	0.025/0.022
D6/ditch	2.891/6.026	0.107/0.223	0.231/0.482	0.054/0.113	0.022/0.046	0.022/0.045	0.029/0.060
R1/pond	0.501/0.866	0.019/0.032	0.040/0.069	0.009/0.016	0.004/0.007	0.004/0.006	0.005/0.009
R1/stream	3.559/6.032	0.132/0.223	0.285/0.483	0.067/0.113	0.027/0.046	0.027/0.045	0.036/0.060
R2 1 st /stream	2.210/2.590	0.082/0.096	0.177/0.207	0.041/0.049	0.017/0.020	0.016/0.019	0.022/0.026
R2 2 nd /stream	2.248/2.138	0.083/0.079	0.180/0.171	0.042/0.040	0.017/0.016	0.017/0.016	0.022/0.021
R3/stream	4.206/5.414	0.156/0.201	0.336/0.433	0.079/0.102	0.032/0.041	0.031/0.040	0.042/0.054
R4/stream	6.082/7.637	0.225/0.283	0.487/0.611	0.114/0.143	0.046/0.058	0.045/0.057	0.061/0.076

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

zRMS comments:

The PEC/RAC ratio for a.s.- boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in carrots, beetroot, celery root, radish, horseradish, swedes, turnip, chicory roots and salsifies (root vegetables, BBCH 11 as worst case) (single/multiple application) was below 1 indicated acceptable risk.

Table 9.5-35: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in onion, shallot, onion “seven years old and ornamentals (bulb vegetables, BBCH 13 as worst case) (single/multiple application)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		EC ₅₀ 2700	NOEC 125	EC ₅₀ 5330	NOEC 1310	EC ₅₀ 1340	NOEC 1000
AF		100	10	100	10	10	10
RAC (µg/L)		27	12.5	53.3	131	134	100
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
	70.68/141.35	2.618/5.235	5.654/11.308	1.326/2.652	0.540/ 1.079	0.527/ 1.055	0.707/ 1.414
Step 2							
S-Europe	26.01/50.95	0.963/ 1.887	2.081/4.076	0.488/0.956	0.199/0.389	0.194/0.380	0.260/0.510
N-Europe	14.11/27.42	0.523/ 1.016	1.129/2.194	0.265/0.514	0.108/0.209	0.105/0.205	0.141/0.274
Step 3							
D3/ditch	2.537/2.222	0.094/0.082	0.203/0.178	0.048/0.042	0.019/0.017	0.019/0.017	0.025/0.022
D4/pond	1.731/3.893	0.064/0.144	0.138/0.311	0.032/0.073	0.013/0.030	0.013/0.029	0.017/0.039
D4/stream	2.079/4.350	0.077/0.161	0.166/0.348	0.039/0.082	0.016/0.033	0.016/0.032	0.021/0.044
D6 1 st /ditch	3.293/6.237	0.122/0.231	0.263/0.499	0.062/0.117	0.025/0.048	0.025/0.047	0.033/0.062
D6 2 nd /ditch	11.39/19.55	0.422/0.724	0.911/ 1.564	0.214/0.367	0.087/0.149	0.085/0.146	0.114/0.196
R1/pond	0.429/0.830	0.016/0.031	0.034/0.066	0.008/0.016	0.003/0.006	0.003/0.006	0.004/0.008
R1/stream	3.625/5.285	0.134/0.196	0.290/0.423	0.068/0.099	0.028/0.040	0.027/0.039	0.036/0.053
R2/stream	2.213/2.064	0.082/0.076	0.177/0.165	0.042/0.039	0.017/0.016	0.017/0.015	0.022/0.021
R3/stream	3.386/7.539	0.125/0.279	0.271/0.603	0.064/0.141	0.026/0.058	0.025/0.056	0.034/0.075
R4/stream	5.679/10.76	0.210/0.399	0.454/0.861	0.107/0.202	0.043/0.082	0.042/0.080	0.057/0.108

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

zRMS comments:

The PEC/RAC ratio for a.s.-boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in onion, shallot, onion “seven years old and ornamentals (bulb vegetables, BBCH 13 as worst case) (single/multiple application) for all scenarios except D6 was below 1 indicated acceptable risk.

Further refinement is needed for D6 scenario only for chronic risk assessment for fish.

Table 9.5-36: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in cabbage, strawberry, parsnip and parsley (leafy vegetables, BBCH 15 as worst case) (single/multiple application)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		EC ₅₀ 2700	NOEC 125	EC ₅₀ 5330	NOEC 1310	EC ₅₀ 1340	NOEC 1000
AF		100	10	100	10	10	10
RAC (µg/L)		27	12.5	53.3	131	134	100
FOCUS Sce- nario	PEC _{gl-max} (µg/L)						
Step 1							
	70.68/141.35	2.618/5.235	5.654/11.308	1.326/2.652	0.540/1.079	0.527/1.055	0.707/1.414
Step 2							
S-Europe	22.04/43.24	0.816/ 1.601	1.763/3.459	0.414/0.811	0.168/0.330	0.164/0.323	0.220/0.432
N-Europe	12.13/23.57	0.449/0.873	0.970/ 1.886	0.228/0.442	0.093/0.180	0.091/0.176	0.121/0.236
Step 3							
D3 1 st /ditch	3.051/2.675	0.113/0.099	0.244/0.214	0.057/0.050	0.023/0.020	0.023/0.020	0.031/0.027
D3 2 nd /ditch	3.036/2.660	0.112/0.099	0.243/0.213	0.057/0.050	0.023/0.020	0.023/0.020	0.030/0.027
D4/pond	1.702/4.087	0.063/0.151	0.136/0.327	0.032/0.077	0.013/0.031	0.013/0.031	0.017/0.041
D4/stream	2.320/5.017	0.086/0.186	0.186/0.401	0.044/0.094	0.018/0.038	0.017/0.037	0.023/0.050
D6/ditch	7.978/18.81	0.295/0.697	0.638/ 1.505	0.150/0.353	0.061/0.144	0.060/0.140	0.080/0.188
R1 1 st /pond	0.857/1.813	0.032/0.067	0.069/0.145	0.016/0.034	0.007/0.014	0.006/0.014	0.009/0.018
R1 2 nd /pond	0.626/1.234	0.023/0.046	0.050/0.099	0.012/0.023	0.005/0.009	0.005/0.009	0.006/0.012
R1 1 st /stream	3.955/5.954	0.146/0.221	0.316/0.476	0.074/0.112	0.030/0.045	0.030/0.044	0.040/0.060
R1 2 nd /stream	2.779/6.266	0.103/0.232	0.222/0.501	0.052/0.118	0.021/0.048	0.021/0.047	0.028/0.063
R2 1 st /stream	2.662/2.302	0.099/0.085	0.213/0.184	0.050/0.043	0.020/0.018	0.020/0.017	0.027/0.023
R2 2 nd /stream	2.704/2.338	0.100/0.087	0.216/0.187	0.051/0.044	0.021/0.018	0.020/0.017	0.027/0.023
R3 1 st /stream	3.961/8.330	0.147/0.309	0.317/0.666	0.074/0.156	0.030/0.064	0.030/0.062	0.040/0.083
R3 2 nd /stream	4.177/8.301	0.155/0.307	0.334/0.664	0.078/0.156	0.032/0.063	0.031/0.062	0.042/0.083
R4 1 st /stream	5.896/13.33	0.218/0.494	0.472/ 1.066	0.111/0.250	0.045/0.102	0.044/0.099	0.059/0.133
R4 2 nd /stream	5.929/10.83	0.220/0.401	0.474/0.866	0.111/0.203	0.045/0.083	0.044/0.081	0.059/0.108

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

zRMS comments:

The PEC/RAC ratio for a.s.-boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in cabbage, strawberry, parsnip and parsley (leafy vegetables, BBCH 15 as worst case) (single/multiple application) except D6 and R4 was below 1 indicated acceptable risk.
Further refinement is needed for D6 and R4 scenario only for chronic risk assessment for fish.

Table 9.5-37: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in cherry (apple early application as worst case, BBCH 60) (single/multiple application)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		EC ₅₀ 2700	NOEC 125	EC ₅₀ 5330	NOEC 1310	EC ₅₀ 1340	NOEC 1000
AF		100	10	100	10	10	10
RAC (µg/L)		27	12.5	53.3	131	134	100
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
	70.71/141.41	2.619/5.237	5.657/11.313	1.327/2.653	0.540/ 1.079	0.528/ 1.055	0.707/ 1.414
Step 2							
S-Europe	25.99/39.51	0.963/ 1.463	2.079/3.161	0.488/0.741	0.198/0.302	0.194/0.295	0.260/0.395
N-Europe	25.99/36.36	0.963/ 1.347	2.079/2.909	0.488/0.682	0.198/0.278	0.194/0.271	0.260/0.364
Step 3							
D3/ditch	20.81/17.97	0.771/0.666	1.665/1.438	0.390/0.337	0.159/0.137	0.155/0.134	0.208/0.180
D4/pond	1.261/2.072	0.047/0.077	0.101/0.166	0.024/0.039	0.010/0.016	0.009/0.015	0.013/0.021
D4/stream	22.05/18.86	0.817/0.699	1.764/1.509	0.414/0.354	0.168/0.144	0.165/0.141	0.221/0.189
D5/pond	1.345/2.323	0.050/0.086	0.108/0.186	0.025/0.044	0.010/0.018	0.010/0.017	0.013/0.023
D5/stream	23.82/20.35	0.882/0.754	1.906/1.628	0.447/0.382	0.182/0.155	0.178/0.152	0.238/0.204
R1/pond	1.261/2.082	0.047/0.077	0.101/0.167	0.024/0.039	0.010/0.016	0.009/0.016	0.013/0.021
R1/stream	16.90/14.43	0.626/0.534	1.352/1.154	0.317/0.271	0.129/0.110	0.126/0.108	0.169/0.144
R2/stream	22.65/19.34	0.839/0.716	1.812/1.547	0.425/0.363	0.173/0.148	0.169/0.144	0.227/0.193
R3/stream	23.65/20.34	0.876/0.753	1.892/1.627	0.444/0.382	0.181/0.155	0.176/0.152	0.237/0.203
R4/stream	16.52/14.42	0.612/0.534	1.322/1.154	0.310/0.271	0.126/0.110	0.123/0.108	0.165/0.144

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

zRMS comments:

The PEC/RAC ratio for a.s.-boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in cherry (apple early application as worst case, BBCH 60) (single/multiple application) except D3, D4, D5 and R1(stream), R2, R3, R4 was below 1 indicated acceptable risk. Further refinement is needed for D3, D4, D5 and R1(stream), R2, R3, R4 scenarios for chronic risk assessment for fish.

Table 9.5-38: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in raspberry, blackcurrant, ornamentals, redcurrant and white currant (vines and apple late application as worst case, BBCH 61) (single/multiple application)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		EC ₅₀ 2700	NOEC 125	EC ₅₀ 5330	NOEC 1310	EC ₅₀ 1340	NOEC 1000
AF		100	10	100	10	10	10
RAC (µg/L)		27	12.5	53.3	131	134	100
FOCUS Sce- nario	PEC _{gl-max} (µg/L)						
Step 1							
	93.44/186.87	3.461/6.921	7.475/14.950	1.753/3.506	0.713/1.426	0.697/1.395	0.934/1.869
Step 2							
S-Europe	17.28/32.54	0.640/ 1.205	1.382/2.603	0.324/0.611	0.132/0.248	0.129/0.243	0.173/0.325
N-Europe	14.10/26.26	0.522/0.973	1.128/2.101	0.265/0.493	0.108/0.200	0.105/0.196	0.141/0.263
Step 3							
D3/ditch	8.216/7.294	0.304/0.270	0.657/0.584	0.154/0.137	0.063/0.056	0.061/0.054	0.082/0.073
D4/pond	0.294/0.479	0.011/0.018	0.024/0.038	0.006/0.009	0.002/0.004	0.002/0.004	0.003/0.005
D4/stream	7.903/6.985	0.293/0.259	0.632/0.559	0.148/0.131	0.060/0.053	0.059/0.052	0.079/0.070
D6/ditch	8.124/7.391	0.301/0.274	0.650/0.591	0.152/0.139	0.062/0.056	0.061/0.055	0.081/0.074
R1/pond	0.346/0.761	0.013/0.028	0.028/0.061	0.006/0.014	0.003/0.006	0.003/0.006	0.003/0.008
R1/stream	6.038/5.327	0.224/0.197	0.483/0.426	0.113/0.100	0.046/0.041	0.045/0.040	0.060/0.053
R2/stream	8.117/7.161	0.301/0.265	0.649/0.573	0.152/0.134	0.062/0.055	0.061/0.053	0.081/0.072
R3/stream	8.502/7.530	0.315/0.279	0.680/0.602	0.160/0.141	0.065/0.057	0.063/0.056	0.085/0.075
R4/stream	6.055/5.342	0.224/0.198	0.484/0.427	0.114/0.100	0.046/0.041	0.045/0.040	0.061/0.053

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

zRMS comments:

The PEC/RAC ratio for a.s.-boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in raspberry, blackcurrant, ornamentals, redcurrant and white currant (vines and apple late application as worst case, BBCH 61) (single/multiple application) was below 1 indicated acceptable risk.

Pyraclostrobin: for all intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish as characterised by an LC₅₀ for *Oncorhynchus mykiss* of 6 µg a.s./L in connection with an assessment factor of 100) in all FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies.

Metabolites of Pyraclostrobin: for all intended uses, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms. Therefore, no further assessment is necessary.

Boscalid: for all intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish as characterised by a NOEC for *Oncorhynchus mykiss* of 125 µg a.s./L in connection with an assessment factor of 10) in D6 2nd/ditch for bulb vegetables, D6/ditch and R4 1st/stream for leafy vegetables and D3 ditch, D4 stream, D5 stream, R1 stream, R2 stream, R3 stream and R4 stream for apple early application. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies.

Pyraclostrobin

Table 9.5-39: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE in sugarbeet (single/multiple application)

Intended use		Sugar beet							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 100							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 ditch	0.172/0.144	0.091/0.075	0.062/0.050	0.047/-	-/-	-/-	-/-	-/-
50 %		0.086/0.072	0.046/0.037	0.031/-	-/-	-/-	-/-	-/-	-/-
75 %		0.043/0.036	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	0.178/0.149	0.094/0.077	0.064/0.052	0.049/-	-/-	-/-	-/-	-/-
50 %		0.089/0.074	0.047/0.039	-/-	-/-	-/-	-/-	-/-	-/-
75 %		0.044/0.037	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.153/-	0.081/-	0.079/-	0.079/-	0.153/0.128	0.081/0.067	0.055/0.052	0.042/0.035
50 %		0.079/-	0.079/-	-/-	-/-	0.077/0.096	0.041/0.067	-/-	-/-
75 %		0.079/-	0.079/-	-/-	-/-	0.052/0.096	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	0.215/-	0.114/-	0.085/-	0.085/-	0.215/0.181	0.114/0.094	0.078/0.063	0.059/0.048
50 %		0.108/-	0.085/-	-/-	-/-	0.108/0.090	0.057/0.050	0.039/0.038	-/-
75 %		0.085/-	0.085/-	-/-	-/-	0.055/0.071	-/-	-/-	-/-

Intended use		Sugar beet							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 100							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
90 %		0.085/-	-/-	-/-	-/-	-/0.071	-/-	-/-	-/-
RAC (µg/L)									
0.06									
PEC/RAC ratio									
None	D3 ditch	2.867/2.400	1.517/1.250	1.033/0.833	0.783/-	-/-	-/-	-/-	-/-
50 %		1.433/1.200	0.767/0.617	0.517/-	-/-	-/-	-/-	-/-	-/-
75 %		0.717/0.600	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	2.967/2.483	1.567/1.283	1.067/0.867	0.817/-	-/-	-/-	-/-	-/-
50 %		1.483/1.233	0.783/0.650	-/-	-/-	-/-	-/-	-/-	-/-
75 %		0.733/0.617	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	2.550/-	1.350/-	1.317/-	1.317/-	2.550/2.133	1.350/1.117	0.917/0.867	0.700/0.583
50 %		1.317/-	1.317/-	-/-	-/-	1.283/1.600	0.683/1.117	-/-	-/-
75 %		1.317/-	1.317/-	-/-	-/-	0.867/1.600	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	3.583/-	1.900/-	1.417/-	1.417/-	3.583/3.017	1.900/1.567	1.300/1.050	0.983/0.800
50 %		1.800/-	1.417/-	-/-	-/-	1.800/1.500	0.950/0.833	0.650/0.633	-/-
75 %		1.417/-	1.417/-	-/-	-/-	0.917/1.183	-/-	-/-	-/-
90 %		1.417/-	-/-	-/-	-/-	-/1.183	-/-	-/-	-/-

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

zRMS comment:

Pyraclostrobin- FOCUS STEP4 PEC_{sw} calculation and refined risk assessment

The PEC/RAC < 1 ratio for Pyraclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE **in sugarbeet (single/multiple application)** indicated an acceptable risk when following buffer zone will be applied to surfacewater bodies:

- 5 meter buffer zone +75 % drift reduction nozzels or 15 m drift buffer zone +50% drift reduction nozzels or 20 meter buffer zone for D3 and D4 scenarios
- 15 meter buffer zone +15 meter vegetative buffer strip or 20 meter buffer zone +20 meter vegetative buffer strip for R1 scenario
- 10 meter buffer strip + 10 meter vegetative buffer strip or 20 meter buffer zone +20 meter vegetative buffer strip for R3 scenario

Table 9.5-40: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE in tomato and eggplant (fruiting vegetables and potato, BBCH 12 as worst case) (single/multiple application)

Intended use		Fruiting vegetables and potato, BBCH 12 as worst case							
Active substance		Pyraclostrobin							
Application rate (g/ha)		3 x 100							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 ditch	0.172/0.123	0.091/0.064	0.062/0.044	0.047/-	-/-	-/-	-/-	-/-
50 %		0.086/0.0606	0.046/0.032	0.031/-	-/-	-/-	-/-	-/-	-/-
75 %		0.043/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	0.188/0.134	0.100/0.070	0.068/0.048	0.052/-	-/-	-/-	-/-	-/-
50 %		0.094/0.067	0.050/0.035	0.034/-	-/-	-/-	-/-	-/-	-/-
75 %		0.047/0.033	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch	0.169/0.122	0.090/0.064	0.0613/0.043	-/-	-/-	-/-	-/-	-/-
50 %		0.085/0.0607	0.045/0.032	-/-	-/-	-/-	-/-	-/-	-/-
75 %		0.042/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.150/-	0.092/-	0.092/-	-/-	0.150/0.130	0.080/0.091	0.054/0.071	0.041/
50 %		0.092/-	0.092/-	-/-	-/-	0.075/0.130	0.042/-	-/-	-/-
75 %		0.092/	-/-	-/-	-/-	0.060/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 stream	0.202/0.146	0.107/0.077	0.073/0.059	0.056/-	-/	-/	-/	-/
50 %		0.101/0.073	0.053/0.059	0.037/-	-/-	-/	-/	-/	-/
75 %		0.051/0.059	-/-	-/-	-/-	-/	-/	-/	-/
90 %		-/-	-/-	-/-	-/-	-/	-/	-/	-/
None	R3 stream	0.215/-	0.114/-	0.098/-	-/-	0.215/0.154	0.114/0.083	0.078/0.064	0.059/0.044
50 %		0.108/-	0.098/-	-/-	-/-	0.108/0.120	0.057/0.083	0.039/-	-/-
75 %		0.098/-	0.098/-	-/-	-/-	0.064/0.120	-/-	-/-	-/-
90 %		0.098/-	-/-	-/-	-/-	0.064/-	-/-	-/-	-/-
None	R4 stream	0.173/-	0.173/-	-/-	-/-	0.153/0.204	0.081/0.142	0.0605/0.109	0.042/0.074
50 %		0.173/-	-/-	-/-	-/-	0.113/0.204	0.079/0.142	-/-	-/-
75 %		-/-	-/-	-/-	-/-	0.113/-	0.079/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
RAC (µg/L)									

Intended use		Fruiting vegetables and potato, BBCH 12 as worst case							
Active substance		Pyraclostrobin							
Application rate (g/ha)		3 x 100							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
0.06 PEC/RAC ratio									
None	D3 ditch	2.867/2.050	1.517/1.067	1.033/0.733	0.783/-	-/-	-/-	-/-	-/-
50 %		1.433/1.010	0.767/0.533	0.517/-	-/-	-/-	-/-	-/-	-/-
75 %		0.717/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	3.133/2.233	1.667/1.167	1.133/0.800	0.867/-	-/-	-/-	-/-	-/-
50 %		1.567/1.117	0.833/0.583	0.567/-	-/-	-/-	-/-	-/-	-/-
75 %		0.783/0.550	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch	2.817/2.033	1.500/1.067	1.022/0.717	-/-	-/-	-/-	-/-	-/-
50 %		1.417/1.012	0.750/0.533	-/-	-/-	-/-	-/-	-/-	-/-
75 %		0.700/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	2.500/-	1.533/-	1.533/-	-/-	2.500/2.167	1.333/1.517	0.900/1.183	-/0.683
50 %		1.533/-	1.533/-	-/-	-/-	1.250/2.167	0.700/-	-/-	-/-
75 %		1.533/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 stream	3.367/2.433	1.783/1.283	1.217/0.983	0.933/-	-/-	-/-	-/-	-/-
50 %		1.683/1.217	0.883/0.983	0.617/-	-/-	-/-	-/-	-/-	-/-
75 %		0.850/0.983	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	3.583/-	1.900/-	1.633/-	-/-	3.583/2.567	1.900/1.383	1.300/1.067	0.983/0.733
50 %		1.800/-	1.633/-	-/-	-/-	1.800/2.000	0.950/1.383	0.650/-	-/-
75 %		1.633/-	1.633/-	-/-	-/-	1.067/2.000	-/-	-/-	-/-
90 %		1.633/-	-/-	-/-	-/-	1.067/-	-/-	-/-	-/-
None	R4 stream	2.883/-	2.883/-	-/-	-/-	2.550/3.400	1.350/2.367	1.008/1.817	0.700/1.233
50 %		2.883/-	-/-	-/-	-/-	1.883/3.400	1.317/2.367	-/-	-/-
75 %		-/-	-/-	-/-	-/-	1.883/-	1.317/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

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

zRMS comment:

Pyraclostrobin - FOCUS STEP4 PECsw calculations and refined risk assessment

The PEC/RAC < 1 ratio for Pyraclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE in tomato and eggplant (fruiting vegetables and potato, BBCH 12 as worst case) (single/multiple application) indicated an acceptable risk when following buffer zone will be applied to surfacewater bodies:

- 5 meter buffer zone +75 % drift reduction nozzels or 15 m drift buffer zone +50% drift reduction nozzels or 20 meter buffer zone for D3, D4 (stream) and D6 scenarios
- 20 meter buffer zone +20 meter vegetative buffer strip for R1, R2 and R3 scenario
- **An acceptable risk was not indicated for R4 scenario with 20 m DBZ and 10 VBS**

Table 9.5-41: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE in carrots, beetroot, celery root, radish, horseradish, swedes, turnip, chicory roots and salsifies (root vegetables, BBCH 11 as worst case) (single/multiple application)

Intended use		Root vegetables							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 100							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 ditch	0.172/0.144	0.091/0.075	0.062/0.050	0.047/-	-/-	-/-	-/-	-/-
50 %	D3 ditch	0.086/0.072	0.046/0.037	0.031/-	-/	-/-	-/-	-/-	-/-
75 %		0.043/0.036	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch	0.172/0.144	0.091/0.075	0.062/0.051	0.047/-	-/-	-/-	-/-	-/-
50 %	D6 ditch	0.086/0.072	0.046/0.038	0.031/-	-/-	-/-	-/-	-/-	-/-
75 %		0.043/0.036	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.153/-	0.093/-	0.093/-	-/-	0.153/0.128	0.091/0.077	0.055/0.059	0.042/-
50 %	R1 stream	0.093/-	0.093/-	-/-	-/-	0.076/0.111	0.042/0.077	-/-	-/-
75 %		0.093/-	-/-	-/-	-/-	0.061/0.111	-/-	-/-	-/-
None	R2 1 st stream	0.202/0.169	0.107/0.088	0.073/0.062	0.056/0.062	-/0.169	-/0.088	-/0.059	-/0.045
50 %	R2 1 st stream	0.101/0.084	0.054/0.062	0.037/0.062	-/-	-/0.084	-/0.044	-/-	-/-
75 %		0.050/0.062	-/0.062	-/-	-/-	-/0.042	-/-	-/-	-/-
None	R2 2 nd stream	0.205/0.172	0.109/0.089	0.074/0.0602	0.057/-	-/-	-/	-/-	-/-
50 %	R2 2 nd stream	0.103/0.086	0.054/0.045	0.037/-	-/-	-/-	-/-	-/-	-/-
75 %		0.051/0.043	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	0.215/	0.114/-	0.105/-	-/-	0.215/0.179	0.114/0.093	0.078/0.063	0.059/0.047
50 %	R3 stream	0.107/	0.105/-	-/-	-/-	0.107/0.097	0.057/0.068	0.039/0.052	-/-
75 %		0.105/	-/-	-/-	-/-	0.068/0.097	-/0.068	-/-	-/-
None	R4 stream	0.167/	0.167/-	-/-	-/-	0.151/0.180	0.080/0.125	0.058/0.096	0.042/0.066
50 %	R4 stream	0.167/	-/-	-/-	-/-	0.109/0.180	0.076/0.125	-/0.096	-/0.066
75 %		-/-	-/-	-/-	-/-	0.109/-	0.076/-	-/-	-/-
RAC (µg/L)									
0.06									
PEC/RAC ratio									
None	D3 ditch	2.867/2.400	1.517/1.250	1.033/0.833	0.783/-	-/-	-/-	-/-	-/-
50 %		1.433/1.200	0.767/0.617	0.517/-	-/-	-/-	-/-	-/-	-/-
75 %		0.717/0.600	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch	2.867/2.400	1.517/1.250	1.033/0.850	0.783/-	-/-	-/-	-/-	-/-
50 %	D6 ditch	1.433/1.200	0.767/0.633	0.517/-	-/-	-/-	-/-	-/-	-/-

Intended use		Root vegetables							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 100							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
75 %		0.717/0.600	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	2.550/-	1.550/-	1.550/-	-/-	2.550/2.133	1.517/1.283	0.917/0.983	0.700/-
50 %		1.550/-	1.550/-	-/-	-/-	1.267/1.850	0.700/1.283	-/-	-/-
75 %		1.550/-	-/-	-/-	-/-	1.017/1.850	-/-	-/-	-/-
None	R2 1 st stream	3.367/2.817	1.783/1.467	1.217/1.033	0.933/1.033	-/2.817	-/1.467	-/0.983	-/0.750
50 %		1.683/1.400	0.900/1.033	0.617/1.033	-/-	-/1.400	-/0.733	-/-	-/-
75 %		0.833/1.033	-/1.033	-/-	-/-	-/0.700	-/-	-/-	-/-
None	R2 2 nd stream	3.417/2.867	1.817/1.483	1.233/1.003	0.950/-	-/-	-/-	-/-	-/-
50 %		1.717/1.433	0.900/0.750	0.617/-	-/-	-/-	-/-	-/-	-/-
75 %		0.850/0.717	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	3.583/-	1.900/-	1.750/-	-/-	3.583/2.983	1.900/1.550	1.300/1.050	0.983/0.783
50 %		1.783/-	1.750/-	-/-	-/-	1.783/1.617	0.950/1.133	0.650/0.867	-/-
75 %		1.750/-	-/-	-/-	-/-	1.133/1.617	-/1.133	-/-	-/-
None	R4 stream	2.783/-	2.783/-	-/-	-/-	2.517/3.000	1.333/2.083	0.967/1.600	0.700/1.100
50 %		2.783/-	-/-	-/-	-/-	1.817/3.000	1.267/2.083	-/1.600	-/1.100
75 %		-/-	-/-	-/-	-/-	1.817/-	1.267/-	-/-	-/-

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

zRMS comment:

Pyraclostrobin - FOCUS STEP4 PECsw calculations and refined risk assessment

The PEC/RAC < 1 ratio for Pyraclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE in carrots, beetroot, celery root, radish, horseradish, swedes, turnip, chicory roots and salsifies (root vegetables, BBCH 11 as worst case) (single/multiple application) indicated an acceptable risk when following buffer zone will be applied to surface water bodies:

- 20 meter buffer zone +20 meter vegetative buffer strip for R1 and R2 and R3 scenarios or 10 meter buffer zone +10 meter vegetative buffer strip with 50% drift reduction nozzels

No acceptable risk was not indicated for R4 scenario with 20 m DBZ and 10 VBS

Table 9.5-42: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE in onion, shallot, onion “seven years old and ornamentals (bulb vegetables, BBCH 13 as worst case) (single/multiple application)

Intended use		Bulb vegetables							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 100							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 ditch	0.172/0.144	0.091/0.075	0.062/0.051	0.047/-	-/-	-/-	-/-	-/-
50 %		0.086/0.072	0.046/0.037	0.031/-	-/-	-/-	-/-	-/-	-/-
75 %		0.043/0.036	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	0.175/0.146	0.093/0.076	0.063/0.051	0.048/-	-/-	-/-	-/-	-/-
50 %		0.088/0.073	0.046/0.038	0.032/-	-/-	-/-	-/-	-/-	-/-
75 %		0.044/0.037	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch 1 st	0.173/0.155	0.092/0.080	0.063/0.054	0.048/-	-/-	-/-	-/-	-/-
50 %		0.086/0.077	0.046/0.040	0.031/-	-/-	-/-	-/-	-/-	-/-
75 %		0.043/0.039	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch 2 nd	0.173/0.145	0.092/0.075	0.063/0.051	0.048/-	-/-	-/-	-/-	-/-
50 %		0.087/0.072	0.046/0.038	0.031/-	-/-	-/-	-/-	-/-	-/-
75 %		0.043/0.036	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.150/-	0.092/-	0.092/-	-/-	0.150/0.126	0.080/0.065	0.054/0.049	0.041/-
50 %		0.092/-	0.092/-	-/-	-/-	0.075/0.092	0.042/0.064	-/-	-/-
75 %		0.092/-	-/-	-/-	-/-	0.0601/0.092	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 stream	0.202/0.169	0.107/0.087	0.073/0.059	0.056/-	-/-	-/-	-/-	-/-
50 %		0.101/0.085	0.054/0.048	0.037/-	-/-	-/-	-/-	-/-	-/-
75 %		0.051/0.048	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	0.214/	0.114/-	0.085/-	0.085/-	0.214/0.180	0.114/0.093	0.078/0.063	0.059/0.048
50 %		0.107/-	0.085/-	0.085/-	-/-	0.107/0.119	0.057/0.048	0.039/0.063	-/-
75 %		0.085/-	0.085/-	-/-	-/-	0.055/0.119	-/-	-/-	-/-
90 %		0.085/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 stream	0.156/-	0.156/-	-/-	-/-	0.152/0.206	0.088/0.143	0.055/0.110	0.042/0.075

Intended use		Bulb vegetables							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 100							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
50 %		0.156/-	-/-	-/-	-/-	0.101/0.206	0.071/0.143	-/-	-/-
75 %		-/-	-/-	-/-	-/-	0.101/-	0.071/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
RAC (µg/L)									
0.06								PEC/RAC ratio	
None	D3 ditch	2.867/2.400	1.517/1.250	1.033/0.850	0.783/-	-/-	-/-	-/-	-/-
50 %		1.433/1.200	0.767/0.617	0.517/-	-/-	-/-	-/-	-/-	-/-
75 %		0.717/0.600	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	2.917/2.433	1.550/1.267	1.050/0.850	0.800/-	-/-	-/-	-/-	-/-
50 %		1.467/1.217	0.767/0.633	0.533/-	-/-	-/-	-/-	-/-	-/-
75 %		0.733/0.617	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch 1 st	2.883/2.583	1.533/1.333	1.050/0.900	0.800/-	-/-	-/-	-/-	-/-
50 %		1.433/1.283	0.767/0.667	0.517/-	-/-	-/-	-/-	-/-	-/-
75 %		0.717/0.650	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch 2 nd	2.883/2.417	1.533/1.250	1.050/0.850	0.800/-	-/-	-/-	-/-	-/-
50 %		1.450/1.200	0.767/0.633	0.517/-	-/-	-/-	-/-	-/-	-/-
75 %		0.717/0.600	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	2.500/-	1.533/-	1.533/-	-/-	2.500/2.100	1.333/1.083	0.900/0.817	0.683/-
50 %		1.533/-	1.533/-	-/-	-/-	1.250/1.533	0.700/1.067	-/-	-/-
75 %		1.533/-	-/-	-/-	-/-	1.002/1.533	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 stream	3.367/2.817	1.783/1.450	1.217/0.983	0.933/-	-/-	-/-	-/-	-/-
50 %		1.683/1.417	0.900/0.800	0.617/-	-/-	-/-	-/-	-/-	-/-
75 %		0.850/0.800	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	3.567/-	1.900/-	1.417/-	1.417/-	3.567/3.000	1.900/1.550	1.300/1.050	0.983/0.800
50 %		1.783/-	1.417/-	1.417/-	-/-	1.783/1.983	0.950/0.800	0.650/1.050	-/-
75 %		1.417/-	1.417/-	-/-	-/-	0.917/1.983	-/-	-/-	-/-
90 %		1.417/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

Intended use		Bulb vegetables							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 100							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	R4 stream	2.600/-	2.600/-	-/-	-/-	2.533/3.433	1.467/2.383	0.917/1.833	0.700/1.250
50 %		2.600/-	-/-	-/-	-/-	1.683/3.433	1.183/2.383	-/-	-/-
75 %		-/-	-/-	-/-	-/-	1.683/-	1.183/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

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

zRMS comment:

Pyraclostrobin - FOCUS STEP4 PECsw calculations and refined risk assessment

The PEC/RAC < 1 ratio for Pyraclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE in onion, shallot, onion “seven years old and ornamentals (bulb vegetables, BBCH 13 as worst case) (single/multiple application) when following buffer zone will be applied to surfacewater bodies:

- 5 meter buffer zone +75 % drift reduction nozzels or 15 m drift buffer zone +50% drift reduction nozzels or 20 meter buffer zone for D3 , D4 (stream) and D6 (ditch) and R2 scenarios
- 15 meter buffer zone +15 meter vegetative buffer strip or 20 meter buffer zone +20 meter vegetative buffer strip for R1 scenario
- 20 meter buffer zone +20 meter vegetative buffer strip for R3 scenario
- **No safe use for R4 scenario with 20 meter buffer zone +20 meter vegetative buffer strip**

Table 9.5-43: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE in cabbage, strawberry, parsnip and parsley (leafy vegetables, BBCH 15 as worst case) (single/multiple application)

Intended use		Leafy vegetables							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 121							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 1 st ditch	0.208/0.175	0.110/0.091	0.075/0.0611	0.057/-	-/-	-/-	-/-	-/-
50 %		0.104/0.087	0.055/0.045	0.038/-	-/-	-/-	-/-	-/-	-/-
75 %		0.051/0.044	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D3 2 nd ditch	0.207/0.174	0.110/0.090	0.075/0.0608	0.057/-	-/-	-/-	-/-	-/-
50 %		0.104/0.087	0.055/0.045	0.038/-	-/-	-/-	-/-	-/-	-/-
75 %		0.052/0.043	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	0.209/0.179	0.111/0.093	0.076/0.063	0.057/0.047	-/-	-/-	-/-	-/-
50 %		0.104/0.089	0.055/0.046	0.038/0.031	-/-	-/-	-/-	-/-	-/-
75 %		0.052/0.045	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch	0.205/0.173	0.109/0.090	0.074/0.0607	0.057/-	-/-	-/-	-/-	-/-
50 %		0.103/0.087	0.054/0.045	0.037/-	-/-	-/-	-/-	-/-	-/-
75 %		0.051/0.43	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 1 st stream	0.183/-	0.102/-	0.102/-	-/-	0.183/0.153	0.097/0.079	0.066/0.054	0.050/0.040
50 %		0.102/-	0.102/-	-/-	-/-	0.091/0.099	0.048/0.069	0.035/-	-/-
75 %		0.102/-	-/-	-/-	-/-	0.066/0.099	-/0.069	-/-	-/-
90 %		-/-	-/-	-/-	-/-	0.066/-	-/-	-/-	-/-
None	R1 2 nd stream	0.185/-	0.098/-	0.067/-	0.066/-	0.185/0.155	0.098/0.081	0.067/0.054	0.051/0.041
50 %		0.093/-	0.066/-	0.066/-	0.066/-	0.093/0.096	0.049/0.067	0.034/-	-/-
75 %		0.066/-	0.066/-	-/-	-/-	0.046/0.096	-/0.067	-/-	-/-
90 %		0.066/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 1 st stream	0.245/0.205	0.130/0.106	0.089/0.072	0.067/0.054	-/-	-/-	-/-	-/-
50 %		0.122/0.102	0.065/0.053	0.044/0.048	0.034/-	-/-	-/-	-/-	-/-
75 %		0.0612/0.051	0.032/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 2 nd	0.249/0.208	0.132/0.108	0.090/0.073	0.068/0.055	-/-	-/-	-/-	-/-

Intended use		Leafy vegetables							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 121							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
50 %	stream	0.124/0.104	0.066/0.054	0.045/0.036	0.034/-	-/-	-/-	-/-	-/-
75 %	stream	0.062/0.052	0.033/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		0.025/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream 1 st	0.261/-	0.139/-	0.099/-	0.099/-	0.261/0.219	0.139/0.114	0.095/0.077	0.072/0.058
50 %		0.131/-	0.099/-	0.099/-	-/-	0.131/0.133	0.069/0.093	0.047/0.071	0.036/-
75 %		0.099/-	0.099/-	-/-	-/-	0.065/0.133	0.045/0.093	-/-	-/-
90 %		0.099/-	-/-	-/-	-/-	0.065/-	-/-	-/-	-/-
None	R3 stream 2 nd	0.261/-	0.139/-	0.095/-	0.092/-	0.261/0.219	0.139/0.114	0.095/0.077	0.072/0.058
50 %		0.131/-	0.092/-	0.092/-	-/-	0.131/0.112	0.069/0.078	0.047/0.060	0.036/-
75 %		0.092/-	0.092/-	-/-	-/-	0.065/0.112	0.042/0.078	-/-	-/-
90 %		0.092/-	-/-	-/-	-/-	0.060/-	-/-	-/-	-/-
None	R4 stream 1 st	0.185/-	0.164/-	0.164/-	-/-	0.185/0.236	0.098/0.164	0.067/0.126	0.051/0.086
50 %		0.164/-	0.164/-	-/-	-/-	0.107/0.236	0.075/0.164	0.057/-	-/-
75 %		0.164/-	-/-	-/-	-/-	0.107/-	0.075/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 stream 2 nd	0.184/-	0.157/-	0.157/-	-/-	0.184/0.196	0.098/0.137	0.067/0.105	0.051/0.072
50 %		0.157/-	0.157/-	-/-	-/-	0.103/0.196	0.072/0.137	0.055/-	-/-
75 %		0.157/-	-/-	-/-	-/-	0.103/-	0.072/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
RAC (µg/L)									
0.06								PEC/RAC ratio	
None	D3 ditch 1 st	3.467/2.917	1.833/1.517	1.250/1.018	0.950/-	-/-	-/-	-/-	-/-
50 %		1.733/1.450	0.917/0.750	0.633/-	-/-	-/-	-/-	-/-	-/-
75 %		0.850/0.733	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D3 ditch 2 nd	3.450/2.900	1.833/1.500	1.250/1.013	0.950/-	-/-	-/-	-/-	-/-
50 %		1.733/1.450	0.917/0.750	0.633/-	-/-	-/-	-/-	-/-	-/-
75 %		0.867/0.717	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	3.483/2.983	1.850/1.550	1.267/1.050	0.950/0.783	-/-	-/-	-/-	-/-
50 %		1.733/1.483	0.917/0.767	0.633/0.517	-/-	-/-	-/-	-/-	-/-
75 %		0.867/0.750	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

Intended use		Leafy vegetables							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 121							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D6 ditch	3.417/2.883	1.817/1.500	1.233/1.012	0.950/-	-/-	-/-	-/-	-/-
50 %		1.717/1.450	0.900/0.750	0.617/-	-/-	-/-	-/-	-/-	-/-
75 %		0.850/7.167	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 1 st stream	3.050/-	1.700/-	1.700/-	-/-	3.050/2.550	1.617/1.317	1.100/0.900	0.833/0.667
50 %		1.700/-	1.700/-	-/-	-/-	1.517/1.650	0.800/1.150	0.583/-	-/-
75 %		1.700/-	-/-	-/-	-/-	1.100/1.650	-/1.150	-/-	-/-
90 %		-/-	-/-	-/-	-/-	1.100/-	-/-	-/-	-/-
None	R1 2 nd stream	3.083/-	1.633/-	1.117/-	1.100/-	3.083/2.583	1.633/1.350	1.117/0.900	0.850/0.683
50 %		1.550/-	1.100/-	1.100/-	1.100/-	1.550/1.600	0.817/1.117	0.567/-	-/-
75 %		1.100/-	1.100/-	-/-	-/-	0.767/1.600	-/1.117	-/-	-/-
90 %		1.100/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 1 st stream	4.083/3.417	2.167/1.767	1.483/1.200	1.117/0.900	-/-	-/-	-/-	-/-
50 %		2.033/1.700	1.083/0.883	0.733/0.800	0.567/-	-/-	-/-	-/-	-/-
75 %		1.020/0.850	0.533/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 2 nd stream	4.150/3.467	2.200/1.800	1.500/1.217	1.133/0.917	-/-	-/-	-/-	-/-
50 %		2.067/1.733	1.100/0.900	0.750/0.600	0.567/-	-/-	-/-	-/-	-/-
75 %		1.033/0.867	0.550/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		0.417/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 1 st stream	4.350/-	2.317/-	1.650/-	1.650/-	4.350/3.650	2.317/1.900	1.583/1.283	1.200/0.967
50 %		2.183/-	1.650/-	1.650/-	-/-	2.183/2.217	1.150/1.550	0.783/1.183	0.600/-
75 %		1.650/-	1.650/-	-/-	-/-	1.083/2.217	0.750/1.550	-/-	-/-
90 %		1.650/-	-/-	-/-	-/-	1.083/-	-/-	-/-	-/-
None	R3 2 nd stream	4.350/-	2.317/-	1.583/-	1.533/-	4.350/3.650	2.317/1.900	1.583/1.283	1.200/0.967
50 %		2.183/-	1.533/-	1.533/-	-/-	2.183/1.867	1.150/1.300	0.783/1.000	0.600/-
75 %		1.533/-	1.533/-	-/-	-/-	1.083/1.867	0.700/1.300	-/-	-/-
90 %		1.533/-	-/-	-/-	-/-	1.000/-	-/-	-/-	-/-
None	R4 1 st stream	3.083/-	2.733/-	2.733/-	-/-	3.083/3.933	1.633/2.733	1.117/2.100	0.850/1.433
50 %		2.733/-	2.733/-	-/-	-/-	1.783/3.933	1.250/2.733	0.950/-	-/-
75 %		2.733/-	-/-	-/-	-/-	1.783/-	1.250/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 2 nd	3.067/-	2.617/-	2.617/-	-/-	3.067/3.267	1.633/2.283	1.117/1.750	0.850/1.200

Intended use		Leafy vegetables							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 121							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
50 %	stream	2.617/-	2.617/-	-/-	-/-	1.717/3.267	1.200/2.283	0.917/-	-/-
75 %		2.617/-	-/-	-/-	-/-	1.717/-	1.200/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

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

zRMS comment:

Pyraclostrobin - FOCUS STEP4 PECsw calculations and refined risk assessment

The PEC/RAC < 1 ratio for Pyraclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE in cabbage, strawberry, parsnip and parsley (leafy vegetables, BBCH 15 as worst case) (single/multiple application) when following buffer zone will be applied to surfacewater bodies:

- 5 meter buffer zone +75 % drift reduction nozzels or 15 m drift buffer zone +50% drift reduction nozzels or 20 meter buffer zone for D3, D4 (stream) and D6 (ditch) scenarios
- 20 meter buffer zone +20 meter vegetative buffer strip for R1 scenario
- 20 meter buffer zone + 50% drift reduction nozzels for R2 scenario
- 20 meter buffer zone +20 meter vegetative buffer strip + 50% drift reduction nozzels for R3 scenario
- **No safe use for R4 scenario with 20 meter buffer zone +20 meter vegetative buffer strip**

Table 9.5-44: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE in cherry (apple early application as worst case, BBCH 60) (single/multiple application)

Intended use		Apple early application							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 67							
Nozzl red.	Vegetative strip (m)	None							
	No spray buffer (m)	5	10	15	20	30	40	50	
None	D3 ditch	4.101/3.479	2.519/2.055	1.133/1.128	0.576/0.532	0.220/0.182	0.111/0.085	0.065/0.047	
50 %		2.051/1.739	1.260/1.028	0.567/0.564	0.288/0.266	0.110/0.091	0.055/0.043	0.033/-	

Intended use		Apple early application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 67						
Nozzl red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
75 %		1.026/0.870	0.630/0.514	0.283/0.282	0.144/0.133	0.055/0.046	-/-	-/-
90 %		0.410/0.348	0.252/0.206	0.113/0.113	0.058/0.059	-/-	-/-	-/-
None	D4 pond	0.356/0.562	0.195/0.319	0.103/0.167	0.063/0.096	0.031/0.043	-/-	-/-
50 %		0.178/0.281	0.098/0.159	0.052/0.084	0.032/0.048	-/-	-/-	-/-
75 %		0.089/0.140	0.049/0.080	-/0.042	-/-	-/-	-/-	-/-
90 %		0.036/0.056	-/0.032	-/-	-/-	-/-	-/-	-/-
None	D4 stream	4.755/4.019	2.920/2.374	1.314/1.303	0.668/0.615	0.255/0.211	0.129/0.099	0.075/0.054
50 %		2.377/2.009	1.460/1.187	0.657/0.652	0.334/0.307	0.128/0.106	0.064/0.049	0.038/-
75 %		1.189/1.005	0.730/0.594	0.329/0.326	0.167/0.154	0.064/0.053	0.032/-	-/-
90 %		0.476/0.402	0.292/0.237	0.131/0.130	0.067/0.0615	0.026/-	-/-	-/-
None	D5 pond	0.356/0.532	0.195/0.302	0.103/0.159	0.063/0.091	0.031/0.040	-/-	-/-
50 %		0.178/0.266	0.098/0.151	0.052/0.079	0.032/0.045	-/-	-/-	-/-
75 %		0.089/0.133	0.049/0.075	-/0.040	-/-	-/-	-/-	-/-
90 %		0.036/0.053	-/0.030	-/-	-/-	-/-	-/-	-/-
None	D5 stream	5.135/4.337	3.153/2.561	1.419/1.406	0.721/0.663	0.276/0.228	0.139/0.106	0.081/0.059
50 %		2.567/2.168	1.577/1.281	0.709/0.703	0.361/0.332	0.138/0.114	0.069/0.053	0.041/-
75 %		1.284/1.084	0.788/0.641	0.355/0.352	0.180/0.166	0.069/0.057	0.035/-	-/-
90 %		0.514/0.434	0.315/0.256	0.142/0.141	0.072/0.066	0.028/-	-/-	-/-
None	R1 pond	0.356/0.525	0.195/0.300	0.103/0.159	0.063/0.093	0.031/0.043	-/-	-/-
50 %		0.178/0.264	0.098/0.151	0.052/0.082	0.032/0.048	-/-	-/-	-/-
75 %		0.089/0.134	0.049/0.077	-/0.042	-/-	-/-	-/-	-/-
90 %		0.036/0.055	-/0.033	-/-	-/-	-/-	-/-	-/-
None	R1 stream	3.644/3.074	2.237/1.816	1.007/0.997	0.512/0.470	0.196/0.162	0.099/0.075	0.058/0.054
50 %		1.822/1.537	1.119/0.908	0.503/0.498	0.256/0.235	0.098/0.081	0.052/0.054	-/-
75 %		0.911/0.768	0.559/0.454	0.252/0.249	0.128/0.118	0.052/0.054	-/-	-/-
90 %		0.364/0.307	0.224/0.182	0.101/0.100	0.052/0.054	-/-	-/-	-/-
None	R2 stream	4.884/4.121	2.999/2.434	1.349/1.336	0.686/0.630	0.262/0.217	0.132/0.101	0.077/0.056
50 %		2.442/2.060	1.500/1.217	0.674/0.668	0.343/0.315	0.131/0.108	0.066/0.051	0.039-
75 %		1.221/1.030	0.750/0.609	0.337/0.334	0.171/0.158	0.066/0.054	0.033/-	-/-
90 %		0.488/0.412	0.300/0.243	0.135/0.134	0.069/0.063	0.026/-	-/-	-/-
None	R3 stream	5.099/4.334	3.131/2.560	1.409/1.405	0.716/0.663	0.274/0.228	0.138/0.106	0.081/0.059
50 %		2.549/2.166	1.566/1.280	0.704/0.702	0.358/0.331	0.137/0.114	0.069/0.053	0.040/-
75 %		1.275/1.083	0.783/0.640	0.352/0.351	0.179/0.166	0.068/0.057	0.034/-	-/-

Intended use		Apple early application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 67						
Nozzl red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
90 %		0.510/0.433	0.313/0.256	0.141/0.141	0.072/0.066	0.027/-	-/-	-/-
None	R4 stream	3.561/3.074	2.187/1.185	0.984/0.996	0.500/0.470	0.191/0.162	0.096/0.078	0.056/0.078
50 %		1.780/1.536	1.094/0.908	0.492/0.498	0.250/0.235	0.096/0.081	0.048/0.078	-/-
75 %		0.890/0.768	0.547/0.454	0.246/0.249	0.125/0.118	0.048/0.078	-/-	-/-
90 %		0.356/0.307	0.219/0.182	0.098/0.100	0.050/0.078	-/0.078	-/-	-/-
RAC (µg/L)								
0.06								
PEC/RAC ratio								
None	D3 ditch	68.350/57.983	41.983/34.250	18.883/18.800	9.600/8.867	3.667/3.033	1.850/1.417	1.083/0.783
50 %		34.183/28.983	21.000/17.133	9.450/9.400	4.800/4.433	1.833/1.517	0.917/0.717	0.550/-
75 %		17.100/14.500	10.500/8.567	4.717/4.700	2.400/2.217	0.917/0.767	-/-	-/-
90 %		6.833/5.800	4.200/3.433	1.883/1.883	0.967/0.983	-/-	-/-	-/-
None	D4 pond	5.933/9.367	3.250/5.317	1.717/2.783	1.050/1.600	0.517/0.717	-/-	-/-
50 %		2.967/4.683	1.633/2.650	0.867/1.400	0.533/0.800	-/-	-/-	-/-
75 %		1.483/2.333	0.817/1.333	-/0.700	-/-	-/-	-/-	-/-
90 %		0.600/0.933	-/0.533	-/-	-/-	-/-	-/-	-/-
None	D4 stream	79.250/66.983	48.667/39.567	21.900/21.717	11.133/10.250	4.250/3.517	2.150/1.650	1.250/0.900
50 %		39.617/33.483	24.333/19.783	10.950/10.867	5.567/5.117	2.133/1.767	1.067/0.817	0.633/-
75 %		19.817/16.750	12.167/9.900	5.483/5.433	2.783/2.567	1.067/0.883	0.533/-	-/-
90 %		7.933/6.700	4.867/3.950	2.183/2.167	1.117/1.025	0.433/-	-/-	-/-
None	D5 pond	5.933/8.867	3.250/5.033	1.717/2.650	1.050/1.517	0.517/0.667	-/-	-/-
50 %		2.967/4.433	1.633/2.517	0.867/1.317	0.533/0.750	-/-	-/-	-/-
75 %		1.483/2.217	0.817/1.250	-/0.667	-/-	-/-	-/-	-/-
90 %		0.600/0.883	-/0.500	-/-	-/-	-/-	-/-	-/-
None	D5 stream	85.583/72.283	52.550/42.683	23.650/23.433	12.017/11.050	4.600/3.800	2.317/1.767	1.350/0.983
50 %		42.783/36.133	26.283/21.350	11.817/11.717	6.017/5.533	2.300/1.900	1.150/0.883	0.683/-
75 %		21.400/18.067	13.133/10.683	5.917/5.867	3.000/2.767	1.150/0.950	0.583/-	-/-
90 %		8.567/7.233	5.250/4.267	2.367/2.350	1.200/1.100	0.467/-	-/-	-/-
None	R1 pond	5.933/8.750	3.250/5.000	1.717/2.650	1.050/1.550	0.517/0.717	-/-	-/-
50 %		2.967/4.400	1.633/2.517	0.867/1.367	0.533/0.800	-/-	-/-	-/-
75 %		1.483/2.233	0.817/1.283	-/0.700	-/-	-/-	-/-	-/-
90 %		0.600/0.917	-/0.550	-/-	-/-	-/-	-/-	-/-
None	R1 stream	60.733/51.233	37.283/30.267	16.783/16.617	8.533/7.833	3.267/2.700	1.650/1.250	0.967/0.900
50 %		30.367/25.617	18.650/15.133	8.383/8.300	4.267/3.917	1.633/1.350	0.867/0.900	-/-

Intended use		Apple early application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 67						
Nozzl red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
75 %		15.183/12.800	9.317/7.567	4.200/4.150	2.133/1.967	0.867/0.900	-/-	-/-
90 %		6.067/5.117	3.733/3.033	1.683/1.667	0.867/0.900	-/-	-/-	-/-
None	R2 stream	81.400/68.683	49.983/40.567	22.483/22.267	11.433/10.500	4.367/3.617	2.200/1.683	1.283/0.933
50 %		40.700/34.333	25.000/20.283	11.233/11.133	5.717/5.250	2.183/1.800	1.100/0.850	0.650/-
75 %		20.350/17.167	12.500/10.150	5.617/5.567	2.850/2.633	1.100/0.900	0.550/-	-/-
90 %		8.133/6.867	5.000/4.050	2.250/2.233	1.150/1.050	0.433/-	-/-	-/-
None	R3 stream	84.983/72.233	52.183/42.667	23.483/23.417	11.933/11.050	4.567/3.800	2.300/1.767	1.350/0.983
50 %		42.483/36.100	26.100/21.333	11.733/11.700	5.967/5.517	2.283/1.900	1.150/0.883	0.667/-
75 %		21.250/18.050	13.050/10.667	5.867/5.850	2.983/2.767	1.133/0.950	0.567/-	-/-
90 %		8.500/7.217	5.217/4.267	2.350/2.350	1.200/1.100	0.450/-	-/-	-/-
None	R4 stream	59.350/51.233	36.450/19.750	16.400/16.600	8.333/7.833	3.183/2.700	1.600/1.300	0.933/1.300
50 %		29.667/25.600	18.233/15.133	8.200/8.300	4.167/3.917	1.600/1.350	0.800/1.300	-/-
75 %		14.833/12.800	9.117/7.567	4.100/4.150	2.083/1.967	0.800/1.300	-/-	-/-
90 %		5.933/5.117	3.650/3.033	1.633/1.667	0.833/1.300	-/1.300	-/-	-/-

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

zRMS comment:

Pyraclostrobin - FOCUS STEP4 PEC_{sw} calculations and refined risk assessment:

The PEC/RAC < 1 ratio for Pyrclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE in cherry (apple early application as worst case, BBCH 60) (single/multiple application) when following buffer zone will be applied to surfacewater bodies:

- 50 meter buffer zone +50 % drift reduction nozzels for D3 (ditch), D4 (stream) and D5 (stream) scenarios
- 30 meter buffetr zone for D5 pond, R1 pond
- 50 meter buffer zone for R1 scenario
- 50 meter buffer zone + 50% drift reduction nozzels for R2 and R3 scenarios
- **No safe use for R4 scenario with 50 meter buffer zone**

Table 9.5-45: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE in raspberry, blackcurrant, ornamentals, redcurrant and white currant (vines late application as worst case, BBCH 61) (single/multiple application)

Intended use		Vines late application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 121						
Nozzl red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
None	D3 ditch	1.250/1.105	0.453/0.397	0.273/0.239	0.159/0.138	0.085/0.074	0.055/0.047	-/-
50 %		0.625/0.553	0.226/0.198	0.137/0.119	0.079/0.069	0.043/0.037	-/-	-/-
75 %		0.313/0.276	0.113/0.099	0.068/0.060	0.040/0.035	-/-	-/-	-/-
90 %		0.125/0.111	0.045/0.040	0.027/-	-/-	-/-	-/-	-/-
None	D4 pond	0.086/0.136	0.047/0.074	-/0.054	-/-	-/-	-/-	-/-
50 %		0.048/0.068	-/0.037	-/-	-/-	-/-	-/-	-/-
75 %		-/0.034	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	1.207/1.064	0.437/0.382	0.264/0.230	0.153/0.133	0.082/0.071	0.053/0.045	-/-
50 %		0.604/0.532	0.219/0.191	0.132/0.115	0.077/0.066	0.041/0.035	-/-	-/-
75 %		0.302/0.266	0.109/0.096	0.066/0.057	0.038/0.033	-/-	-/-	-/-
90 %		0.121/0.106	0.044/0.038	0.026/-	-/-	-/-	-/-	-/-
None	D6 ditch	1.248/1.120	0.452/0.402	0.246/0.217	0.158/0.140	0.085/0.075	0.055/0.048	-/-
50 %		0.624/0.560	0.226/0.201	0.123/0.109	0.079/0.070	0.043/0.036	-/-	-/-
75 %		0.312/0.280	0.113/0.101	0.0614/0.054	0.040/0.035	-/-	-/-	-/-
90 %		0.125/0.112	0.045/0.040	-/-	-/-	-/-	-/-	-/-
None	R1 pond	0.086/0.119	0.047/0.066	-/0.045	-/-	-/-	-/-	-/-
50 %		0.043/0.060	-/0.036	-/-	-/-	-/-	-/-	-/-
75 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	1.107/0.973	0.401/0.350	0.218/0.189	0.141/0.166	0.081/0.166	0.081/-	-/-
50 %		0.553/0.487	0.200/0.175	0.109/0.166	0.081/0.166	0.081/-	-/-	-/-
75 %		0.277/0.244	0.100/0.166	0.081/0.166	0.081/-	-/-	-/-	-/-
90 %		0.111/0.166	0.081/0.166	0.081/-	-/-	-/-	-/-	-/-
None	R2 stream	1.488/1.309	0.539/0.470	0.293/0.254	0.189/0.164	0.102/0.087	0.065/0.056	0.046/-
50 %		0.744/0.655	0.269/0.235	0.146/0.127	0.095/0.082	0.051/0.044	0.033/-	-/-
75 %		0.372/0.327	0.135/0.118	0.073/0.064	0.047/0.041	-/-	-/-	-/-
90 %		0.149/0.131	0.054/0.047	0.029/0.025	-/-	-/-	-/-	-/-

Intended use		Vines late application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 121						
Nozzl red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
None	R3 stream	1.558/1.376	0.564/0.495	0.307/0.267	0.198/0.172	0.106/0.092	0.068/0.059	0.048/
50 %		0.779/0.688	0.282/0.247	0.153/0.134	0.099/0.086	0.053/0.046	0.034/-	-/-
75 %		0.389/0.344	0.141/0.124	0.077/0.067	0.049/0.045	-/-	-/-	-/-
90 %		0.156/0.138	0.056/0.049	0.031/0.045	-/-	-/-	-/-	-/-
None	R4 stream	1.110/0.976	0.402/0.351	0.218/0.190	0.141/0.122	0.076/0.074	0.049/0.074	-/-
50 %		0.555/0.488	0.201/0.175	0.109/0.095	0.070/0.074	0.038/0.074	-/-	-/-
75 %		0.277/0.244	0.101/0.088	0.055/0.074	0.035/0.074	-/-	-/-	-/-
90 %		0.111/0.098	0.040/0.074	-/0.074	-/-	-/-	-/-	-/-
RAC (µg/L)								
0.06								
PEC/RAC ratio								
None	D3 ditch	20.833/18.417	7.550/6.617	4.550/3.983	2.650/2.300	1.417/1.233	0.917/0.783	-/-
50 %		10.417/9.217	3.767/3.300	2.283/1.983	1.317/1.150	0.717/0.617	-/-	-/-
75 %		5.217/4.600	1.883/1.650	1.133/1.000	0.667/0.583	-/-	-/-	-/-
90 %		2.083/1.850	0.750/0.667	0.450/-	-/-	-/-	-/-	-/-
None	D4 pond	1.433/2.267	0.783/1.233	-/0.900	-/-	-/-	-/-	-/-
50 %		0.800/1.133	-/0.617	-/-	-/-	-/-	-/-	-/-
75 %		-/0.567	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	20.117/17.733	7.283/6.367	4.400/3.833	2.550/2.217	1.367/1.183	0.883/0.750	-/-
50 %		10.067/8.867	3.650/3.183	2.200/1.917	1.283/1.100	0.683/0.583	-/-	-/-
75 %		5.033/4.433	1.817/1.600	1.100/0.950	0.633/0.550	-/-	-/-	-/-
90 %		2.017/1.767	0.733/0.633	0.433/-	-/-	-/-	-/-	-/-
None	D6 ditch	20.800/18.667	7.533/6.700	4.100/3.617	2.633/2.333	1.417/1.250	0.917/0.800	-/-
50 %		10.400/9.333	3.767/3.350	2.050/1.817	1.317/1.167	0.717/0.600	-/-	-/-
75 %		5.200/4.667	1.883/1.683	1.023/0.900	0.667/0.583	-/-	-/-	-/-
90 %		2.083/1.867	0.750/0.667	-/-	-/-	-/-	-/-	-/-
None	R1 pond	1.433/1.983	0.783/1.100	-/0.750	-/-	-/-	-/-	-/-
50 %		0.717/1.000	-/0.600	-/-	-/-	-/-	-/-	-/-
75 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	18.450/16.217	6.683/5.833	3.633/3.150	2.350/2.767	1.350/2.767	1.350/-	-/-
50 %		9.217/8.117	3.333/2.917	1.817/2.767	1.350/2.767	1.350/-	-/-	-/-
75 %		4.617/4.067	1.667/2.767	1.350/2.767	1.350/-	-/-	-/-	-/-

Intended use		Vines late application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 121						
Nozzl red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
90 %		1.850/2.767	1.350/2.767	1.350/-	-/-	-/-	-/-	-/-
None	R2 stream	24.800/21.817	8.983/7.833	4.883/4.233	3.150/2.733	1.700/1.450	1.083/0.933	0.767/-
50 %		12.400/10.917	4.483/3.917	2.433/2.117	1.583/1.367	0.850/0.733	0.550/-	-/-
75 %		6.200/5.450	2.250/1.967	1.217/1.067	0.783/0.683	-/-	-/-	-/-
90 %		2.483/2.183	0.900/0.783	0.483/0.417	-/-	-/-	-/-	-/-
None	R3 stream	25.967/22.933	9.400/8.250	5.117/4.450	3.300/2.867	1.767/1.533	1.133/0.983	0.800/-
50 %		12.983/11.467	4.700/4.117	2.550/2.233	1.650/1.433	0.883/0.767	0.567/-	-/-
75 %		6.483/5.733	2.350/2.067	1.283/1.117	0.817/0.750	-/-	-/-	-/-
90 %		2.600/2.300	0.933/0.817	0.517/0.750	-/-	-/-	-/-	-/-
None	R4 stream	18.500/16.267	6.700/5.850	3.633/3.167	2.350/2.033	1.267/1.233	0.817/1.233	-/-
50 %		9.250/8.133	3.350/2.917	1.817/1.583	1.167/1.233	0.633/1.233	-/-	-/-
75 %		4.617/4.067	1.683/1.467	0.917/1.233	0.583/1.233	-/-	-/-	-/-
90 %		1.850/1.633	0.667/1.233	-/1.233	-/-	-/-	-/-	-/-

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

zRMS comment:

Pyraclostrobin - FOCUS STEP4 PEC_{sw} calculations and refined risk assessment:

The PEC/RAC < 1 ratio for Pyraclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE in raspberry, blackcurrant, ornamentals, redcurrant and white currant (vines late application as worst case, BBCH 61) (single/multiple application) when following buffer zone will be applied to surface water bodies:

- 40 meter buffer zone for D3 (ditch), D4 (stream) and D5 (stream) and D6 scenarios
- 15 meter buffer zone for D4 pond, R1 pond
- 50 meter buffer zone for R1 scenario
- 50 meter buffer zone for R2 and R3 scenarios
- **No safe use for R1 scenario with 50 meter buffer zone**
- **No safe use for R4 scenario with 40 meter buffer zone**

After step 4 calculations, the PEC/RAC ratio calculated were still above the trigger of 1 for:

- R4 stream scenario in fruiting vegetables
- R4 stream scenario in root vegetables
- R4 stream scenario in bulb vegetables
- R4 1st stream and R4 2nd stream scenarios in leafy vegetables
- R4 stream scenario in apple early application
- R1 stream and R4 stream scenarios in vines late application

Therefore, a further refinement was necessary.

Refinement of the risk assessment for the most sensitive group of aquatic organisms: Fish

In the monograph of Pyraclostrobin, acute toxicity laboratory studies of seven different fish species are available for Pyraclostrobin and for the representative formulation BAS 500 00 F (Pyraclostrobin 247.83 g a.s./L) . From this data it appears that the rainbow trout is the most sensitive species, but the carp (species tested in the mesocosm) is not the least sensitive species. The Applicant wishes to consider that the geomean value of LC₅₀ of 24.82 µg a.s./L from these seven different fish species studies with an assessment factor of 100 is more appropriate to use in the refinement of the risk. The value of the RAC obtained is **0.248 µg a.s./L**.

Moreover, together with the assessment using the RAC_{geomean}, new PEC/RAC calculations were included based on the RAC of 0.2 µg/L for chronic risk assessment to fish.

Table 9.5-46: Available LC₅₀ values for pyraclostrobin

Test item	Fish species	LC ₅₀ (mg a.s./L)
Pyraclostrobin	<i>Lepomis macrochirus</i>	0.0196
		0.0335
	<i>Oncorhynchus mykiss</i>	0.00616
Formulated (BAS 500 00 F)	<i>Cyprinus carpio</i>	0.0121
		0.0258
	<i>Oryzias latipes</i>	0.0325
		0.0885
	<i>Pimephales promelas</i>	0.012
		0.0235
	<i>Brachydanio rerio</i>	0.0417
		0.087
	<i>Leuciscus idus melanotus</i>	0.0135
		0.027
	Geomean (µg a.s./L)	24.82

Table 9.5-47: Fish: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and geomean toxicity data for acute fish with mitigation of spray drift and run-off for the use of CASINO ROYALE in sugar beet (single/multiple application)

Intended use		Sugar beet							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 100							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 ditch	0.172/0.144	0.091/0.075	0.062/0.050	0.047/-	-/-	-/-	-/-	-/-
None	D4 stream	0.178/0.149	0.094/0.077	0.064/0.052	0.049/-	-/-	-/-	-/-	-/-
None	R1 stream	0.153/-	0.081/-	0.079/-	0.079/-	0.153/0.128	0.081/0.067	0.055/0.052	0.042/0.035
None	R3 stream	0.215/-	0.114/-	0.085/-	0.085/-	0.215/0.181	0.114/0.094	0.078/0.063	0.059/0.048
RAC (µg/L)									
0.248		PEC/RAC ratio							
None	D3 ditch	0.694/0.581	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	0.718/0.601	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.617/0.000	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	0.867/0.000	-/-	-/-	-/-	-/-	-/-	-/-	-/-
RAC (µg/L)									
0.2		PEC/RAC ratio							
None	D3 ditch	0.860/0.720	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	0.890/0.745	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.765/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	1.075/-	0.570/-	-/-	-/-	1.075/0.905	0.570/0.470	-/-	-/-

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

Table 9.5-48: Fish: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and geomean toxicity data for acute fish with mitigation of spray drift and run-off for the use of CASINO ROYALE in tomato and eggplant (fruiting vegetables and potato, BBCH 12 as worst case) (single/multiple application)

Intended use		Fruiting vegetables and potato, BBCH 12 as worst case							
Active substance		Pyraclostrobin							
Application rate (g/ha)		3 x 100							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 ditch	0.172/0.123	0.091/0.064	0.062/0.044	0.047/-	-/-	-/-	-/-	-/-
None	D4 stream	0.188/0.134	0.100/0.070	0.068/0.048	0.052/-	-/-	-/-	-/-	-/-
None	D6 ditch	0.169/0.122	0.090/0.064	0.0613/0.043	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.150/-	0.092/-	0.092/-	-/-	0.150/0.130	0.080/0.091	0.054/0.071	0.041/-
None	R2 stream	0.202/0.146	0.107/0.077	0.073/0.059	0.056/-	-/-	-/-	-/-	-/-
None	R3 stream	0.215/-	0.114/-	0.098/-	-/-	0.215/0.154	0.114/0.083	0.078/0.064	0.059/0.044
None	R4 stream	0.173/-	0.173/-	-/-	-/-	0.153/0.204	0.081/0.142	0.0605/0.109	0.042/0.074
RAC (µg/L)									
0.248								PEC/RAC ratio	
None	D3 ditch	0.694/0.496	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	0.758/0.540	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch	0.681/0.492	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.605/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 stream	0.815/0.589	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	0.867/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 stream	0.698/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
RAC (µg/L)									
0.2								PEC/RAC ratio	
None	D3 ditch	0.860/0.615	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	0.940/0.670	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch	0.845/0.610	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.750/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 stream	1.010/0.730	0.535/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	1.075/-	0.570/-	-/-	-/-	1.075/0.770	0.570/-	-/-	-/-
None	R4 stream	0.865/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

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

Table 9.5-49: Fish: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and a geomean toxicity data for acute fish with mitigation of spray drift and run-off for the use of CASINO ROYALE in carrots, beetroot, celery root, radish, horseradish, swedes, turnip, chicory roots and salsifies (root vegetables, BBCH 11 as worst case) (single/multiple application)

Intended use		Root vegetables							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 100							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 ditch	0.172/0.144	0.091/0.075	0.062/0.050	0.047/-	-/-	-/-	-/-	-/-
None	D6 ditch	0.172/0.144	0.091/0.075	0.062/0.051	0.047/-	-/-	-/-	-/-	-/-
None	R1 stream	0.153/-	0.093/-	0.093/-	-/-	0.153/0.128	0.091/0.077	0.055/0.059	0.042/-
None	R2 1 st stream	0.202/0.169	0.107/0.088	0.073/0.062	0.056/0.062	-/0.169	-/0.088	-/0.059	-/0.045
None	R2 2 nd stream	0.205/0.172	0.109/0.089	0.074/0.0602	0.057/-	-/-	-/-	-/-	-/-
None	R3 stream	0.215/-	0.114/-	0.105/-	-/-	0.215/0.179	0.114/0.093	0.078/0.063	0.059/0.047
None	R4 stream	0.167/-	0.167/-	-/-	-/-	0.151/0.180	0.080/0.125	0.058/0.096	0.042/0.066
RAC (µg/L)									
0.248		PEC/RAC ratio							
None	D3 ditch	0.694/0.581	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch	0.694/0.581	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.617/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 1 st stream	0.815/0.681	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 2 nd stream	0.827/0.694	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	0.867/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 stream	0.673/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
RAC (µg/L)									
0.2		PEC/RAC ratio							
None	D3 ditch	0.860/0.720	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch	0.860/0.720	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.765/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 1 st stream	1.010/0.845	0.535/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 2 nd stream	1.025/0.860	0.545/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	1.075/-	0.570/-	-/-	-/-	1.075/0.895	0.570/-	-/-	-/-
None	R4 stream	0.835/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

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

Table 9.5-50: Fish: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and a geomean toxicity data for acute fish with mitigation of spray drift and run-off for the use of CASINO ROYALE in onion, shallot, onion “seven years old and ornamentals (bulb vegetables, BBCH 13 as worst case) (single/multiple application)

Intended use		Bulb vegetables							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 100							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 ditch	0.172/0.144	0.091/0.075	0.062/0.051	0.047/-	-/-	-/-	-/-	-/-
None	D4 stream	0.175/0.146	0.093/0.076	0.063/0.051	0.048/-	-/-	-/-	-/-	-/-
None	D6 1 st ditch	0.173/0.155	0.092/0.080	0.063/0.054	0.048/-	-/-	-/-	-/-	-/-
None	D6 2 nd ditch	0.173/0.145	0.092/0.075	0.063/0.051	0.048/-	-/-	-/-	-/-	-/-
None	R1 stream	0.150/-	0.092/-	0.092/-	-/-	0.150/0.126	0.080/0.065	0.054/0.049	0.041/-
None	R2 stream	0.202/0.169	0.107/0.087	0.073/0.059	0.056/-	-/-	-/-	-/-	-/-
None	R3 stream	0.214/-	0.114/-	0.085/-	0.085/-	0.214/0.180	0.114/0.093	0.078/0.063	0.059/0.0
None	R4 stream	0.156/-	0.156/-	-/-	-/-	0.152/0.206	0.088/0.143	0.055/0.110	0.042/0.0
RAC (µg/L)									
0.248						PEC/RAC ratio			
None	D3 ditch	0.694/0.581	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	0.706/0.589	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 1 st ditch	0.698/0.625	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 2 nd ditch	0.698/0.585	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.605/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 stream	0.815/0.681	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	0.863/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 stream	0.629/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
RAC (µg/L)									
0.2						PEC/RAC ratio			
None	D3 ditch	0.860/0.720	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	0.875/0.730	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 1 st ditch	0.865/0.775	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 2 nd ditch	0.865/0.725	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.750/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 stream	1.010/0.845	0.535/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	1.070/-	0.570/-	-/-	-/-	1.070/0.900	0.570/-	-/-	-/-
None	R4 stream	0.780/-	-/-	-/-	-/-	0.760/1.030	-/0.715	-/-	-/-

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

Table 9.5-51: Fish: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and a geomean toxicity data for acute fish with mitigation of spray drift and run-off for the use of CASINO ROYALE in cabbage, strawberry, parsnip and parsley (leafy vegetables, BBCH 15 as worst case) (single/multiple application)

Intended use		Leafy vegetables							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 121							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 1 st ditch	0.208/0.175	0.110/0.091	0.075/0.0611	0.057/-	-/-	-/-	-/-	-/-
None	D3 2 nd ditch	0.207/0.174	0.110/0.090	0.075/0.0608	0.057/-	-/-	-/-	-/-	-/-
None	D4 stream	0.209/0.179	0.111/0.093	0.076/0.063	0.057/0.047	-/-	-/-	-/-	-/-
None	D6 ditch	0.205/0.173	0.109/0.090	0.074/0.0607	0.057/-	-/-	-/-	-/-	-/-
None	R1 1 st stream	0.183/-	0.102/-	0.102/-	-/-	0.183/0.153	0.097/0.079	0.066/0.054	0.050/0.040
None	R1 2 nd stream	0.185/-	0.098/-	0.067/-	0.066/-	0.185/0.155	0.098/0.081	0.067/0.054	0.051/0.041
None	R2 1 st stream	0.245/0.205	0.130/0.106	0.089/0.072	0.067/0.054	-/-	-/-	-/-	-/-
None	R2 2 nd stream	0.249/0.208	0.132/0.108	0.090/0.073	0.068/0.055	-/-	-/-	-/-	-/-
50 %		0.124/0.104	0.066/0.054	0.045/0.036	0.034/-	-/-	-/-	-/-	-/-
None	R3 1 st stream	0.261/-	0.139/-	0.099/-	0.099/-	0.261/0.219	0.139/0.114	0.095/0.077	0.072/0.058
50 %		0.131/-	0.099/-	0.099/-	-/-	0.131/0.133	0.069/0.093	0.047/0.071	0.036/-
None	R3 2 nd stream	0.261/-	0.139/-	0.095/-	0.092/-	0.261/0.219	0.139/0.114	0.095/0.077	0.072/0.058
50 %		0.131/-	0.092/-	0.092/-	-/-	0.131/0.112	0.069/0.078	0.047/0.060	0.036/-
None	R4 1 st stream	0.185/-	0.164/-	0.164/-	-/-	0.185/0.236	0.098/0.164	0.067/0.126	0.051/0.086
None	R4 2 nd stream	0.184/-	0.157/-	0.157/-	-/-	0.184/0.196	0.098/0.137	0.067/0.105	0.051/0.072
RAC (µg/L)									
0.248									
PEC/RAC ratio									
None	D3 1 st ditch	0.839/0.706	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D3 2 nd ditch	0.835/0.702	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	0.843/0.722	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch	0.827/0.698	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 1 st stream	0.738/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 2 nd stream	0.746/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 1 st stream	0.988/0.827	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 2 nd stream	1.004/0.839	0.532/-	-/-	-/-	-/-	-/-	-/-	-/-
50 %		0.500/0.419	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 1 st stream	1.052/-	0.560/-	-/-	-/-	-/-	-/-	-/-	-/-
50 %		0.528/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 2 nd stream	1.052/-	0.560/-	-/-	-/-	-/-	-/-	-/-	-/-

Intended use		Leafy vegetables							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 121							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
50 %		0.528/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 1 st stream	0.746/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 2 nd stream	0.742/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
RAC (µg/L)									
0.2		PEC/RAC ratio							
None	D3 1 st ditch	1.040/0.875	0.550/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D3 2 nd ditch	1.035/0.870	0.550/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	1.045/0.895	0.555/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch	1.025/0.865	0.545/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 1 st stream	0.915/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 2 nd stream	0.925/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 1 st stream	1.225/1.025	0.650/0.530	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 2 nd stream	1.245/1.040	0.660/0.540	-/-	-/-	-/-	-/-	-/-	-/-
50 %		0.620/0.520	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 1 st stream	1.305/-	0.695/-	-/-	-/-	1.305/1.095	0.695/0.570	-/-	-/-
50 %		0.655/-	-/-	-/-	-/-	0.655/0.665	-/-	-/-	-/-
None	R3 2 nd stream	1.305/-	0.695/-	-/-	-/-	1.305/1.095	0.695/0.570	-/-	-/-
50 %		0.655/-	-/-	-/-	-/-	0.655/0.560	-/-	-/-	-/-
None	R4 1 st stream	0.925/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 2 nd stream	0.920/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

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

Table 9.5-52: Fish: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and a geomean toxicity data for acute fish with mitigation of spray drift and run-off for the use of CASINO ROYALE in cherry (apple early application as worst case, BBCH 60) (single/multiple application)

Intended use		Apple early application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 67						
Nozzle red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
None	D3 ditch	4.101/3.479	2.519/2.055	1.133/1.128	0.576/0.532	0.220/0.182	0.111/0.085	0.065/0.047
50 %		2.051/1.739	1.260/1.028	0.567/0.564	0.288/0.266	0.110/0.091	0.055/0.043	0.033/-
75 %		1.026/0.870	0.630/0.514	0.283/0.282	0.144/0.133	0.055/0.046	-/-	-/-
90 %		0.410/0.348	0.252/0.206	0.113/0.113	0.058/0.059	-/-	-/-	-/-
None	D4 pond	0.356/0.562	0.195/0.319	0.103/0.167	0.063/0.096	0.031/0.043	-/-	-/-
50 %		0.178/0.281	0.098/0.159	0.052/0.084	0.032/0.048	-/-	-/-	-/-
75 %		0.089/0.140	0.049/0.080	-/0.042	-/-	-/-	-/-	-/-
90 %		0.036/0.056	-/0.032	-/-	-/-	-/-	-/-	-/-
None	D4 stream	4.755/4.019	2.920/2.374	1.314/1.303	0.668/0.615	0.255/0.211	0.129/0.099	0.075/0.054
50 %		2.377/2.009	1.460/1.187	0.657/0.652	0.334/0.307	0.128/0.106	0.064/0.049	0.038/-
75 %		1.189/1.005	0.730/0.594	0.329/0.326	0.167/0.154	0.064/0.053	0.032/-	-/-
90 %		0.476/0.402	0.292/0.237	0.131/0.130	0.067/0.0615	0.026/-	-/-	-/-
None	D5 pond	0.356/0.532	0.195/0.302	0.103/0.159	0.063/0.091	0.031/0.040	-/-	-/-
50 %		0.178/0.266	0.098/0.151	0.052/0.079	0.032/0.045	-/-	-/-	-/-
75 %		0.089/0.133	0.049/0.075	-/0.040	-/-	-/-	-/-	-/-
90 %		0.036/0.053	-/0.030	-/-	-/-	-/-	-/-	-/-
None	D5 stream	5.135/4.337	3.153/2.561	1.419/1.406	0.721/0.663	0.276/0.228	0.139/0.106	0.081/0.059
50 %		2.567/2.168	1.577/1.281	0.709/0.703	0.361/0.332	0.138/0.114	0.069/0.053	0.041/-
75 %		1.284/1.084	0.788/0.641	0.355/0.352	0.180/0.166	0.069/0.057	0.035/-	-/-
90 %		0.514/0.434	0.315/0.256	0.142/0.141	0.072/0.066	0.028/-	-/-	-/-
None	R1 pond	0.356/0.525	0.195/0.300	0.103/0.159	0.063/0.093	0.031/0.043	-/-	-/-
50 %		0.178/0.264	0.098/0.151	0.052/0.082	0.032/0.048	-/-	-/-	-/-
75 %		0.089/0.134	0.049/0.077	-/0.042	-/-	-/-	-/-	-/-
90 %		0.036/0.055	-/0.033	-/-	-/-	-/-	-/-	-/-
None	R1 stream	3.644/3.074	2.237/1.816	1.007/0.997	0.512/0.470	0.196/0.162	0.099/0.075	0.058/0.054
50 %		1.822/1.537	1.119/0.908	0.503/0.498	0.256/0.235	0.098/0.081	0.052/0.054	-/-
75 %		0.911/0.768	0.559/0.454	0.252/0.249	0.128/0.118	0.052/0.054	-/-	-/-
90 %		0.364/0.307	0.224/0.182	0.101/0.100	0.052/0.054	-/-	-/-	-/-
None	R2 stream	4.884/4.121	2.999/2.434	1.349/1.336	0.686/0.630	0.262/0.217	0.132/0.101	0.077/0.056

Intended use		Apple early application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 67						
Nozzl red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
50 %		2.442/2.060	1.500/1.217	0.674/0.668	0.343/0.315	0.131/0.108	0.066/0.051	0.039-
75 %		1.221/1.030	0.750/0.609	0.337/0.334	0.171/0.158	0.066/0.054	0.033/-	-/-
90 %		0.488/0.412	0.300/0.243	0.135/0.134	0.069/0.063	0.026/-	-/-	-/-
None	R3 stream	5.099/4.334	3.131/2.560	1.409/1.405	0.716/0.663	0.274/0.228	0.138/0.106	0.081/0.059
50 %		2.549/2.166	1.566/1.280	0.704/0.702	0.358/0.331	0.137/0.114	0.069/0.053	0.040/-
75 %		1.275/1.083	0.783/0.640	0.352/0.351	0.179/0.166	0.068/0.057	0.034/-	-/-
90 %		0.510/0.433	0.313/0.256	0.141/0.141	0.072/0.066	0.027/-	-/-	-/-
None	R4 stream	3.561/3.074	2.187/1.185	0.984/0.996	0.500/0.470	0.191/0.162	0.096/0.078	0.056/0.078
50 %		1.780/1.536	1.094/0.908	0.492/0.498	0.250/0.235	0.096/0.081	0.048/0.078	-/-
75 %		0.890/0.768	0.547/0.454	0.246/0.249	0.125/0.118	0.048/0.078	-/-	-/-
90 %		0.356/0.307	0.219/0.182	0.098/0.100	0.050/0.078	-/0.078	-/-	-/-
RAC (µg/L)								
0.248		PEC/RAC ratio						
None	D3 ditch	16.536/14.028	10.157/8.286	4.569/4.548	2.323/2.145	0.887/0.734	-/-	-/-
50 %		8.270/7.012	5.081/4.145	2.286/2.274	1.161/1.073	0.444/0.367	-/-	-/-
75 %		4.137/3.508	2.540/2.073	1.141/1.137	0.581/0.536	-/-	-/-	-/-
90 %		1.653/1.403	1.016/0.831	0.456/0.456	-/-	-/-	-/-	-/-
None	D4 pond	1.435/2.266	0.786/1.286	0.415/0.673	-/-	-/-	-/-	-/-
50 %		0.718/1.133	0.395/0.641	-/-	-/-	-/-	-/-	-/-
75 %		0.359/0.565	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	19.173/16.206	11.774/9.573	5.298/5.254	2.694/2.480	1.028/0.851	0.520/0.399	-/-
50 %		9.585/8.101	5.887/4.786	2.649/2.629	1.347/1.238	0.516/0.427	-/-	-/-
75 %		4.794/4.052	2.944/2.395	1.327/1.315	0.673/0.621	-/-	-/-	-/-
90 %		1.919/1.621	1.177/0.956	0.528/0.524	-/-	-/-	-/-	-/-
None	D5 pond	1.435/2.145	0.786/1.218	0.415/0.641	-/-	-/-	-/-	-/-
50 %		0.718/1.073	0.395/0.609	-/-	-/-	-/-	-/-	-/-
75 %		0.359/0.536	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D5 stream	20.706/17.488	12.714/10.327	5.722/5.669	2.907/2.673	1.113/0.919	0.560/0.427	-/-
50 %		10.351/8.742	6.359/5.165	2.859/2.835	1.456/1.339	0.556/0.460	-/-	-/-
75 %		5.177/4.371	3.177/2.585	1.431/1.419	0.726/0.669	-/-	-/-	-/-
90 %		2.073/1.750	1.270/1.032	0.573/0.569	-/-	-/-	-/-	-/-

Intended use		Apple early application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 67						
Nozzl red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
None	R1 pond	1.435/2.117	0.786/1.210	0.415/0.641	-/-	-/-	-/-	-/-
50 %		0.718/1.065	0.395/0.609	-/-	-/-	-/-	-/-	-/-
75 %		0.359/0.540	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	14.694/12.395	9.020/7.323	4.060/4.020	2.065/1.895	0.790/0.653	-/-	-/-
50 %		7.347/6.198	4.512/3.661	2.028/2.008	1.032/0.948	0.395/0.327	-/-	-/-
75 %		3.673/3.097	2.254/1.831	1.016/1.004	0.516/0.476	-/-	-/-	-/-
90 %		1.468/1.238	0.903/0.734	-/-	-/-	-/-	-/-	-/-
None	R2 stream	19.694/16.617	12.093/9.815	5.440/5.387	2.766/2.540	1.056/0.875	0.532/0.407	-/-
50 %		9.847/8.306	6.048/4.907	2.718/2.694	1.383/1.270	0.528/0.435	-/-	-/-
75 %		4.923/4.153	3.024/2.456	1.359/1.347	0.690/0.637	-/-	-/-	-/-
90 %		1.968/1.661	1.210/0.980	0.544/0.540	-/-	-/-	-/-	-/-
None	R3 stream	20.560/17.476	12.625/10.323	5.681/5.665	2.887/2.673	1.105/0.919	0.556/0.427	-/-
50 %		10.278/8.734	6.315/5.161	2.839/2.831	1.444/1.335	0.552/0.460	-/-	-/-
75 %		5.141/4.367	3.157/2.581	1.419/1.415	0.722/0.669	-/-	-/-	-/-
90 %		2.056/1.746	1.262/1.032	0.569/0.569	-/-	-/-	-/-	-/-
None	R4 stream	14.359/12.395	8.819/4.778	3.968/4.016	2.016/1.895	0.770/0.653	-/-	-/-
50 %		7.177/6.194	4.411/3.661	1.984/2.008	1.008/0.948	0.387/0.327	-/-	-/-
75 %		3.589/3.097	2.206/1.831	0.992/1.004	0.504/0.476	-/-	-/-	-/-
90 %		1.435/1.238	0.883/0.734	-/-	-/-	-/-	-/-	-/-
RAC (µg/L)								
0.2								
PEC/RAC ratio								
None	D3 ditch	20.505/17.395	12.595/10.275	5.665/5.640	2.880/2.660	1.100/0.910	0.555/-	-/-
50 %		10.255/8.695	6.300/5.140	2.835/2.820	1.440/1.330	0.550/0.455	-/-	-/-
75 %		5.130/4.350	3.150/2.570	1.415/1.410	0.720/0.665	-/-	-/-	-/-
90 %		2.050/1.740	1.260/1.030	0.565/0.565	-/-	-/-	-/-	-/-
None	D4 pond	1.780/2.810	0.975/1.595	-/0.835	-/-	-/-	-/-	-/-
50 %		0.890/1.405	-/0.795	-/-	-/-	-/-	-/-	-/-
75 %		0.445/0.700	-/-	-/-	-/-	-/-	-/-	-/-
90 %		0.180/0.280	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	23.775/20.095	14.600/11.870	6.570/6.515	3.340/3.075	1.275/1.055	0.645/0.495	-/-
50 %		11.885/10.045	7.300/5.935	3.285/3.260	1.670/1.535	0.640/0.530	-/-	-/-
75 %		5.945/5.025	3.650/2.970	1.645/1.630	0.835/0.770	-/-	-/-	-/-

Intended use		Apple early application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 67						
Nozzl red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
90 %		2.380/2.010	1.460/1.185	0.655/0.650	-/-	-/-	-/-	-/-
None	D5 pond	1.780/2.660	0.975/ 1.510	-/0.795	-/-	-/-	-/-	-/-
50 %		0.890/ 1.330	-/0.755	-/-	-/-	-/-	-/-	-/-
75 %		0.445/0.665	-/-	-/-	-/-	-/-	-/-	-/-
90 %		0.180/0.265	-/-	-/-	-/-	-/-	-/-	-/-
None	D5 stream	25.675/21.685	15.765/12.805	7.095/7.030	3.605/3.315	1.380/1.140	0.695/0.530	-/-
50 %		12.835/10.840	7.885/6.405	3.545/3.515	1.805/1.660	0.690/0.570	-/-	-/-
75 %		6.420/5.420	3.940/3.205	1.775/1.760	0.900/0.830	-/-	-/-	-/-
90 %		2.570/2.170	1.575/1.280	0.710/0.705	-/-	-/-	-/-	-/-
None	R1 pond	1.780/2.625	0.975/ 1.500	-/0.795	-/-	-/-	-/-	-/-
50 %		0.890/ 1.320	-/0.755	-/-	-/-	-/-	-/-	-/-
75 %		0.445/0.670	-/-	-/-	-/-	-/-	-/-	-/-
90 %		0.180/0.275	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	18.220/15.370	11.185/9.080	5.035/4.985	2.560/2.350	0.980/0.810	-/-	-/-
50 %		9.110/7.685	5.595/4.540	2.515/2.490	1.280/1.175	0.490/0.405	-/-	-/-
75 %		4.555/3.840	2.795/2.270	1.260/1.245	0.640/0.590	-/-	-/-	-/-
90 %		1.820/1.535	1.120/0.910	0.505/-	-/-	-/-	-/-	-/-
None	R2 stream	24.420/20.605	14.995/12.170	6.745/6.680	3.430/3.150	1.310/1.085	0.660/0.505	-/-
50 %		12.210/10.300	7.500/6.085	3.370/3.340	1.715/1.575	0.655/0.540	-/-	-/-
75 %		6.105/5.150	3.750/3.045	1.685/1.670	0.855/0.790	-/-	-/-	-/-
90 %		2.440/2.060	1.500/1.215	0.675/0.670	-/-	-/-	-/-	-/-
None	R3 stream	25.495/21.670	15.655/12.800	7.045/7.025	3.580/3.315	1.370/1.140	0.690/0.530	-/-
50 %		12.745/10.830	7.830/6.400	3.520/3.510	1.790/1.655	0.685/0.570	-/-	-/-
75 %		6.375/5.415	3.915/3.200	1.760/1.755	0.895/0.830	-/-	-/-	-/-
90 %		2.550/2.165	1.565/1.280	0.705/0.705	-/-	-/-	-/-	-/-
None	R4 stream	17.805/15.370	10.935/5.925	4.920/4.980	2.500/2.350	0.955/0.810	-/-	-/-
50 %		8.900/7.680	5.470/4.540	2.460/2.490	1.250/1.175	0.480/0.405	-/-	-/-
75 %		4.450/3.840	2.735/2.270	1.230/1.245	0.625/0.590	-/-	-/-	-/-
90 %		1.780/1.535	1.095/0.910	0.490/-	-/-	-/-	-/-	-/-

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

Table 9.5-53: Fish: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and a geomean toxicity data for acute fish with mitigation of spray drift and run-off for the use of CASINO ROYALE in raspberry, blackcurrant, ornamentals, redcurrant and white currant (vines late application as worst case, BBCH 61) (single/multiple application)

Intended use		Vines late application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 121						
Nozzl red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
None	D3 ditch	1.250/1.105	0.453/0.397	0.273/0.239	0.159/0.138	0.085/0.074	0.055/0.047	-/-
50 %		0.625/0.553	0.226/0.198	0.137/0.119	0.079/0.069	0.043/0.037	-/-	-/-
75 %		0.313/0.276	0.113/0.099	0.068/0.060	0.040/0.035	-/-	-/-	-/-
90 %		0.125/0.111	0.045/0.040	0.027/-	-/-	-/-	-/-	-/-
None	D4 pond	0.086/0.136	0.047/0.074	-/0.054	-/-	-/-	-/-	-/-
50 %		0.048/0.068	-/0.037	-/-	-/-	-/-	-/-	-/-
75 %		-/0.034	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	1.207/1.064	0.437/0.382	0.264/0.230	0.153/0.133	0.082/0.071	0.053/0.045	-/-
50 %		0.604/0.532	0.219/0.191	0.132/0.115	0.077/0.066	0.041/0.035	-/-	-/-
75 %		0.302/0.266	0.109/0.096	0.066/0.057	0.038/0.033	-/-	-/-	-/-
90 %		0.121/0.106	0.044/0.038	0.026/-	-/-	-/-	-/-	-/-
None	D6 ditch	1.248/1.120	0.452/0.402	0.246/0.217	0.158/0.140	0.085/0.075	0.055/0.048	-/-
50 %		0.624/0.560	0.226/0.201	0.123/0.109	0.079/0.070	0.043/0.036	-/-	-/-
75 %		0.312/0.280	0.113/0.101	0.0614/0.054	0.040/0.035	-/-	-/-	-/-
90 %		0.125/0.112	0.045/0.040	-/-	-/-	-/-	-/-	-/-
None	R1 pond	0.086/0.119	0.047/0.066	-/0.045	-/-	-/-	-/-	-/-
50 %		0.043/0.060	-/0.036	-/-	-/-	-/-	-/-	-/-
75 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	1.107/0.973	0.401/0.350	0.218/0.189	0.141/0.166	0.081/0.166	0.081/-	-/-
50 %		0.553/0.487	0.200/0.175	0.109/0.166	0.081/0.166	0.081/-	-/-	-/-
75 %		0.277/0.244	0.100/0.166	0.081/0.166	0.081/-	-/-	-/-	-/-
90 %		0.111/0.166	0.081/0.166	0.081/-	-/-	-/-	-/-	-/-
None	R2 stream	1.488/1.309	0.539/0.470	0.293/0.254	0.189/0.164	0.102/0.087	0.065/0.056	0.046/-
50 %		0.744/0.655	0.269/0.235	0.146/0.127	0.095/0.082	0.051/0.044	0.033/-	-/-
75 %		0.372/0.327	0.135/0.118	0.073/0.064	0.047/0.041	-/-	-/-	-/-
90 %		0.149/0.131	0.054/0.047	0.029/0.025	-/-	-/-	-/-	-/-

Intended use		Vines late application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 121						
Nozzl red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
None	R3 stream	1.558/1.376	0.564/0.495	0.307/0.267	0.198/0.172	0.106/0.092	0.068/0.059	0.048/
50 %		0.779/0.688	0.282/0.247	0.153/0.134	0.099/0.086	0.053/0.046	0.034/-	-/-
75 %		0.389/0.344	0.141/0.124	0.077/0.067	0.049/0.045	-/-	-/-	-/-
90 %		0.156/0.138	0.056/0.049	0.031/0.045	-/-	-/-	-/-	-/-
None	R4 stream	1.110/0.976	0.402/0.351	0.218/0.190	0.141/0.122	0.076/0.074	0.049/0.074	-/-
50 %		0.555/0.488	0.201/0.175	0.109/0.095	0.070/0.074	0.038/0.074	-/-	-/-
75 %		0.277/0.244	0.101/0.088	0.055/0.074	0.035/0.074	-/-	-/-	-/-
90 %		0.111/0.098	0.040/0.074	-/0.074	-/-	-/-	-/-	-/-
RAC (µg/L)								
0.248								
PEC/RAC ratio								
None	D3 ditch	5.040/4.456	1.827/1.601	1.101/0.964	0.641/0.556	-/-	-/-	-/-
50 %		2.520/2.230	0.911/0.798	-/-	-/-	-/-	-/-	-/-
75 %		1.262/1.113	0.456/0.399	-/-	-/-	-/-	-/-	-/-
90 %		0.504/0.448	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 pond	0.347/0.548	-/-	-/-	-/-	-/-	-/-	-/-
50 %		0.194/0.274	-/-	-/-	-/-	-/-	-/-	-/-
75 %		-/0.137	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	4.867/4.290	1.762/1.540	1.065/0.927	0.617/0.536	-/-	-/-	-/-
50 %		2.435/2.145	0.883/0.770	-/-	-/-	-/-	-/-	-/-
75 %		1.218/1.073	0.440/0.387	-/-	-/-	-/-	-/-	-/-
90 %		0.488/0.427	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch	5.032/4.516	1.823/1.621	0.992/0.875	-/-	-/-	-/-	-/-
50 %		2.516/2.258	0.911/0.810	-/-	-/-	-/-	-/-	-/-
75 %		1.258/1.129	0.456/0.407	-/-	-/-	-/-	-/-	-/-
90 %		0.504/0.452	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 pond	0.347/0.480	-/-	-/-	-/-	-/-	-/-	-/-
50 %		0.173/0.242	-/-	-/-	-/-	-/-	-/-	-/-
75 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	4.464/3.923	1.617/1.411	0.879/0.762	-/-	-/-	-/-	-/-
50 %		2.230/1.964	0.806/0.706	-/-	-/-	-/-	-/-	-/-
75 %		1.117/0.984	0.403/0.669	-/-	-/-	-/-	-/-	-/-

Intended use		Vines late application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 121						
Nozzl red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
90 %		0.448/0.669	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 stream	6.000/5.278	2.173/1.895	1.181/1.024	0.762/0.661	-/-	-/-	-/-
50 %		3.000/2.641	1.085/0.948	0.589/0.512	-/-	-/-	-/-	-/-
75 %		1.500/1.319	0.544/0.476	-/-	-/-	-/-	-/-	-/-
90 %		0.601/0.528	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	6.282/5.548	2.274/1.996	1.238/1.077	0.798/0.694	-/-	-/-	-/-
50 %		3.141/2.774	1.137/0.996	0.617/0.540	-/-	-/-	-/-	-/-
75 %		1.569/1.387	0.569/0.500	-/-	-/-	-/-	-/-	-/-
90 %		0.629/0.556	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 stream	4.476/3.935	1.621/1.415	0.879/0.766	-/-	-/-	-/-	-/-
50 %		2.238/1.968	0.810/0.706	-/-	-/-	-/-	-/-	-/-
75 %		1.117/0.984	0.407/0.355	-/-	-/-	-/-	-/-	-/-
90 %		0.448/0.395	-/-	-/-	-/-	-/-	-/-	-/-
RAC (µg/L)								
0.2								
PEC/RAC ratio								
None	D3 ditch	6.250/5.525	2.265/1.985	1.365/1.195	0.795/0.690	-/-	-/-	-/-
50 %		3.125/2.765	1.130/0.990	0.685/-	-/-	-/-	-/-	-/-
75 %		1.565/1.380	0.565/0.495	-/-	-/-	-/-	-/-	-/-
90 %		0.625/0.555	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 pond	0.430/0.680	-/-	-/-	-/-	-/-	-/-	-/-
50 %		0.240/0.340	-/-	-/-	-/-	-/-	-/-	-/-
75 %		-/0.170	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	6.035/5.320	2.185/1.910	1.320/1.150	0.765/0.665	-/-	-/-	-/-
50 %		3.020/2.660	1.095/0.955	0.660/-	-/-	-/-	-/-	-/-
75 %		1.510/1.330	0.545/0.480	-/-	-/-	-/-	-/-	-/-
90 %		0.605/0.530	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch	6.240/5.600	2.260/2.010	1.230/1.085	0.790/0.700	-/-	-/-	-/-
50 %		3.120/2.800	1.130/1.005	0.615/0.545	-/-	-/-	-/-	-/-
75 %		1.560/1.400	0.565/0.505	-/-	-/-	-/-	-/-	-/-
90 %		0.625/0.560	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 pond	0.430/0.595	-/-	-/-	-/-	-/-	-/-	-/-
50 %		0.215/0.300	-/-	-/-	-/-	-/-	-/-	-/-

Intended use		Vines late application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 121						
Nozzl red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
75 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	5.535/4.865	2.005/1.750	1.090/0.945	0.705/-	-/-	-/-	-/-
50 %		2.765/2.435	1.000/0.875	0.545/-	-/-	-/-	-/-	-/-
75 %		1.385/1.220	0.500/0.830	-/-	-/-	-/-	-/-	-/-
90 %		0.555/0.830	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 stream	7.440/6.545	2.695/2.350	1.465/1.270	0.945/0.820	-/-	-/-	-/-
50 %		3.720/3.275	1.345/1.175	0.730/0.635	-/-	-/-	-/-	-/-
75 %		1.860/1.635	0.675/0.590	-/-	-/-	-/-	-/-	-/-
90 %		0.745/0.655	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	7.790/6.880	2.820/2.475	1.535/1.335	0.990/0.860	-/-	-/-	-/-
50 %		3.895/3.440	1.410/1.235	0.765/0.670	-/-	-/-	-/-	-/-
75 %		1.945/1.720	0.705/0.620	-/-	-/-	-/-	-/-	-/-
90 %		0.780/0.690	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 stream	5.550/4.880	2.010/1.755	1.090/0.950	0.705/-	-/-	-/-	-/-
50 %		2.775/2.440	1.005/0.875	0.545/-	-/-	-/-	-/-	-/-
75 %		1.385/1.220	0.505/0.440	-/-	-/-	-/-	-/-	-/-
90 %		0.555/0.490	-/-	-/-	-/-	-/-	-/-	-/-

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

zRMS comments:

It should be noted that according to EFSA ADG, 2009 the SSD approach for acute fish risk assessment is rather recommended than geomean approach for aquatic invertebrates:

In AGD, 2013: „Proposal for the derivation of RACs for aquatic organisms when a limited number of additional single species toxicity tests is available. When applying this approach scientific arguments should be given why the selected toxicity data (on which the Geomean is based) concern the same taxonomic group relevant for the RA. If more data than indicated in the second column (≥ 5 or ≥ 8) are available, the Geomean approach could still be applied, but it is recommended to preferably apply the SSD approach (see section 8.3)”.

Pyraclostrobin

Based on the geomean approach provided by the applicant it should be noted that RAC_{acute} based on this calculation ($0.248 \mu\text{g a.s./L}$, 7 species tested) is closed to $RAC_{chronic} = 0.2 \mu\text{g/L}$.

In addition, the difference in endpoints of acute toxicity tests is close to the endpoints from chronic tests for the most sensitive species for rainbow trout.

The applicant provided the refined risk assessment based on $RAC_{geomean}$ approach for acute risk assessment. ~~No further refinement was provided for chronic risk.~~

~~In RMS's opinion the slight difference between the refined RAC_{acute} and $RAC_{chronic}$ (Tier1) for fish seems doesn't change the final risk mitigation measures for fish.~~

~~However, for completeness the applicant should provide the relevant calculations based on RAC_{of} 0.2 $\mu\text{g/L}$ with STEP 4 PEC_{sw} for chronic risk assessment to long-term fish for request MSs, if relevant, during commenting period.~~

~~Based on the risk assessment the following risk mitigation measures are required:~~

~~Sugar beet, Fruiting vegetables and potato, Root vegetables and Bulb vegetables—Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 5 m to surface water bodies.~~

~~Leafy vegetables—Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 10 m with 5m vegetative strip to surface water bodies.~~

~~Apple (early application)—Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 40 m to surface water bodies OR respect an unsprayed buffer zone of 30 m to surface water bodies with 50% of nozzles reduction OR respect an unsprayed buffer zone of 20 m to surface water bodies with 75% of nozzles reduction OR respect an unsprayed buffer zone of 15 m to surface water bodies with 90% of nozzles reduction.~~

~~Vines (late application)—Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 20 m to surface water bodies OR respect an unsprayed buffer zone of 15 m to surface water bodies with 50% of nozzles reduction OR respect an unsprayed buffer zone of 10 m to surface water bodies with 75% of nozzles reduction OR respect an unsprayed buffer zone of 5 m to surface water bodies with 90% of nozzles reduction.~~

~~It should be noted, that if any of refinement option for a.s. pyraclostrobin (geomean approach for acute risk for fish , chronic risk for fish) for aquatic organism is not accepted by some MSs, they should conclude this issue on MS level.~~

The applicant provided the new calculations of chronic risk assessment during Commenting Period and the final conclusion was updated below:

For completeness reasons, together with the assessment using the $RAC_{geomean}$, new PEC/RAC calculations were included based on the **RAC of 0.2 $\mu\text{g/L}$ for Pyraclostrobin** for chronic risk assessment to fish. After this refinement, an acceptable risk was obtained **for the worst case scenario for each uses** with the following mitigation measures:

Pyraclostrobin

- Sugar beet: no-spray buffer zone of 10 m
- Fruiting vegetables and potato: no-spray buffer zone of 10 m
- Root vegetables: no-spray buffer zone of 10 m
- Bulb vegetables: no-spray buffer zone of 10 m
- Leafy vegetables: no-spray buffer zone of 10 m
- Apple (early application): no-spray buffer zone of 40 m OR no-spray buffer zone of 30 m + 50% nozzles OR no-spray buffer zone of 20 m + 75% nozzles OR no-spray buffer zone of 15 m + 90% nozzles
- Vines (late application): no-spray buffer zone of 20 m OR no-spray buffer zone of 15 m + 50% nozzles OR no-spray buffer zone of 10 m + 75% nozzles OR no-spray buffer zone of 5 m + 90%

nozzles

In addition, it should be indicated that greenhouse uses are considered acceptable.

Finally, the final risk mitigation measures should be decided at MSs level depen on the relevant scenarios for each countries.

Refinement of the risk assessment for the other aquatic organisms

An aquatic mesocosm study in outdoor consitions (*Dohmen, G.P, 2000*) was submitted in the *Monograph of Pyraclostrobin Annex B.9: Ecotoxicology (2001)*. A large number of different species (approximately 260 taxa) was observed in this mesocosm study at varying abundances during the course of the experiment. The results of a complex mesocosm study show, that BAS 500 F can have effects on few species at concentrations of 24 µg as/L (equivalent to the nine-fold of the 5% drift scenario) and higher. Fish and molluscs may be affected at this concentration, too. For all planktonic species the effects were found to be reversible. No clear effects were observed at 8 µg as/L, which is equivalent to the threefold of a 5% drift scenario in shallow, static water bodies. The multitude of endpoints and species and environmental conditions in this mesocosm study show clearly that at this (8 µg as/L and lower) concentration no adverse effects on aquatic communities can be expected even after multiple applications. The ecologically acceptable concentration (EAC) is thus > 8 µg as/L. Therefore the results obtained were:

NOEC: 8 µg as/L.

LOEC: 24 µg/L

EAC: > 8 µg as/L

The Applicant wishes consider that the use of the derived NOEC value of 8 µg/L from the mesocosm study with an assessment factor of 4 as worst case, according to the EFSA *Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters* (EFSA Journal 2013;11(7):3290). Therefore a RAC of 2 µg/L has been considered for refinement of the risk assessment for other aquatic organisms than fish.

Table 9.5-54: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyrclostrobin based on FOCUS Step 2-3 calculations and toxicity data from mesocosm study for the use of CASINO ROYALE

Group		Higher-tier information
Test species		Species sp. (≈260 taxa)
Endpoint		NOEC
(µg/L)		8
AF		4
RAC (µg/L)		2
FOCUS scenario	PEC _{gl-max} (µg/L)	PEC/RAC ratio
Sugar beet, 2 x 100 g a.s./ha		
FOCUS Step2	0.92/0.89	0.46/0.45
Fruiting vegetables and potato, 3 x 100 g a.s./ha		
FOCUS Step2	0.92/2.05	0.46/ 1.03
D6/ditch*	0.624/0.459	0.31/0.23

Group		Higher-tier information
Root vegetables, 2 x 100 g a.s./ha		
FOCUS Step2	0.92/1.50	0.46/0.75
Bulb vegetables, 2 x 100 g a.s./ha		
FOCUS Step2	0.97/1.79	0.49/0.90
Leafy vegetables, 2 x 121 g a.s./ha		
FOCUS Step2	0.92/1.55	0.46/0.78
Apple early application, 2 x 67 g a.s./ha		
FOCUS Step2	6.52/6.32	3.26/3.16
Step 3 D5/stream*	5.977/5.107	2.99/2.55
Step 4 D5 stream (15m buffer, none nozzles)**	1.419/1.406	0.71/0.70
Vines and apple late application, 2 x 121 g a.s./ha		
FOCUS Step2	3.24/3.17	1.62/1.59
Step 3 R3/stream*	2.139/1.894	1.07/0.95
Step 4 R3 stream (5m buffer, none nozzles)**	1.558/1.376	0.78/0.69

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

*Worst FOCUS step 3 scenario.

**Worst FOCUS step 4 scenario.

zRMS comment:

We agree with refinement risk assessment based on RAC of 2 µg a.s./L obtained from mesocosms study evaluated at EU level. The used AF of 4 representing conservative approach is sufficient to cover all uncertainty from one available mesocosm study.

The risk PEC/RAC is below 1 when the risk mitigation measures for the worst case scenario are applied to surface water bodies:

- for D5 scenario 15 meter buffer zone for use in apple early application, 2 x 67 g a.s./ha
- for R3 scenario 5meter buffer zone

The final risk mitigation measures should be applied to surface water bodies at MSs level.

Boscalid

Table 9.5-55: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Boscalid based on FOCUS Step 4 calculations and toxicity data for chronic fish with mitigation of spray drift and run-off for the use of CASINO ROYALE in onion, shallot, onion “seven years old and ornamentals (bulb vegetables, BBCH 13 as worst case) (single/multiple application)

Intended use		Bulb vegetables
Active substance		Boscalid
Application rate (g/ha)		2 x 400
Nozzle reduction	Vegetative strip (m)	None
	No spray buffer (m)	5
None	D6 2 nd ditch	-/19.55
RAC (µg/L)		

Intended use		Bulb vegetables
Active substance		Boscalid
Application rate (g/ha)		2 x 400
Nozzle reduction	Vegetative strip (m)	None
	No spray buffer (m)	5
12.5		PEC/RAC ratio
None	D6 2 nd ditch	-/1.564

Table 9.5-56: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Boscalid based on FOCUS Step 4 calculations and toxicity data for chronic fish with mitigation of spray drift and run-off for the use of CASINO ROYALE in cabbage, strawberry, parsnip and parsley (leafy vegetables, BBCH 15 as worst case) (single/multiple application)

Intended use		Leafy vegetables		
Active substance		Boscalid		
Application rate (g/ha)		2 x 481		
Nozzle reduction	Vegetative strip (m)	None	5	10
	No spray buffer (m)	5	5	10
None	D6 ditch	-/18.81	-/-	-/-
None	R4 1 st stream	-/13.33	-/8.693	-/6.991
RAC (µg/L)				
12.5		PEC/RAC ratio		
None	D6 ditch	-/1.505	-/-	-/-
None	R4 1 st stream	-/1.066	-/0.695	-/0.559

Table 9.5-57: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Boscalid based on FOCUS Step 4 calculations and toxicity data for chronic fish with mitigation of spray drift and run-off for the use of CASINO ROYALE in cherry (apple early application as worst case, BBCH 60) (single/multiple application)

Intended use		Apple early application		
Active substance		Boscalid		
Application rate (g/ha)		2 x 267		
Nozzle reduction	Vegetative strip (m)	None		
	No spray buffer (m)	5	10	15
None	D3 ditch	16.35/13.85	10.04/8.184	-/-
50 %		8.172/6.927	-/-	-/-
None	D4 stream	18.95/16.01	11.63/9.461	-/-
50 %		9.475/8.007	-/-	-/-
None	D5 stream	20.46/17.28	12.56/10.21	5.652/-
50 %		10.23/8.638	6.282/-	-/-
None	R1 stream	14.52/12.25	8.915/-	-/-
50 %		7.261/-	-/-	-/-
None	R2 stream	19.46/16.42	11.95/9.699	-/-
50 %		9.732/8.209	-/-	-/-
None	R3 stream	20.32/17.26	12.48/10.20	-/-
50 %		10.16/8.632	-/-	-/-
None	R4 stream	14.19/12.25	8.714/-	-/-
50 %		7.097/-	-/-	-/-
RAC (µg/L)				
12.5		PEC/RAC ratio		
None	D3 ditch	1.308/1.108	0.803/0.655	-/-
50 %		0.654/0.554	-/-	-/-
None	D4 stream	1.516/1.281	0.930/0.757	-/-
50 %		0.758/0.641	-/-	-/-
None	D5 stream	1.637/1.382	1.005/0.817	0.452/-
50 %		0.818/0.691	0.503/-	-/-
None	R1 stream	1.162/0.980	0.713/-	-/-
50 %		0.581/-	-/-	-/-
None	R2 stream	1.557/1.314	0.956/0.776	-/-
50 %		0.779/0.657	-/-	-/-
None	R3 stream	1.626/1.381	0.998/0.816	-/-
50 %		0.813/0.691	-/-	-/-
None	R4 stream	1.135/0.980	0.697/-	-/-
50 %		0.568/-	-/-	-/-

After step 4 calculations, the PEC/RAC ratio values calculated were below the trigger of 1 for all intended uses. Therefore no further refinement was necessary. However, the PEC/RAC ratio values calculated were still above the trigger of 1 for D6 2nd ditch in bulb vegetables and D6 ditch scenario in leafy vegetables for multiple application. However, D6 scenario is not relevant for CEU countries.

zRMS comment:

Boscalid

After step 4 calculations, the PEC/RAC ratio values calculated were below the trigger of 1 for the following scenarios:

- R4 scenaro in cabbage, strawberry, parsnip and parsley (leafy vegetables, BBCH 15 as worst case) (single/multiple application) when 5 meter buffer zone is applied to surfacewater bodies
- D3, D4, D5, R1, R2, R3 and R4 scenarios when 10 meter buffer zone or 5 meter buffer zone +50% drift reduction nozzels are pplied to surfacewater bodies in cherry (apple early application as worst case, BBCH 60) (single/multiple application)

However, the PEC/RAC ratio values calculated were still above the trigger of 1 for D6 2nd ditch in bulb vegetables and D6 ditch scenario in leafy vegetables for multiple application.

It should be taken into account that the D6 scenario is not relevant for CEU countries.

Greenhouse intended uses

Regarding the intended use of tomatoes, eggplants and ornamentals for greenhouse, CASINO ROYALE is expected to apply in enclosed spaces. These uses are considered to be covered by the assessment in field conditions.

However, the PEC_{sw} and PEC_{sed} have been calculated using TOXSWA v1.2. Please, refer to the B8 core dossier for more information.

Table 9.5-58: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid & Pyraclostrobin and metabolites for each organism group based on TOXSWA v1.2 calculations for the use of CASINO ROYALE in greenhouse (single/multiple applications)

PYRACLOSTROBIN AND METABOLITES			
Group		Mesocosm study	Mesocosm study
Test species		Fish	Planktonic species
Endpoint		LC ₅₀	NOEC
(µg/L)		24.82	8
AF		100	4
RAC (µg/L)		0.248	2
TOXSWA Scenario	PEC _{sw} actual (µg/L)		
NL standard - Spring	0.0611/0.099	0.246/0.399	0.031/0.050
NL standard - Autumn	0.0611/0.063	0.246/0.254	0.031/0.032
BOSCALID			
Group		Fish prolonged	
Test species		<i>O. mykiss</i>	
Endpoint		NOEC	

(µg/L)		125	
AF		10	
RAC (µg/L)		12.5	
TOXSWA Scenario	PEC_{sw} actual (µg/L)		
NL standard - Spring	0.253/0.468	0.020/0.037	
NL standard - Autumn	0.253/0.255	0.020/0.020	

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

zRMS comment:

We agree with the risk assessment provided by the applicant for greenhouse uses with consideration PEC_{sw} values agreed in Section 8.

In addition, it should be noted that greenhouse uses are also covered by field uses.

Risk assessment for the combinations of a.s. in the formulation

Following the dilution and spraying of the formulated product, much of the formulation constituents are likely to be lost by volatilisation. Therefore, shortly after application of a formulated product, aquatic organisms are mainly exposed to the active substance present in the formulation. In addition, as demonstrated in the short-term studies here above there are no indications for interactions of the active substances (no synergisms or additional toxicity occurs due to the co-formulants) given that the formulation does not cause an (unexpected) increased toxicity compared to the active substances. An evaluation of the risk posed by the intact formulation is therefore relevant only for the acute/short-term assessment. The long-term risk was assessed considering data for the active substances in the formulation and no chronic combined risk assessment has been performed.

According to the new EFSA Scientific Opinion (EFSA, 2013) measured and calculated mixture toxicity should be compared to determine synergistic, additive or antagonistic effects of the formulation. In the following the concentration addition (CA) model is used as proposed by EFSA.

To determine the respective formulation effect, EFSA proposed to calculate the model deviation ratio (MDR), which divides the calculated mixture toxicity (LC₅₀/EC₅₀ mix-CA) by the measured mixture toxicity (LC₅₀/EC₅₀ CASINO ROYALE). Ecotoxicity studies are biological test systems which underlie a certain natural biological variability when repeating a study. Hence, a threshold has to be defined when an increased/decreased mixture toxicity effect cannot be seen as only additive any longer. EFSA proposes a factor of 5, *i.e.* if the MDR is between 0.2 and 5 the observed and calculated mixture toxicities are considered in agreement.

Active substance / species	Test system	Endpoint (mg a.s./L)
Pyraclostrobin		
<i>Oncorhynchus mykiss</i>	LC ₅₀ 96h	0.006
<i>Daphnia magna</i>	EC ₅₀ 48h	0.016
<i>P. subcapitata</i>	ErC ₅₀ 72h	0.843
Boscalid		
<i>Oncorhynchus mykiss</i>	LC ₅₀ 96h	2.7
<i>Daphnia magna</i>	EC ₅₀ 48h	5.33
<i>P. subcapitata</i>	EC ₅₀ 96h	1.34

The calculated MDR values are between 0.2 and 5 for each organism except algae (see Table 9.5-59), indicating that the formulation does cause an (unexpected) increased toxicity compared to the active substances for these organisms. No synergisms or additional toxicity occurs due to the co-formulants. The apparent antagonism for algae (toxicity of the formulation lower than expected) can be explained by the fact that endpoints for individual active substances are "higher than" values.

Table 9.5-59: Summary of results obtained in the studies with the formulated product CASINO ROYALE and comparison of calculated and measured mixture toxicity

Test species	Endpoint & Test system	LC ₅₀ / EC ₅₀ [mg/L]			
		Measured toxicity of CASINO ROYALE (LC ₅₀ CASINO ROYALE or EC ₅₀ CASINO ROYALE) (mg/L)	Measured toxicity of CASINO ROYALE (converted to be a.i. based) (LC ₅₀ CASINO ROYALE or EC ₅₀ CASINO ROYALE) (mg a.s./L)	Calculated mixture toxicity ^a LC ₅₀ mix-CA or EC ₅₀ mix-CA	Model deviation ratio (MDR = EC ₅₀ mix-CA / EC ₅₀ CASINO ROYALE)
<i>O. mykiss</i>	LC ₅₀ , acute, 96 h	0.054	0.018	0.030	1.644
<i>D. magna</i>	EC ₅₀ , acute, 48 h	0.254	0.085	0.079	0.929
Algae	EbC ₅₀ , 72 h	28.75	9.603	1.198	0.125

^a The mixture toxicity of the formulation was re-calculated based on the nominal contents of Pyraclostrobin (67 g/Kg) and Boscalid (267 g/Kg) within the formulation.

The calculated factors fall in 0.8-1.2 (see Table 9.5-60), indicating that the mixture composition in the formulation study giving the measured mixture toxicity is similar to the mixture composition at the PEC_{mix}.

Table 9.5-60: Comparison of mixture composition in the formulation study (giving the measured mixture toxicity) and mixture composition at the PEC_{mix}

Test species	Endpoint & Test system	LC ₅₀ / EC ₅₀ [mg/L]		
		Calculated mixture toxicity (a.s. in CASINO ROYALE) LC ₅₀ mix-CA or EC ₅₀ mix-CA	Calculated mixture toxicity (a.s. in PEC _{mix}) ^b LC ₅₀ mix-CA or EC ₅₀ mix-CA at lower exposure tier	Factors (EC ₅₀ mix-CA (a.s. in CASINO ROYALE)/EC ₅₀ mix-CA (a.s. in PEC _{mix})) at lower exposure tier
<i>O. mykiss</i>	LC ₅₀ , acute, 96 h	0.030	0.030	1.000
<i>D. magna</i>	EC ₅₀ , acute, 48 h	0.079	0.079	1.000
Algae	EbC ₅₀ , static, 72 h	1.198	1.198	1.000

^a The mixture toxicity of the formulation was re-calculated based on the nominal contents of Pyraclostrobin (67 g/Kg) and Boscalid (267 g/Kg) within the formulation.

^b The mixture toxicity of the formulation was re-calculated based on the mixture composition at the PEC_{mix} for Pyraclostrobin (0.005977 mg/L at Step 3 (D5/stream) scenario) and Boscalid (0.02382 mg/L at Step 3 for D5/stream scenario).

Table 9.5-61: Comparison of calculated mixture toxicity and toxicity per fraction of a single a.s.

Test species	Endpoint & Test system	LC ₅₀ / EC ₅₀ [mg/L]		
		Calculated mixture toxicity (a.s. in CASINO ROYALE) LC ₅₀ mix-CA or EC ₅₀ mix-CA	Calculated toxicity per fraction of CASINO ROYALE (based on each a.s.) (1/TU _i) ^a	Deviation from mixture toxicity (1-EC _x mix-CA x (1/EC _x mix-CA - TU _i)) [%]
<i>O. mykiss</i>	LC ₅₀ , acute, 96 h	0.030	Pyraclostrobin: 0.030 Boscalid: 3.378	Pyraclostrobin: 99.12% Boscalid: 0.88%
<i>D. magna</i>	EC ₅₀ , acute, 48 h	0.079	Pyraclostrobin: 0.080 Boscalid: 6.667	Pyraclostrobin: 98.82% Boscalid: 1.18%
Algae	E _b C ₅₀ , static, 72 h	1.198	Pyraclostrobin: 4.202 Boscalid: 1.676	Pyraclostrobin: 28.51% Boscalid: 71.49%

^a TU_i is defined as the concentration of the ith a.s. at the EC₅₀ CASINO ROYALE (re-calculated to the sum of a.s.) divided by the respective single-substance toxicity (EC₅₀ a.s.). This is calculated based on the nominal contents of of Pyraclostrobin (67 g/Kg) and Boscalid (267 g/Kg) within the formulation.

With regard to the mixture risk assessment EFSA further states that if the toxicity of the mixture is largely explained by the toxicity of a single active substance, a sufficient protection level might be achieved by simply basing the RA on the toxicity data for that single ‘driver’.

Regarding CASINO ROYALE, Pyraclostrobin is clearly driving the acute risk. The studies performed with the formulated product reflect the toxicity of Pyraclostrobin in fish and daphnids, as the formulation toxicity – endpoint recalculated to each active substance concentrations – come for 90 % (of more) from the toxicity per fraction of a single a.s. (TU_i) (see Table 9.5-61).

Table 9.5-62: Conduct a mixture RA based on calculated mixture toxicity according to 10.3.8 from EFSA AGD in apple (early application) (worst case) for fish

Exposure	Lower exposure tier		Higher exposure tier	
	Pyraclostrobin	Boscalid	Pyraclostrobin	Boscalid
Exposure tier (FOCUS step)	Step 3 (D5/stream)	Step 3 (D5/stream)	Step 4 (R3/stream) - 50 m	Step 4 (D5/stream) - 15 m
PEC _{sw} [mg a.s./L]	0.005977	0.023820	0.000081	0.005652
Relative proportions of the individual mixture components in the environment (pi PEC)	0.201	0.799	0.014	0.986
Total exposure concentration of the mixture (a.s. based) (PEC _{mix}) [mg/L]	0.029797		0.005733	
Calculated mixture toxicity (a.s. in PEC _{mix}) (EC _x mix-CA = ∑ (pi PEC/EC _x i)) [mg a.s./L]	0.030		0.368	
ETR _{mix} = PEC _{mix} /EC _x PPP	1.0050		0.0156	
Trigger	0.01			

Applicability of such approach is justified following the EFSA AGD *Decision scheme for mixture toxicity risk assessment* for fish.

Step	EFSA AGD provisions	Option	Justification	Outcome
1	Are measured toxicity data (ECx) available for the given endpoint (typically chronic data available only for a.s.)?	For both formulation (ECxPPP) and a.s. (ECxa.s.):	Please refer to table 9.5-3	Go to 2
2	Check the plausibility of the measured formulation toxicity (ECxPPP) against the calculated mixture toxicity EC _{xmix} -CA (assuming CA, Equation 13) for exactly the mixture composition of the a.s. in the formulation (ECxPPP) by means of the model deviation ratio (MDR = EC _{xmix} -CA/ECxPPP).	MDR = 0.2–5 (CA approximately holds for the mixture)	Please refer to table 9.5-59	Go to 3
3	Check whether the mixture composition in the formulation study giving the measured mixture toxicity (ECxPPP) in terms of the relative proportions of the individual a.s. is similar to the mixture composition at the PEC _{mix} . As a direct comparison on the basis of the relative proportions of the a.s. at the ECxPPP with the relative proportion at the PEC _{mix} is not informative as such, the comparison is done based on calculated mixture toxicity (assuming CA) for both mixture compositions. Therefore, calculate EC _{xmix} -CA (see Equation 13) for the mixture composition of the a.s. at the PEC _{mix} and compare with the estimate calculated for the formulation (as already done in step 2 above).	EC _x mix-CA (a.s. in product)/EC _x mix-CA (a.s. in PEC _{mix}) is 0.8-1.2	Please refer to table 9.5-60	Go to 4
4	Conduct a mixture RA based on measured mixture toxicity, with the exposure-toxicity ratio (ETR _{mix}) being defined as the PEC _{mix} divided by the measured ECxPPP and compare the outcome with the acceptability criterion (trigger value) decisive for the specific endpoint/exposure scenario combination.	If ETR _{mix} < 0.01 for fish: Low risk	Please refer to table 9.5-62	Not acceptable risk

Table 9.5-63: Conduct a mixture RA based on calculated mixture toxicity according to 10.3.8 from EFSA AGD in apple (early application) (worst case) for *Daphnia*

Exposure	Lower exposure tier		Higher exposure tier	
	Pyraclostrobin	Boscalid	Pyraclostrobin	Boscalid
Exposure tier (FOCUS step)	Step 3 (D5/stream)	Step 3 (D5/stream)	Step 4 (R3/stream) - 50 m	Step 4 (D5/stream) - 15 m
PEC _{sw} [mg a.s./L]	0.005977	0.023820	0.000081	0.005652
Relative proportions of the individual mixture components in the environment (pi PEC)	0.201	0.799	0.014	0.986
Total exposure concentration of the mixture (a.s. based) (PEC _{mix}) [mg/L]	0.029797		0.005733	
Calculated mixture toxicity (a.s. in PEC _{mix}) (EC _x mix-CA = ∑ (pi PEC/EC _x i)) [mg a.s./L]	0.079		0.936	
ETR _{mix} = PEC _{mix} /EC _x PPP	0.3772		0.006	
Trigger	0.01			

Applicability of such approach is justified following the EFSA AGD *Decision scheme for mixture toxicity risk assessment for Daphnia*.

Step	EFSA AGD provisions	Option	Justification	Outcome
1	Are measured toxicity data (EC _x) available for the given endpoint (typically chronic data available only for a.s.)?	For both formulation (EC _x PPP) and a.s. (EC _x a.s.):	Please refer to table 9.5-3	Go to 2
2	Check the plausibility of the measured formulation toxicity (EC _x PPP) against the calculated mixture toxicity EC _x mix-CA (assuming CA, Equation 13) for exactly the mixture composition of the a.s. in the formulation (EC _x PPP) by means of the model deviation ratio (MDR = EC _x mix-CA/EC _x PPP).	MDR = 0.2–5 (CA approximately holds for the mixture)	Please refer to table 9.5-59	Go to 3
3	Check whether the mixture composition in the formulation study giving the measured mixture toxicity (EC _x PPP) in terms of the relative proportions of the individual a.s. is similar to the mixture composition at the PEC _{mix} . As a direct comparison on the basis of the relative proportions of the a.s. at the EC _x PPP with the relative proportion at the PEC _{mix} is not informative as such, the comparison is done based on calculated mixture toxicity (assuming CA) for both mixture compositions. Therefore, calculate EC _x mix-CA (see Equation 13) for the mixture composition of the a.s. at the PEC _{mix} and compare with the estimate calculated for the formulation (as already done in step 2 above).	EC _x mix-CA (a.s. in product)/EC _x mix-CA (a.s. in PEC _{mix}) is 0.8-1.2	Please refer to table 9.5-60	Go to 4

4	Conduct a mixture RA based on measured mixture toxicity, with the exposure-toxicity ratio (ETR _{mix}) being defined as the PEC _{mix} divided by the measured EC _x PPP and compare the outcome with the acceptability criterion (trigger value) decisive for the specific endpoint/exposure scenario combination.	If ETR _{mix} < 0.01 for fish: Low risk	Please refer to table 9.5-63	Not acceptable risk
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Table 9.5-64: Conduct a mixture RA based on calculated mixture toxicity according to 10.3.8 from EFSA AGD in apple (early application) (worst case) for alga

Exposure	Lower exposure tier		Higher exposure tier	
	Pyraclostrobin	Boscalid	Pyraclostrobin	Boscalid
Exposure tier (FOCUS step)	Step 3 (D5/stream)	Step 3 (D5/stream)	Step 4 (R3/stream) - 50 m	Step 4 (D5/stream) - 15 m
PEC _{sw} [mg a.s./L]	0.005977	0.023820	0.000081	0.005652
Relative proportions of the individual mixture components in the environment (pi PEC)	0.201	0.799	0.014	0.986
Total exposure concentration of the mixture (a.s. based) (PEC _{mix}) [mg/L]	0.029797		0.005733	
Calculated mixture toxicity (a.s. in PEC _{mix}) (EC _x mix-CA = ∑ (pi PEC/EC _x i)) [mg a.s./L]	1.198		1.329	
ETR _{mix} = PEC _{mix} /EC _x PPP	0.025		0.004	
Trigger	0.1			

Applicability of such approach is justified following the EFSA AGD *Decision scheme for mixture toxicity risk assessment* for alga.

Step	EFSA AGD provisions	Option	Justification	Outcome
1	Are measured toxicity data (EC _x) available for the given endpoint (typically chronic data available only for a.s.)?	For both formulation (EC _x PPP) and a.s. (EC _x a.s.):	Please refer to table 9.5-3	Go to 2
2	Check the plausibility of the measured formulation toxicity (EC _x PPP) against the calculated mixture toxicity EC _x mix-CA (assuming CA, Equation 13) for exactly the mixture composition of the a.s. in the formulation (EC _x PPP) by means of the model deviation ratio (MDR = EC _x mix-CA/EC _x PPP).	MDR = <0.2	Please refer to table 9.5-59	Go to 9
9	Carefully recheck the apparent antagonism as observed in the measured mixture toxicity data (EC _x PPP) regarding potential impacts of the default assumption of CA and/or heterogeneous input data used for the CA calculation. Does the apparent antagonism remain and no toxicologically plausible explanation is available (e.g. special feature of the formulation type)?	No (measured mixture toxicity plausible):		Go to 3

3	Check whether the mixture composition in the formulation study giving the measured mixture toxicity (ECx PPP) in terms of the relative proportions of the individual a.s. is similar to the mixture composition at the PECmix. As a direct comparison on the basis of the relative proportions of the a.s. at the ECx PPP with the relative proportion at the PECmix is not informative as such, the comparison is done based on calculated mixture toxicity (assuming CA) for both mixture compositions. Therefore, calculate ECx mix-CA (see Equation 13) for the mixture composition of the a.s. at the PECmix and compare with the estimate calculated for the formulation (as already done in step 2 above).	ECx mix-CA (a.s. in product)/ECx mix-CA (a.s. in PECmix) is 0.8-1.2	Please refer to table 9.5-60	Go to 4
4	Conduct a mixture RA based on measured mixture toxicity, with the exposure-toxicity ratio (ETR _{mix}) being defined as the PECmix divided by the measured ECxPPP and compare the outcome with the acceptability criterion (trigger value) decisive for the specific endpoint/exposure scenario combination.	If ETR _{mix} < 0.1 for fish: Low risk	Please refer to table 9.5-64	Low risk

Refinement with the endpoint from the available microcosm study

Based on the results obtained for mixture risk assessment, a non acceptable risk was observed for fish and *Daphnia*. Therefore, the same refinement criteria for fish and other microorganisms which was followed for pyraclostrobin technical will be followed here, i.e. the use of a reliable mesocosm study, with a LC₅₀ of 24.82 µg a.s./L as endpoint for fish and a derived NOEC value of 8 µg/L from the mesocosm study with an assessment factor of 4 as worst case. Consequently, the trigger value would change to 0.25, considering an Assessment Factor of 4, and the assessment would be as follows:

To determine the respective formulation effect, EFSA proposed to calculate the model deviation ratio (MDR), which divides the calculated mixture toxicity (LC₅₀/EC₅₀ mix-CA) by the measured mixture toxicity (LC₅₀/EC₅₀ CASINO ROYALE). Ecotoxicity studies are biological test systems which underlie a certain natural biological variability when repeating a study. Hence, a threshold has to be defined when an increased/decreased mixture toxicity effect cannot be seen as only additive any longer. EFSA proposes a factor of 5, i.e. if the MDR is between 0.2 and 5 the observed and calculated mixture toxicities are considered in agreement.

Active substance / species	Test system	Endpoint (mg a.s./L)
Pyraclostrobin		
<i>Oncorhynchus mykiss</i> (Mesocosm study)	LC ₅₀ 96h	0.248
<i>Daphnia magna</i> (Mesocosm study)	NOEC	0.002
<i>P. subcapitata</i>	E _r C ₅₀ 72h	0.843
Boscalid		
<i>Oncorhynchus mykiss</i>	LC ₅₀ 96h	2.7
<i>Daphnia magna</i>	EC ₅₀ 48h	5.33
<i>P. subcapitata</i>	EC ₅₀ 96h	1.34

The calculated MDR values are not between 0.2 and 5 for each organism (see Table 9.5-65), indicating that the formulation does not cause an (unexpected) increased toxicity compared to the active substances for these organisms. No synergisms or additional toxicity occurs due to the co-formulants.

Table 9.5-65: Summary of results obtained in the studies with the formulated product CASINO ROYALE and comparison of calculated and measured mixture toxicity

Test species	Endpoint & Test system	LC ₅₀ / EC ₅₀ [mg/L]			
		Measured toxicity of CASINO ROYALE (LC ₅₀ CASINO ROYALE or EC ₅₀ CASINO ROYALE) (mg/L)	Measured toxicity of CASINO ROYALE (converted to be a.i. based) (LC ₅₀ CASINO ROYALE or EC ₅₀ CASINO ROYALE) (mg a.s./L)	Calculated mixture toxicity ^a LC ₅₀ mix-CA or EC ₅₀ mix-CA	Model deviation ratio (MDR = EC ₅₀ mix-CA / EC ₅₀ CASINO ROYALE)
<i>O. mykiss</i>	LC ₅₀ , acute, 96 h	0.054	0.018	0.905	50.179
<i>D. magna</i>	EC ₅₀ , acute, 48 h	0.254	0.085	0.010	0.117
Algae	E _b C ₅₀ , 72 h	28.75	9.603	1.198	0.125

^a The mixture toxicity of the formulation was re-calculated based on the nominal contents of Pyraclostrobin (67 g/Kg) and Boscalid (267 g/Kg) within the formulation.

The calculated factors fall in 0.8-1.2 (see Table 9.5-66), indicating that the mixture composition in the formulation study giving the measured mixture toxicity is similar to the mixture composition at the PEC_{mix}.

Table 9.5-66: Comparison of mixture composition in the formulation study (giving the measured mixture toxicity) and mixture composition at the PEC_{mix}

Test species	Endpoint & Test system	LC ₅₀ / EC ₅₀ [mg/L]		
		Calculated mixture toxicity (a.s. in CASINO ROYALE) LC ₅₀ mix-CA or EC ₅₀ mix-CA	Calculated mixture toxicity (a.s. in PEC _{mix}) ^b LC ₅₀ mix-CA or EC ₅₀ mix-CA at lower exposure tier	Factors (EC ₅₀ mix-CA (a.s. in CASINO ROYALE)/EC ₅₀ mix-CA (a.s. in PEC _{mix})) at lower exposure tier
<i>O. mykiss</i>	LC ₅₀ , acute, 96 h	0.905	0.905	1.000
<i>D. magna</i>	EC ₅₀ , acute, 48 h	0.010	0.010	1.000
Algae	E _b C ₅₀ , static, 72 h	1.198	1.198	1.000

^a The mixture toxicity of the formulation was re-calculated based on the nominal contents of Pyraclostrobin (67 g/Kg) and Boscalid (267 g/Kg) within the formulation.

^b The mixture toxicity of the formulation was re-calculated based on the mixture composition at the PEC_{mix} for Pyraclostrobin (0.005977 mg/L at Step 3 (D5/stream) scenario) and Boscalid (0.02382 mg/L at Step 3 for D5/stream scenario).

Table 9.5-67: Comparison of calculated mixture toxicity and toxicity per fraction of a single a.s.

Test species	Endpoint & Test system	LC ₅₀ / EC ₅₀ [mg/L]		
		Calculated mixture toxicity (a.s. in CASINO ROYALE) LC ₅₀ mix-CA or EC ₅₀ mix-CA	Calculated toxicity per fraction of CASINO ROYALE (based on each a.s.) (1/TU _i) ^a	Deviation from mixture toxicity (1-EC _x mix-CA x (1/EC _x mix-CA - TU _i)) [%]
<i>O. mykiss</i>	LC ₅₀ , acute, 96 h	0.905	Pyraclostrobin: 1.236 Boscalid: 3.378	Pyraclostrobin: 73.20% Boscalid: 26.80%
<i>D. magna</i>	EC ₅₀ , acute, 48 h	0.010	Pyraclostrobin: 0.010 Boscalid: 6.667	Pyraclostrobin: 99.85% Boscalid: 0.15%
Algae	E _b C ₅₀ , static, 72 h	1.198	Pyraclostrobin: 4.202 Boscalid: 1.676	Pyraclostrobin: 28.51% Boscalid: 71.49%

^a TU_i is defined as the concentration of the ith a.s. at the EC₅₀ CASINO ROYALE (re-calculated to the sum of a.s.) divided by the respective single-substance toxicity (EC₅₀ a.s.). This is calculated based on the nominal contents of of Pyraclostrobin (67 g/Kg) and Boscalid (267 g/Kg) within the formulation.

With regard to the mixture risk assessment EFSA further states that if the toxicity of the mixture is largely explained by the toxicity of a single active substance, a sufficient protection level might be achieved by simply basing the RA on the toxicity data for that single ‘driver’.

Regarding CASINO ROYALE, Pyraclostrobin is clearly driving the acute risk. The studies performed with

the formulated product reflect the toxicity of Pyraclostrobin in daphnids, as the formulation toxicity – endpoint recalculated to each active substance concentrations – come for 90 % (of more) from the toxicity per fraction of a single a.s. (TUi) (see Table 9.5-67).

Table 9.5-68: Conduct a mixture RA based on calculated mixture toxicity according to 10.3.8 from EFSA AGD in apple (early application) (worst case) for fish

Exposure	Lower exposure tier		Higher exposure tier	
	Pyraclostrobin	Boscalid	Pyraclostrobin	Boscalid
Exposure tier (FOCUS step)	Step 3 (D5/stream)	Step 3 (D5/stream)	Step 4 (R3/stream) - 40 m	Step 4 (D5/stream) - 15 m
PEC _{sw} [mg a.s./L]	0.005977	0.023820	0.000138	0.005652
Relative proportions of the individual mixture components in the environment (pi PEC)	0.201	0.799	0.024	0.976
Total exposure concentration of the mixture (a.s. based) (PEC _{mix}) [mg/L]	0.029797		0.005790	
Calculated mixture toxicity (a.s. in PEC _{mix}) (EC _x mix-CA = ∑ (pi PEC/EC _x i)) [mg a.s./L]	0.905		2.185	
ETR _{mix} = PEC _{mix} /EC _x PPP	0.0329		0.0026	
Trigger	0.01			

Applicability of such approach is justified following the EFSA AGD *Decision scheme for mixture toxicity risk assessment* for fish.

Step	EFSA AGD provisions	Option	Justification	Outcome
1	Are measured toxicity data (EC _x) available for the given endpoint (typically chronic data available only for a.s.)?	For both formulation (EC _x PPP) and a.s. (EC _x a.s.):	Please refer to table 9.5-3	Go to 2
2	Check the plausibility of the measured formulation toxicity (EC _x PPP) against the calculated mixture toxicity EC _x mix-CA (assuming CA, Equation 13) for exactly the mixture composition of the a.s. in the formulation (EC _x PPP) by means of the model deviation ratio (MDR = EC _x mix-CA/EC _x PPP).	MDR = >5	Please refer to table 9.5-65	Go to 10
10	Carefully recheck the apparent synergism as observed in the measured mixture toxicity data (EC _x PPP) regarding potential impacts of heterogeneous input data (a.s.) and of co-formulants ignored in the CA calculation. Does the apparent synergism remain?	Measured data not available		Go to 8
8	Conduct a mixture RA based on calculated mixture toxicity according to 10.3.8	If ETR _{mix} < 0.01 for fish: Low risk	Please refer to table 9.5-68	Low risk

Table 9.5-69: Conduct a mixture RA based on calculated mixture toxicity according to 10.3.8 from EFSA AGD in apple (early application) (worst case) for *Daphnia*

Exposure	Lower exposure tier		Higher exposure tier	
	Pyraclostrobin	Boscalid	Pyraclostrobin	Boscalid
Exposure tier (FOCUS step)	Step 3 (D5/stream)	Step 3 (D5/stream)	Step 4 (R3/stream) - 40 m	Step 4 (D5/stream) - 15 m
PEC _{sw} [mg a.s./L]	0.005977	0.023820	0.000138	0.005652
Relative proportions of the individual mixture components in the environment (pi PEC)	0.201	0.799	0.024	0.976
Total exposure concentration of the mixture (a.s. based) (PEC _{mix}) [mg/L]	0.029797		0.005790	
Calculated mixture toxicity (a.s. in PEC _{mix}) (EC _x mix-CA = ∑ (pi PEC/EC _x i)) [mg a.s./L]	0.010		0.083	
ETR _{mix} = PEC _{mix} /EC _x PPP	2.980		0.070	
Trigger	0.25			

Applicability of such approach is justified following the EFSA AGD *Decision scheme for mixture toxicity risk assessment for Daphnia*.

Step	EFSA AGD provisions	Option	Justification	Outcome
1	Are measured toxicity data (EC _x) available for the given endpoint (typically chronic data available only for a.s.)?	For both formulation (EC _x PPP) and a.s. (EC _x a.s.):	Please refer to table 9.5-3	Go to 2
2	Check the plausibility of the measured formulation toxicity (EC _x PPP) against the calculated mixture toxicity EC _x mix-CA (assuming CA, Equation 13) for exactly the mixture composition of the a.s. in the formulation (EC _x PPP) by means of the model deviation ratio (MDR = EC _x mix-CA/EC _x PPP).	MDR = <0.2	Please refer to table 9.5-65	Go to 9
9	Carefully recheck the apparent antagonism as observed in the measured mixture toxicity data (EC _x PPP) regarding potential impacts of the default assumption of CA and/or heterogeneous input data used for the CA calculation. Does the apparent antagonism remain and no toxicologically plausible explanation is available (e.g. special feature of the formulation type)?	No (measured mixture toxicity plausible)		Go to 3

3	Check whether the mixture composition in the formulation study giving the measured mixture toxicity (ECxPPP) in terms of the relative proportions of the individual a.s. is similar to the mixture composition at the PECmix. As a direct comparison on the basis of the relative proportions of the a.s. at the ECxPPP with the relative proportion at the PECmix is not informative as such, the comparison is done based on calculated mixture toxicity (assuming CA) for both mixture compositions. Therefore, calculate ECxm _{mix} -CA (see Equation 13) for the mixture composition of the a.s. at the PECmix and compare with the estimate calculated for the formulation (as already done in step 2 above).	ECx mix-CA (a.s. in product)/ECx mix-CA (a.s. in PECmix) is 0.8-1.2	Please refer to table 9.5-66	Go to 4
4	Conduct a mixture RA based on measured mixture toxicity, with the exposure-toxicity ratio (ETR _{mix}) being defined as the PECmix divided by the measured ECxPPP and compare the outcome with the acceptability criterion (trigger value) decisive for the specific endpoint/exposure scenario combination.	If ETR _{mix} < 0.25 for fish: Low risk	Please refer to table 9.5-69	Low risk

Table 9.5-70: Conduct a mixture RA based on calculated mixture toxicity according to 10.3.8 from EFSA AGD in apple (early application) (worst case) for alga

Exposure	Lower exposure tier		Higher exposure tier	
	Pyraclostrobin	Boscalid	Pyraclostrobin	Boscalid
Exposure tier (FOCUS step)	Step 3 (D5/stream)	Step 3 (D5/stream)	Step 4 (R3/stream) - 40 m	Step 4 (D5/stream) - 15 m
PEC _{sw} [mg a.s./L]	0.005977	0.023820	0.000138	0.005652
Relative proportions of the individual mixture components in the environment (pi PEC)	0.201	0.799	0.024	0.976
Total exposure concentration of the mixture (a.s. based) (PEC _{mix}) [mg/L]	0.029797		0.005790	
Calculated mixture toxicity (a.s. in PEC _{mix}) (EC _x mix-CA = ∑ (pi PEC/EC _x i)) [mg a.s./L]	1.198		1.321	
ETR _{mix} = PEC _{mix} /EC _x PPP	0.025		0.004	
Trigger	0.1			

Applicability of such approach is justified following the EFSA AGD *Decision scheme for mixture toxicity risk assessment* for alga.

Step	EFSA AGD provisions	Option	Justification	Outcome
1	Are measured toxicity data (ECx) available for the given endpoint (typically chronic data available only for a.s.)?	For both formulation (ECxPPP) and a.s. (ECxa.s.):	Please refer to table 9.5-3	Go to 2

2	Check the plausibility of the measured formulation toxicity (ECxPPP) against the calculated mixture toxicity EC _{xmix} -CA (assuming CA, Equation 13) for exactly the mixture composition of the a.s. in the formulation (ECxPPP) by means of the model deviation ratio ($MDR = EC_{xmix}\text{-CA}/EC_{xPPP}$).	$MDR = <0.2$	Please refer to table 9.5-65	Go to 9
9	Carefully recheck the apparent antagonism as observed in the measured mixture toxicity data (EC _x PPP) regarding potential impacts of the default assumption of CA and/or heterogeneous input data used for the CA calculation. Does the apparent antagonism remain and no toxicologically plausible explanation is available (e.g. special feature of the formulation type)?	No (measured mixture toxicity plausible):		Go to 3
3	Check whether the mixture composition in the formulation study giving the measured mixture toxicity (EC _x PPP) in terms of the relative proportions of the individual a.s. is similar to the mixture composition at the PEC _{mix} . As a direct comparison on the basis of the relative proportions of the a.s. at the EC _x PPP with the relative proportion at the PEC _{mix} is not informative as such, the comparison is done based on calculated mixture toxicity (assuming CA) for both mixture compositions. Therefore, calculate EC _x mix-CA (see Equation 13) for the mixture composition of the a.s. at the PEC _{mix} and compare with the estimate calculated for the formulation (as already done in step 2 above).	EC _x mix-CA (a.s. in product)/EC _x mix-CA (a.s. in PEC _{mix}) is 0.8-1.2	Please refer to table 9.5-66	Go to 4
4	Conduct a mixture RA based on measured mixture toxicity, with the exposure-toxicity ratio (ETR _{mix}) being defined as the PEC _{mix} divided by the measured EC _x PPP and compare the outcome with the acceptability criterion (trigger value) decisive for the specific endpoint/exposure scenario combination.	If $ETR_{mix} < 0.1$ for fish: Low risk	Please refer to table 9.5-70	Low risk

No unacceptable risk to aquatic organisms is expected from the exposure to the combined active substances following proposed uses of the product and described mitigation measures.

zRMS comment:

The refined the mixture toxicity assessment should be considered at Ms level.

9.1.3 Overall conclusions

Pyraclostrobin

For all intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish as characterised by an LC_{50} for *Oncorhynchus mykiss* o of 6 µg a.s./L in connection with an assessment factor of 100) in all FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies. For all the intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in R4 stream scenario in fruiting vegetables, R4 stream scenario in root vegetables, R4 stream scenario in bulb vegetables, R4 1st stream and R4 2nd stream

scenarios in leafy vegetables, R4 stream scenario in apple early application and R1 stream and R4 stream scenarios in vines late application. Therefore, a further refinement was necessary. A refinement for fish with RAC value of 0.248 µg a.s./L based on a geomean LC₅₀ from 7 acute toxicity laboratory studies on different fish species available in the monograph of Pyraclostrobin was used. Moreover a refinement for the other aquatic organisms with a RAC value of 2 µg a.s./L based on mesocosms study available in Monograph of the active substance was also used. After the refinement, an acceptable risk was obtained with the following mitigation measures:

- Sugar beet: no-spray buffer zone of 5 m
- Fruiting vegetables and potato: no-spray buffer zone of 5m
- Root vegetables: no-spray buffer zone of 5m
- Bulb vegetables: no-spray buffer zone of 5m
- Leafy vegetables: no-spray buffer zone of 10m
- Apple (early application): no-spray buffer zone of 40m OR no-spray buffer zone of 30m + 50% nozzles OR no-spray buffer zone of 20m + 75% nozzles OR no-spray buffer zone of 15m + 90% nozzles
- Vines (late application): no-spray buffer zone of 20m OR no-spray buffer zone of 15m + 50% nozzles OR no-spray buffer zone of 10m + 75% nozzles OR no-spray buffer zone of 5m + 90% nozzles

Moreover, for completeness reasons, together with the assessment using the RAC_{geomean}, new PEC/RAC calculations were included based on the RAC of 0.2 µg/L for chronic risk assessment to fish. After this refinement, an acceptable risk was obtained with the following mitigation measures:

- Sugar beet: no-spray buffer zone of 10 m
- Fruiting vegetables and potato: no-spray buffer zone of 10 m
- Root vegetables: no-spray buffer zone of 10 m
- Bulb vegetables: no-spray buffer zone of 10 m
- Leafy vegetables: no-spray buffer zone of 10 m
- Apple (early application): no-spray buffer zone of 40 m OR no-spray buffer zone of 30 m + 50% nozzles OR no-spray buffer zone of 20 m + 75% nozzles OR no-spray buffer zone of 15 m + 90% nozzles
- Vines (late application): no-spray buffer zone of 20 m OR no-spray buffer zone of 15 m + 50% nozzles OR no-spray buffer zone of 10 m + 75% nozzles OR no-spray buffer zone of 5 m + 90% nozzles

Metabolites of Pyraclostrobin

For all intended uses, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms. Therefore, no further assessment is necessary.

Boscalid

For all intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish as characterised by a NOEC for *Oncorhynchus mykiss* of 125 µg a.s./L in connection with an assessment factor of 10) in D6 2nd/ditch for bulb vegetables, D6/ditch and R4 1st/stream for leafy vegetables and D3 ditch, D4 stream, D5 stream, R1 stream, R2 stream, R3 stream and R4 stream for apple early application. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies. After step 4 calculations, the PEC/RAC ratio values calculated were below the trigger of 1 for all intended uses. An acceptable risk was obtained with the following mitigation measures:

- Leafy vegetables: no-spray buffer zone of 5m with 5m vegetative strip.
- Apple early application: no-spray buffer zone of 15m OR no-spray buffer zone of 5m + 50% of nozzle reduction.

However, the PEC/RAC ratio values calculated were still above the trigger of 1 for D6 2nd ditch in bulb vegetables and D6 ditch scenario in leafy vegetables for multiple application. However, D6 scenario is not relevant for CEU countries.

Conclusions

Sugar beet, Fruiting vegetables and potato, Root vegetables and Bulb vegetables – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 5 m to surface water bodies.

Leafy vegetables – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 10 m with 5m vegetative strip to surface water bodies.

Apple (early application) – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 40 m to surface water bodies OR respect an unsprayed buffer zone of 30 m to surface water bodies with 50% of nozzles reduction OR respect an unsprayed buffer zone of 20 m to surface water bodies with 75% of nozzles reduction OR respect an unsprayed buffer zone of 15 m to surface water bodies with 90% of nozzles reduction.

Vines (late application) – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 20 m to surface water bodies OR respect an unsprayed buffer zone of 15 m to surface water bodies with 50% of nozzles reduction OR respect an unsprayed buffer zone of 10 m to surface water bodies with 75% of nozzles reduction OR respect an unsprayed buffer zone of 5 m to surface water bodies with 90% of nozzles reduction.

zRMS comments:

Based on the aquatic risk assessment the following risk mitigation measures should be applied to surface water bodies:

~~*Sugar beet, Fruiting vegetables and potato, Root vegetables and Bulb vegetables – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 5 m to surface water bodies.*~~

~~*Leafy vegetables – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 10 m with 5m vegetative strip to surface water bodies.*~~

~~*Apple (early application) – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 40 m to surface water bodies OR respect an unsprayed buffer zone of 30 m to surface water bodies with 50% of nozzles reduction OR respect an unsprayed buffer zone of 20 m to surface water bodies with 75% of nozzles reduction OR respect an unsprayed buffer zone of 15 m to surface water bodies with 90% of nozzles reduction.*~~

~~*Vines (late application) – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 20 m to surface water bodies OR respect an unsprayed buffer zone of 15 m to surface water bodies with 50% of nozzles reduction OR respect an unsprayed buffer zone of 10 m to surface water bodies with 75% of nozzles reduction OR respect an unsprayed buffer zone of 5 m to surface water bodies with 90% of nozzles reduction.*~~

The applicant provided the new calculations of chronic risk assessment **during Commenting Period** and the final conclusion based on refinement **of both active substances** for the worst case scenarios for each uses was updated below:

- **Sugar beet: no-spray buffer zone of 10 m**
- **Fruiting vegetables and potato: no-spray buffer zone of 10 m**
- **Root vegetables: no-spray buffer zone of 10 m**
- **Bulb vegetables: no-spray buffer zone of 10 m**
- **Leafy vegetables: no-spray buffer zone of 10 m with 5 meter vegetative buffer zone**

- **Apple (early application): no-spray buffer zone of 40 m OR no-spray buffer zone of 30 m + 50% nozzles OR no-spray buffer zone of 20 m + 75% nozzles OR no-spray buffer zone of 15 m + 90% nozzles**
- **Vines (late application): no-spray buffer zone of 20 m OR no-spray buffer zone of 15 m + 50% nozzles OR no-spray buffer zone of 10 m + 75% nozzles OR no-spray buffer zone of 5 m + 90% nozzles**

In addition, it should be indicated that greenhouse uses are considered acceptable.

The final risk mitigation measures for aquatic organism should be decided at MSs level depended on relevant scenarios for each countries.

***Remark zRMS's e- fate expert from Section 8:**

For PEC_{sw/sed} calculations at STEP 4, the values used for reduction in run off volume and flux and erosion mass and flux is 0.5 and 0.8 for 5 meters of vegetative buffer strip according to the Austrian Environmental Agency (AGES) and the values uses for reduction in run off volume and flux and erosion mass and flux were 0.7 and 0.9 respectively for 15 meters of vegetative buffer strip.

In opinion of zRMS-PL, the Step 4 PEC_{sw} calculations are not accepted because of according to Working Document of the Central Zone in the Authorisation of Plant Protection Products (2018), the following approaches for simulating in Step 4 are recommended for the Core Assessment: Landscape And Mitigation Factors In Aquatic Risk Assessment. Volume 1. Extended Summary and Recommendations". Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0. 169 pp and FOCUS (2007) and Working Document of the Central Zone in the Autorisation of Plant Protection Products (Environmental Fate and Behaviour. Ver.1.rev1. 2018).

However, 5 or 15 meters of vegetative buffer strip can be used at national level.

The PEC_{sw} in STEP4 and mitigation measure should be considered by individual MS.

~~In addition, it should be noted, that if any of refinement option for a.s.-pyraclostrobin (geomean approach for acute risk for fish, chronic risk for fish) is not accepted by some MSs, they should conclude this issue on MS level.~~

~~The final risk mitigation measures should be decided at MSs level.~~

9.1.3.1 Effects on bees (KCP 10.3.1)

First-tier assessments indicate that no unacceptable risk for bees exposed to the product Casino Royale is expected according to the proposed intended uses. According to Reg 284/2009 the chronic risk for larvae and chronic risk for adult for bees for Casino Royale should be provided by the applicant.

9.1.3.2 Effects on arthropods other than bees (KCP 10.3.2)

The in-field and off-field HQ values calculated for the product Casino Royale for the representative species *Typhlodromus pyri* and *A. rhopalosiphi* are lower than the trigger of 2 for Tier I tests, indicating no risk to non-target arthropods in vegetated off-field areas following application according to the proposed use patterns.

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

microbial activity (KCP 10.5)

All the TERa values on earthworms for both active substances are higher than the Annex VI trigger value of 10, indicating that Casino Royale poses low acute risk to earthworms when applied according to the proposed use rates. The TERlt values on earthworms, *Folsomia* and *Hypoaspis* were higher than the Annex VI trigger value of 5, indicating low risk for non-target soil organisms with the application of Casino Royale.

However, TERlt values on earthworms for both active substances are lower than the Annex VI trigger value of 5, being necessary a further refinement. After refinement considering the field studies submitted in DAR for both active substances, a low long-term risk is expected indicating that Casino Royale poses low long-term risk to earthworms and other non-target soil organisms when applied according to the proposed use rates.

Risk assessments conducted with relevant PEC_{soil} for Casino Royale indicate a low risk to soil microorganisms when applied according to the proposed use rates.

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

Risk assessment conducted with relevant toxicity data on non-target terrestrial plants for Casino Royale shows that the Annex VI trigger value of 5 is not exceeded, indicating that Casino Royale poses a low risk to non-target terrestrial plants when applied according to the proposed use rates.

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

No additional data are available.

9.1.4 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 formulation grouped according to criterion

Grouping according to criterion			
Group	Intended uses	Relevant use parameters for grouping	Relevant parameter or value for sorting
Sugar beet	Sugar beet	Specific indicator species	Specific indicator species for the assessment for birds and mammals
Fruiting vegetables	Tomato (use 2) Tomato (use 3) Eggplant (uses 19 and 20)	Same application rate (0.1 kg as/ha and 0.4 kg a.s./ha for Pyraclostrobin and Boscalid respectively), and same number of applications or lower for tomato use 2 (2 applications instead of 3)	Highest number of applications for birds and mammals risk assessment
Bush and cane fruit	Raspberry, Blackcurrant, Redcurrant, White currant	Same application rate (0.121 kg as/ha and 0.481 kg a.s./ha for Pyraclostrobin and Boscalid respectively), and same number of applications.	Specific indicator species for the assessment for birds and mammals

Root and stem vegetables	Carrot, Beetroot, Celery root, Parsnip, Parsley, Radish, Horseradish, Swedes / rutabagas, Turnip, Salsifies	Carrot as the highest application rate (0.1 kg as/ha and 0.4 kg a.s./ha for Pyraclostrobin and Boscalid respectively) and highest number of applications. Specific indicator species for BBCH 41-49 cover the indicator species for the rest of BBCH stages.	Highest dose and number of applications for birds and mammals risk assessment
Bulbs and onion like crops	Onion, Shallot, Onion “7 years old”	Onion as the highest application rate (0.1 kg as/ha and 0.4 kg a.s./ha for Pyraclostrobin and Boscalid respectively) and highest number of applications. Specific indicator species for BBCH 41-49 cover the indicator species for the rest of BBCH stages.	Highest dose and number of applications for birds and mammals risk assessment
Onion “7 years old”	Onion “7 years old”	-	Worst case parameter for PECsoil calculations for assessment of secondary poisoning for birds and mammals and soil organisms
Leafy vegetables	Cabbage, Chicory roots	Specific indicator species. Chicory roots as the highest application rate (0.1 kg as/ha and 0.4 kg a.s./ha for Pyraclostrobin and Boscalid respectively)	Specific indicator species for the assessment for birds and mammals
Strawberry	Strawberry	Specific indicator species.	Specific indicator species for the assessment for birds and mammals
Cherry	Cherry	Specific indicator species.	Specific indicator species for the assessment for birds and mammals
Orchards	Apple early application	-	Worst case parameter for PECsw calculations for assessment of secondary poisoning for birds and mammals
Ornamentals	Ornamentals (uses 26, 27 and 28)	Specific indicator species. Highest application rate (12.1 g as/ha and 48.1 g a.s./ha for Pyraclostrobin and Boscalid respectively)	Highest dose of application. Specific indicator species for the assessment for birds and mammals
All crops		Same application rate (0.1 kg as/ha and 0.4 kg a.s./ha for Pyraclostrobin and Boscalid respectively) or lower, same number of applications or lower.	Highest application rate, number of applications and drift value for assessment for bees and in-field for arthropods other than bees

Regarding the intended use of tomatoes, eggplants and ornamentals for greenhouse, CASINO ROYALE is expected to apply in enclosed spaces. Therefore, according to the REGULATION (EU) No 283/2013, the effects of the active substance on birds and mammals should not be considered.

9.1.5 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 Casino Royale is indicated in the table.

Table 9.1-3: Metabolites of Pyraclostrobin

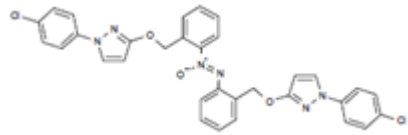
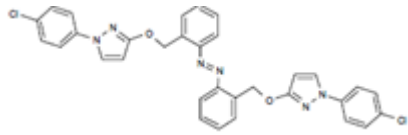
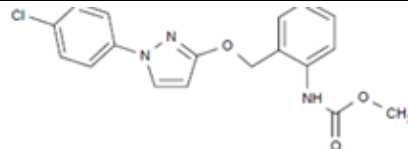
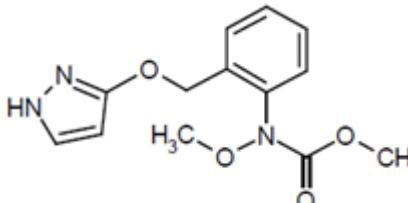
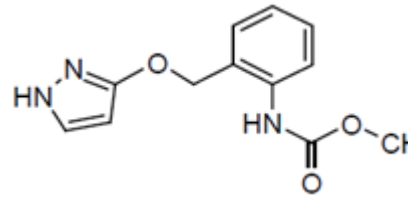
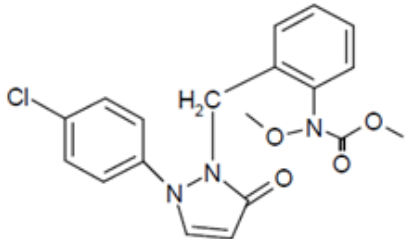
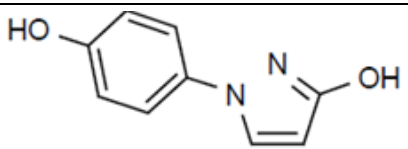
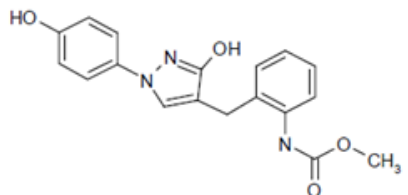
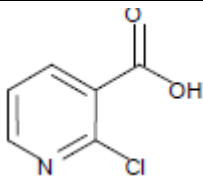
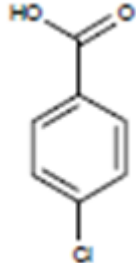
Metabolite	Molar mass	Chemical structure	Maximum occurrence in compartments	Risk assessment required?
BF 500-6	611.5		Soil: max. 31 % after 120 d Sediment : 6.5 % after 61 d	Yes, for non-target soil meso- and macrofauna and soil microbial activity
BF 500-7	595.5		Soil: max. 13 % after 62 d Sediment: 6.3% after 61 d	Yes, for non-target soil meso- and macrofauna and soil microbial activity
BF 500-3	357.8		Soil: max. 95.8 % after 7 d (tolyl-label), anaerobic conditions Water: 2.3% after 61 d Sediment: 65.7 % after 14 d (river system)	No
BF 500-11	277.3		Water/photolysis study: 44.5 % after 21 d (tolyl label)	Yes, for aquatic organisms
BF 500-13	247.3		Water/photolysis study: 16.8 % after 6 d (tolyl label)	Yes, for aquatic organisms
BF 500-14	387.8		Water/photolysis study: 20.7 % after 3 h (Chlorophenyl label)	Yes, for aquatic organisms
BF 500-15	176.2		Water/photolysis study: 26.6 % after 1 day (Chlorophenyl label)	No
500 M 58	-339.3		Water/photolysis study: 22.7 % after 6 h (chlorophenyl label)	No

Table 9.1-3 Metabolites of Boscalid

Metabolite	Molar mass	Chemical structure	Maximum occurrence in compartments	Risk assessment required?
M510F47	157.6		Soil: anaerobic conditions. 2.6 % after 3 d, 6 % after 62 d, 5.9 % after 90 d, 6.7 % after 120 d	No
M510F64	156.56		Sediment: under outdoor condit. 7.3 % after 7 d 9 % after 14 d 9.4 % after 30 d 1.9 % after 120 d	No

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with Pyraclostrobin and Boscalid and their relevant metabolites. Full details of these studies are provided in the respective EU DAR.

Effects on birds of Casino Royale were not evaluated as part of the EU assessment of Pyraclostrobin and Boscalid.

However, the provision of further data on Casino Royale is not considered essential, because endpoints obtained with the active substances are sufficient to evaluate the risk and new studies should not be conducted in regards of animal welfare (EFSA Journal 2009; 7(12):1438).

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

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

Species	Substance	Exposure System	Results	Reference
<i>Colinus virginianus</i>	Pyraclostrobin	Oral Acute	LD ₅₀ > 2000 mg/kg bw	SANCO/1420/2001- Final
<i>Anas platyrhynchos L.</i> <i>Colinus virginianus</i>	Pyraclostrobin	Dietary Short-term	LC ₅₀ > 5000 ppm	SANCO/1420/2001- Final
<i>Colinus virginianus</i>	Pyraclostrobin	Dietary Short-term	LC₅₀ > 1176 mg/kg bw	SANCO/1420/2001- Final
<i>Anas platyrhynchos L.</i>	Pyraclostrobin	Dietary Short-term	LC ₅₀ > 1320 mg/kg bw	SANCO/1420/2001- Final

Species	Substance	Exposure System	Results	Reference
<i>Anas platyrhynchos L.</i> <i>Colinus virginianus</i>	Pyraclostrobin	Dietary Reproductive toxicity	NOEL = 1000 ppm	SANCO/1420/2001-Final
<i>Colinus virginianus</i>	Pyraclostrobin	Dietary Reproductive toxicity	NOEL = 105 mg/kg bw/d	SANCO/1420/2001-Final
<i>Anas platyrhynchos L.</i>	Pyraclostrobin	Dietary Reproductive toxicity	NOEL = 128 mg/kg bw/d	SANCO/1420/2001-Final
<i>Colinus virginianus</i>	Boscalid	Oral Acute	LD₅₀ > 2000 mg/kg bw	SANCO/3919 /2007-rev. 5
<i>Anas platyrhynchos L.</i> <i>Colinus virginianus</i>	Boscalid	Dietary Short-term	LC ₅₀ > 5000 mg/kg feed	SANCO/3919 /2007-rev. 5
<i>Colinus virginianus</i>	Boscalid	Dietary Reproductive toxicity	NOEL = 24.1 mg/kg bw/d	SANCO/3919 /2007-rev. 5

9.2.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

Selection of the endpoint used for acute risk assessment:

According to the Guidance EFSA/2009/1438, where the dietary LC₅₀ is lower than the acute LD₅₀, the dietary value should be used in the acute risk assessment. Therefore, LC₅₀ > 1176 mg a.s./kg bw was used in the acute risk assessment as a worst case for active substance.

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. Here, the assessment for the use group fruiting vegetables also covers the risk for birds from all other intended uses in group fruiting vegetables. The assessment for the group bush and cane fruit also covers the risk from uses in groups raspberry, blackcurrant, redcurrant, white currant. The assessment for the group root and stem vegetables also covers the risk from uses in groups carrot, beetroot, celery root, parsnip, parsley, radish, horseradish, swedes / rutabagas, turnip, salsifies. The assessment for the group bulbs and onion like crops also covers the risk from uses in groups onion, shallot, onion “7 years old”. The assessment for the group leafy vegetables also covers the risk from uses in groups cabbage, chicory roots. In addition, the uses sugar beet, strawberry, cherry and ornamentals have also been assessed separately (see 9.1.4).

Regarding the intended use of tomatoes, eggplants and ornamentals for greenhouse, CASINO ROYALE is expected to apply in enclosed spaces. Therefore, according to the REGULATION (EU) No 283/2013, the effects of the active substance on birds should not be considered.

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 Casino Royale in sugar beet (use sugar beet/use group sugar beet)

Intended use	Sugar beet				
Active substance/product	Pyraclostrobin				
Application rate (g/ha)	2 x 100				
Acute toxicity (mg/kg bw)	> 1176				
TER criterion	10				
Crop scenario Growth stage	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Sugar beet	Indicator species for screening	158.8	1.38	21.91	53.7
Reprod. toxicity (mg/kg bw/d)	105				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Sugar beet	Indicator species for screening	64.8	1.57 × 0.53	5.39	19.5
Intended use	Sugar beet				
Active substance/product	Boscalid				
Application rate (g/ha)	2 x 400				
Acute toxicity (mg/kg bw)	> 2000				
TER criterion	10				
Crop scenario Growth stage	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Sugar beet	Indicator species for screening	158.8	1.38	87.66	22.8
Reprod. toxicity (mg/kg bw/d)	24.1				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Sugar beet BBCH 20 - 49	Small insectivorous bird “wag-tail”. Ground invertebrates with interception. 100% soil dwelling invertebrates	2.8	1.57 × 0.53	0.93	25.9
Sugar beet BBCH 20 - 49	Small insectivorous bird “wag-tail”. Ground invertebrates with interception. 50% ground arthropods, 50% foliar arthropods	9.7	1.57 × 0.53	3.2	7.5
Sugar beet late (summer/ autumn) (BBCH 30-49)	Small granivorous bird "finch" Small seeds. 100% weed seeds	11.4	1.57 × 0.53	3.8	6.4

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 9.2-3: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of Casino Royale in fruiting vegetables (uses tomato 2 & 3 and eggplant 19 & 20/use group fruiting vegetables)

Intended use		Fruiting vegetables				
Active substance/product		Pyraclostrobin				
Application rate (g/ha)		3 x 100				
Acute toxicity (mg/kg bw)		> 1176				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Fruiting vegetables	Indicator species for screening	158.8	1.57	24.93	47.2	
Reprod. toxicity (mg/kg bw/d)		105				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Fruiting vegetables	Indicator species for screening	64.8	1.9 × 0.53	6.53	16.1	
Intended use		Fruiting vegetables				
Active substance/product		Boscalid				
Application rate (g/ha)		3 x 400				
Acute toxicity (mg/kg bw)		> 2000				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Fruiting vegetables	Indicator species for screening	158.8	1.57	99.73	20.1	
Reprod. toxicity (mg/kg bw/d)		24.1				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Fruiting vegetables BBCH ≥ 20	Small insectivorous bird “wag-tail”. Ground invertebrates with interception. 50% ground arthropods, 50% foliar arthropods	9.7	1.9 × 0.53	3.91	6.2	
Fruiting vegetables BBCH 10 - 49	Small granivorous bird “finch”. Small seeds. 100% weed seeds	11.4	1.9 × 0.53	4.59	5.3	
Fruiting vegetables BBCH ≥ 50	Small granivorous bird “finch”. Small seeds. 100% weed seeds	3.4	1.9 × 0.53	1.37	17.6	
Fruiting vegetables BBCH 10 - 49	Small omnivorous bird “lark”. Combination (invertebrates without interception). 25% crop leaves, 25% weed seeds, 50% ground arthropods	10.9	1.9 × 0.53	4.39	5.5	

Fruiting vegetables BBCH \geq 50	Small omnivorous bird “lark”. Combination (invertebrates with- out interception). 25% crop leaves, 25% weed seeds, 50% ground arthropods	3.3	1.9×0.53	1.33	18.1
Fruiting vegetables Fruit stage BBCH 71- 89	Frugivorous bird “crow”. Gourds. 100% fruit	32.0	1.9×0.53	12.89	1.9
Fruiting vegetables Fruit stage BBCH 71- 89	Frugivorous bird “Starling”. To- mato. 100% fruit	20.7	1.9×0.53	8.34	2.9

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 9.2-4: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of Casino Royale in bush and cane fruit (use raspberry/use group bush and cane fruit)

Intended use	Bush and cane fruit				
Active substance/product	Pyraclostrobin				
Application rate (g/ha)	2 x 121				
Acute toxicity (mg/kg bw)	> 1176				
TER criterion	10				
Crop scenario Growth stage	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Bush and cane fruit	Indicator species for screening	52.2	1.4	8.84	133.0
Reprod. toxicity (mg/kg bw/d)	105				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Bush and cane fruit	Indicator species for screening	23	1.6×0.53	2.36	44.5
Intended use	Bush and cane fruit				
Active substance/product	Boscalid				
Application rate (g/ha)	2 x 481				
Acute toxicity (mg/kg bw)	> 2000				
TER criterion	10				
Crop scenario Growth stage	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Bush and cane fruit	Indicator species for screening	52.2	1.4	35.15	56.9
Reprod. toxicity (mg/kg bw/d)	24.1				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}

Bush and cane fruit Fruit stage BBCH 71-79 currants	Frugivorous bird "blackcap". Berries. 100% fruit	23.0	1.6×0.53	9.38	2.6
Bush and cane fruit Whole season BBCH 00-79 Currants	Small insectivorous bird "warbler". Foliar insects. 100% foliar insects	20.3	1.6×0.53	8.28	2.9

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 9.2-5: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of Casino Royale in root and stem vegetables (use carrot/use group root and stem vegetables)

Intended use	Root and stem vegetables				
Active substance/product	Pyraclostrobin				
Application rate (g/ha)	2 x 100				
Acute toxicity (mg/kg bw)	> 1176				
TER criterion	10				
Crop scenario Growth stage	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Root and stem vegetables	Indicator species for screening	158.8	1.38	21.91	53.7
Reprod. toxicity (mg/kg bw/d)	105				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Root and stem vegetables	Indicator species for screening	64.8	1.57×0.53	5.39	19.5
Intended use	Root and stem vegetables				
Active substance/product	Boscalid				
Application rate (g/ha)	2 x 400				
Acute toxicity (mg/kg bw)	> 2000				
TER criterion	10				
Crop scenario Growth stage	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Root and stem vegetables	Indicator species for screening	158.8	1.38	87.66	22.8
Reprod. toxicity (mg/kg bw/d)	24.1				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Root and stem vegetables BBCH ≥ 40	Small granivorous bird "finch". Small seeds. 100% weed seeds.	3.4	1.57×0.53	1.13	21.3

Root and stem vegetables BBCH \geq 40	Small omnivorous bird “lark”. Combination (invertebrates without interception). 25% crop leaves, 25% weed seeds, 50% ground arthropods.	3.3	1.57×0.53	1.10	21.9
Root and stem vegetables BBCH \geq 20	Small insectivorous bird “wag-tail”. Ground invertebrates with interception. 50% ground arthropods, 50% foliar arthropods.	9.7	1.57×0.53	3.23	7.5

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 9.2-6: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of Casino Royale in bulbs and onion like crops (use onion/use group bulbs and onion like crops)

Intended use		Bulbs and onion like crops				
Active substance/product		Pyraclostrobin				
Application rate (g/ha)		2 x 100				
Acute toxicity (mg/kg bw)		> 1176				
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	Indicator species for screening		158.8	1.2	19.06	61.7
Reprod. toxicity (mg/kg bw/d)		105				
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	Indicator species for screening		64.8	1.4 × 0.53	4.81	21.8
Intended use		Bulbs and onion like crops				
Active substance/product		Boscalid				
Application rate (g/ha)		2 x 400				
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
Bulbs and onion like crops	Indicator species for screening		158.8	1.2	76.22	26.2
Reprod. toxicity (mg/kg bw/d)		24.1				
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 BBCH ≥ 40	Small granivorous bird “finch”. Small seeds. 100% weed seeds		6.9	1.4 × 0.53	2.05	11.8

Bulbs and onion like crops BBCH ≥ 40	Small omnivorous bird “lark”. Combination (invertebrates without interception). 25% crop leaves, 25% weed seeds, 50% ground arthropods	6.5	1.4×0.53	1.93	12.5
Bulbs and onion like crops BBCH ≥ 20	Small insectivorous bird “wag-tail”. Ground invertebrates with interception. 50% ground, arthropods, 50% foliar arthropods	9.7	1.4×0.53	2.88	8.4

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 9.2-7: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of Casino Royale in leafy vegetables (use chicory roots/use group leafy vegetables)

Intended use	Leafy vegetables				
Active substance/product	Pyraclostrobin				
Application rate (g/ha)	2 x 100				
Acute toxicity (mg/kg bw)	> 1176				
TER criterion	10				
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Growth stage					
Leafy vegetables	Indicator species for screening	158.8	1.2	19.06	61.7
Reprod. toxicity (mg/kg bw/d)	105				
TER criterion	5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Growth stage					
Leafy vegetables	Indicator species for screening	64.8	1.4×0.53	4.81	21.8
Intended use	Leafy vegetables				
Active substance/product	Boscalid				
Application rate (g/ha)	2 x 400				
Acute toxicity (mg/kg bw)	> 2000				
TER criterion	10				
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Growth stage					
Leafy vegetables	Indicator species for screening	158.8	1.2	76.22	26.2
Reprod. toxicity (mg/kg bw/d)	24.1				
TER criterion	5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Growth stage					
Leafy vegetables BBCH 10 - 49	Small granivorous bird "finch". Small seeds. 100% seeds	12.6	1.4×0.53	3.74	6.4

Leafy vegetables BBCH 10 - 49	Small omnivorous bird “lark”. Combination (invertebrates with- out interception). 25% crop leaves, 25% weed seeds, 50% ground arthropods	10.9	1.4×0.53	3.24	7.5
Leafy vegetables Leaf development BBCH 10-19	Medium herbivorous/granivorous bird "pigeon". Non-grass herbs. 100% leaves	37.0	1.4×0.53	10.98	2.2
Leafy vegetables BBCH 10 - 19	Small insectivorous bird “wag- tail”. Ground invertebrates with- out interception. 50% groun ar- thropods, 50% foliar arthropods	11.3	1.4×0.53	3.35	7.2
Leafy vegetables BBCH ≥ 20	Small insectivorous bird “wag- tail”. Ground invertebrates with interception. 50% ground arthro- pods, 50% foliar arthropods	9.7	1.4×0.53	2.88	8.4

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

Intended use	Strawberry				
Active substance/product	Pyraclostrobin				
Application rate (g/ha)	2 x 121				
Acute toxicity (mg/kg bw)	> 1176				
TER criterion	10				
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Growth stage					
Strawberry	Indicator species for screening	158.8	1.48	28.44	41.4
Reprod. toxicity (mg/kg bw/d)	105				
TER criterion	5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Growth stage					
Strawberry	Indicator species for screening	64.8	1.7×0.53	7.06	14.9
Intended use	Strawberry				
Active substance/product	Boscalid				
Application rate (g/ha)	2 x 481				
Acute toxicity (mg/kg bw)	> 2000				
TER criterion	10				
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Growth stage					
Strawberry	Indicator species for screening	158.8	1.48	113.05	17.7
Reprod. toxicity (mg/kg bw/d)	24.1				

TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Strawberries BBCH ≥ 40	Small omnivorous bird “lark”. Combination (invertebrates without interception). 25% crop leaves, 25% weed seeds, 50% ground arthropods	4.4	1.7 × 0.53	1.91	12.6
Strawberries Late (Flowering/ development of fruit/ Maturity of fruit) BBCH 61-89	Frugivorous bird “Starling”. Berries. 100% fruit	13.4	1.7 × 0.53	5.81	4.2
Strawberries BBCH ≥ 20	Small insectivorous bird “wag-tail”. Ground invertebrates with interception. 50% ground arthropods, 50% foliar arthropods	9.7	1.7 × 0.53	4.20	5.7

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

Intended use		Cherry			
Active substance/product		Pyraclostrobin			
Application rate (g/ha)		2 x 67			
Acute toxicity (mg/kg bw)		> 1176			
TER criterion		10			
Crop scenario Growth stage	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Cherry	Indicator species for screening	46.8	1.48	4.64	253.4
Reprod. toxicity (mg/kg bw/d)		105			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Cherry	Indicator species for screening	18.2	1.7 × 0.53	1.10	95.6
Intended use		Cherry			
Active substance/product		Boscalid			
Application rate (g/ha)		2 x 267			
Acute toxicity (mg/kg bw)		> 2000			
TER criterion		10			
Crop scenario Growth stage	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Cherry	Indicator species for screening	46.8	1.48	18.49	108.2
Reprod. toxicity (mg/kg bw/d)		24.1			

TER criterion	5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Growth stage					
Cherry	Indicator species for screening	18.2	1.7 × 0.53	4.38	5.5

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 9.2-10: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of Casino Royale in ornamentals (use ornamentals 26, 27 & 28/use group ornamentals)

Intended use	Ornamentals				
Active substance/product	Pyraclostrobin				
Application rate (g/ha)	2 x 12.1				
Acute toxicity (mg/kg bw)	> 1176				
TER criterion	10				
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Growth stage					
Ornamentals	Indicator species for screening	46.8	1.4	0.79	1483.4
Reprod. toxicity (mg/kg bw/d)	105				
TER criterion	5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Growth stage					
Ornamentals	Indicator species for screening	18.2	1.6 × 0.53	0.19	562.3
Intended use	Ornamentals				
Active substance/product	Boscalid				
Application rate (g/ha)	2 x 48.1				
Acute toxicity (mg/kg bw)	> 2000				
TER criterion	10				
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Growth stage					
Ornamentals	Indicator species for screening	46.8	1.4	3.15	634.6
Reprod. toxicity (mg/kg bw/d)	24.1				
TER criterion	5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Growth stage					
Ornamentals	Indicator species for screening	18.2	1.6 × 0.53	0.74	32.5

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.

Conclusion

Sugar beet, root and stem vegetables, bulbs and onion like crops, cherry and ornamentals

According to the screening and first-tier assessments, all the TER_a and TER_{lt} values for active substances Pyraclostrobin and Boscalid are greater than the Annex VI trigger of 10 and 5, respectively, indicating that

Casino Royale presents no unacceptable acute and long-term risk to birds according to the intended uses on sugar beet, root and stem vegetables, bulbs and onion like crops, cherry and ornamentals.

Fruiting vegetables, bush and cane fruit, leafy vegetables and strawberry

According to the screening assessment for fruiting vegetables, all the TER_a and TER_{lt} values for the active substance Pyraclostrobin are greater than the Annex VI trigger of 10 and 5, respectively. After screening assessment for active substance Boscalid, the TER_a value are greater than the trigger of 10, indicating that Casino Royale presents no unacceptable acute risk to birds. However, according to the first-tier assessment for fruiting vegetables, TER_{lt} values are lower than the Annex VI trigger of 5, indicating that Casino Royale presents an unacceptable long-term risk to birds. Therefore, higher-tier risk assessments were conducted only for the long-term risk for the next crops and species:

- Fruiting vegetables (BBCH 71-89). Frugivorous bird "crow". Gourds.
- Fruiting vegetables (BBCH 71-89). Frugivorous bird "starling". Tomato.
- Bush and cane fruit (BBCH 71-79 currants). Frugivorous bird "blackcap". Berries.
- Bush and cane fruit (BBCH 00-79 currants). Small insectivorous bird "warbler". Foliar insects.
- Leafy vegetables (BBCH 10-19). Medium herbivorous/granivorous bird "pigeon". Non-grass herbs.
- Strawberries (BBCH 61-89). Frugivorous bird "starling". Berries.

zRMS comments:

The risk assessment at screening and Tier 1 is considered acceptable. 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).

The conclusion of the risk assessment based on the TER_A and TER_{LT} values results for birds for uses proposed in the GAP are as follow:

Sugar beet, root and stem vegetables, bulbs and onion like crops, cherry and ornamentals

According to the screening and first-tier assessments, all the TER_a and TER_{lt} values for active substances Pyraclostrobin and Boscalid are greater than the Annex VI trigger of 10 and 5, respectively, indicating that Casino Royale presents no unacceptable acute and long-term risk to birds according to the intended uses on sugar beet, root and stem vegetables, bulbs and onion like crops, cherry and ornamentals.

Fruiting vegetables, bush and cane fruit, leafy vegetables and strawberry

According to the screening assessment for fruiting vegetables, all the TER_a and TER_{lt} values for the active substance Pyraclostrobin are greater than the Annex VI trigger of 10 and 5, respectively. After screening assessment for active substance Boscalid, the TER_a value are greater than the trigger of 10, indicating that Casino Royale presents no unacceptable acute risk to birds. However, according to the first-tier assessment for fruiting vegetables, TER_{lt} values are lower than the Annex VI trigger of 5, indicating that Casino Royale presents an unacceptable long-term risk to birds.

Therefore, higher-tier risk assessments were conducted only for the long-term risk for the next crops and species:

- Fruiting vegetables (BBCH 71-89). Frugivorous bird "crow". Gourds.
- Fruiting vegetables (BBCH 71-89). Frugivorous bird "starling". Tomato.
- Bush and cane fruit (BBCH 71-79 currants). Frugivorous bird "blackcap". Berries.
- Bush and cane fruit (BBCH 00-79 currants). Small insectivorous bird "warbler". Foliar insects.
- Leafy vegetables (BBCH 10-19). Medium herbivorous/granivorous bird "pigeon". Non-grass herbs.
- Strawberries (BBCH 61-89). Frugivorous bird "starling". Berries.

According to the EFSA Journal (2009)¹, the simultaneous exposure of animals to residues of two or more potential toxic substances should be considered in the risk assessment. Therefore, for the assessment of acute effects, a surrogate LD₅₀ for the mixture of active substances with known toxicity was derived assuming dose additivity of toxicity. 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

LD₅₀ (a.s._i) = acute toxicity value for each a.s.

Acute risks from combined exposure

The active substance content of the formulation Casino Royale addressed in this dossier is 26.7% Boscalid and 6.7% Pyraclostrobin, making up a total of 334 g a.s./L product. According to GAP, the maximum application rate is 1.8 L product/ha, therefore, an application rate of 601.2 g a.s./ha was considered in the assessment.

Table 9.2-11 shows the calculation of the predicted LD₅₀ (mix) of boscalid and pyraclostrobin when mixed in these proportions (step 1 in Appendix 2 to the EFSA GD 2009).

Table 9.2-11: Avian LD₅₀ (mix) for boscalid and pyraclostrobin when combined as Casino Royale (step 1 in EFSA GD 2009, Appendix B)

	Boscalid	Pyraclostrobin
Content in the formulation Casino Royale	26.7%	6.7%
Fraction in the a.s. mixture	0.7994	0.2006
LD ₅₀ of a.s. [mg/kg bw]	2000	1176
Fraction / LD ₅₀	0.00040	0.00017
Sum	0.00057	
1/ sum = predicted LD ₅₀ (mix)	1753.53 mg mix/kg bw	

It is obvious from the comparison of the (low) acute oral toxicity of the active substances, and their relative proportions of the formulated product Casino Royale.

¹ European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA. EFSA Journal 2009; 7(12): 1438. [139 pp.].

Table 9.2-12: Avian “tox per fraction” for the Casino Royale (step 1 in EFSA GD 2009, Appendix B)

	Boscalid	Pyraclostrobin	“mix”
Content in the formulation Casino Royale	26.7%	6.7%	33.4%
Fraction in mixture	0.7994	0.2006	1.0
LD ₅₀ (mg/kg bw)	2000	1176	1753.53
Tox per fraction	2501.87	5862.45	1753.53
Contribution to predicted toxicity	70.09%	29.91%	

Boscalid contributes to 70.09% to mixture toxicity, while the pyraclostrobin have an impact on the predicted risk of 29.91%, therefore, surrogate LD₅₀ was used in the acute risk assessment.

Table 9.2-13: Screening step assessment of the acute risk for birds due to the use of Casino Royale in all crops

Intended use		All crops				
Active substance/product						
Application rate (g/ha)						
LD ₅₀ (mix) (mg/kg bw)		1753.53				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀	TER _a	
Growth stage				(mg/kg bw/d)		
Screening	Indicator species for screening	158.8	1.57	149.89	11.7	

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.

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

Regarding chronic risk assessment, the Applicant considers that, according to EFSA/2009/1438, the calculation of a combined toxicity is not applicable to the risk assessment for reproductive effect. Due to differences in evaluated endpoints and the dependency of the derived NOEL of the test design, any calculated TER_{mix} value can only be used for illustrating purposes. Hence, in the case of an unacceptable TER_{mix}, it has to be discussed if the results of the toxicity studies present any evidence for a possible concentration additivity of the effects and risks.

In addition, the combined toxicological effect of these two active substances has not been investigated with regard to repeated dose toxicity. Possibly, the combined exposure to these active substances may lead to a different toxicological profile than the profile(s) based on the individual substances.

zRMS comments:

We agree with the acute combined risk assessment provided by the applicant.
According to recommendation given in Central Zone the reproductive combined toxicity endpoint should be calculated.
Therefore, zRMS calculated the combined long-term risk and performed these calculations in the Tables below:

Table 9-2-14. Long-term NOEL for the mixture of active substances for birds.

Test substance	Concentration of active substance in formulation (g/kg)	Fraction of active substance in the formulation mixture ^a	NOEL toxicity end-point (mg as/kg bw)	Fraction of active substance/NOEL for the active substance	NOELmix (mg/kg bw)
Pyraclostrobin	67	0.20	105	0.0019	28.57
Boscalid	267	0.80	24.1	0.033	
Total	334			0.035	
		1	-		

^a Concentration of an active substance in the formulation, divided by, the total concentration of all active substances in the formulation.

Table 9-2-15. Comparison of the measured and predicted endpoints for casino Royale Casino using the long-term toxicity data for birds.

Test substance	Concentration of active substance in formulation (g/kg)	Fraction of active substance in the formulation mixture ^a	Long term toxicity end-point (mg as/kg bw)	Tox per fraction a.s.	Tox per fraction mix	Deviation (%)
Pyraclostrobin	67	0.20	105	525	28.57	94.56
Boscalid	267	0.80	24.1	30.125		5.2
Total	334					

^a Concentration of an active substance in the formulation, divided by, the total concentration of all active substances in the formulation.

The deviation between the tox per fraction of boscalid and mixture is < 10 %.
Consequently, the long-term risk assessment for the mixture toxicity is covered by driver - a.s. boscalid.

9.2.2.2 Higher-tier risk assessment

Fruiting vegetables

The Tier I risk assessment showed an unacceptable long-term risk for frugivorous bird “crow” and frugivorous bird “starling” in fruiting vegetables. A further higher-tier risk assessment was needed, and the following parameters were refined:

RUD

For Frugivorous bird “crow” a RUD mean value of 34.3 mg/kg for fruits type gourds was used as worst case. However, according to the Table 1 from Appendix F of EFSA/2009/1438, a more realistic residue value of 12.8 mg/kg for tomato fruits was considered more appropriate and used for the refinement.

Table 9.2-14: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Casino Royale in fruiting vegetables– refined parameters (*) are further described and justified in the text

Intended use	Fruiting vegetables
Active substance/product	Boscalid
Application rate (g/ha)	3 x 400

Reprod. toxicity (mg/kg bw/d)		24.1					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m* × DF (mg/kg food)	MAF_m × TWA	PT	DDD_m (mg/kg bw/d)	TER_{lt}
Crow (<i>Corvus brachyrhynchos</i>)	100% fruit	0.93 ¹	12.8 ² × 1.0	1.9 × 0.53	1	4.79	5.0
Starling (<i>Sturnus vulgaris</i>)	100% fruit	1.62 ¹	12.8 ² × 1.0	1.9 × 0.53	1	8.35	2.9

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

¹ According to Appendix A of EFSA/2009/1438.

² According to Appendix F of EFSA/2009/1438.

Even after refinement, the TER_{lt} value is still below the trigger for starling. A further refinement was necessary. The following parameter was refined:

RUD

The specific residues on fruit tomatoes as reported by the Applicant from studies using the formulated product in the context of the periodic review of residues in crops were used to refine the risk to frugivorous bird “starling”. Summary of residues trials from Poland and Hungary (KCP 10.1.1.2-01 and KCP 10.1.1.2-02) (only the studies where initial residues have been estimated) are summarized in the Table 9.2-15. Calculation of the refinement of the risk assessment is presented in the Table 9.2-16.

Table 9.2-15: Results of residue trials with foliar treatment of boscalid conducted in fruiting vegetables (K. Łukaszewski, 2018; P. Iszak, 2019).

CROP Country, Year Location (variety)	Application					PHI days	Com- modity	Residues, mg/kg boscalid	RUD	Ref. Reg.DocID
	For- mula- tion	Kg a.i./ha	Kg a.i./hL	Water L/ha	No.					
Poland / NEU / 2018	WG	0.407	-	610	2	0	Fruit	0.216	0.53	18SGS18 PL03
Hungary NEU / 2019	WG	0.399	-	749	2	0	Fruit	0.078	0.20	SHRU19-192- 034FR
Hungary NEU / 2019	WG	0.406	-	762	2	0	Fruit	0.278	0.68	SHRU19-193- 034FR
Hungary NEU / 2019	WG	0.412	-	772	2	0	Fruit	0.138	0.33	SHRU19-194- 034FR
RUD_{mean}									0.44	
RUD _{geomean}									0.39	
RUD 90 th									0.64	
SD									0.22	

The geomean value of RUD was 0.39 and the mean value was 0.44. For the refinement of log-term risk the RUD_{mean} value of 0.44 mg/kg was used as worst case.

Table 9.2-16: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Casino Royale in fruiting vegetables– refined parameters (*) are further described and justified in the text

Intended use		Fruiting vegetables					
Active substance/product		Boscalid					
Application rate (g/ha)		3 x 400					
Reprod. toxicity (mg/kg bw/d)		24.1					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m* × DF (mg/kg food)	MAF_m × TWA	PT	DDD_m (mg/kg bw/d)	TER_{it}
Starling (<i>Sturnus vulgaris</i>)	100% fruit	1.62	0.44 ² × 1.0	1.9 × 0.53	1	0.29	83.9

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

¹ According to Appendix A of EFSA/2009/1438.

² RUDmean value according to boscalid residues on fruit tomatoes reported by Applicant.

Bush and cane fruit

The Tier I risk assessment showed an unacceptable long-term risk for frugivorous bird "blackcap" in bush and cane fruits. A further higher-tier risk assessment was needed, and the following parameters were refined for frugivorous:

RUD

The specific residues on grapes as reported in the Monograph for Boscalid (*Nicobifen Report, 08 November 2002*), from studies using a formulated product in the context of the periodic review of residues in crops were used to refine the risk to frugivorous bird “blackcap” as surrogate crops for berries. Summary of residues trials from France and Germany (only the studies where initial residues have been estimated) are summarized in the Table 9.2-17. Calculation of the refinement of the risk assessment is presented in the Table 9.2-18.

Table 9.2-17: Results of residue trials with foliar treatment of boscalid conducted in grapes.

CROP Country, Year Location (variety)	Application					PHI days	Com- modity	Residues, mg/kg boscalid	RUD	Ref. Reg.DocID
	For- mula- tion	Kg a.i./ha	Kg a.i./hL	Water L/ha	No.					
FR - 69480 Lachassagne (EU North) 02.05.2001	SC	0.700	0.700	100	3	0	Pinot blanc	2.01	2.87	RIP2001-333
R - 69480 Lachassagne (EU North) 02.05.2001	SC	0.700	0.700	100	3	0	Gamay	2.68	3.83	RIP2001-333
DE - 54518 Kesten (EU North) 02.05.2001	SC	0.700	0.117	600	3	0	Kerner	2.43	3.47	RIP2001-334

CROP Country, Year Location (variety)	Application					PHI days	Com- modity	Residues, mg/kg boscalid	RUD	Ref. Reg.DocID
	For- mula- tion	Kg a.i./ha	Kg a.i./hL	Water L/ha	No.					
DE - 53474 Bad NeuenahrAhrweiler (EU North) 02.05.2001	SC	0.700	0.117	600	3	0	Dorn- felder	5.76	8.23	RIP2001-334
DE - 76833 Böchingen (EU North) 02.05.2001	SC	0.700	0.117	600	3	0	Müller- Thurgau	2.81	4.01	RIP2001-334
FR - 51200 Brimont (EU North) 02.05.2001	SC	0.700	0.117	600	3	0	Pinot Noir 41B	2.42	3.46	RIP2001-335
FR - 51220 Brimont (EU North) 02.05.2001	SC	0.700	0.700	100	3	0	Pinot meunier	2.16	3.09	RIP2001-336
FR - 37210 Roche Corbon (EU North) 02.05.2001	SC	0.700	0.700	100	3	0	Chenin blanc	1.97	2.81	RIP2001-336
DE - 54518 Kesten (EU North) 02.05.02001	SC	0.700	0.117	600	3	0	Kerner	1.39	1.99	RIP2001-337
DE – 69168 Wiesloch (EU North) 02.05.2001	SC	0.700	0.117	600	3	0	Müller- Thurgau	0.910	1.30	RIP2001-337
DE - 76831 Eschbach (EU North) 02.05.20001	SC	0.700	0.117	600	3	0	Portu- gieser	1.16	1.66	RIP2001-337
FR - 51220 Merfy (EU North) 02.05.2001	SC	0.700	0.117	600	3	0	Pinot Noir	1.45	2.07	RIP2001-338
FR - 51220 Brimont (EU North) 02.05.2001	WG	0.600	0.600	100	3	0	Pinot meunier	1.49	2.48	RIP2001-336
FR - 37210 Roche Corbon (EU North) 02.05.2001	WG	0.600	0.600	100	3	0	Chenin blanc	1.84	3.07	RIP2001-336
DE - 54518 Kesten (EU North) 02.05.2001	WG	0.600	0.100	600	3	0	Kerner	1.32	2.20	RIP2001-337
D E- 69168 Wiesloch (EU North) 02.05.2001	WG	0.600	0.100	600	3	0	Müller- Thurgau	1.03	1.72	RIP2001-337
DE - 76831 Eschbach (EU North) 02.05.2001	WG	0.600	0.100	600	3	0	Portu- gieser	0.910	1.52	RIP2001-337

CROP Country, Year Location (variety)	Application					PHI days	Com- modity	Residues, mg/kg boscalid	RUD	Ref. Reg.DocID
	For- mula- tion	Kg a.i./ha	Kg a.i./hL	Water L/ha	No.					
FR - 51220 Merfy (EU North) 02.05.2001	WG	0.700	0.117	600	3	0	Pinot Noir	1.21	1.73	RIP2001-338
RUD _{mean}									2.86	
RUD _{geomean}									2.58	
RUD 90 th									3.88	
SD									1.57	

The geomean value of RUD was 2.58 and the mean value was 2.86. For the refinement of log-term risk the RUD_{mean} value of 2.86 mg/kg was used as worst case.

Table 9.2-18: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Casino Royale in bush and cane fruits (frugivorous birds)– refined parameters (*) are further described and justified in the text

Intended use		Bush and cane fruit						
Active substance/product		Boscalid						
Application rate (g/ha)		2 x 481						
Reprod. toxicity (mg/kg bw/d)		24.1						
TER criterion		5						
Focal species	Food category, % in diet	FIR/bw	RUD _m * × DF (mg/kg food)	MAF _m × TWA	PT	DDD _m (mg/kg bw/d)	TER _{lt}	
Blackcap (<i>Sylvia atricapilla</i>)	100% fruit	2.77	2.86 ² × 1.0	1.6 × 0.53	1	3.23	7.5	

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

¹ According to Appendix A of EFSA/2009/1438.

² RUDmean value according to boscalid residues on grapes reported in the Monograph.

The Tier I risk assessment also showed an unacceptable long-term risk for small insectivorous bird "warbler" in bush and cane fruit. A further higher-tier risk assessment was needed, and the following parameters were refined for insectivorous:

Diet

According to the dossier for the Pesticide Risk Assessment for Birds and Mammals, and its selection of relevant species and development of standard scenarios for higher tier risk assessment in the Northern Zone in accordance with Regulation EC 1107/2009 (May 2015, Version 1.2), Willow warbler (*Phylloscopus trochilus*) is a widespread and abundant species throughout the zone, which diet can be assumed to consist almost entirely of foliar arthropods (95%) and ground arthropods (5%). Hence, a mixed diet consisting of 0.95 foliar and 0.05 ground arthropods will be considered in the risk assessment.

Deposition factor

Casino Royale will be applied directly to crop. Since ground arthropods will be covered by the crop, an interception by the crop has to be taken into account. According to the values of FOCUS (2000)², bushberries have assigned an interception factor of 40% (as a worst case during the whole season), which corresponds to a deposition factor of 0.6. Moreover, since the application is to the crop, to assess the foliar arthropods exposure, the mentioned interception factor of 40% in bushberries will also be considered during the risk assessment.

Multiple application factor

According to the Registration Report for Bellis³ (25.2% boscalid + 12.8% pyraclostrobin WG) (CTGB, admission number 12845 N, 29 July 2008), the default DT₅₀ of 10 days which is applied to plant-like food items can also be used for insects. Multiple applications on the same individual insect are not expected, therefore the exposure is equal for single and multiple uses. This implies that the ftwa of 0.53 (currently only used for herbivorous species) can also be used for insects. Hence, the MAF_m used in the insectivorous risk assessment will be equal to 1.

² FOCUS (2012) "Focus groundwater scenarios in the EU review of active substances" Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference Sanco/321/2000 rev.2, 202 pp.

³ <https://toelatingen.ctgb.nl/nl/authorisations/9322>

Table 9.2-19: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Casino Royale in bush and cane fruits (insectivorous birds)– refined parameters (*) are further described and justified in the text

Intended use		Bush and cane fruit						
Active substance/product		Boscalid						
Application rate (g/ha)		2 x 481						
Reprod. toxicity (mg/kg bw/d)		24.1						
TER criterion		5						
Focal species	Food category, % in diet	PD*	FIR/bw	RUD_m × DF* (mg/kg food)	MAF_m* × TWA	ETE (mg/kg bw/d)	ETE_{total}	TER_{It}
Warbler (<i>Phylloscopus trochilus</i>)	95% foliar arthropods	0.95 ¹	0.96 ²	21 × 0.4 ⁴	1.0 ⁵ × 0.53	1.95	1.98	12.2
	5% ground arthropods	0.05 ¹	0.96 ²	3.5 ³ × 0.6 ⁴	1.0 ⁵ × 0.53	0.03		

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

¹ According to Pesticide Risk Assessment for Birds and Mammals dossier

² According to Appendix A of EFSA/2009/1438.

³ According to Table 1 from Appendix F of EFSA/2009/1438.

⁴ Deposition factor according to FOCUS groundwater guidance.

⁵ According to Registration Report for Bellis (CTGB, 2008)

Leafy vegetables

The Tier I risk assessment showed an unacceptable long-term risk for medium herbivorous/granivorous bird "pigeon" in leafy vegetables. A further higher-tier risk assessment was needed, and the following parameters were refined:

RUD

The specific residues on winter rape as reported in the Monograph for Boscalid (*Nicobifen Report, 08 November 2002*), from studies using a formulated product in the context of the periodic review of residues in crops were used to refine the risk to herbivorous bird "pigeon" as surrogate crops for leafy vegetables. Summary of residues trials from Germany, Denmark, France, Great Britain and Sweden (only the studies where initial residues have been estimated) are summarized in the Table 9.2-20. Calculation of the refinement of the risk assessment is presented in the Table 9.2-21.

Table 9.2-20: Results of residue trials with foliar treatment of boscalid conducted in winter rape.

CROP Country, Year Location (variety)	Application					PHI days	Com- modity	Residues, mg/kg boscalid*	RUD	Ref. Reg.DocID
	For- mula- tion	Kg a.i./ha	Kg a.i./hL	Water L/ha	No.					
DE - 24625 Großharrie (EU North) 02.05.2001	WG	0.250	0.083	300	1	0	Artus	2.02	8.08	RIP2001-339
DE - 85445 Oberding (EU North) 02.05.2001	WG	0.250	0.083	300	1	0	Express	2.75	11.00	RIP2001-339

CROP Country, Year Location (variety)	Application					PHI days	Com- modity	Residues, mg/kg boscalid*	RUD	Ref. Reg.DocID
	For- mula- tion	Kg a.i./ha	Kg a.i./hL	Water L/ha	No.					
DE - 24625 Großharrie (EU North) 02.05.2001	WG	0.250	0.083	300	2	0	Artus	2.67	10.68	RIP2001-340
DK - 5500 Middelfart (EU North) 02.05.2001	WG	0.250	0.083	300	1	0	Elite	0.71	2.84	RIP2001-339
FR - 62580 Neuvireuil (EU North) 02.05.2001	WG	0.250	0.083	300	1	0	Adelie	2.30	9.20	RIP2001-339
FR - 21310 Beze (EU North) 02.05.2001	WG	0.250	0.083	300	1	0	Colum- bus	1.11	4.44	RIP2001-339
GB - Leaminton Spa CU33 9QB (EU North) 02.05.2001	WG	0.250	0.083	300	1	0	Apex	3.21	12.84	RIP2001-339
GB - Radcliffe MK18 4AB Buckingham (EU North) 02.05.2001	WG	0.250	0.083	300	1	0	Contact	2.41	9.64	RIP2001-339
GB - Leaminton Spa CV33 9QB (EU North) 02.05.2001	WG	0.250	0.083	300	2	0	Apex	2.16	8.64	RIP2001-340
SE - 23791 Bjärred (EU North) 02.05.2001	WG	0.250	0.083	300	2	0	Capitol	2.27	9.08	RIP2001-340
RUD _{mean}									8.64	
RUD _{geomean}									8.00	
RUD 90 th									11.18	
SD									2.99	

* plant without roots

The geomean value of RUD was 8.00 and the mean value was 8.64. For the refinement of log-term risk the RUD_{mean} value of 8.64 mg/kg was used as worst case.

Table 9.2-21: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Casino Royale in leafy vegetables – refined parameters (*) are further described and justified in the text

Intended use	Leafy vegetables
Active substance/product	Boscalid
Application rate (g/ha)	2 x 400
Reprod. toxicity (mg/kg bw/d)	24.1
TER criterion	5

Focal species	Food category, % in diet	FIR/bw	RUD _m * × DF (mg/kg food)	MAF _m × TWA	PT	DDD _m (mg/kg bw/d)	TER _{lt}
Pigeon (<i>Columba palumbus</i>)	Non-grass herbs. 100% leaves	1.29 ¹	8.64 ² × 1.0	1.4 × 0.53	1	3.31	7.3

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

¹ According to Appendix A of EFSA/2009/1438.

² RUDmean value according to boscalid residues on oilseed rape reported in the Monograph.

Strawberries

The Tier I risk assessment showed an unacceptable long-term risk for frugivorous bird “starling” in strawberries. A further higher-tier risk assessment was needed, and the following parameters were refined:

RUD

As used for bush and cane fruit crops, the specific residues on grapes as reported in the Monograph for Boscalid (*Nicobifen Report, 08 November 2002*), from studies using a formulated product in the context of the periodic review of residues in crops were used to refine the risk to frugivorous bird “starling” as surrogate crops for strawberries. Summary of residues trials are summarized in the Table 9.2-19. The geomean value of RUD was 2.58 and the mean value was 2.86. For the refinement of log-term risk the RUD_{mean} value of 2.86 mg/kg was used as worst case.

Calculation of the refinement of the risk assessment is presented in the Table 9.2-22.

Table 9.2-22: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Casino Royale in strawberries– refined parameters (*) are further described and justified in the text

Intended use		Strawberries					
Active substance/product		Boscalid					
Application rate (g/ha)		2 x 481					
Reprod. toxicity (mg/kg bw/d)		24.1					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD _m * × DF (mg/kg food)	MAF _m × TWA	PT	DDD _m (mg/kg bw/d)	TER _{lt}
Starling (<i>Sturnus vulgaris</i>)	100% fruit	1.62 ¹	2.86 ² × 1.0	1.7 × 0.53	1	2.01	12.0

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

¹ According to Appendix A of EFSA/2009/1438.

² RUDmean value according to boscalid residues on grapes reported in the Monograph.

zRMS comment:

Fruiting vegetables:

The Tier I risk assessment showed an unacceptable long-term risk for frugivorous bird “crow” and frugivorous bird “starling” in fruiting vegetables. A further higher-tier risk assessment was needed. Therefore, the RUD parameter in fruit was refined by applicant.

We agree with RUD=12.8 mg/kg value used by the applicant according to the Table 1 from Appendix F of EFSA/2009/1438.

In addition, the applicant for further refinement used the RUD (mean) value from residue trials from studies using the formulated product to refine the risk to frugivorous bird “starling”.

Summary of residues trials from Poland and Hungary were submitted (please see at Point : KCP 10.1.1.2-01 and KCP 10.1.1.2-02) (only the studies where initial residues have been estimated).

These studies were considered as an acceptable in Residue Section , B7 for ppp Casino Royale.

In zRMS's opinion the RUD value of 90th might be used as the worst case scenario for refinement of risk.

Table 9.2-23_{corr}: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Casino Royale in fruiting vegetables– refined parameters (*) are further described and justified in the text.

Intended use		Fruiting vegetables					
Active substance/product		Boscalid					
Application rate (g/ha)		3 x 400					
Reprod. toxicity (mg/kg bw/d)		24.1					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m* × DF (mg/kg food)	MAF_m × TWA	PT	DDD_m (mg/kg bw/d)	TER_{lt}
Starling (<i>Sturnus vulgaris</i>)	100% fruit	1.62 ¹	0.64 ² × 1.0	1.9 × 0.53	1	0.417	12

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

¹ According to Appendix A of EFSA/2009/1438.

² According to Appendix F of EFSA/2009/1438.

² RUD (90th percentile) value according to boscalid residues on fruit tomatoes reported by applicant.

After refinement the TER_{LT} value is above the trigger of 5 indicating an acceptable risk for fruiting vegetables.

Bush and cane fruit

We agree with risk assessment for frugivorous bird “blackcap” as surrogate crops for berries.

In case of the risk assessment for this species we can accept using the 90th percentile of RUD as a worst case scenario in refined risk assessment.

In case of risk assessment for insectivorous birds for foliar arthropods the Deposition Factor is not recommend to use.

The own zRMS's risk assessment is provided in the Table below:

Table 9.2-24_{corr}: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Casino Royale in bush and cane fruits (frugivorous birds)– refined parameters (*) are further described and justified in the text

Intended use		Bush and cane fruit					
Active substance/product		Boscalid					
Application rate (g/ha)		2 x 481					
Reprod. toxicity (mg/kg bw/d)		24.1					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m* × DF (mg/kg food)	MAF_m × TWA	PT	DDD_m (mg/kg bw/d)	TER_{It}
Blackcap (<i>Sylvia atricapilla</i>)	100% fruit	2.77 ¹	3.88 ² × 1.0	1.6 × 0.53	1	4.38	5.5

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

¹ According to Appendix A of EFSA/2009/1438.

² RUD 90th value according to boscalid residues on grapes reported in the Monograph.

Ater refinement the TER_{LT} value is above the trigger of 5 indicating an acceptable risk for bash and cane fruits.

Table 9.2-25_{corr}: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Casino Royale in bush and cane fruits (insectivorous birds)– refined parameters (*) are further described and justified in the text

Intended use		Bush and cane fruit						
Active substance/product		Boscalid						
Application rate (g/ha)		2 x 481						
Reprod. toxicity (mg/kg bw/d)		24.1						
TER criterion		5						
Focal species	Food category, % in diet	PD*	FIR/bw	RUD_m × DF* (mg/kg food)	MAF_m* × TWA	ETE (mg/kg bw/d)	ETE_{total}	TER_{It}
Warbler (<i>Phylloscopus trochilus</i>)	95% foliar arthropods	0.95 ¹	0.96 ²	21 x1	1.0 × 0.53	4.88	4.91	4.90
	5% ground arthropods	0.05 ¹	0.96 ²	3.5 ³ × 0.6 ⁴	1.0 × 0.53	0.03		

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

¹ According to Pesticide Risk Assessment for Birds and Mammals dossier

² According to Appendix A of EFSA/2009/1438.

³ According to Table 1 from Appendix F of EFSA/2009/1438.

⁴ Deposition factor according to FOCUS groundwater guidance.

The TER_{LT} value (4.90) for the worst case scenario is close to trigger of 5. zRMS is in the opinion that because of slight deviation the risk can be considered as an acceptable.

Leafy vegetables

We agree with risk assessment for pigeon as surrogate crops for leafy vegetables.

In case of the risk assessment for this species we can accept using the 90th percentile of RUD as a worst case scenario in the risk assessment.

Therefore, the own zRMS's risk assessment is provided in the Table below:

Table 9.2-26_{corr}: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Casino Royale in leafy vegetables – refined parameters (*) are further described and justified in the text

Intended use		Leafy vegetables					
Active substance/product		Boscalid					
Application rate (g/ha)		2 x 400					
Reprod. toxicity (mg/kg bw/d)		24.1					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m* × DF (mg/kg food)	MAF_m × TWA	PT	DDD_m (mg/kg bw/d)	TER_{lt}
Pigeon (<i>Columba palumbus</i>)	Non-grass herbs. 100% leaves	1.29 ¹	11.18 ² × 1.0	1.4 × 0.53	1	4.28	5.63

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

¹ According to Appendix A of EFSA/2009/1438.

² RUD 90th percentile value according to boscalid residues on oilseed rape reported in the Monograph.

After refinement, the TER_{LT} value is above the trigger of 5 indicating an acceptable risk for leafy vegetables.

Strawberry

We agree with risk assessment for starling as surrogate crops for strawberry.

In case of the risk assessment for this species we can accept using the 90th percentile of RUD as a worst case scenario.

Therefore, the own zRMS risk assessment is provided in the Table below:

Table 9.2-27_{corr}: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Casino Royale in strawberries– refined parameters (*) are further described and justified in the text.

Intended use		Strawberries					
Active substance/product		Boscalid					
Application rate (g/ha)		2 x 481					
Reprod. toxicity (mg/kg bw/d)		24.1					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m* × DF (mg/kg food)	MAF_m × TWA	PT	DDD_m (mg/kg bw/d)	TER_{lt}
Starling (<i>Sturnus vulgaris</i>)	100% fruit	1.62 ¹	3.88 ² × 1.0	1.7 × 0.53	1	2.72	8.86

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

² RUD 90 %th percentile value according to boscalid residues on grapes reported in the Monograph.

After refinement the TER_{LT} value is above the trigger of 5 indicating an acceptable risk for strawberry.

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 Casino Royale is 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 must be considered.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group leafy vegetables also covers the risk for birds from all other intended uses in groups cabbage and chicory roots (see 9.1.4).

Table 9.2-28: Assessment of the acute risk for birds due to exposure to Pyraclostrobin via contaminated drinking water in leaf whorls

Intended use		Leafy vegetables				
Active substance		Pyraclostrobin				
Application rate (g/ha)		2 × 100				
Acute toxicity (mg/kg bw)		> 1176				
TER criterion		10				
(Single) ap- plic. rate (g/ha)	Water applic. rate (L/ha)	C _{spray-sol.} (g/L)	PEC _{leaf-whorl} = C _{spray-sol.} /5 (mg/L)	DW uptake (L/kg bw/d)	Daily dose (mg/kg bw/d)	TER _a
100	300	0.33	0.07	0.46	0.03	38347.83

C_{spray-sol.}: concentration in spray solution; PEC_{leaf-whorl}: concentration in pools in leaf whorls; DW: drinking water; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-29: Assessment of the acute risk for birds due to exposure to Boscalid via contaminated drinking water in leaf whorls

Intended use		Leafy vegetables				
Active substance		Boscalid				
Application rate (g/ha)		2 × 400				
Acute toxicity (mg/kg bw)		> 2000				
TER criterion		10				
(Single) ap- plic. rate (g/ha)	Water applic. rate (L/ha)	C _{spray-sol.} (g/L)	PEC _{leaf-whorl} = C _{spray-sol.} /5 (mg/L)	DW uptake (L/kg bw/d)	Daily dose (mg/kg bw/d)	TER _a
400	300	1.33	0.27	0.46	0.12	16304.35

C_{spray-sol.}: concentration in spray solution; PEC_{leaf-whorl}: concentration in pools in leaf whorls; DW: drinking water; TER: toxicity to

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

zRMS comment:

zRMS agrees with the ratio calculations and the risk assessment for drinking water exposure.
 zRMS considers that use of according to GAP does not pose an unacceptable acute risk to birds through drinking water exposure.

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 ($K_{oc} < 500$ L/kg) or 3000 in the case of more sorptive substances ($K_{oc} \geq 500$ L/kg).

With a $K(f)_{oc}$ of 8855.9 (geomean, $n = 6$; Review Report, 2004), Pyraclostrobin belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group strawberries also covers the risk for birds from all other intended uses (see 9.1.4).

Effective application rate (g/ha) =	179.1/205.7			
Acute toxicity (mg/kg bw) =	1176	quotient	=	0.15
Reprod. toxicity (mg/kg bw/d) =	105	quotient	=	1.96

With a $K(f)_{oc}$ of 742.6 (geomean, $n = 6$; Review Report, 2008), Boscalid belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group fruiting vegetables also covers the risk for birds from all other intended uses (see 9.1.4).

Effective application rate (g/ha) =	711.9/817.7			
Acute toxicity (mg/kg bw) =	2000	quotient	=	0.36
Reprod. toxicity (mg/kg bw/d) =	24.1	quotient	=	33.93

zRMS comment:

RMS agrees with the calculation for puddle scenario.

9.2.2.4 Effects of secondary poisoning

The log P_{ow} of Pyraclostrobin amounts to 3.99 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

The log P_{ow} of Boscalid amounts to 2.96 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

zRMS comment:

The log P_{ow} of the active substance boscalid was determined to be 2.96 (P_{ow} 915) and a bioaccumulation study in fish was performed (see Monograph, Vol. 3, Annex B.9, 2002). The bioconcentration factors for whole fish were 57 (low concentration) and 70 (high concentration). The half-lives for elimination varied between 0.4 and 1.0 days. The time for elimination of 90% of the activity varied between 1.4 and 3.3 days. The nature of radioactivity in fish tissues after 28 days of exposure proved to primarily consist of the parent substance (84.9% - 97.0%). Due to the low accumulation and rapid excretion of boscalid from fish it is concluded that there is no risk of bioaccumulation in food chains.

The log P_{ow} of Pyraclostrobin amounts to 3.99 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 predicted concentrations in soil.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group onion “7 years old” also covers the risk for birds from all other intended uses (see 9.1.4).

Table 9.2-30: Assessment of the risk for earthworm-eating birds due to exposure to Pyraclostrobin via bioaccumulation in earthworms (secondary poisoning) for the intended uses (use group all crops)

Parameter	Pyraclostrobin	Comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.162	PEC_{soil} (twa = 21 d) for multiple applications using onion “7 years old” GAP
$\log P_{ow} / P_{ow}$	3.99 / 9772.37	SANCO/1420/2001-Final
Koc	8855.9	Geomean, n = 6; Review Report, 2004
foc	0.02	Default
BCF_{worm}	0.667	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC_{worm}	0.11	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.11	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	105	SANCO/1420/2001-Final
TER_{lt}	925.5	No risk, $TER_{lt} > 5$

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 as a limit value for admissible concentrations of Pyraclostrobin in water.

Table 9.2-31: Assessment of the risk for fish-eating birds due to exposure to Pyraclostrobin via bioaccumulation in fish (secondary poisoning) for the intended use in all crops (use group all crops)

Parameter	Pyraclostrobin	Comments
PEC _{sw} (tw _a = 21 d) (mg/L)	0.00652	Worst case value drawn from use cherry (apple early application as worst case, BBCH 60), FOCUS step 2
BCF _{fish}	736	Whole fish, tolyl label. SANCO/1420/2001-Final
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	4.80	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.76	DDD = PEC _{fish} × 0.159
NOEL (mg/kg bw/d)	105	SANCO/1420/2001-Final
TER _{lt}	137.6	No risk, TER _{lt} > 5

TER values shown in bold fall below the relevant trigger.

zRMS comments:

We agree with the calculations of the risk for fish-eating birds and earthworm-eating birds in all crops (use group all crops).

The TER_{LT} values were above trigger of 5 indicating an acceptable risk.

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

9.2.4 Overall conclusions

Fruiting vegetables, bush and cane fruit, leafy vegetables and strawberry

According to the screening assessment, all the TER_a and TER_{lt} values for the active substance Pyraclostrobin are greater than the Annex VI trigger of 10 and 5, respectively. After screening assessment for active substance Boscalid, the TER_a value are greater than the trigger of 10, indicating that Casino Royale presents no unacceptable acute risk to birds. However, according to the first-tier assessment, TER_{lt} values are lower than the Annex VI trigger of 5 for frugivorous bird "crow" and frugivorous bird "Starling" (fruiting vegetables), frugivorous bird "blackcap" and small insectivorous bird "warbler" (bush and cane fruit), medium herbivorous/granivorous bird "pigeon" (leafy vegetables) and frugivorous bird "starling" (strawberries), indicating that Casino Royale presents an unacceptable long-term risk to birds. A refinement of the risk was done by refining of RUD, diet type, deposition factor and MAF, and the TER values were above the trigger showing no risk. Therefore, the acute and long-term risk to birds after the application of Casino Royale according to the GAP is considered acceptable

Sugar beet, root and stem vegetables, bulbs and onion like crops, cherry and ornamentals

According to the screening and first-tier assessments, all the TER_a and TER_{lt} values for active substances Pyraclostrobin and Boscalid are greater than the Annex VI trigger of 10 and 5, respectively, indicating that Casino Royale presents no unacceptable acute and long-term risk to birds according to the intended uses on sugar beet, root and stem vegetables, bulbs and onion like crops, cherry and ornamentals.

Pyraclostrobin has been shown to have the potential for bioaccumulation, however, there is no risk to earthworm and fish-eating birds according to the intended uses of Casino Royale.

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 Pyraclostrobin and Boscalid and their relevant metabolites. Full details of these studies are provided in the respective EU DAR.

Effects on mammals of Casino Royale were not evaluated as part of the EU assessment of Pyraclostrobin and Boscalid. However, the provision of further data on the formulation Casino Royale is not considered essential, because risk may be reliably assessed using the EU-agreed endpoints only and new studies should not be conducted in regards of animal welfare (EFSA Journal 2009; 7(12):1438).

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

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

Species	Substance	Exposure System	Results	Reference
Rat	Pyraclostrobin	Oral Acute	LD₅₀ > 5000 mg/kg bw	SANCO/1420/2001-Final.
Rat	Pyraclostrobin	Long-term	NOAEL = 75 ppm (equivalent to 8.2 mg/kg bw/d)	DAR, 2001
Rat	Boscalid	Oral 1 d Acute	LD₅₀ > 5000 mg/kg bw	SANCO/3919 /2007-rev. 5
Rat	Boscalid	Dietary Reproductive toxicity Two-generation study	NOAED = 67 mg/kg bw/d	SANCO/3919 /2007-rev. 5

9.3.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

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. Here, the assessment for the use group fruiting vegetables also covers the risk for birds from all other intended uses in group fruiting vegetables. The assessment for the group bush and cane fruit also covers the risk from uses in groups raspberry, blackcurrant, redcurrant, white currant. The assessment for the group root and stem vegetables also covers the risk from uses in groups carrot, beetroot, celery root, parsnip, parsley, radish, horseradish, swedes / rutabagas, turnip, salsifies. The assessment for the group bulbs and onion like crops also covers the risk from uses in groups onion, shallot, onion “7 years old”. The assessment for the group leafy vegetables also covers the risk from uses in groups cabbage, chicory roots. In addition, the uses sugar beet, strawberry, cherry and ornamentals have also been assessed separately (see 9.1.4).

Regarding the intended use of tomatoes, eggplants and ornamentals for greenhouse, CASINO ROYALE is expected to apply in enclosed spaces. Therefore, according to the REGULATION (EU) No 283/2013, the effects of the active substance on mammals should not be considered.

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 Casino Royale in sugar beet (use sugar beet/use group sugar beet)

Intended use	Sugar beet				
Active substance/product	Pyraclostrobin				
Application rate (g/ha)	2 x 100				
Acute toxicity (mg/kg bw)	> 5000				
TER criterion	10				
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Growth stage					
Sugar beet	Indicator species for screening	118.4	1.38	16.34	306.0
Reprod. toxicity (mg/kg bw/d)	8.2				
TER criterion	5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Growth stage					
Sugar beet BBCH ≥ 20	Small insectivorous mammal "shrew". Ground dwelling invertebrates with interception. 100% ground arthropods	1.9	1.57 × 0.53	0.16	51.9
Sugar beet BBCH 10-39	Large herbivorous mammal “lagomorph”. Non-grass herbs. 100% crop leaves	14.3	1.57 × 0.53	1.19	6.9
Sugar beet BBCH 10-39	Small omnivorous mammal “mouse”. Combination (invertebrates with interception). 25% weeds, 50% weed seeds, 25% ground arthropods	7.8	1.57 × 0.53	0.65	12.6

Intended use	Sugar beet				
Active substance/product	Boscalid				
Application rate (g/ha)	2 x 400				
Acute toxicity (mg/kg bw)	> 5000				
TER criterion	10				
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Growth stage					
Sugar beet	Indicator species for screening	118.4	1.38	65.36	76.5
Reprod. toxicity (mg/kg bw/d)	67				
TER criterion	5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Growth stage					
Sugar beet BBCH ≥ 20	Small insectivorous mammal "shrew". Ground dwelling invertebrates with interception. 100% ground arthropods	1.9	1.57 × 0.53	0.63	106.0
Sugar beet BBCH 10-39	Large herbivorous mammal "lagomorph". Non-grass herbs. 100% crop leaves	14.3	1.57 × 0.53	4.76	14.1
Sugar beet BBCH 10-39	Small omnivorous mammal "mouse". Combination (invertebrates with interception). 25% weeds, 50% weed seeds, 25% ground arthropods	7.8	1.57 × 0.53	2.60	25.8

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 9.3-3: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of Casino Royale in fruiting vegetables (uses tomato 2 & 3 and eggplant 19 & 20/use group fruiting vegetables)

Intended use	Fruiting vegetables				
Active substance/product	Pyraclostrobin				
Application rate (g/ha)	3 x 100				
Acute toxicity (mg/kg bw)	> 5000				
TER criterion	10				
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Growth stage					
Fruiting vegetables	Indicator species for screening	136.4	1.57	21.41	233.5
Reprod. toxicity (mg/kg bw/d)	8.2				
TER criterion	5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Growth stage					

Fruiting vegetables BBCH ≥ 20	Small insectivorous mammal "shrew". Ground dwelling invertebrates with interception. 100% ground arthropods	1.9	1.9×0.53	0.19	42.9
Fruiting vegetables BBCH 10 - 49	Small herbivorous mammal "vole". Grass + cereals. 100% grass	72.3	1.9×0.53	7.28	1.1
Fruiting vegetables BBCH ≥ 50	Small herbivorous mammal "vole". Grass + cereals. 100% grass	21.7	1.9×0.53	2.19	3.8
Fruiting vegetables BBCH 10 - 49	Small omnivorous mammal "mouse". Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	7.8	1.9×0.53	0.79	10.4
Fruiting vegetables BBCH ≥ 50	Small omnivorous mammal "mouse". Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	2.3	1.9×0.53	0.23	35.4
Fruiting vegetables Fruit stage BBCH 71-89	Frugivorous mammal "rat". Gourds. 100% fruit	25.2	1.9×0.53	2.54	3.2
Intended use		Fruiting vegetables			
Active substance/product		Boscalid			
Application rate (g/ha)		3 x 400			
Acute toxicity (mg/kg bw)		> 5000			
TER criterion		10			
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Growth stage					
Fruiting vegetables	Indicator species for screening	136.4	1.57	85.66	58.4
Reprod. toxicity (mg/kg bw/d)		67			
TER criterion		5			
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Growth stage					
Fruiting vegetables BBCH ≥ 20	Small insectivorous mammal "shrew". Ground dwelling invertebrates with interception. 100% ground arthropods	1.9	1.9×0.53	0.77	87.6
Fruiting vegetables BBCH 10 - 49	Small herbivorous mammal "vole". Grass + cereals. 100% grass	72.3	1.9×0.53	29.12	2.3
Fruiting vegetables BBCH ≥ 50	Small herbivorous mammal "vole". Grass + cereals. 100% grass	21.7	1.9×0.53	8.74	7.7

Fruiting vegetables BBCH 10 - 49	Small omnivorous mammal "mouse". Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	7.8	1.9×0.53	3.14	21.3
Fruiting vegetables BBCH ≥ 50	Small omnivorous mammal "mouse". Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	2.3	1.9×0.53	0.93	72.3
Fruiting vegetables Fruit stage BBCH 71-89	Frugivorous mammal "rat". Gourds. 100% fruit	25.2	1.9×0.53	10.15	6.6

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 9.3-4: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of Casino Royale in bush and cane fruits (use raspberry/use group bush and cane fruits)

Intended use		Bush and cane fruits				
Active substance/product		Pyraclostrobin				
Application rate (g/ha)		2 x 121				
Acute toxicity (mg/kg bw)		> 5000				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Bush and cane fruits	Indicator species for screening	81.9	1.4	13.87	360.4	
Reprod. toxicity (mg/kg bw/d)		8.2				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Bush & cane fruit BBCH ≥ 20	Small insectivorous mammal “shrew”. Ground dwelling invertebrates with interception. 100% ground arthropods	1.9	1.6 × 0.53	0.19	42.1	
Bush & cane fruit BBCH ≥ 40	Small herbivorous mammal “vole”. Grass + cereals. 100% grass	21.7	1.6 × 0.53	2.23	3.7	
Bush & cane fruit Fruit stage BBCH 71-79 currants	Frugivorous mammal "dormouse". Berries. 100% fruit	9.7	1.6 × 0.53	1.00	8.2	
Bush & cane fruit BBCH ≥ 40	Small omnivorous mammal “mouse”. Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	2.3	1.6 × 0.53	0.24	34.8	
Intended use		Bush and cane fruits				
Active substance/product		Boscalid				

Application rate (g/ha)		2 x 481				
Acute toxicity (mg/kg bw)		> 5000				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Bush and cane fruits	Indicator species for screening	81.9	1.4	55.15	90.7	
Reprod. toxicity (mg/kg bw/d)		67				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Bush & cane fruit BBCH ≥ 20	Small insectivorous mammal “shrew”. Ground dwelling invertebrates with interception. 100% ground arthropods	1.9	1.6 × 0.53	0.77	86.5	
Bush & cane fruit BBCH ≥ 40	Small herbivorous mammal “vole”. Grass + cereals. 100% grass	21.7	1.6 × 0.53	8.85	7.6	
Bush & cane fruit Fruit stage BBCH 71-79 currants	Frugivorous mammal "dormouse". Berries. 100% fruit	9.7	1.6 × 0.53	3.96	16.9	
Bush & cane fruit BBCH ≥ 40	Small omnivorous mammal “mouse”. Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	2.3	1.6 × 0.53	0.94	71.4	

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 9.3-5: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of Casino Royale in root and stem vegetables (use carrot/use group root and stem vegetables)

Intended use		Root and stem vegetables				
Active substance/product		Pyraclostrobin				
Application rate (g/ha)		2 x 100				
Acute toxicity (mg/kg bw)		> 5000				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Root and stem vegetables	Indicator species for screening	118.4	1.38	16.34	306.0	
Reprod. toxicity (mg/kg bw/d)		8.2				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						

Root & stem vegetables BBCH \geq 20	Small insectivorous mammal “shrew”. Ground dwelling invertebrates with interception. 100% ground arthropods	1.9	1.57×0.53	0.16	51.9
Root & stem vegetables BBCH \geq 40	Small herbivorous mammal “vole”. Grass + cereals. 100% grass	21.7	1.57×0.53	1.81	4.5
Root & stem vegetables BBCH \geq 40	Small omnivorous mammal “mouse”. Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	2.3	1.57×0.53	0.19	42.9
Intended use		Root and stem vegetables			
Active substance/product		Boscalid			
Application rate (g/ha)		2 x 400			
Acute toxicity (mg/kg bw)		> 5000			
TER criterion		10			
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Growth stage					
Root and stem vegetables	Indicator species for screening	118.4	1.38	65.36	76.5
Reprod. toxicity (mg/kg bw/d)		67			
TER criterion		5			
Crop scenario	Indicator/generic focal species	SV_m	MAF_m \times TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Growth stage					
Root & stem vegetables BBCH \geq 20	Small insectivorous mammal “shrew”. Ground dwelling invertebrates with interception. 100% ground arthropods	1.9	1.57×0.53	0.63	106.0
Root & stem vegetables BBCH \geq 40	Small herbivorous mammal “vole”. Grass + cereals. 100% grass	21.7	1.57×0.53	7.22	9.3
Root & stem vegetables BBCH \geq 40	Small omnivorous mammal “mouse”. Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	2.3	1.57×0.53	0.77	87.5

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 9.3-6: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of Casino Royale in bulbs and onion like crops (use onion/use group bulbs and onion like crops)

Intended use	Bulbs and onion like crops
Active substance/product	Pyraclostrobin
Application rate (g/ha)	2 x 100
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	Indicator species for screening	118.4	1.2	14.21	351.9	
Reprod. toxicity (mg/kg bw/d)		8.2				
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 & onion like crops BBCH ≥ 20	Small insectivorous mammal “shrew”. Ground dwelling invertebrates with interception. 100% ground arthropods	1.9	1.4 × 0.53	0.14	58.2	
Bulbs & onion like crops BBCH ≥ 40	Small herbivorous mammal “vole”. Grass + cereals. 100% grass	43.4	1.4 × 0.53	3.22	2.6	
Bulbs & onion like crops BBCH ≥ 40	Small omnivorous mammal “mouse”. Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	4.7	1.4 × 0.53	0.35	23.5	
Intended use		Bulbs and onion like crops				
Active substance/product		Boscalid				
Application rate (g/ha)		2 x 400				
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	Indicator species for screening	118.4	1.2	56.83	88.0	
Reprod. toxicity (mg/kg bw/d)		67				
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 & onion like crops BBCH ≥ 20	Small insectivorous mammal “shrew”. Ground dwelling invertebrates with interception. 100% ground arthropods	1.9	1.4 × 0.53	0.56	118.8	
Bulbs & onion like crops BBCH ≥ 40	Small herbivorous mammal “vole”. Grass + cereals. 100% grass	43.4	1.4 × 0.53	12.88	5.2	
Bulbs & onion like crops BBCH ≥ 40	Small omnivorous mammal “mouse”. Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	4.7	1.4 × 0.53	1.39	48.0	

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 9.3-7: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of Casino Royale in leafy vegetables (use chicory roots, cabbage /use group leafy vegetables)

Intended use		Leafy vegetables				
Active substance/product		Pyraclostrobin				
Application rate (g/ha)		2 x 100				
Acute toxicity (mg/kg bw)		> 5000				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Leafy vegetables	Indicator species for screening	136.4	1.2	16.37	305.5	
Reprod. toxicity (mg/kg bw/d)		8.2				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Leafy vegetables BBCH 10 - 19	Small insectivorous mammal “shrew”. Ground dwelling invertebrates without interception. 100% ground arthropods	4.2	1.4 × 0.53	0.31	26.3	
Leafy vegetables BBCH ≥ 20	Small insectivorous mammal “shrew”. Ground dwelling invertebrates with interception. 100% ground arthropods	1.9	1.4 × 0.53	0.14	58.2	
Leafy vegetables BBCH 40-49	Small herbivorous mammal “vole”. Grass + cereals. 100% grass	72.3	1.4 × 0.53	5.36	1.5	
Leafy vegetables All season	Large herbivorous mammal “lagomorph”. Non grass herbs. 100% leaves	14.3	1.4 × 0.53	1.06	7.7	
Leafy vegetables BBCH 10-49	Small omnivorous mammal “mouse”. Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	7.8	1.4 × 0.53	0.58	14.2	
Intended use		Leafy vegetables				
Active substance/product		Boscalid				
Application rate (g/ha)		2 x 400				
Acute toxicity (mg/kg bw)		> 5000				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Leafy vegetables	Indicator species for screening	136.4	1.2	65.47	76.4	
Reprod. toxicity (mg/kg bw/d)		67				
TER criterion		5				

Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{tt}
Leafy vegetables BBCH 10 - 19	Small insectivorous mammal “shrew”. Ground dwelling invertebrates without interception. 100% ground arthropods	4.2	1.4 × 0.53	1.25	53.8
Leafy vegetables BBCH ≥ 20	Small insectivorous mammal “shrew”. Ground dwelling invertebrates with interception. 100% ground arthropods	1.9	1.4 × 0.53	0.56	118.8
Leafy vegetables BBCH 40-49	Small herbivorous mammal “vole”. Grass + cereals. 100% grass	72.3	1.4 × 0.53	21.46	3.1
Leafy vegetables All season	Large herbivorous mammal “lagomorph”. Non grass herbs. 100% leaves	14.3	1.4 × 0.53	4.24	15.8
Leafy vegetables BBCH 10-49	Small omnivorous mammal “mouse”. Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	7.8	1.4 × 0.53	2.32	28.9

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 9.3-8: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of Casino Royale in strawberry (use strawberry/use group strawberry)

Intended use	Strawberry				
Active substance/product	Pyraclostrobin				
Application rate (g/ha)	2 x 121				
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
Strawberry	Indicator species for screening	118.4	1.48	21.20	235.8
Reprod. toxicity (mg/kg bw/d)	8.2				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{tt}
Strawberries BBCH ≥ 20	Small insectivorous mammal “shrew”. Ground dwelling invertebrates with interception. 100% ground arthropods	1.9	1.7 × 0.53	0.21	39.6
Strawberries BBCH ≥ 40	Small herbivorous mammal “vole”. Grass + cereals. 100% grass	28.9	1.7 × 0.53	3.15	2.6

Strawberries BBCH \geq 40	Large herbivorous mammal “lag-omorph”. Non-grass herbs. 100% Non-grass herbs	5.7	1.7×0.53	0.62	13.2
Strawberries BBCH \geq 40	Small omnivorous mammal “mouse”. Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	3.1	1.7×0.53	0.34	24.3
Intended use		Strawberry			
Active substance/product		Boscalid			
Application rate (g/ha)		2 x 481			
Acute toxicity (mg/kg bw)		> 5000			
TER criterion		10			
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Growth stage					
Strawberry	Indicator species for screening	118.4	1.48	84.29	59.3
Reprod. toxicity (mg/kg bw/d)		67			
TER criterion		5			
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Growth stage					
Strawberries BBCH \geq 20	Small insectivorous mammal “shrew”. Ground dwelling invertebrates with interception. 100% ground arthropods	1.9	1.7×0.53	0.82	81.4
Strawberries BBCH \geq 40	Small herbivorous mammal “vole”. Grass + cereals. 100% grass	28.9	1.7×0.53	12.52	5.4
Strawberries BBCH \geq 40	Large herbivorous mammal “lag-omorph”. Non-grass herbs. 100% Non-grass herbs	5.7	1.7×0.53	2.47	27.1
Strawberries BBCH \geq 40	Small omnivorous mammal “mouse”. Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	3.1	1.7×0.53	1.34	49.9

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 9.3-9: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of Casino Royale in cherry (use cherry/use group cherry)

Intended use	Cherry
Active substance/product	Pyraclostrobin
Application rate (g/ha)	2 x 67
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
Cherry	Indicator species for screening	136.4	1.48	13.53	369.7
Reprod. toxicity (mg/kg bw/d)		8.2			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}
Orchards Application crop directed BBCH ≥ 40	Small herbivorous mammal “vole”. Grass + cereals. 100% grass	21.7	1.7 × 0.53	1.31	6.3
Orchards Application crop directed BBCH ≥ 40	Large herbivorous mammal “lag- omorph”. Non-grass herbs. 100% Non-grass herbs	4.3	1.7 × 0.53	0.26	31.6
Orchards Application crop directed BBCH ≥ 40	Small omnivorous mammal “mouse”. Combination (inverte- brates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	2.3	1.7 × 0.53	0.14	59.1
Intended use		Cherry			
Active substance/product		Boscalid			
Application rate (g/ha)		2 x 267			
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
Cherry	Indicator species for screening	136.4	1.48	53.90	92.8
Reprod. toxicity (mg/kg bw/d)		67			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}
Orchards Application crop directed BBCH ≥ 40	Small herbivorous mammal “vole”. Grass + cereals. 100% grass	21.7	1.7 × 0.53	5.22	12.8
Orchards Application crop directed BBCH ≥ 40	Large herbivorous mammal “lag- omorph”. Non-grass herbs. 100% Non-grass herbs	4.3	1.7 × 0.53	1.03	64.8
Orchards Application crop directed BBCH ≥ 40	Small omnivorous mammal “mouse”. Combination (inverte- brates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	2.3	1.7 × 0.53	0.55	121.1

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.

Table 9.3-10: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of Casino Royale in ornamentals (use ornamentals/use ornamentals)

Intended use	Ornamentals				
Active substance/product	Pyraclostrobin				
Application rate (g/ha)	2 x 12.1				
Acute toxicity (mg/kg bw)	> 5000				
TER criterion	10				
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Growth stage					
Ornamentals	Indicator species for screening	136.4	1.4	2.31	2163.9
Reprod. toxicity (mg/kg bw/d)	8.2				
TER criterion	5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Growth stage					
Ornamentals	Indicator species for screening	72.3	1.6 × 0.53	0.74	11.1
Intended use	Ornamentals				
Active substance/product	Boscalid				
Application rate (g/ha)	2 x 48.1				
Acute toxicity (mg/kg bw)	> 5000				
TER criterion	10				
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Growth stage					
Ornamentals	Indicator species for screening	136.4	1.4	9.19	544.4
Reprod. toxicity (mg/kg bw/d)	67				
TER criterion	5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Growth stage					
Ornamentals	Indicator species for screening	72.3	1.6 × 0.53	2.95	22.7

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.

Conclusion

Sugar beet, cherry and ornamentals

According to the screening and first-tier assessments for sugar beet, all the TER_a and TER_{lt} values for active substances Pyraclostrobin and Boscalid are greater than the Annex VI trigger of 10 and 5, respectively, indicating that Casino Royale presents no unacceptable acute and long-term risk to mammals according to the intended uses on sugar beet and orchards.

Fruiting vegetables and leafy vegetables

According to the screening assessment for fruiting vegetables, all the TER_a values for the active substance Pyraclostrobin and Boscalid are greater than the Annex VI trigger of 10. After first-tier assessment for active substance Pyraclostrobin and Boscalid, some TER_{lt} values are lower than the Annex VI trigger of 5, indicating that Casino Royale presents an unacceptable long-term risk to mammals. Therefore, higher-tier risk assessments were conducted only for the long-term risk.

Bush and cane fruits, root and stem vegetables, bulbs and onion like crops and strawberry

According to the screening assessment, all the TER_a values for the active substance Pyraclostrobin and Boscalid are greater than the Annex VI trigger of 10. After first-tier assessment for active substance Pyraclostrobin, some TER_{lt} values are lower than the Annex VI trigger of 5, indicating that Casino Royale presents an unacceptable long-term risk to mammals. Therefore, higher-tier risk assessments were conducted only for the long-term risk for the next crops and species:

Pyraclostrobin

- Fruiting vegetables (BBCH 10 – 49). Small herbivorous mammal “vole”. Grass + cereals.
- Fruiting vegetables (BBCH ≥ 50). Small herbivorous mammal “vole”. Grass + cereals.
- Fruiting vegetables (Fruit stage BBCH 71-89). Frugivorous mammal "rat". Gourds.
- Bush & cane fruit (BBCH ≥ 40). Small herbivorous mammal “vole”. Grass + cereals.
- Root & stem vegetables (BBCH ≥ 40). Small herbivorous mammal “vole”. Grass + cereals.
- Bulbs & onion like crops (BBCH ≥ 40). Small herbivorous mammal “vole”. Grass + cereals.
- Leafy vegetables (BBCH 40-49). Small herbivorous mammal “vole”. Grass + cereals.
- Strawberries (BBCH ≥ 40). Small herbivorous mammal “vole”. Grass + cereals.

Boscalid

- Fruiting vegetables (BBCH 10 – 49). Small herbivorous mammal “vole”. Grass + cereals.
- Leafy vegetables (BBCH 40-49). Small herbivorous mammal “vole”. Grass + cereals.

zRMS comments:

The risk assessment at screening and Tier 1 is considered acceptable. 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).

Based on the results the following conclusion of the risk assessment for mammals for uses proposed in the GAP are as follow:

Sugar beet, cherry and ornamentals

According to the screening and first-tier assessments for sugar beet, all the TER_a and TER_{lt} values for active substances Pyraclostrobin and Boscalid are greater than the Annex VI trigger of 10 and 5, respectively, indicating that Casino Royale presents no unacceptable acute and long-term risk to mammals according to the intended uses on sugar beet and orchards.

Fruiting vegetables and leafy vegetables

According to the screening assessment for fruiting vegetables, all the TER_a values for the active substance Pyraclostrobin and Boscalid are greater than the Annex VI trigger of 10. After first-tier assessment for active substance Pyraclostrobin and Boscalid, some TER_{lt} values are lower than the Annex VI trigger of 5, indicating that Casino Royale presents an unacceptable long-term risk to mammals. Therefore, higher-tier risk assessments were conducted only for the long-term risk.

Bush and cane fruits, root and stem vegetables, bulbs and onion like crops and strawberry

According to the screening assessment, all the TERa values for the active substance Pyraclostrobin and Boscalid are greater than the Annex VI trigger of 10. After first-tier assessment for active substance Pyraclostrobin, some TERlt values are lower than the Annex VI trigger of 5, indicating that Casino Royale presents an unacceptable long-term risk to mammals.

Therefore, higher-tier risk assessments were conducted only for the long-term risk for the next crops and species:

Pyraclostrobin

- Fruiting vegetables (BBCH 10 – 49). Small herbivorous mammal “vole”. Grass + cereals.
- Fruiting vegetables (BBCH ≥ 50). Small herbivorous mammal “vole”. Grass + cereals.
- Fruiting vegetables (Fruit stage BBCH 71-89). Frugivorous mammal "rat". Gourds.
- Bush & cane fruit (BBCH ≥ 40). Small herbivorous mammal “vole”. Grass + cereals.
- Root & stem vegetables (BBCH ≥ 40). Small herbivorous mammal “vole”. Grass + cereals.
- Bulbs & onion like crops (BBCH ≥ 40). Small herbivorous mammal “vole”. Grass + cereals.
- Leafy vegetables (BBCH 40-49). Small herbivorous mammal “vole”. Grass + cereals.
- Strawberries (BBCH ≥ 40). Small herbivorous mammal “vole”. Grass + cereals.

Boscalid

- Fruiting vegetables (BBCH 10 – 49). Small herbivorous mammal “vole”. Grass + cereals.
- Leafy vegetables (BBCH 40-49). Small herbivorous mammal “vole”. Grass + cereals.

Risk Assessment for combined exposure

According to the EFSA Journal (2009)⁴, the simultaneous exposure of animals to residues of two or more potential toxic substances should be considered in the risk assessment. Therefore, for the assessment of acute effects, a surrogate LD₅₀ for the mixture of active substances with known toxicity was derived assuming dose additivity of toxicity. 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

LD₅₀ (a.s._i) = acute toxicity value for each a.s.

Acute risks from combined exposure

The active substance content of the formulation Casino Royale addressed in this dossier is 26.7% Boscalid and 6.7% Pyraclostrobin, making up a total of 334 g a.s./L product. According to GAP, the maximum application rate is 1.8 L product/ha, therefore, an application rate of 601.2 g a.s./ha was considered in the assessment.

Table 9.3-11 shows the calculation of the predicted LD₅₀ (mix) of boscalid and pyraclostrobin when mixed in these proportions (step 1 in Appendix B to the EFSA GD 2009).

⁴ European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA. EFSA Journal 2009; 7(12): 1438. [139 pp.].

Table 9.3-11: Mammalian LD₅₀ (mix) for boscalid and pyraclostrobin when combined as Casino Royale (step 1 in EFSA GD 2009, Appendix B)

	Boscalid	Pyraclostrobin
Content in the formulation Casino Royale	26.7%	6.7%
Fraction in the a.s. mixture	0.7994	0.2006
LD ₅₀ of a.s. [mg/kg bw]	5000	5000
Fraction / LD ₅₀	0.000160	0.000040
Sum	0.0002	
1/ sum = predicted LD ₅₀ (mix)	5000.00 mg mix/kg bw	

Table 9.3-12: Mammalian “tox per fraction” for Casino Royale (step 1 in EFSA GD 2009, Appendix B)

	Boscalid	Pyraclostrobin	“mix”
Content in the formulation Casino Royale	26.7%	6.7%	33.4%
Fraction in mixture	0.7994	0.2006	1.0
LD ₅₀ (mg/kg bw)	5000	5000	5000
Tox per fraction	6254.68	24925.37	5000
Contribution to predicted toxicity	79.94%	20.06%	

Boscalid contributes to 79.94% to mixture toxicity, while the Pyraclostrobin have an impact on the predicted risk of 20.06%, therefore, surrogate LD₅₀ was used in the acute risk assessment.

Table 9.3-13: First-tier assessment of the acute risk for mammals due to the use of Casino Royale in all crops

Intended use		All crops				
Active substance/product		Casino Royale				
Application rate (g/ha)		3 x 601.2				
LD ₅₀ (mix) (mg/kg bw)		5000				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Screening	Indicator species for screening	136.4	1.57	128.75	38.8	

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.

According to results, no unacceptable acute risk is obtained for combined exposure according to the proposed GAP.

Regarding chronic risk assessment, the Applicant considers that, according to EFSA/2009/1438, the calculation of a combined toxicity is not applicable to the risk assessment for reproductive effect. Due to differences in evaluated endpoints and the dependency of the derived NOEL of the test design, any calculated TER_{mix} value can only be used for illustrating purposes. Hence, in the case of an unacceptable

TERMix, it has to be discussed if the results of the toxicity studies present any evidence for a possible concentration additivity of the effects and risks.

In addition, the combined toxicological effect of these two active substances has not been investigated with regard to repeated dose toxicity. Possibly, the combined exposure to these active substances may lead to a different toxicological profile than the profile(s) based on the individual substances.

zRMS comments:

We agree with the acute combined risk assessment provided by the applicant.
According to recommendation given in the Central Zone the reproductive combined toxicity endpoint should be calculated.
Therefore, zRMS calculated the combined long-term risk and performed these calculations in the Tables below:

Table 9-3-14. Long-term NOEL for the mixture of active substances for mammals.

Test substance	Concentration of active substance in formulation (g/kg)	Fraction of active substance in the formulation mixture ^a	NOEL toxicity end-point (mg as/kg bw)	Fraction of active substance/NOEL for the active substance	NOELmix (mg/kg bw)
Pyraclostrobin	67	0.20	8.2	0.024	27.77
Boscalid	267	0.80	67	0.012	
Total	334			0.036	
		1	-		

^a Concentration of an active substance in the formulation, divided by, the total concentration of all active substances in the formulation.

Table 9-3-15. Comparison of the measured and predicted endpoints for casino Royale Casino using the long-term toxicity data for mammals.

Test substance	Concentration of active substance in formulation (g/kg)	Fraction of active substance in the formulation mixture ^a	Long term toxicity endpoint (mg as/kg bw)	Tox per fraction a.s.	Tox per fraction mix	Deviation (%)
Pyraclostrobin	67	0.20	8.2	41	27.77	32.27
Boscalid	267	0.80	67	83.75		67.77
Total	334					

^a Concentration of an active substance in the formulation, divided by, the total concentration of all active substances in the formulation.

The deviation between the tox per fraction of both active substances and mixture is >10 %.
Consequently, the risk assessment is performed with the surrogate NOEL of 27.77 for the mixture of active substances.

~~First-tier assessment of the long-term risk for mammals due to the use of Casino Royale in all crops.~~

Intended use	Sugar beet, fruiting vegetables, Bush & cane fruit, Root & stem Vegetables, Bulbs & onion like crops, Leafy vegetables, orchards
Active substance/product	Casino Royale
Application rate (g/ha)	3 x 500

NOEL (mix) (mg/kg bw)		27.77				
TER criterion		5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _t	
Sugar beet BBCH ≥ 20	Small insectivorous mammal "shrew". Ground dwelling invertebrates with interception. 100% ground arthropods	1.9	1.57 × 0.53	0.79	35.15	
Sugar beet BBCH 10–39	Large herbivorous mammal "lagomorph". Non grass herbs. 100% crop leaves	14.3	1.57 × 0.53	5.94	4.7*	
Sugar beet BBCH 10–39	Small omnivorous mammal "mouse". Combination (invertebrates with interception). 25% weeds, 50% weed seeds, 25% ground arthropods	7.8	1.57 × 0.53	3.2	8.5	
Fruiting vegetables BBCH ≥ 20	Small insectivorous mammal "shrew". Ground dwelling invertebrates with interception. 100% ground arthropods	1.9	1.9 × 0.53	0.95	29.93	
Fruiting vegetables BBCH 10–49	Small herbivorous mammal "vole". Grass + cereals. 100% grass	72.3	1.9 × 0.53	36.40	0.76	
Fruiting vegetables BBCH ≥ 50	Small herbivorous mammal "vole". Grass + cereals. 100% grass	21.7	1.9 × 0.53	10.92	2.54	
Fruiting vegetables BBCH 10–49	Small omnivorous mammal "mouse". Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	7.8	1.9 × 0.53	3.92	7.08	
Bush & cane fruit BBCH ≥ 20	Small insectivorous mammal "shrew". Ground dwelling invertebrates with interception. 100% ground arthropods	1.9	1.6 × 0.53	0.8	34.71	
Bush & cane fruit BBCH ≥ 40	Small herbivorous mammal "vole". Grass + cereals. 100% grass	21.7	1.6 × 0.53	9.2	3.01	
Bush & cane fruit Fruit stage BBCH 71–79 currants	Frugivorous mammal "dormouse". Berries. 100% fruit	9.7	1.6 × 0.53	4.11	6.75	
Bush & cane fruit BBCH ≥ 40	Small omnivorous mammal "mouse". Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	2.3	1.6 × 0.53	0.97	28.62	
Root & stem vegetables BBCH ≥ 20	Small insectivorous mammal "shrew". Ground dwelling invertebrates with interception. 100% ground arthropods	1.9	1.57 × 0.53	0.79	35.15	

Root & stem vegetables BBCH ≥ 40	Small herbivorous mammal "vole". Grass + cereals. 100% grass	21.7	1.57 $\times 0.53$	9.02	3.07
Root & stem vegetables BBCH ≥ 40	Small omnivorous mammal "mouse". Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	2.3	1.57 $\times 0.53$	0.95	29.23
Bulbs & onion like crops BBCH ≥ 20	Small insectivorous mammal "shrew". Ground-dwelling invertebrates with interception. 100% ground arthropods	1.9	1.4 $\times 0.53$	0.7	39.67
Bulbs & onion like crops BBCH ≥ 40	Small herbivorous mammal "vole". Grass + cereals. 100% grass	43.4	1.4 $\times 0.53$	16.10	1.72
Bulbs & onion like crops BBCH ≥ 40	Small omnivorous mammal "mouse". Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	4.7	1.4 $\times 0.53$	1.7	16.33
Leafy vegetables BBCH 10 – 19	Small insectivorous mammal "shrew". Ground-dwelling invertebrates without interception. 100% ground arthropods	4.2	1.4 $\times 0.53$	1.55	17.91
Leafy vegetables BBCH ≥ 20	Small insectivorous mammal "shrew". Ground-dwelling invertebrates with interception. 100% ground arthropods	1.9	1.4 $\times 0.53$	0.7	39.67
Leafy vegetables BBCH 40-49	Small herbivorous mammal "vole". Grass + cereals. 100% grass	72.3	1.4 $\times 0.53$	26.82	1.035
Leafy vegetables BBCH 10-49	Small omnivorous mammal "mouse". Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	7.8	1.4 $\times 0.53$	2.89	9.6
Orchards Application crop directed BBCH ≥ 40	Small herbivorous mammal "vole". Grass + cereals. 100% grass	21.7	1.7 $\times 0.53$	9.77	2.84
Orchards Application crop directed BBCH ≥ 40	Large herbivorous mammal "lagomorph". Non-grass herbs. 100% Non-grass herbs	4.3	1.7 $\times 0.53$	1.93	14.3
Orchards Application crop directed BBCH ≥ 40	Small omnivorous mammal "mouse". Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	2.3	1.7 $\times 0.53$	1.036	26.80

Intended-use	Strawberries and ornamentals				
Active-sub-stance/product	Casino Royale				
Application-rate (g/ha)	3 x 601.2				
NOEL (mix) (mg/kg bw)	27.77				
TER-criterion	5				
Strawberries BBCH ≥ 20	Small insectivorous mammal "shrew". Ground-dwelling invertebrates with interception. 100% ground arthropods	1.9	1.7 × 0.53	1.03	26.89
Strawberries BBCH ≥ 40	Small herbivorous mammal "vole". Grass + cereals. 100% grass	28.9	1.7 × 0.53	15.65	1.77
Strawberries BBCH ≥ 40	Large herbivorous mammal "lagomorph". Non-grass herbs. 100% Non-grass herbs	5.7	1.7 × 0.53	3.08	9.0
Strawberries BBCH ≥ 40	Small omnivorous mammal "mouse". Combination (invertebrates without interception): 25% weeds, 50% weed seeds, 25% ground arthropods	3.1	1.7 × 0.53	1.68	16.49
Ornamentals BBCH 40-49	Small insectivorous mammal "vole"	72.3	1.6 × 0.53	36.85	0.75
Ornamentals BBCH > 50	Small insectivorous mammal "vole"	36.1	1.6 × 0.53	18.40	1.51
Ornamentals BBCH 10-49	Small omnivorous mammals mouse	7.8	1.6 × 0.53	3.97	7.0
Ornamentals BBCH > BBCH-50	Small omnivorous mammals mouse	3.9	1.6 × 0.53	1.98	14.03

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.

*in ZRMS's opinion the TER_{LT} is closed to trigger of 5 and is considered as acceptable

zRMS comment:

The combined long risk assessment needs further refinement for the following scenarios:

- Fruiting vegetables: BBCH 10 – 49 Small herbivorous mammal “vole”. Grass + cereals. 100% grass
- Fruiting vegetables: BBCH > 50 Small herbivorous mammal “vole”. Grass + cereals. 100% grass
- Bush & cane fruit BBCH ≥ 40 Small herbivorous mammal “vole”. Grass + cereals. 100% grass
- Root & stem vegetables BBCH ≥ 40 Small herbivorous mammal “vole”. Grass + cereals. 100% grassy
- Leafy vegetables BBCH 40-49 Small herbivorous mammal “vole”. Grass + cereals. 100% grass
- Orchards Application crop directed BBCH ≥ 40 Small herbivorous mammal “vole”. Grass + cereals. 100% grass
- Strawberries BBCH ≥ 40 Small herbivorous mammal “vole”. Grass + cereals. 100% grass
- Ornamentals : Ornamentals BBCH 40-49 and BBCH > 50 Small insectivorous mammal “vole”

Therefore, further refinement for these scenarios for combined long term risk assessment is required at MSs level.

Applicant update – September 2021

The above provided first-tier approach was considered for further refinements. However, some inaccuracies were detected in relation to the application dose associated to specific uses. In detail, “**orchards**” and “**bush & cane vegetables**” are included in the assessment with an application of 500 g/ha, but should be assessed considering 334 and 601.2 g/ha, respectively. Similarly, “**ornamentals**” groups are located within the application group of 601.2 g/ha, but the application for this group is 60.12 g/ha. The summary of applications rates for each group of uses would be as below:

- Sugar beet, Fruiting vegetables, Root and stem vegetables, Bulbs and onion like crops, Leafy vegetables (application rate = 1.5 L product/ha) = 501 g a.s./ha.
- Bush and cane fruits, Strawberry (application rate = 1.8 L product/ha) = 601.2 g a.s./ha.
- Cherry (application rate = 1.0 L product/ha) = 334 g a.s./ha.
- Ornamentals (application rate = 0.18 L product/ha) = 60.12 g a.s./ha.

Hence, a new table with the first-tier approach is included below:

First-tier assessment of the long-term risk for mammals due to the use of Casino Royale in all crops.

Intended use	Sugar beet, fruiting vegetables, Root & stem vegetables, Vegetables, Bulbs & onion like crops, Leafy vegetables				
Active substance/product	Casino Royale				
Application rate (g/ha)	3 x 500				
NOEL (mix) (mg/kg bw)	27.77				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}
Sugar beet BBCH ≥ 20	Small insectivorous mammal "shrew". Ground dwelling invertebrates with interception. 100% ground arthropods	1.9	1.57 × 0.53	0.79	35.1
Sugar beet BBCH 10-39	Large herbivorous mammal "lagomorph". Non-grass herbs. 100% crop leaves	14.3	1.57 × 0.53	5.95	4.7*

Sugar beet BBCH 10-39	Small omnivorous mammal "mouse". Combination (invertebrates with interception). 25% weeds, 50% weed seeds, 25% ground arthropods	7.8	1.57×0.53	3.25	8.6
Fruiting vegetables BBCH ≥ 20	Small insectivorous mammal "shrew". Ground dwelling invertebrates with interception. 100% ground arthropods	1.9	1.9×0.53	0.96	29.0
Fruiting vegetables BBCH 10 - 49	Small herbivorous mammal "vole". Grass + cereals. 100% grass	72.3	1.9×0.53	36.40	0.8
Fruiting vegetables BBCH ≥ 50	Small herbivorous mammal "vole". Grass + cereals. 100% grass	21.7	1.9×0.53	10.93	2.5
Fruiting vegetables BBCH 10 - 49	Small omnivorous mammal "mouse". Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	7.8	1.9×0.53	3.93	7.1
Root & stem vegetables BBCH ≥ 20	Small insectivorous mammal "shrew". Ground dwelling invertebrates with interception. 100% ground arthropods	1.9	1.57×0.53	0.79	35.1
Root & stem vegetables BBCH ≥ 40	Small herbivorous mammal "vole". Grass + cereals. 100% grass	21.7	1.57×0.53	9.03	3.1
Root & stem vegetables BBCH ≥ 40	Small omnivorous mammal "mouse". Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	2.3	1.57×0.53	0.96	29.0
Bulbs & onion like crops BBCH ≥ 20	Small insectivorous mammal "shrew". Ground dwelling invertebrates with interception. 100% ground arthropods	1.9	1.4×0.53	0.7	39.4
Bulbs & onion like crops BBCH ≥ 40	Small herbivorous mammal "vole". Grass + cereals. 100% grass	43.4	1.4×0.53	16.10	1.7
Bulbs & onion like crops BBCH ≥ 40	Small omnivorous mammal "mouse". Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	4.7	1.4×0.53	1.74	15.9
Leafy vegetables BBCH 10 - 19	Small insectivorous mammal "shrew". Ground dwelling invertebrates without interception. 100% ground arthropods	4.2	1.4×0.53	1.56	17.8

Leafy vegetables BBCH ≥ 20	Small insectivorous mammal "shrew". Ground dwelling invertebrates with interception. 100% ground arthropods	1.9	1.4×0.53	0.70	39.4
Leafy vegetables BBCH 40-49	Small herbivorous mammal "vole". Grass + cereals. 100% grass	72.3	1.4×0.53	26.82	1.0
Leafy vegetables BBCH 10-49	Small omnivorous mammal "mouse". Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	7.8	1.4×0.53	2.89	9.6
Intended use	Bush and cane fruits, strawberry				
Active substance/product	Casino Royale				
Application rate (g/ha)	3 x 601.2				
NOEL (mix) (mg/kg bw)	27.77				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m \times TWA	DDD _m (mg/kg bw/d)	TER _{tt}
Bush & cane fruit BBCH ≥ 20	Small insectivorous mammal "shrew". Ground dwelling invertebrates with interception. 100% ground arthropods	1.9	1.6×0.53	0.97	28.7
Bush & cane fruit BBCH ≥ 40	Small herbivorous mammal "vole". Grass + cereals. 100% grass	21.7	1.6×0.53	11.06	2.5
Bush & cane fruit Fruit stage BBCH 71-79 currants	Frugivorous mammal "dormouse". Berries. 100% fruit	9.7	1.6×0.53	4.95	5.6
Bush & cane fruit BBCH ≥ 40	Small omnivorous mammal "mouse". Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	2.3	1.6×0.53	1.17	23.7
Strawberries BBCH ≥ 20	Small insectivorous mammal "shrew". Ground dwelling invertebrates with interception. 100% ground arthropods	1.9	1.7×0.53	1.03	27.0
Strawberries BBCH ≥ 40	Small herbivorous mammal "vole". Grass + cereals. 100% grass	28.9	1.7×0.53	15.65	1.8
Strawberries BBCH ≥ 40	Large herbivorous mammal "lagomorph". Non-grass herbs. 100% Non-grass herbs	5.7	1.7×0.53	3.09	9.0
Strawberries BBCH ≥ 40	Small omnivorous mammal "mouse". Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	3.1	1.7×0.53	1.68	16.5

Intended use		Cherry (Orchards)				
Active substance/product		Casino Royale				
Application rate (g/ha)		3 x 334				
NOEL (mix) (mg/kg bw)		27.77				
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 Application crop directed BBCH ≥ 40	Small herbivorous mammal “vole”. Grass + cereals. 100% grass	21.7	1.7 × 0.53	6.53	4.3	
Orchards Application crop directed BBCH ≥ 40	Large herbivorous mammal “lagomorph”. Non-grass herbs. 100% Non-grass herbs	4.3	1.7 × 0.53	1.29	21.5	
Orchards Application crop directed BBCH ≥ 40	Small omnivorous mammal “mouse”. Combination (invertebrates without interception). 25% weeds, 50% weed seeds, 25% ground arthropods	2.3	1.7 × 0.53	0.69	40.1	
Intended use		Ornamentals				
Active substance/product		Casino Royale				
Application rate (g/ha)		3 x 60.12				
NOEL (mix) (mg/kg bw)		27.77				
TER criterion		5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Ornamentals BBCH 40-49	Small insectivorous mammal ‘vole’	72.3	1.6 × 0.53	3.69	7.5	
Ornamentals BBCH > 50	Small insectivorous mammal ‘vole’	36.1	1.6 × 0.53	1.84	15.1	
Ornamentals BBCH 10-49	Small omnivorous mammals mouse	7.8	1.6 × 0.53	0.40	69.8	
Ornamentals BBCH >BBCH 50	Small omnivorous mammals mouse	3.9	1.6 × 0.53	0.20	139.7	

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.

*in ZRMS's opinion the TER_{LT} is closed to trigger of 5 and is considered as acceptable

The Tier I risk assessment showed an unacceptable long-term risk for small herbivorous mammal “vole” in fruiting vegetables, root and stem vegetables, bulbs and onion like crops, leafy vegetables, bush and cane fruits, strawberries and cherry

A further higher-tier risk assessment was needed, and the following parameters were refined:

Deposition factor (DF)

The residue unit doses (RUDs) are derived from trials in which the plants are directly oversprayed. However, there will often be situations where particular food items for mammals have lower concentrations due to the compound being partly intercepted by the crop before it reaches the food item. It may therefore be appropriate to include an interception factor (or rather its complement, a deposition factor) in the estimation of residues and the Daily Dietary Dose. According to Appendix E of EFSA/2009/1438, regarding to deposition estimates for tier 1, states that “*the deposition factors provided for the different crops and growth stages are likely to reflect conservative estimates. In the context of a higher-tier assessment, the more detailed values of FOCUS groundwater report (FOCUS, 2000) may therefore also be used...*”.

Therefore, the refinement of the risk will be done considering FOCUS groundwater interception values. According to FOCUS groundwater⁵, the following interception values were considered:

- For **fruiting vegetables** (BBCH 20-87), the interception (percent) value of 70% at this growth stage as worst case, a DF of 0.3 was considered.
- For **root and stem vegetables** (BBCH 41-49), the interception (percent) value of 80% at this growth stage as worst case, a DF of 0.2 was considered.
- For **bulbs and onion like crops** (BBCH 41-49), the interception (percent) value of 40% at this growth stage as worst case, a DF of 0.6 was considered.
- For **leafy vegetables** (BBCH 40-49), the interception (percent) value of 70% at this growth stage as worst case, a DF of 0.3 was considered.
- For **bush and cane fruits** (BBCH 51-90), the interception (percent) value of 60% at this growth stage as worst case, a DF of 0.4 was considered.
- For **strawberries** (BBCH 60-81), the interception (percent) value of 60% at this growth stage as worst case, a DF of 0.4 was considered.
- For **cherry** (BBCH 60-67), the interception (percent) value of 60% at this growth stage as worst case, a DF of 0.4 was considered.

Table 9.3-16: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of Casino Royale in fruiting vegetables – refined parameters (*) are further described and justified in the text

Intended use		Fruiting vegetables					
Active substance/product		Casino Royale					
Application rate (g/ha)		3 x 500					
Reprod. toxicity (mg/kg bw/d)		27.77					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF* (mg/kg food)	MAF_m × TWA	PT	DDD_m (mg/kg bw/d)	TER_{It}
Common vole (<i>Microtus arvalis</i>)	100% grass	1.33 ¹	28.7 ¹ × 0.3 ²	1.9 × 0.53	1.0	5.77	4.8

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

¹ According to Appendix A of EFSA/2009/1438.

² Deposition factor according to FOCUS groundwater guidance.

⁵ Generic Guidance for Tier 1 FOCUS Ground Water Assessments. Version: 2.2 Date: May 2014

Table 9.3-17: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of Casino Royale in root and stem vegetables – refined parameters (*) are further described and justified in the text

Intended use		Root and stem vegetables					
Active substance/product		Casino Royale					
Application rate (g/ha)		2 x 500					
Reprod. toxicity (mg/kg bw/d)		27.77					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF* (mg/kg food)	MAF_m × TWA	PT	DDD_m (mg/kg bw/d)	TER_{It}
Common vole (<i>Microtus arvalis</i>)	100% grass	1.33 ¹	28.7 ¹ × 0.2 ²	1.57 × 0.53	1.0	3.18	8.7

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

¹ According to Appendix A of EFSA/2009/1438.

² Deposition factor according to FOCUS groundwater guidance.

Table 9.3-18: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of Casino Royale in leafy vegetables – refined parameters (*) are further described and justified in the text

Intended use		Leafy vegetables					
Active substance/product		Casino Royale					
Application rate (g/ha)		2 x 500					
Reprod. toxicity (mg/kg bw/d)		27.77					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF* (mg/kg food)	MAF_m × TWA	PT	DDD_m (mg/kg bw/d)	TER_{It}
Common vole (<i>Microtus arvalis</i>)	100% grass	1.33 ¹	28.7 ¹ × 0.3 ²	1.4 × 0.53	1.0	4.25	6.5

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

¹ According to Appendix A of EFSA/2009/1438.

² Deposition factor according to FOCUS groundwater guidance.

Table 9.3-19: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of Casino Royale in bush & cane fruit – refined parameters (*) are further described and justified in the text

Intended use		Bush & cane fruit					
Active substance/product		Casino Royale					
Application rate (g/ha)		2 x 601.2					
Reprod. toxicity (mg/kg bw/d)		27.77					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF* (mg/kg food)	MAF_m × TWA	PT	DDD_m (mg/kg bw/d)	TER_{It}
Common vole (<i>Microtus arvalis</i>)	100% grass	1.33 ¹	28.7 ¹ × 0.3 ¹	1.6 × 0.53	1.0	5.84	4.8

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

¹ According to Appendix A of EFSA/2009/1438.

Table 9.3-20: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of Casino Royale in strawberry – refined parameters (*) are further described and justified in the text

Intended use		Strawberry					
Active substance/product		Casino Royale					
Application rate (g/ha)		2 x 601.2					
Reprod. toxicity (mg/kg bw/d)		27.77					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF* (mg/kg food)	MAF_m × TWA	PT	DDD_m (mg/kg bw/d)	TER_{It}
Common vole (<i>Microtus arvalis</i>)	100% grass	1.33 ¹	28.7 ¹ × 0.4 ²	1.7 × 0.53	1.0	8.27	3.4

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

¹ According to Appendix A of EFSA/2009/1438.

² Deposition factor according to FOCUS groundwater guidance.

Table 9.3-21: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of Casino Royale in bulbs and onion like crops – refined parameters (*) are further described and justified in the text

Intended use		Bulbs and onion like crops					
Active substance/product		Casino Royale					
Application rate (g/ha)		2 x 500					
Reprod. toxicity (mg/kg bw/d)		27.77					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF* (mg/kg food)	MAF_m × TWA	PT	DDD_m (mg/kg bw/d)	TER_{LT}
Common vole (<i>Microtus arvalis</i>)	100% grass	1.33 ¹	28.7 ¹ × 0.6 ²	1.4 × 0.53	1.0	8.50	3.3

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

¹ According to Appendix A of EFSA/2009/1438.

² Deposition factor according to FOCUS groundwater guidance.

Table 9.3-22: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of Casino Royale in cherry – refined parameters (*) are further described and justified in the text

Intended use		Orchards (cherry)					
Active substance/product		Casino Royale					
Application rate (g/ha)		3 x 334					
Reprod. toxicity (mg/kg bw/d)		27.77					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF* (mg/kg food)	MAF_m × TWA	PT	DDD_m (mg/kg bw/d)	TER_{LT}
Common vole (<i>Microtus arvalis</i>)	100% grass	1.33 ¹	28.7 ¹ × 0.3 ¹	1.7 × 0.53	1.0	3.45	8.1

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

¹ According to Appendix A of EFSA/2009/1438.

After above refinements, an unacceptable risk was observed for vole in strawberries and bulbs and onion like crops. Hence, further refinement would be needed. A limitation in number of application is suggested. Below are the refined assessments. For fruiting vegetables and bush and cane fruits, the TER_{LT} is closed to trigger of 5 and is considered as acceptable.

MAF refinement – number of applications

In order to get an acceptable risk, the number of applications in **bulbs and onion like crops** (Onion, Shallot and Onion “seven years old”) and **strawberries**, were reduced from 2 to 1.

Table 9.3-23: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of Casino Royale in strawberry – refined parameters (*) are further described and justified in the text

Intended use		Strawberry					
Active substance/product		Casino Royale					
Application rate (g/ha)		1 x 601.2					
Reprod. toxicity (mg/kg bw/d)		27.77					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF* (mg/kg food)	MAF_m × TWA	PT	DDD_m (mg/kg bw/d)	TER_{It}
Common vole (<i>Microtus arvalis</i>)	100% grass	1.33 ¹	28.7 ¹ × 0.4 ²	1.0 × 0.53	1.0	4.87	5.7

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

¹ According to Appendix A of EFSA/2009/1438.

Table 9.3-24: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of Casino Royale in bulbs and onion like crops – refined parameters (*) are further described and justified in the text

Intended use		Bulbs and onion like crops					
Active substance/product		Casino Royale					
Application rate (g/ha)		1 x 500, 1 x 334 (shallot)					
Reprod. toxicity (mg/kg bw/d)		27.77					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m × DF* (mg/kg food)	MAF_m × TWA	PT	DDD_m (mg/kg bw/d)	TER_{It}
Common vole (<i>Microtus arvalis</i>)	100% grass	1.33 ¹	28.7 ¹ × 0.6 ²	1.0 × 0.53	1.0	6.07 4.05	4.6 6.85

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

¹ According to Appendix A of EFSA/2009/1438.

After this reduction, an acceptable risk was not obtained in bulbs and onion like crops except shallot (lower application rate) , and a further refinement of the long-term risk is needed.

According to Central Zone Steering Committee in the document *Bullet Points: CZSC January and April 2016 Bullet Points*:

“when the CA combitox assessment indicates no acceptable risk, applicants may present information to demonstrate that adverse effects of the actives are not similar.”

The Applicant wishes to refer to the previous risk assessment of the active substances and the corresponding refinement where no unacceptable long-term risk to mammals was demonstrated. Therefore, the adverse effects on the combitox of the actives were not similar.

In addition, according to the document. *Bullet Points: Ecotoxicology - Combination toxicology Article 43* (November, 2017):

“For higher Tier refinements, there are various approaches by the MS, most of whom would rely on a WoE approach if no agreed methods/ guidance are available; some MS would exhaust single a.s. refinements as a first step for the refined combitox assessment.”

Therefore, the Applicant wishes to offer the following weight of evidence approach:

Weight of evidence approach

Ecology of the common vole (*Microtus arvalis*) and use of crops:

According to *Fluazifop-P Confirmatory data_Addendum Vol3 B9 Revised Oct 2014*:

There are many reports from the literature that the optimum or prime habitat' of common voles is undisturbed grassland or set-aside at a vegetation height of minimum 20 cm (De Jonge and Dienske, 1979; Delattre et al., 1996; Butet and Leroux, 2001; Giraudoux et al., 1994; Gorman and Reynolds, 1993) or perennial crops like alfalfa (Truszkowski, 1982).

The preference for primary habitats is underlined by the findings of Briner et al. (2005), who demonstrated by using automatic radio tracking, that M. arvalis developed high population densities containing 90% of the total home range in wild flower strips neighbouring crop fields, but hardly ever entered the nearby crops, even when those were highly palatable. Also, Koks et al. (2007) showed that vole abundance was twice as high in set aside land and in high and dense vegetation than in neighbouring non fallow habitat types like plantations or cereals.

Therefore, it can be stated that

a.) When local population densities are low, Common voles are prone to spend much less time in crop fields, which only serve as transient habitats.

b.) Secondary populations of the Common vole in-field (as opposed to the primary population in the margins) are also of little to no importance for the survival of the local populations, since harvest and ploughing will destroy their home range habitat at least once a year.

Since this species is so prolific, it can additionally be stated that a slight reduction in the growth potential of secondary populations in field crops will usually also be of little to no importance for the population of local predator species.

Therefore, it is may be more appropriate to consider the other small mammals, such as the wood mouse (*Apodemus sylvaticus*) and common shrew (*Sorex araneus*), as relevant focal species in crop habitats. The

risk assessment is considered to be covered through the assessment of other small mammalian species for the following reasons:

- 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

Summarizing, taking into account that:

- the adverse effects on the combitox were not similar than the actives, as demonstrated in the risk assessment and refinement for the active substances, and
- for WoE indicated above, an acceptable risk to vole when Casino Royale is applied according to the proposed use pattern can be concluded.

zRMS comment after Commenting period:

The TER_{LT} for bush and cane fruits and fruiting vegetables is closed to 5 (**being 4.8**), indicating acceptable risk for vole.

After refinement MAF by reduction no of application from 2 to 1 in strawberry and bulbs and onion like crops for max.application rate, the risk for vole for strawberry is slight below 5 (**being 4.6**) which can be considered acceptable.

The combined risk assessment for vole should be considered at MSs level.

9.3.2.2 Higher-tier risk assessment for active substances

The Tier I risk assessment showed an unacceptable long-term risk for small herbivorous mammal "vole" in fruiting vegetables, bush and cane fruits, root and stem vegetables, bulbs and onion like crops, leafy vegetables and strawberries for Pyraclostrobin; and in fruiting vegetables and leafy vegetables for Boscalid. In addition, the Tier I risk assessment showed an unacceptable long-term risk for frugivorous mammal "rat" in fruiting vegetables for Pyraclostrobin.

A further higher-tier risk assessment was needed, and the following parameters were refined:

Deposition factor (DF)

Casino Royale will be applied directly to crop. Since grass will be covered by the crop, an interception by the crop has to be taken into account.

For fruiting vegetables, BBCH stages 20-87 corresponds with the stem elongation, and according to the interception values of FOCUS (2000)⁶, for tomatoes at this growth stage, an interception factor of 70% should be considered as highest worst case. Therefore, for the refinement of the risk a deposition factor of 0.3 should be applied.

For bush and cane fruits, BBCH stage 51-90 corresponds with the flowering, and according to the interception values of FOCUS (2000), for bushberries at this growth stage, an interception factor of 60%

⁶ FOCUS (2012) "Focus groundwater scenarios in the EU review of active substances" Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference Sanco/321/2000 rev.2, 202 pp.

should be considered as highest worst case. Therefore, for the refinement of the risk a deposition factor of 0.4 should be applied.

For root and stem vegetables, BBCH stage 41-49 corresponds with the flowering, and according to the interception values of FOCUS (2000), for carrots at this growth stage, an interception factor of 80% should be considered. Therefore, for the refinement of the risk a deposition factor of 0.2 should be applied.

For bulbs and onion like crops, BBCH stage 41-49 corresponds with the flowering, and according to the interception values of FOCUS (2000), for onions at this growth stage, an interception factor of 40% should be considered. Therefore, for the refinement of the risk a deposition factor of 0.6 should be applied.

For leafy vegetables, BBCH stage BBCH 41-49 corresponds with the flowering, and according to the interception values of FOCUS (2000), for cabbage at this growth stage, an interception factor of 70% should be considered. Therefore, for the refinement of the risk a deposition factor of 0.3 should be applied.

For strawberries, BBCH stage BBCH 60-81 corresponds with the flowering, and according to the interception values of FOCUS (2000), for strawberries at this growth stage, an interception factor of 60% should be considered. Therefore, for the refinement of the risk a deposition factor of 0.4 should be applied.

RUD

For frugivorous mammal "rat" a RUDmean value of 34.3 mg/kg for fruits type gourds was used as worst case. However, according to the Table 1 from Appendix F of EFSA/2009/1438, a more realistic residue value of 12.8 mg/kg for tomato fruits was considered more appropriate and used for the refinement.

To refine risk for small herbivorous "vole" for Pyraclostrobin, residue values were used. As report in *Pyraclostrobin DAR (2001)– Annex B.7: Residue data*, residue trials were available in barley and wheat for Northern EU region. In the following table are summarized residue trials suitable to refine risk assessment.

Table 9.3-14: Residue trials suitable to refine mammals risk assessment

Report-No. Location incl. Postal code and date	Crop	Com- modity/ Variety	Application rate per treatment			Growth stage at last treatment or date	Portion analysed	Residue Day 0 (mg/kg)	RUD	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl					
Belgium-3470 Kortenaken 00-01-31	Spring barley	Riviera	0.244	296	0.082	60	Whole plants w/o roots	5.68	23.28	RIP 2000- 1031
Germany- 67149 Meckenheim 00-01-31	Spring barley	Scarlett	0.244	296	0.082	59	Whole plants w/o roots	5.35	21.93	RIP 2000- 1031
Sweden-23791 Bjärred Borgeby Gard 00-01-31	Spring barley	Scarlett	0.250	303	0.083	59	Whole plants w/o roots	5.99	23.96	RIP 2000- 1031
France-62580 Neuville Saint Vaast 00-01-31	Spring barley	Scarlett	0.247	300	0.082	69	Whole plants w/o roots	6.46	26.15	RIP 2000- 1072
Sweden-23791 Bjärred 00-01-31	Spring barley	Scarlett	0.270	327	0.082	69	Whole plants w/o roots	6.43	23.81	RIP 2000- 1072
Germany- 67149 Meckenhei	Spring barley	Scarlett	0.232	281	0.083	59	Whole plants w/o roots	4.88	21.03	RIP 2000- 1073

Report-No. Location incl. Postal code and date	Crop	Com- modity/ Variety	Application rate per treatment			Growth stage at last treatment or date	Portion analysed	Residue Day 0 (mg/kg)	RUD	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl					
Sweden-23791 Bjärred 00-01-31	Spring barley	Scarlett	0.261	317	0.082	59	Whole plants w/o roots	4.46	17.09	RIP 2000- 1073
Belgium-3470 Kortenaken 00-01-31	Spring barley	Riviera	0.243	304	0.080	60	Whole plants w/o roots	4.80	19.75	RIP 2000- 1031
Germany- 67149 Meckenheim 00-01-31	Spring barley	Scarlett	0.242	303	0.080	59	Whole plants w/o roots	6.01	24.83	RIP 2000- 1031
Sweden-23791 Bjärred Borgeby Gard 00-01-31	Spring barley	Scarlett	0.249	312	0.080	59	Whole plants w/o roots	6.22	24.98	RIP 2000- 1031
Belgium-3470 Kortenaken 00-01-31	Spring barley	Riviera	0.244	305	0.080	60	Whole plants w/o roots	3.61	14.80	RIP 2000- 1031
Germany- 67149 Meckenheim 00-01-31	Spring barley	Scarlett	0.233	291	0.080	59	Whole plants w/o roots	6.70	28.76	RIP 2000- 1031
Sweden-23791 Bjärred Borgeby Gard 00-01-31	Spring barley	Scarlett	0.266	332	0.080	59	Whole plants w/o roots	3.01	11.32	RIP 2000- 1031
Great Britain NN13 6DY Brackley 00-01-31	Winter barley	Fighter	0.253	307	0.082	59	Whole plants w/o roots	6.89	27.23	RIP 2000- 1031
Great Britain CV9 2JS Atherstone 00-01-31	Winter barley	Musca	0.247	297	0.083	65	Whole plants w/o roots	3.35	13.56	RIP 2000- 1031
Germany- 24625 Großharrie 00-01-31	Winter barley	Landi	0.253	306	0.083	61	Whole plants w/o roots	6.03	23.83	RIP 2000- 1072
Great Britain- CV9 2JS Atherstone 00-01-31	Winter barley	Musket	0.252	306	0.082	65	Whole plants w/o roots	4.4	17.46	RIP 2000- 1072
Great Britain NN13 6DY Brackley 00-01-31	Winter barley	Fighter	0.232	289	0.080	59	Whole plants w/o roots	6.83	29.44	RIP 2000- 1031
Great Britain CV9 2JS Atherstone 00-01-31	Winter barley	Muscat	0.235	294	0.080	65	Whole plants w/o roots	5.68	24.17	RIP 2000- 1031
Great Britain NN13 6DY Brackley 00-01-31	Winter barley	Fighter	0.233	291	0.080	59	Whole plants w/o roots	7.51	32.23	RIP 2000- 1031
Great Britain CV9 2JS Atherstone 00-01-31	Winter barley	Muscat	0.244	304	0.080	65	Whole plants w/o roots	5.10	20.90	RIP 2000- 1031
Denmark-5500 Middelfart 00-01-31	Spring wheat	Dragon	0.254	309	0.082	65-69	Whole plants w/o roots	4.98	19.61	RIP 2000- 1072

Report-No. Location incl. Postal code and date	Crop	Com- modity/ Variety	Application rate per treatment			Growth stage at last treatment or date	Portion analysed	Residue Day 0 (mg/kg)	RUD	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl					
Netherland- 5853 EJ Siebengewald 00-01-31	Winter wheat	Briga- dier	0.239	290	0.082	69	Whole plants w/o roots	4.27	17.87	RIP 2000- 1031
Germany- 24625 Großharrie 00-01-31	Winter wheat	Pepital	0.265	321	0.083	69-71	Whole plants w/o roots	5.35	20.19	RIP 2000- 1031
France-62580 Nothorn France Neuville Saint Vaast 00-01-31	Winter wheat	Baltha- zar	0.248	300	0.083	65	Whole plants w/o roots	4.92	19.84	RIP 2000- 1031
Great Britain AB30IXJ Grampian Marykirk 00-01-31	Winter wheat	Riband	0.226	273	0.083	69-72	Whole plants w/o roots	3.32	14.69	RIP 2000- 1031
Germany- 88445 Oberding 00-01-31	Winter wheat	Kanzler	0.261	317	0.082	69	Whole plants w/o roots	4.71	18.05	RIP 2000- 1072
Great Brit- ainTQ7 2BU Kinesbridge 00-01-31	Winter wheat	Hussar	0.253	307	0.082	69	Whole plants w/o roots	3.54	13.99	RIP 2000- 1072
Great Brit- ainNN13 6DY Brackley 00-01-31	Winter wheat	Consort	0.240	290	0.082	65	Whole plants w/o roots	2.67	11.13	RIP 2000- 1072
Germany- 16356 Blumberg 00-01-31	Winter wheat	Flair	0.245	297	0.082	61	Whole plants w/o roots	8.93	36.45	RIP 2000- 1073
Sweden-23791 Bjärred 00-01-31	Winter wheat	Meridien	0.254	308	0.082	69	Whole plants w/o roots	5.21	20.51	RIP 2000- 1073
Netherland- 5853 EJ Siebengewald 00-01-31	Winter wheat	Briga- dier	0.247	309	0.080	69	Whole plants w/o roots	4.04	16.36	RIP 2000- 1031
Germany- 24625 Großharrie 00-01-31	Winter wheat	Pepital	0.239	298	0.080	69-71	Whole plants w/o roots	5.75	24.06	RIP 2000- 1031
France-62580 Neuville Saint Vaast 00-01-31	Winter wheat	Baltha- zar	0.243	303	0.080	65	Whole plants w/o roots	6.49	26.71	RIP 2000- 1031
Great Britain AB30IXJ Grampian Marykirk 00-01-31	Winter wheat	Riband	0.226	282	0.080	69-72	Whole plants w/o roots	3.10	13.72	RIP 2000- 1031
Netherland- 5853 EJ Siebengewald 00-01-31	Winter wheat	Briga- dier	0.231	289	0.080	69	Whole plants w/o roots	2.80	12.12	RIP 2000- 1031

Report-No. Location incl. Postal code and date	Crop	Com- modity/ Variety	Application rate per treatment			Growth stage at last treatment or date	Portion analysed	Residue Day 0 (mg/kg)	RUD	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl					
Germany- 24625 Großharrie 00-01-31	Winter wheat	Pepital	0.239	299	0.080	69-71	Whole plants w/o roots	8.23	34.44	RIP 2000- 1031
France-62580 Neuville Saint Vaast 00-01-31	Winter wheat	Baltha- zar	0.238	297	0.080	65	Whole plants w/o roots	4.06	17.06	RIP 2000- 1031
Great Britain AB30IXJ Grampian Marykirk 00-01-31	Winter wheat	Riband	0.246	307	0.080	69-72	Whole plants w/o roots	3.93	15.98	RIP 2000- 1031
mean									21.11	
geomean									20.22	
90th %ile									28.89	
SD									6.23	

The geomean value of RUD was 20.22 mg/kg and the mean value was 21.11 mg/kg. For the refinement of log-term risk the RUD_{mean} value of 21.11 mg/kg was used as worst case.

Table 9.3-15: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of Casino Royale in fruiting vegetables – refined parameters (*) are further described and justified in the text

Intended use		Fruiting vegetables						
Active substance/product		Pyraclostrobin						
Application rate (g/ha)		3 x 100						
Reprod. toxicity (mg/kg bw/d)		8.2						
TER criterion		5						
Focal species	Food category, % in diet	FIR/bw	RUD _m * × DF* (mg/kg food)	MAF _m × TWA	PT	DDD _m (mg/kg bw/d)	TER _{lt}	
Common vole (<i>Microtus arvalis</i>)	100% grass	1.33 ¹	21.11² × 0.3³ 28.89 ² × 0.3 ³	1.9 × 0.53	1.0	0.85 1.16	9.7 7.06	
Brown rat (<i>Rattus norvegicus</i>)	100% fruit	0.73 ¹	12.8 ⁴ × 1.0	1.9 × 0.53	1.0	0.94	8.7	
Intended use		Fruiting vegetables						
Active substance/product		Boscalid						
Application rate (g/ha)		3 x 400						
Reprod. toxicity (mg/kg bw/d)		67						
TER criterion		5						
Focal species	Food category, % in diet	FIR/bw	RUD _m * × DF* (mg/kg food)	MAF _m × TWA	PT	DDD _m (mg/kg bw/d)	TER _{lt}	
Common vole (<i>Microtus arvalis</i>)	100% grass	1.33 ¹	54.2 ¹ × 0.3 ³	1.9 × 0.53	1.0	8.71	7.7	

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the

crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

¹ According to Appendix A of EFSA/2009/1438.

² Value obtained from residue data in barley and wheat in Northern Europe (please refer to the *Pyraclostrobin DAR (2001)– Annex B.7: Residue data*). 90%th percentile used by zRMS

³ Deposition factor according to FOCUS groundwater guidance.

⁴ According to Table 1 from Appendix F of EFSA/2009/1438.

Table 9.3-16: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of Casino Royale in bush and cane fruits – refined parameters (*) are further described and justified in the text

Intended use		Bush and cane fruit						
Active substance/product		Pyraclostrobin						
Application rate (g/ha)		2 x 121						
Reprod. toxicity (mg/kg bw/d)		8.2						
TER criterion		5						
Focal species	Food category, % in diet	FIR/bw	RUD_m* × DF* (mg/kg food)	MAF_m × TWA	PT	DDD_m (mg/kg bw/d)	TER_{it}	
Common vole (<i>Microtus arvalis</i>)	100% grass	1.33 ¹	21.11 ² × 0.4 ³ 28.89 ²	1.6 × 0.53	1.0	4.15 1.57	7.1 5.22	

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

¹ According to Appendix A of EFSA/2009/1438.

² Value obtained from residue data in barley and wheat in Northern Europe (please refer to the *Pyraclostrobin DAR (2001)– Annex B.7: Residue data*). 90%th percentile used by zRMS.

³ Deposition factor according to FOCUS groundwater guidance.

Table 9.3-17: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of Casino Royale in root and stem vegetables – refined parameters (*) are further described and justified in the text

Intended use		Root and stem vegetables						
Active substance/product		Pyraclostrobin						
Application rate (g/ha)		2 x 100						
Reprod. toxicity (mg/kg bw/d)		8.2						
TER criterion		5						
Focal species	Food category, % in diet	FIR/bw	RUD_m* × DF* (mg/kg food)	MAF_m × TWA	PT	DDD_m (mg/kg bw/d)	TER_{it}	
Common vole (<i>Microtus arvalis</i>)	100% grass	1.33 ¹	21.11 ² × 0.2 ³ 28.89	1.57 × 0.53	1.0	0.47 0.64	17.6 12.81	

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

¹ According to Appendix A of EFSA/2009/1438.

² Value obtained from residue data in barley and wheat in Northern Europe (please refer to the *Pyraclostrobin DAR (2001)– Annex B.7: Residue data*). 90%th percentile used by zRMS.

³ Deposition factor according to FOCUS groundwater guidance.

Table 9.3-18: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of Casino Royale in bulbs and onion like crops – refined parameters (*) are further described and justified in the text

Intended use		Bulbs and onion like crops					
Active substance/product		Pyraclostrobin					
Application rate (g/ha)		2 x 100					
Reprod. toxicity (mg/kg bw/d)		8.2					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m* × DF* (mg/kg food)	MAF_m × TWA	PT	DDD_m (mg/kg bw/d)	TER_{lt}
Common vole (<i>Microtus arvalis</i>)	100% grass	1.33 ¹	21.1 ¹ × 0.6 ³ 28.89 ²	1.4 × 0.53	1.0	1.25 1.71	6.6 4.8*

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

¹ According to Appendix A of EFSA/2009/1438.

² Value obtained from residue data in barley and wheat in Northern Europe (please refer to the *Pyraclostrobin DAR (2001)– Annex B.7: Residue data*). 90%th percentile used by zRMS

³ Deposition factor according to FOCUS groundwater guidance.

*TER_{LT} closed to 5 and considered as acceptable by zRMS

Table 9.3-19: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of Casino Royale in leafy vegetables – refined parameters (*) are further described and justified in the text

Intended use		Leafy vegetables					
Active substance/product		Pyraclostrobin					
Application rate (g/ha)		2 x 100					
Reprod. toxicity (mg/kg bw/d)		8.2					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m* × DF* (mg/kg food)	MAF_m × TWA	PT	DDD_m (mg/kg bw/d)	TER_{lt}
Common vole (<i>Microtus arvalis</i>)	100% grass	1.33 ¹	21.1 ¹ × 0.3 ³ 28.89	1.4 × 0.53	1.0	0.62 0.85	13.1 9.64
Intended use		Fruiting vegetables					
Active substance/product		Boscalid					
Application rate (g/ha)		2 x 400					
Reprod. toxicity (mg/kg bw/d)		67					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD_m* × DF* (mg/kg food)	MAF_m × TWA	PT	DDD_m (mg/kg bw/d)	TER_{lt}
Common vole (<i>Microtus arvalis</i>)	100% grass	1.33 ¹	54.2 ¹ × 0.3 ³	1.4 × 0.53	1.0	6.42	10.4

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

¹ According to Appendix A of EFSA/2009/1438.

² Value obtained from residue data in barley and wheat in Northern Europe (please refer to the *Pyraclostrobin DAR (2001)– Annex*

B.7: Residue data). 90th percentile used by zRMS

³Deposition factor according to FOCUS groundwater guidance.

Table 9.3-20: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of Casino Royale in strawberries – refined parameters (*) are further described and justified in the text

Intended use		Strawberries						
Active substance/product		Pyraclostrobin						
Application rate (g/ha)		2 x 121						
Reprod. toxicity (mg/kg bw/d)		8.2						
TER criterion		5						
Focal species	Food category, % in diet	FIR/bw	RUD_m* × DF* (mg/kg food)	MAF_m × TWA	PT	DDD_m (mg/kg bw/d)	TER_{lt}	
Common vole (<i>Microtus arvalis</i>)	100% grass	1.33 ¹	21.11 ² × 0.4 ³ 28.89 ²	1.7 × 0.53	1.0	1.22 1.67	6.7 4.91*	

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

¹ According to Appendix A of EFSA/2009/1438.

² Value obtained from residue data in barley and wheat in Northern Europe (please refer to the *Pyraclostrobin DAR (2001)– Annex B.7: Residue data*). 90th percentile used by zRMS.

³ Deposition factor according to FOCUS groundwater guidance.

***TER_{LT} closed to 5 and considered as acceptable by zRMS**

zRMS comment:

Based on the refined parameters such as : RUD and DF verified by zRMS, the following conclusions for the risk assessment for mammals are provided:

Sugar beet, cherry and ornamentals

According to the screening and first-tier assessments, all the TER_a and TER_{lt} values for active substances Pyraclostrobin and Boscalid are greater than the Annex VI trigger of 10 and 5, respectively, indicating that Casino Royale presents no unacceptable acute and long-term risk to mammals according to the intended uses on sugar beet, cherry and ornamentals.

Fruiting vegetables and leafy vegetables

According to the screening assessments, all the TER_a values for the active substance Pyraclostrobin and Boscalid are greater than the Annex VI trigger of 10. After first-tier assessment for active substance Pyraclostrobin and Boscalid, some TER_{lt} values are lower than the Annex VI trigger of 5, for small herbivorous mammal "vole" in both active substance and frugivorous mammal "rat" for Pyraclostrobin in fruiting vegetables, indicating that Casino Royale presents an unacceptable long-term risk to mammals. A refinement of the risk was done by refining of RUD and DF, and the TER values were above the trigger showing no risk. Therefore, the acute and long-term risk to mammals after the application of Casino Royale according to the GAP is considered acceptable.

Bush and cane fruits, root and stem vegetables, bulbs and onion like crops and strawberry

According to the screening assessments, all the TER_a values for the active substance Pyraclostrobin and Boscalid are greater than the Annex VI trigger of 10. After first-tier assessment for active substance Pyraclostrobin, the TER_{lt} values are lower than the Annex VI trigger of 5 for small herbivorous mammal

"vole", indicating that Casino Royale presents an unacceptable long-term risk to mammals. A refinement of the risk was done by refining of RUD and DF, and the TER values were above the trigger showing no risk. Therefore, the acute and long-term risk to mammals after the application of Casino Royale according to the GAP is considered acceptable.

It should be noted, that if any of refinement option is not accepted by some MSs, they should conclude this issue on MS level.

In addition, the combined long risk assessment provided at Tier I needs further refinement for the following scenarios:

~~Fruiting vegetables: BBCH 10–49 Small herbivorous mammal "vole". Grass + cereals. 100% grass~~
~~Fruiting vegetables: BBCH > 50 Small herbivorous mammal "vole". Grass + cereals. 100% grass~~
~~Bush & cane fruit BBCH ≥ 40 Small herbivorous mammal "vole". Grass + cereals. 100% grass~~
~~Root & stem vegetables BBCH ≥ 40 Small herbivorous mammal "vole". Grass + cereals. 100% grassy~~
~~Leafy vegetables BBCH 40–49 Small herbivorous mammal "vole". Grass + cereals. 100% grass~~
~~Orchards Application crop directed BBCH ≥ 40 Small herbivorous mammal "vole". Grass + cereals. 100% grass~~
~~Strawberries BBCH ≥ 40: Small herbivorous mammal "vole". Grass + cereals. 100% grass~~
~~Ornamentals : Ornamentals BBCH 40–49 and BBCH > 50 Small insectivorous mammal "vole"~~

Further refinement for combined long-term risk assessment for these scenarios is required at MSs level.

The refinement of the combined risk assessment for vole should be considered at MSs level.

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).

Leaf scenario

Since Casino Royale is 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 must be considered.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group leafy vegetables also covers the risk for mammals from all other intended uses.

Assessment of the acute risk for mammals due to exposure to Pyraclostrobin via contaminated drinking water in leaf whorls

Intended use		Leafy vegetables				
Active substance		Pyraclostrobin				
Application rate (g/ha)		2 × 100				
Acute toxicity (mg/kg bw)		> 5000				
TER criterion		10				
(Single) ap- plic. rate (g/ha)	Water applic. rate (L/ha)	C _{spray-sol.} (g/L)	PEC _{leaf-whorl} = C _{spray-sol./5} (mg/L)	DW uptake (L/kg bw/d)	Daily dose (mg/kg bw/d)	TER _a

100	300	0.33	0.07	0.24	0.017	294 117.65
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C_{spray-sol}: concentration in spray solution; PEC_{leaf-whorl}: concentration in pools in leaf whorls; DW: drinking water; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Assessment of the acute risk for mammals due to exposure to Boscalid via contaminated drinking water in leaf whorls

Intended use		Leafy vegetables				
Active substance		Boscalid				
Application rate (g/ha)		2 × 400				
Acute toxicity (mg/kg bw)		> 5000				
TER criterion		10				
(Single) ap- plic. rate (g/ha)	Water applic. rate (L/ha)	C_{spray-sol} (g/L)	PEC_{leaf-whorl} = C_{spray-sol}/5 (mg/L)	DW uptake (L/kg bw/d)	Daily dose (mg/kg bw/d)	TER_a
400	300	1.33	0.27	0.24	0.064	78 125

C_{spray-sol}: concentration in spray solution; PEC_{leaf-whorl}: concentration in pools in leaf whorls; DW: drinking water; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

zRMS comment:

zRMS considers that use of according to GAP does not pose an unacceptable acute risk to birds through drinking water exposure.

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 (K_{oc} < 500 L/kg) or 3000 in the case of more sorptive substances (K_{oc} ≥ 500 L/kg).

With a K(f)_{oc} of 8855.9 (geomean, n = 6; Review Report, 2004), Pyraclostrobin belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group strawberries also covers the risk for mammals from all other intended uses (see 9.1.4).

Effective application rate (g/ha) =	179.1/205.7		
Acute toxicity (mg/kg bw) =	5000	quotient	= 0.04
Reprod. toxicity (mg/kg bw/d) =	8.2	quotient	= 25.09

With a K(f)_{oc} of 742.6 (geomean, n = 6; Review Report, 2008), Boscalid belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group strawberries also covers the risk for mammals from all other intended uses (see 9.1.4).

Effective application rate (g/ha) =	711.9/817.7		
Acute toxicity (mg/kg bw) =	5000	quotient	= 0.14
Reprod. toxicity (mg/kg bw/d) =	67	quotient	= 12.2

zRMS comment:

We agree with the calculation of the risk assessment for Pudlle scenario.

9.3.2.4 Effects of secondary poisoning

The log P_{ow} of Pyraclostrobin amounts to 3.99 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

The log P_{ow} of Boscalid amounts to 2.96 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

zRMS comment:

The log P_{ow} of the active substance boscalid was determined to be 2.96 (P_{ow} 915) and a bioaccumulation study in fish was performed (see Monograph, Vol. 3, Annex B.9, 2002). The bioconcentration factors for whole fish were 57 (low concentration) and 70 (high concentration). The half-lives for elimination varied between 0.4 and 1.0 days. The time for elimination of 90% of the activity varied between 1.4 and 3.3 days. The nature of radioactivity in fish tissues after 28 days of exposure proved to primarily consist of the parent substance (84.9% - 97.0%). Due to the low accumulation and rapid excretion of boscalid from fish it is concluded that there is no risk of bioaccumulation in food chains.

The log P_{ow} of Pyraclostrobin amounts to 3.99 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

Risk assessment for earthworm-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous mammals is assessed for a small mammal of 10 g body weight with a daily food consumption of 12.8 g. Bioaccumulation in earthworms is estimated based on predicted concentrations in soil.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group onion “7 years old” also covers the risk for mammals from all other intended uses (see 9.1.4).

Table 9.3-21: Assessment of the risk for earthworm-eating mammals due to exposure to Pyraclostrobin via bioaccumulation in earthworms (secondary poisoning) for the intended use in all crops (use group all crops)

Parameter	Pyraclostrobin	Comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.162	PEC_{soil} (twa = 21 d) for multiple applications using onion “7 years old” GAP
log P_{ow} / P_{ow}	3.99 / 9772.37	SANCO/1420/2001-Final
Koc	8855.9	Geomean, n = 6; Review Report, 2004
foc	0.02	Default
BCF_{worm}	0.667	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.012 \times P_{ow}) / foc \times Koc$

Parameter	Pyraclostrobin	Comments
PEC _{worm}	0.11	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.14	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	8.2	Long-term toxicity to mammals drawn from DAR, 2001
TER _{lt}	59.3	No risk, TER _{lt} > 5

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous mammals is assessed for a mammal of 3000 g body weight with a daily food consumption of 425 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water as a limit value for admissible concentrations of Pyraclostrobin in water.

Table 9.3-22: Assessment of the risk for fish-eating mammals due to exposure to Pyraclostrobin via bioaccumulation in fish (secondary poisoning) for the intended use in all crops (use group all crops)

Parameter	Pyraclostrobin	Comments
PEC _{sw} (twa = 21 d) (mg/L)	0.00652	Worst case value drawn from use cherry (apple early application as worst case, BBCH 60), FOCUS step 2
BCF _{fish}	736	Whole fish, tolyl label. SANCO/1420/2001-Final
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	4.80	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.68	DDD = PEC _{fish} × 0.142
NOEL (mg/kg bw/d)	8.2	Long-term toxicity to mammals drawn from DAR, 2001
TER _{lt}	12.0	No risk, TER _{lt} > 5

TER values shown in bold fall below the relevant trigger.

zRMS comment:

We agree with the calculations of the risk assessment for the a.s.- pyraclostrobin provided by the applicant.

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

9.3.4 Overall conclusions

Sugar beet, cherry and ornamentals

According to the screening and first-tier assessments, all the TER_a and TER_{lt} values for active substances Pyraclostrobin and Boscalid are greater than the Annex VI trigger of 10 and 5, respectively, indicating that Casino Royale presents no unacceptable acute and long-term risk to mammals according to the intended uses on sugar beet, cherry and ornamentals.

Fruiting vegetables and leafy vegetables

According to the screening assessments, all the TER_a values for the active substance Pyraclostrobin and Boscalid are greater than the Annex VI trigger of 10. After first-tier assessment for active substance Pyraclostrobin and Boscalid, some TER_{lt} values are lower than the Annex VI trigger of 5, for small herbivorous mammal "vole" in both active substance and frugivorous mammal "rat" for Pyraclostrobin in fruiting vegetables, indicating that Casino Royale presents an unacceptable long-term risk to mammals. A refinement of the risk was done by refining of RUD and DF, and the TER values were above the trigger showing no risk. Therefore, the acute and long-term risk to mammals after the application of Casino Royale

according to the GAP is considered acceptable.

Bush and cane fruits, root and stem vegetables, bulbs and onion like crops and strawberry

According to the screening assessments, all the TER_a values for the active substance Pyraclostrobin and Boscalid are greater than the Annex VI trigger of 10. After first-tier assessment for active substance Pyraclostrobin, the TER_{it} values are lower than the Annex VI trigger of 5 for small herbivorous mammal "vole", indicating that Casino Royale presents an unacceptable long-term risk to mammals. A refinement of the risk was done by refining of RUD and DF, and the TER values were above the trigger showing no risk. Therefore, the acute and long-term risk to mammals after the application of Casino Royale according to the GAP is considered acceptable.

Pyraclostrobin has been shown to have the potential for bioaccumulation, however, there is no risk to earthworm and fish-eating mammals according to the intended uses of Casino Royale.

It should be noted, that if any of refinement option is not accepted by some MSs, they should conclude this issue on MS level.

In addition the combined long risk assessment for mammals should be further considered at MSs level for the following scenarios:

~~Fruiting vegetables: BBCH 10–49 Small herbivorous mammal "vole". Grass + cereals. 100% grass~~
~~Fruiting vegetables: BBCH > 50 Small herbivorous mammal "vole". Grass + cereals. 100% grass~~
~~Bush & cane fruit BBCH ≥ 40 Small herbivorous mammal "vole". Grass + cereals. 100% grass~~
~~Root & stem vegetables BBCH ≥ 40 Small herbivorous mammal "vole". Grass + cereals. 100% grassy~~
~~Leafy vegetables BBCH 40–49 Small herbivorous mammal "vole". Grass + cereals. 100% grass~~
~~Orchards Application crop directed BBCH ≥ 40 Small herbivorous mammal "vole". Grass + cereals. 100% grass~~
~~Strawberries BBCH ≥ 40: Small herbivorous mammal "vole". Grass + cereals. 100% grass~~
~~Ornamentals : Ornamentals BBCH 40–49 and BBCH > 50 Small insectivorous mammal "vole"~~

The refinement of the combined risk assessment for vole should be considered at MSs level.

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

No data available.

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 Pyraclostrobin and its relevant metabolites, and Boscalid. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on aquatic organisms of Pyraclostrobin 6.7% Boscalid 26.7% WG were not evaluated as part of the EU assessment of Pyraclostrobin and Boscalid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

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

Species	Substance	Exposure System	Results	Reference
<i>Oncorhynchus mykiss</i>	Pyraclostrobin	96 h, s	LC ₅₀ = 0.006 mg a.s./L	SANCO/1420/2001-Final
<i>Oncorhynchus mykiss</i>	BF 500-13	96 h, s	LC ₅₀ > 50 - < 100 mg a.s./L	SANCO/1420/2001-Final
<i>Oncorhynchus mykiss</i>	BF 500-14	96 h, s	LC ₅₀ > 39 - < 83 mg a.s./L	SANCO/1420/2001-Final
<i>Oncorhynchus mykiss</i>	BF 500-11	96 h, s	LC ₅₀ > 100 mg a.s./L	SANCO/1420/2001-Final
<i>Oncorhynchus mykiss</i>	Pyraclostrobin	28 d, f	NOEC = 0.005 mg a.s./L	SANCO/1420/2001-Final
<i>Oncorhynchus mykiss</i>	Pyraclostrobin	98 d, ELS	NOEC = 0.002 mg a.s./L	SANCO/1420/2001-Final
<i>Daphnia magna</i>	Pyraclostrobin	48 h, s	EC ₅₀ = 0.016 mg a.s./L	SANCO/1420/2001-Final
<i>Daphnia magna</i>	BF 500-13	48 h, s	EC ₅₀ > 100 mg a.s./L	SANCO/1420/2001-Final
<i>Daphnia magna</i>	BF 500-14	48 h, s	EC ₅₀ = 61 mg a.s./L	SANCO/1420/2001-Final
<i>Daphnia magna</i>	BF 500-11	48 h, s	EC ₅₀ > 100 mg a.s./L	SANCO/1420/2001-Final
<i>Daphnia magna</i>	Pyraclostrobin	21 d, ss	NOEC = 0.004 mg a.s./L	SANCO/1420/2001-Final
<i>Chironomus riparius</i>	Pyraclostrobin	28 d, s	NOEC = 0.04 mg a.s./L EC ₂₀ > 100 mg a.s./kg	SANCO/1420/2001-Final
<i>Pseudokirchneriella subcapitata</i>	Pyraclostrobin	72 h, s	E_rC₅₀ > 0.843 mg a.s./L E _b C ₅₀ = 0.152 mg a.s./L	SANCO/1420/2001-Final
<i>Pseudokirchneriella subcapitata</i>	BF 500-13	72 h, s	E_rC₅₀ > 100 mg a.s./L E _b C ₅₀ = 66 mg a.s./L	SANCO/1420/2001-Final
<i>Pseudokirchneriella subcapitata</i>	BF 500-14	72 h, s	E_rC₅₀ > 100 mg a.s./L E _b C ₅₀ = 46 mg a.s./L	SANCO/1420/2001-Final
<i>Pseudokirchneriella subcapitata</i>	BF 500-11	72 h, s	E _r C ₅₀ > 100 mg a.s./L	SANCO/1420/2001-Final
<i>Lemna gibba</i>	Not required			SANCO/1420/2001-Final
Higher-tier studies (micro- or mesocosm studies)				

Species	Substance	Exposure System	Results	Reference
Aquatic mesocosm in a large number of different species (approximately 260 taxa) in outdoor conditions for the representative formulation BAS 500 00 F (247.8 g as/L). Results: NOEC 8 µg a.s./L LOEC 24 µg a.s./L EAC ≥ 8 µg a.s./L				

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

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

Species	Substance	Exposure System	Results	Reference
<i>Oncorhynchus mykiss</i>	Boscalid	96 h, s	EC ₅₀ = 2.7 mg a.s./L	SANCO/3919 /2007-rev. 5
<i>Oncorhynchus mykiss</i>	Boscalid	97 d, f	NOEC = 0.125 mg a.s./L	SANCO/3919 /2007-rev. 5
<i>Daphnia magna</i>	Boscalid	48 h, s	EC ₅₀ = 5.33 mg a.s./L	SANCO/3919 /2007-rev. 5
<i>Daphnia magna</i>	Boscalid	21 d, ss	NOEC = 1.31 mg a.s./L	SANCO/3919 /2007-rev. 5
<i>Chironomus riparius</i>	Boscalid	28 d, s	NOEC = 1 mg a.s./L	SANCO/3919 /2007-rev. 5
<i>Pseudokirchneriella subcapitata</i>	Boscalid	96 h, s	EC ₅₀ = 1.34 mg a.s./L	SANCO/3919 /2007-rev. 5

Higher-tier studies (micro- or mesocosm studies)

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.

Table 9.5-3: Endpoints and effect values relevant for the risk assessment for aquatic organisms – CASINO ROYALE

Species	Substance	Exposure System	Results	Reference
<i>Oncorhynchus mykiss</i>	CASINO ROYALE	96 h, ss	LC ₅₀ = 0.054 mg f.p./L ^{nom}	KCP 10.2.1-01 xxx. 2018 W/140/17
<i>Daphnia magna</i>	CASINO ROYALE	48 h, s	EC ₅₀ = 0.254 mg f.p./L ^{nom}	KCP 10.2.1-02 Kulec-Płoszczyca, E., 2018 W/142/17
<i>Pseudokirchneriella subcapitata</i>	CASINO ROYALE	96 h, s	E _r C ₅₀ = 28.75 mg f.p./L ^{nom} E _y C ₅₀ = 2.74 mg f.p./L ^{nom}	KCP 10.2.1-03 Kulec-Płoszczyca, E., 2018 W/141/17

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

There is not deviation from the EU agreed endpoints.

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.

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.

Table 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pyraclostrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in sugar beet (single/multiple application)

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀ 6	NOEC 2	EC ₅₀ 16	NOEC 4	E _r C ₅₀ 843	NOEC 40
AF		100	10	100	10	10	10
RAC (µg/L)		0.06	0.2	0.16	0.4	84.3	4
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
	3.52/7.04	58.67/117.33	17.60/35.20	22.00/44.00	8.800/17.600	0.042/0.084	0.880/1.760
Step 2							

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
S/N-Europe	0.92/0.89	15.333/14.833	4.600/4.450	5.750/5.563	2.300/2.225	0.011/0.011	0.230/0.223
Step 3							
D3/ditch	0.524/0.456	8.733/7.600	2.620/2.280	3.275/2.850	1.310/1.140	0.006/0.005	0.131/0.114
D4/pond	0.021/0.031	0.350/0.517	0.105/0.155	0.131/0.194	0.053/0.078	0.000/0.000	0.005/0.008
D4/stream	0.422/0.363	7.033/6.050	2.110/1.815	2.638/2.269	1.055/0.908	0.005/0.004	0.106/0.091
R1/pond	0.028/0.058	0.467/0.967	0.140/0.290	0.175/0.363	0.070/0.145	0.000/0.001	0.007/0.015
R1/stream	0.364/0.314	6.067/5.233	1.820/1.570	2.275/1.963	0.910/0.785	0.004/0.004	0.091/0.079
R3/stream	0.511/0.442	8.517/7.367	2.555/2.210	3.194/2.763	1.278/1.105	0.006/0.005	0.128/0.111

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 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pyraclostrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in tomato and eggplant (fruiting vegetables and potato, BBCH 12 as worst case) (single/multiple application)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀ 6	NOEC 2	EC ₅₀ 16	NOEC 4	E _r C ₅₀ 843	NOEC 40
AF		100	10	100	10	10	10
RAC (µg/L)		0.06	0.2	0.16	0.4	84.3	4
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
	3.52/10.57	58.67/176.17	17.60/52.85	22.00/66.06	8.80/26.43	0.042/0.125	0.880/2.643
Step 2							
S-Europe	0.92/2.05	15.333/34.167	4.600/10.25	5.750/12.813	2.300/5.125	0.011/0.024	0.230/0.513
N-Europe	0.92/1.12	15.333/18.667	4.600/5.600	5.750/7.000	2.300/2.800	0.011/0.013	0.230/0.280
Step 3							
D3/ditch	0.525/0.382	8.750/6.367	2.625/1.910	3.281/2.388	1.313/0.955	0.006/0.005	0.131/0.096
D4/pond	0.021/0.031	0.350/0.517	0.105/0.155	0.131/0.194	0.053/0.078	0.000/0.000	0.005/0.008
D4/stream	0.447/0.323	7.450/5.383	2.235/1.615	2.794/2.019	1.118/0.808	0.005/0.004	0.112/0.081
D6/ditch	0.624/0.459	10.400/7.650	3.120/2.295	3.900/2.869	1.560/1.148	0.007/0.005	0.156/0.115
R1/pond	0.021/0.043	0.350/0.717	0.105/0.215	0.131/0.269	0.053/0.108	0.000/0.001	0.005/0.011
R1/stream	0.357/0.263	5.950/4.383	1.785/1.315	2.231/1.644	0.893/0.658	0.004/0.003	0.089/0.066
R2/stream	0.553/0.407	9.217/6.783	2.765/2.035	3.456/2.544	1.383/1.018	0.007/0.005	0.138/0.102
R3/stream	0.589/0.429	9.817/7.150	2.945/2.145	3.681/2.681	1.473/1.073	0.007/0.005	0.147/0.107
R4/stream	0.418/0.314	6.967/5.233	2.090/1.570	2.613/1.963	1.045/0.785	0.005/0.004	0.105/0.079

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 Pyraclostrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in carrots, beetroot, celery root, radish, horseradish, swedes, turnip, chicory roots and salsifies (root vegetables, BBCH 11 as worst case) (single/multiple application)

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀	NOEC	EC ₅₀	NOEC	E _r C ₅₀	NOEC
AF		6	2	16	4	843	40
RAC (µg/L)		100	10	100	10	10	10
RAC (µg/L)		0.06	0.2	0.16	0.4	84.3	4
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
	3.52/7.04	58.67/117.3	17.60/35.20	22.00/44.00	8.800/17.60	0.042/0.084	0.880/ 1.760
Step 2							
S-Europe	0.92/1.50	15.33/25.00	4.600/7.500	5.750/9.375	2.300/3.750	0.011/0.018	0.230/0.375
N-Europe	0.92/0.89	15.33/14.83	4.600/4.450	5.750/5.563	2.300/2.225	0.011/0.011	0.230/0.223
Step 3							
D3/ditch	0.634/0.555	10.57/9.250	3.170/2.775	3.963/3.469	1.585/1.388	0.008/0.007	0.159/0.139
D6/ditch	0.633/0.557	10.55/9.283	3.165/2.785	3.956/3.481	1.583/1.393	0.008/0.007	0.158/0.139
R1/pond	0.025/0.040	0.417/0.667	0.125/0.200	0.156/0.250	0.063/0.100	0.000/0.000	0.006/0.010
R1/stream	0.418/0.361	6.967/6.017	2.090/1.805	2.613/2.256	1.045/0.903	0.005/0.004	0.105/0.090
R2 1 st /stream	0.552/0.478	9.200/7.967	2.760/2.390	3.450/2.988	1.380/1.195	0.007/0.006	0.138/0.120
R2 2 nd /stream	0.562/0.486	9.367/8.100	2.810/2.430	3.513/3.038	1.405/1.215	0.007/0.006	0.141/0.122
R3/stream	0.587/0.508	9.783/8.467	2.935/2.540	3.669/3.175	1.468/1.270	0.007/0.006	0.147/0.127
R4/stream	0.413/0.360	6.883/6.000	2.065/1.800	2.581/2.250	1.033/0.900	0.005/0.004	0.103/0.090

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 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pyraclostrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in onion, shallot, onion “seven years old and ornamentals (bulb vegetables, BBCH 13 as worst case) (single/multiple application)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀ 6	NOEC 2	EC ₅₀ 16	NOEC 4	E _r C ₅₀ 843	NOEC 40
AF		100	10	100	10	10	10
RAC (µg/L)		0.06	0.2	0.16	0.4	84.3	4
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
	3.52/7.04	58.67/117.33	17.60/35.20	22.00/44.00	8.800/17.60	0.042/0.084	0.880/ 1.760
Step 2							
S-Europe	0.97/1.79	16.17/29.83	4.850/8.950	6.063/11.19	2.425/4.475	0.012/0.021	0.243/0.448
N-Europe	0.92/0.98	15.33/16.33	4.600/4.900	5.750/6.125	2.300/2.450	0.011/0.012	0.230/0.245
Step 3							
D3/ditch	0.643/0.556	10.72/9.267	3.215/2.780	4.019/3.475	1.608/1.390	0.008/0.007	0.161/0.139
D4/pond	0.022/0.030	0.367/0.500	0.110/0.150	0.138/0.188	0.055/0.075	0.000/0.000	0.006/0.008
D4/stream	0.479/0.415	7.983/6.917	2.395/2.075	2.994/2.594	1.198/1.038	0.006/0.005	0.120/0.104
D6 1 st /ditch	0.638/0.598	10.63/9.967	3.190/2.990	3.988/3.738	1.595/1.495	0.008/0.007	0.160/0.150
D6 2 nd /ditch	0.639/0.558	10.65/9.300	3.195/2.790	3.994/3.488	1.598/1.395	0.008/0.007	0.160/0.140
R1/pond	0.023/0.039	0.383/0.650	0.115/0.195	0.144/0.244	0.058/0.098	0.000/0.000	0.006/0.010
R1/stream	0.411/0.355	6.850/5.917	2.055/1.775	2.569/2.219	1.028/0.888	0.005/0.004	0.103/0.089
R2/stream	0.553/0.479	9.217/7.983	2.765/2.395	3.456/2.994	1.383/1.198	0.007/0.006	0.138/0.120
R3/stream	0.587/0.510	9.783/8.500	2.935/2.550	3.669/3.188	1.468/1.275	0.007/0.006	0.147/0.128
R4/stream	0.415/0.359	6.917/5.983	2.075/1.795	2.594/2.244	1.038/0.898	0.005/0.004	0.104/0.090

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 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pyraclostrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in cabbage, strawberry, parsnip and parsley (leafy vegetables, BBCH 15 as worst case) (single/multiple application)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀ 6	NOEC 2	EC ₅₀ 16	NOEC 4	E _r C ₅₀ 843	NOEC 40
AF		100	10	100	10	10	10
RAC (µg/L)		0.06	0.2	0.16	0.4	84.3	4
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
	3.52/7.04	58.67/117.3	17.60/35.20	22.00/44.00	8.800/17.60	0.042/0.084	0.880/1.760
Step 2							
S-Europe	0.92/1.55	15.33/25.83	4.600/7.750	5.750/9.688	2.300/3.875	0.011/0.018	0.230/0.388
N-Europe	0.92/0.90	15.33/15.00	4.600/4.500	5.750/5.625	2.300/2.250	0.011/0.011	0.230/0.225
Step 3							
D3 1 st /ditch	0.768/0.673	12.80/11.22	3.840/3.365	4.800/4.206	1.920/1.683	0.009/0.008	0.192/0.168
D3 2 nd /ditch	0.764/0.669	12.73/11.15	3.820/3.345	4.775/4.181	1.910/1.673	0.009/0.008	0.191/0.167
D4/pond	0.026/0.036	0.433/0.600	0.130/0.180	0.163/0.225	0.065/0.090	0.000/0.000	0.007/0.009
D4/stream	0.571/0.505	9.517/8.417	2.855/2.525	3.569/3.156	1.428/1.263	0.007/0.006	0.143/0.126
D6/ditch	0.757/0.668	12.62/11.13	3.785/3.340	4.731/4.175	1.893/1.670	0.009/0.008	0.189/0.167
R1 1 st /pond	0.028/0.049	0.467/0.817	0.140/0.245	0.175/0.306	0.070/0.123	0.000/0.001	0.007/0.012
R1 2 nd /pond	0.030/0.059	0.500/0.983	0.150/0.295	0.188/0.369	0.075/0.148	0.000/0.001	0.008/0.015
R1 1 st /stream	0.500/0.433	8.333/7.217	2.500/2.165	3.125/2.706	1.250/1.083	0.006/0.005	0.125/0.108
R1 2 nd /stream	0.507/0.439	8.450/7.317	2.535/2.195	3.169/2.744	1.268/1.098	0.006/0.005	0.127/0.110
R2 1 st /stream	0.670/0.579	11.17/9.650	3.350/2.895	4.188/3.619	1.675/1.448	0.008/0.007	0.168/0.145
R2 2 nd /stream	0.680/0.588	11.33/9.800	3.400/2.940	4.250/3.675	1.700/1.470	0.008/0.007	0.170/0.147
R3 1 st /stream	0.715/0.618	11.92/10.30	3.575/3.090	4.469/3.863	1.788/1.545	0.008/0.007	0.179/0.155
R3 2 nd /stream	0.715/0.619	11.92/10.32	3.575/3.095	4.469/3.869	1.788/1.548	0.008/0.007	0.179/0.155
R4 1 st /stream	0.507/0.438	8.450/7.300	2.535/2.190	3.169/2.738	1.268/1.095	0.006/0.005	0.127/0.110
R4 2 nd /stream	0.505/0.439	8.417/7.317	2.525/2.195	3.156/2.744	1.263/1.098	0.006/0.005	0.126/0.110

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 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pyraclostrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in cherry (apple early application as worst case, BBCH 60) (single/multiple application)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀ 6	NOEC 2	EC ₅₀ 16	NOEC 4	E _r C ₅₀ 843	NOEC 40
AF		100	10	100	10	10	10
RAC (µg/L)		0.06	0.2	0.16	0.4	84.3	4
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
	8.26/16.53	137.7/275.5	41.30/82.65	51.63/103.31	20.65/41.33	0.098/0.196	2.065/4.133
Step 2							
S/N-Europe	6.52/6.32	108.7/105.3	32.60/31.60	40.75/39.50	16.30/15.80	0.077/0.075	1.630/1.580
Step 3							
D3/ditch	5.221/4.153	87.02/69.22	26.11/20.77	32.63/25.96	13.05/10.38	0.062/0.049	1.305/1.038
D4/pond	0.317/0.501	5.283/8.350	1.585/2.505	1.981/3.131	0.793/1.253	0.004/0.006	0.079/0.125
D4/stream	5.534/4.733	92.23/78.88	27.67/23.67	34.59/29.58	13.84/11.83	0.066/0.056	1.384/1.183
D5/pond	0.317/0.474	5.283/7.900	1.585/2.370	1.981/2.963	0.793/1.185	0.004/0.006	0.079/0.119
D5/stream	5.977/5.107	99.62/85.12	29.89/25.54	37.36/31.92	14.94/12.77	0.071/0.061	1.494/1.277
R1/pond	0.316/0.468	5.267/7.800	1.580/2.340	1.975/2.925	0.790/1.170	0.004/0.006	0.079/0.117
R1/stream	4.241/3.620	70.68/60.33	21.21/18.10	26.51/22.63	10.60/9.050	0.050/0.043	1.060/0.905
R2/stream	5.684/4.853	94.73/80.88	28.42/24.27	35.53/30.33	14.21/12.13	0.067/0.058	1.421/1.213
R3/stream	5.935/5.103	98.92/85.05	29.68/25.52	37.09/31.89	14.84/12.76	0.070/0.061	1.484/1.276
R4/stream	4.145/3.620	69.08/60.33	20.73/18.10	25.91/22.63	10.36/9.050	0.049/0.043	1.036/0.905

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 9.5-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Pyraclostrobin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in raspberry, blackcurrant, ornamentals, redcurrant and white currant (vines and apple late application as worst case, BBCH 61)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		LC ₅₀ 6	NOEC 2	EC ₅₀ 16	NOEC 4	ErC ₅₀ 843	NOEC 40
AF		100	10	100	10	10	10
RAC (µg/L)		0.06	0.2	0.16	0.4	84.3	4
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
	6.39/12.77	106.5/212.8	31.95/63.85	39.94/79.81	15.98/31.93	0.076/0.151	1.598/3.193
Step 2							
S/N-Europe	3.24/3.17	54.00/52.83	16.20/15.85	20.25/19.81	8.100/7.925	0.038/0.038	0.810/0.793
Step 3							
D3/ditch	2.067/1.836	34.45/30.60	10.34/9.180	12.92/11.48	5.168/4.590	0.025/0.022	0.517/0.459
D4/pond	0.074/0.117	1.233/1.950	0.370/0.585	0.463/0.731	0.185/0.293	0.001/0.001	0.019/0.029
D4/stream	1.988/1.757	33.13/29.28	9.940/8.785	12.43/10.98	4.970/4.393	0.024/0.021	0.497/0.439
D6/ditch	2.064/1.861	34.40/31.02	10.32/9.305	12.90/11.63	5.160/4.653	0.024/0.022	0.516/0.465
R1/pond	0.074/0.103	1.233/1.717	0.370/0.515	0.463/0.644	0.185/0.258	0.001/0.001	0.019/0.026
R1/stream	1.519/1.340	25.32/22.33	7.595/6.700	9.494/8.375	3.798/3.350	0.018/0.016	0.380/0.335
R2/stream	2.042/1.801	34.03/30.02	10.21/9.005	12.76/11.26	5.105/4.503	0.024/0.021	0.511/0.450
R3/stream	2.139/1.894	35.65/31.57	10.70/9.470	13.37/11.84	5.348/4.735	0.025/0.022	0.535/0.474
R4/stream	1.523/1.344	25.38/22.40	7.615/6.720	9.519/8.400	3.808/3.360	0.018/0.016	0.381/0.336

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

zRMS comment:

The PEC_{sw}/RAC ratio for a.s.- pyraclostrobin for most scenarios for acute/chronic fish and aquatic invertebrates organism risk assessment are above trigger of 1 indicating needs for further refinement with Higher Tier assessment.

The lowest RAC is 0.06 µg/L for acute fish was considered further in the refined risk assessment.

METABOLITES OF PYRACLOSTROBIN

Table 9.5-11: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-11 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in sugarbeet (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 100000	EC ₅₀ 100000	E _r C ₅₀ 100000
AF		100	100	10
RAC (µg/L)		1000	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	10.88/21.77	0.011/0.022	0.011/0.022	0.001/0.002
Step 2				
S-Europe	1.17/2.14	0.001/0.002	0.001/0.002	<0.001/<0.001

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 9.5-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-11 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in tomato and eggplant (fruiting vegetables, BBCH 12 as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 100000	EC ₅₀ 100000	E _r C ₅₀ 100000
AF		100	100	10
RAC (µg/L)		1000	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	10.88/32.65	0.011/0.033	0.011/0.033	0.001/0.003
Step 2				
S-Europe	3.22/8.19	0.003/0.008	0.003/0.008	<0.001/0.001

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 9.5-13: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-11 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in carrots, beetroot, celery root, radish, horseradish, swedes, turnip, chicory roots and salsifies (root vegetables, BBCH 11 as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 100000	EC ₅₀ 100000	ErC ₅₀ 100000
AF		100	100	10
RAC (µg/L)		1000	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	10.88/21.77	0.011/0.022	0.011/0.022	0.001/0.002
Step 2				
S-Europe	3.22/5.94	0.003/0.006	0.003/0.006	<0.001/0.001

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 9.5-14: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-11 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in onion, shallot, onion “seven years old and ornamentals (bulb vegetables, BBCH 13 as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 100000	EC ₅₀ 100000	ErC ₅₀ 100000
AF		100	100	10
RAC (µg/L)		1000	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	10.88/21.77	0.011/0.022	0.011/0.022	0.001/0.002
Step 2				
S-Europe	3.81/7.09	0.004/0.007	0.004/0.007	<0.001/0.001

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 9.5-15: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-11 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in cabbage, strawberry, parsnip and parsley (leafy vegetables, BBCH 15 as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 100000	EC ₅₀ 100000	E _r C ₅₀ 100000
AF		100	100	10
RAC (µg/L)		1000	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	10.88/21.77	0.011/0.022	0.011/0.022	0.001/0.002
Step 2				
S-Europe	3.22/6.10	0.003/0.006	0.003/0.006	<0.001/0.001

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 9.5-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-11 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in cherry (apple early application as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 100000	EC ₅₀ 100000	E _r C ₅₀ 100000
AF		100	100	10
RAC (µg/L)		1000	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	9.17/18.34	0.009/0.018	0.009/0.018	0.001/0.002
Step 2				
S-Europe	2.98/5.35	0.003/0.005	0.003/0.005	<0.001/0.001

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 9.5-17: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-11 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in raspberry, blackcurrant, ornamentals, redcurrant and white currant (vines late application as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 100000	EC ₅₀ 100000	E _r C ₅₀ 100000
AF		100	100	10
RAC (µg/L)		1000	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	13.85/27.69	0.014/0.028	0.014/0.028	0.001/0.003
Step 2				
S-Europe	2.45/4.47	0.002/0.004	0.002/0.004	<0.001/<0.001

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 9.5-18: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-13 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in sugar beet (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 50000	EC ₅₀ 100000	E _r C ₅₀ >100000
AF		100	100	10
RAC (µg/L)		500	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	3.66/7.33	0.007/0.015	0.004/0.007	<0.001/0.001
Step 2				
S-Europe	0.39/0.72	0.001/0.001	<0.001/0.001	<0.001/<0.001

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 9.5-19: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-13 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in tomato and eggplant (fruiting vegetables, BBCH 12 as worst case) (fruiting vegetables) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 50000	EC ₅₀ 100000	E _r C ₅₀ >100000
AF		100	100	10
RAC (µg/L)		500	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	3.66/10.99	0.007/0.022	0.004/0.011	<0.001/0.001
Step 2				
S-Europe	1.09/2.76	0.002/0.006	0.001/0.003	<0.001/<0.001

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 9.5-20: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-13 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in carrots, beetroot, celery root, radish, horseradish, swedes, turnip, chicory roots and salsifies (root vegetables, BBCH 11 as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 50000	EC ₅₀ 100000	E _r C ₅₀ >100000
AF		100	100	10
RAC (µg/L)		500	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	3.66/7.33	0.007/0.015	0.004/0.007	<0.001/0.001
Step 2				
S-Europe	1.09/2.00	0.002/0.004	0.001/0.002	<0.001/<0.001

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 9.5-21: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-13 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in onion, shallot, onion “seven years old and ornamentals (bulb vegetables, BBCH 13 as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 50000	EC ₅₀ 100000	ErC ₅₀ >100000
AF		100	100	10
RAC (µg/L)		500	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	3.66/7.33	0.007/0.015	0.004/0.007	<0.001/0.001
Step 2				
S-Europe	1.28/2.39	0.003/0.005	0.001/0.002	<0.001/<0.001

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 9.5-22: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-13 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in cabbage, strawberry, parsnip and parsley (leafy vegetables, BBCH 15 as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 50000	EC ₅₀ 100000	ErC ₅₀ >100000
AF		100	100	10
RAC (µg/L)		500	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	3.66/7.33	0.007/0.015	0.004/0.007	<0.001/0.001
Step 2				
S-Europe	1.09/2.05	0.002/0.004	0.001/0.002	<0.001/<0.001

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 9.5-23: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-13 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in cherry (apple early application as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 50000	EC ₅₀ 100000	ErC ₅₀ >100000
AF		100	100	10
RAC (µg/L)		500	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	3.09/6.18	0.006/0.012	0.003/0.006	<0.001/0.001
Step 2				
S-Europe	1.00/1.80	0.002/0.004	0.001/0.002	<0.001/<0.001

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 9.5-24: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-13 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in raspberry, blackcurrant, ornamentals, redcurrant and white currant (vines late application as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 50000	EC ₅₀ 100000	ErC ₅₀ >100000
AF		100	100	10
RAC (µg/L)		500	1000	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	4.66/9.32	0.009/0.019	0.005/0.009	<0.001/0.001
Step 2				
S-Europe	0.82/1.49	0.002/0.003	0.001/0.001	<0.001/<0.001

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 9.5-25: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-14 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in sugar beet (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 39000	EC ₅₀ 61000	E _r C ₅₀ 100000
AF		100	100	10
RAC (µg/L)		390	610	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	7.08/14.16	0.018/0.036	0.012/0.023	0.001/0.001
Step 2				
S-Europe	0.76/1.39	0.002/0.004	0.001/0.002	<0.001/<0.001

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 9.5-26: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-14 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in tomato and eggplant (fruiting vegetables, BBCH 12 as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 39000	EC ₅₀ 61000	E _r C ₅₀ 100000
AF		100	100	10
RAC (µg/L)		390	610	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	7.08/21.24	0.018/0.054	0.012/0.035	0.001/0.002
Step 2				
S-Europe	2.10/5.33	0.005/0.014	0.003/0.009	<0.001/0.001

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 9.5-27: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-14 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in carrots, beetroot, celery root, radish, horseradish, swedes, turnip, chicory roots and salsifies (root vegetables, BBCH 11 as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 39000	EC ₅₀ 61000	ErC ₅₀ 100000
AF		100	100	10
RAC (µg/L)		390	610	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	7.08/14.16	0.018/0.036	0.012/0.023	0.001/0.001
Step 2				
S-Europe	2.10/3.86	0.005/0.010	0.003/0.006	<0.001/<0.001

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 9.5-28: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-14 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in onion, shallot, onion “seven years old” and ornamentals (bulb vegetables, BBCH 13 as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 39000	EC ₅₀ 61000	ErC ₅₀ 100000
AF		100	100	10
RAC (µg/L)		390	610	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	7.08/14.16	0.018/0.036	0.012/0.023	0.001/0.001
Step 2				
S-Europe	2.48/4.61	0.006/0.012	0.004/0.008	<0.001/<0.001

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 9.5-29: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-14 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in cabbage, strawberry, parsnip and parsley (leafy vegetables, BBCH 15 as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 39000	EC ₅₀ 61000	ErC ₅₀ 100000
AF		100	100	10
RAC (µg/L)		390	610	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	7.08/14.16	0.018/0.036	0.012/0.023	0.001/0.001
Step 2				
S-Europe	2.10/3.97	0.005/0.010	0.003/0.007	<0.001/<0.001

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 9.5-30: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-14 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in cherry (apple early application as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 39000	EC ₅₀ 61000	ErC ₅₀ 100000
AF		100	100	10
RAC (µg/L)		390	610	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	5.97/11.93	0.015/0.031	0.010/0.020	0.001/0.001
Step 2				
S-Europe	1.94/3.48	0.005/0.009	0.003/0.006	<0.001/<0.001

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 9.5-31: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for BF 500-14 for each organism group based on FOCUS Steps 1 and 2 calculations for the use of CASINO ROYALE in raspberry, blackcurrant, ornamentals, redcurrant and white currant (vines late application as worst case) (single/multiple application)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 39000	EC ₅₀ 61000	E _r C ₅₀ 100000
AF		100	100	10
RAC (µg/L)		390	610	10000
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	9.01/18.02	0.023/0.046	0.015/0.030	0.001/0.002
Step 2				
S-Europe	1.59/2.91	0.004/0.007	0.003/0.005	<0.001/<0.001

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

zRMS comment:

The PEC_{sw}/RAC ratio for metabolites of pyraclostrobin are below trigger of 1 indicating an acceptable risk assessment for aquatic organism.

BOSCALID

Table 9.5-32: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in sugarbeet (single/multiple application)

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		EC ₅₀ 2700	NOEC 125	EC ₅₀ 5330	NOEC 1310	EC ₅₀ 1340	NOEC 1000
AF		100	10	100	10	10	10
RAC (µg/L)		27	12.5	53.3	131	134	100
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
	70.68/141.35	2.618/5.235	5.654/11.308	1.326/2.652	0.540/1.079	0.527/1.055	0.707/1.414
Step 2							
S-Europe	8.16/15.64	0.302/0.579	0.653/ 1.251	0.153/0.293	0.062/0.119	0.061/0.117	0.082/0.156
N-Europe	6.18/11.72	0.229/0.434	0.494/0.938	0.116/0.220	0.047/0.089	0.046/0.087	0.062/0.117
Step 3							
D3/ditch	-/1.823	-/0.068	-/0.146	-/0.034	-/0.014	-/0.014	-/0.018
D4/pond	-/3.306	-/0.122	-/0.264	-/0.062	-/0.025	-/0.025	-/0.033
D4/stream	-/4.412	-/0.163	-/0.353	-/0.083	-/0.034	-/0.033	-/0.044
R1/pond	-/1.395	-/0.052	-/0.112	-/0.026	-/0.011	-/0.010	-/0.014
R1/stream	-/4.679	-/0.173	-/0.374	-/0.088	-/0.036	-/0.035	-/0.047
R3/stream	-/5.472	-/0.203	-/0.438	-/0.103	-/0.042	-/0.041	-/0.055

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

zRMS comments:

The PEC/RAC ratio for a.s.- boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in sugarbeet (single/multiple application) was below 1 indicated acceptable risk .

Table 9.5-33: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in tomato and eggplant (fruiting vegetables and potato, BBCH 12 as worst case) (single/multiple application)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		EC ₅₀ 2700	NOEC 125	EC ₅₀ 5330	NOEC 1310	EC ₅₀ 1340	NOEC 1000
AF		100	10	100	10	10	10
RAC (µg/L)		27	12.5	53.3	131	134	100
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
	70.68/212.03	2.618/7.853	5.654/16.962	1.326/3.978	0.540/ 1.619	0.527/ 1.582	0.707/ 2.120
Step 2							
S-Europe	22.04/62.78	0.816/ 2.325	1.763/5.022	0.414/ 1.178	0.168/0.479	0.164/0.469	0.220/0.628
N-Europe	12.13/33.81	0.449/ 1.252	0.970/ 2.705	0.228/0.634	0.093/0.258	0.091/0.252	0.121/0.338
Step 3							
D3/ditch	2.099/1.528	0.078/0.057	0.168/0.122	0.039/0.029	0.016/0.012	0.016/0.011	0.021/0.015
D4/pond	1.795/6.843	0.066/0.253	0.144/0.547	0.034/0.128	0.014/0.052	0.013/0.051	0.018/0.068
D4/stream	2.237/7.616	0.083/0.282	0.179/0.609	0.042/0.143	0.017/0.058	0.017/0.057	0.022/0.076
D6/ditch	2.556/7.344	0.095/0.272	0.204/0.588	0.048/0.138	0.020/0.056	0.019/0.055	0.026/0.073
R1/pond	0.389/1.011	0.014/0.037	0.031/0.081	0.007/0.019	0.003/0.008	0.003/0.008	0.004/0.010
R1/stream	3.383/8.229	0.125/0.305	0.271/0.658	0.063/0.154	0.026/0.063	0.025/0.061	0.034/0.082
R2/stream	2.213/2.794	0.082/0.103	0.177/0.224	0.042/0.052	0.017/0.021	0.017/0.021	0.022/0.028
R3/stream	4.144/9.703	0.153/0.359	0.332/0.776	0.078/0.182	0.032/0.074	0.031/0.072	0.041/0.097
R4/stream	6.441/-	0.239/-	0.515/-	0.121/-	0.049/-	0.048/-	0.064/-

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

zRMS comments:

The PEC/RAC ratio for a.s.-boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in tomato and eggplant (fruiting vegetables and potato, BBCH 12 as worst case) (single/multiple application) was below 1 indicated acceptable risk.

Table 9.5-34: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in carrots, beetroot, celery root, radish, horseradish, swedes, turnip, chicory roots and salsifies (root vegetables, BBCH 11 as worst case) (single/multiple application)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		EC ₅₀	NOEC	EC ₅₀	NOEC	EC ₅₀	NOEC
AF		2700	125	5330	1310	1340	1000
RAC (µg/L)		100	10	100	10	10	10
RAC (µg/L)		27	12.5	53.3	131	134	100
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
	70.68/141.35	2.618/5.235	5.654/11.308	1.326/2.652	0.540/ 1.079	0.527/ 1.055	0.707/ 1.414
Step 2							
S-Europe	22.04/43.04	0.816/ 1.594	1.763/3.443	0.414/0.808	0.168/0.329	0.164/0.321	0.220/0.430
N-Europe	12.13/23.47	0.449/0.869	0.970/ 1.878	0.228/0.440	0.093/0.179	0.091/0.175	0.121/0.235
Step 3							
D3/ditch	2.537/2.221	0.094/0.082	0.203/0.178	0.048/0.042	0.019/0.017	0.019/0.017	0.025/0.022
D6/ditch	2.891/6.026	0.107/0.223	0.231/0.482	0.054/0.113	0.022/0.046	0.022/0.045	0.029/0.060
R1/pond	0.501/0.866	0.019/0.032	0.040/0.069	0.009/0.016	0.004/0.007	0.004/0.006	0.005/0.009
R1/stream	3.559/6.032	0.132/0.223	0.285/0.483	0.067/0.113	0.027/0.046	0.027/0.045	0.036/0.060
R2 1 st /stream	2.210/2.590	0.082/0.096	0.177/0.207	0.041/0.049	0.017/0.020	0.016/0.019	0.022/0.026
R2 2 nd /stream	2.248/2.138	0.083/0.079	0.180/0.171	0.042/0.040	0.017/0.016	0.017/0.016	0.022/0.021
R3/stream	4.206/5.414	0.156/0.201	0.336/0.433	0.079/0.102	0.032/0.041	0.031/0.040	0.042/0.054
R4/stream	6.082/7.637	0.225/0.283	0.487/0.611	0.114/0.143	0.046/0.058	0.045/0.057	0.061/0.076

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

zRMS comments:

The PEC/RAC ratio for a.s.- boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in carrots, beetroot, celery root, radish, horseradish, swedes, turnip, chicory roots and salsifies (root vegetables, BBCH 11 as worst case) (single/multiple application) was below 1 indicated acceptable risk.

Table 9.5-35: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in onion, shallot, onion “seven years old and ornamentals (bulb vegetables, BBCH 13 as worst case) (single/multiple application)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		EC ₅₀ 2700	NOEC 125	EC ₅₀ 5330	NOEC 1310	EC ₅₀ 1340	NOEC 1000
AF		100	10	100	10	10	10
RAC (µg/L)		27	12.5	53.3	131	134	100
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
	70.68/141.35	2.618/5.235	5.654/11.308	1.326/2.652	0.540/ 1.079	0.527/ 1.055	0.707/ 1.414
Step 2							
S-Europe	26.01/50.95	0.963/ 1.887	2.081/4.076	0.488/0.956	0.199/0.389	0.194/0.380	0.260/0.510
N-Europe	14.11/27.42	0.523/ 1.016	1.129/2.194	0.265/0.514	0.108/0.209	0.105/0.205	0.141/0.274
Step 3							
D3/ditch	2.537/2.222	0.094/0.082	0.203/0.178	0.048/0.042	0.019/0.017	0.019/0.017	0.025/0.022
D4/pond	1.731/3.893	0.064/0.144	0.138/0.311	0.032/0.073	0.013/0.030	0.013/0.029	0.017/0.039
D4/stream	2.079/4.350	0.077/0.161	0.166/0.348	0.039/0.082	0.016/0.033	0.016/0.032	0.021/0.044
D6 1 st /ditch	3.293/6.237	0.122/0.231	0.263/0.499	0.062/0.117	0.025/0.048	0.025/0.047	0.033/0.062
D6 2 nd /ditch	11.39/19.55	0.422/0.724	0.911/ 1.564	0.214/0.367	0.087/0.149	0.085/0.146	0.114/0.196
R1/pond	0.429/0.830	0.016/0.031	0.034/0.066	0.008/0.016	0.003/0.006	0.003/0.006	0.004/0.008
R1/stream	3.625/5.285	0.134/0.196	0.290/0.423	0.068/0.099	0.028/0.040	0.027/0.039	0.036/0.053
R2/stream	2.213/2.064	0.082/0.076	0.177/0.165	0.042/0.039	0.017/0.016	0.017/0.015	0.022/0.021
R3/stream	3.386/7.539	0.125/0.279	0.271/0.603	0.064/0.141	0.026/0.058	0.025/0.056	0.034/0.075
R4/stream	5.679/10.76	0.210/0.399	0.454/0.861	0.107/0.202	0.043/0.082	0.042/0.080	0.057/0.108

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

zRMS comments:

The PEC/RAC ratio for a.s.-boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in onion, shallot, onion “seven years old and ornamentals (bulb vegetables, BBCH 13 as worst case) (single/multiple application) for all scenarios except D6 was below 1 indicated acceptable risk.

Further refinement is needed for D6 scenario only for chronic risk assessment for fish.

Table 9.5-36: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in cabbage, strawberry, parsnip and parsley (leafy vegetables, BBCH 15 as worst case) (single/multiple application)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		EC ₅₀ 2700	NOEC 125	EC ₅₀ 5330	NOEC 1310	EC ₅₀ 1340	NOEC 1000
AF		100	10	100	10	10	10
RAC (µg/L)		27	12.5	53.3	131	134	100
FOCUS Sce- nario	PEC _{gl-max} (µg/L)						
Step 1							
	70.68/141.35	2.618/5.235	5.654/11.308	1.326/2.652	0.540/1.079	0.527/1.055	0.707/1.414
Step 2							
S-Europe	22.04/43.24	0.816/ 1.601	1.763/3.459	0.414/0.811	0.168/0.330	0.164/0.323	0.220/0.432
N-Europe	12.13/23.57	0.449/0.873	0.970/ 1.886	0.228/0.442	0.093/0.180	0.091/0.176	0.121/0.236
Step 3							
D3 1 st /ditch	3.051/2.675	0.113/0.099	0.244/0.214	0.057/0.050	0.023/0.020	0.023/0.020	0.031/0.027
D3 2 nd /ditch	3.036/2.660	0.112/0.099	0.243/0.213	0.057/0.050	0.023/0.020	0.023/0.020	0.030/0.027
D4/pond	1.702/4.087	0.063/0.151	0.136/0.327	0.032/0.077	0.013/0.031	0.013/0.031	0.017/0.041
D4/stream	2.320/5.017	0.086/0.186	0.186/0.401	0.044/0.094	0.018/0.038	0.017/0.037	0.023/0.050
D6/ditch	7.978/18.81	0.295/0.697	0.638/ 1.505	0.150/0.353	0.061/0.144	0.060/0.140	0.080/0.188
R1 1 st /pond	0.857/1.813	0.032/0.067	0.069/0.145	0.016/0.034	0.007/0.014	0.006/0.014	0.009/0.018
R1 2 nd /pond	0.626/1.234	0.023/0.046	0.050/0.099	0.012/0.023	0.005/0.009	0.005/0.009	0.006/0.012
R1 1 st /stream	3.955/5.954	0.146/0.221	0.316/0.476	0.074/0.112	0.030/0.045	0.030/0.044	0.040/0.060
R1 2 nd /stream	2.779/6.266	0.103/0.232	0.222/0.501	0.052/0.118	0.021/0.048	0.021/0.047	0.028/0.063
R2 1 st /stream	2.662/2.302	0.099/0.085	0.213/0.184	0.050/0.043	0.020/0.018	0.020/0.017	0.027/0.023
R2 2 nd /stream	2.704/2.338	0.100/0.087	0.216/0.187	0.051/0.044	0.021/0.018	0.020/0.017	0.027/0.023
R3 1 st /stream	3.961/8.330	0.147/0.309	0.317/0.666	0.074/0.156	0.030/0.064	0.030/0.062	0.040/0.083
R3 2 nd /stream	4.177/8.301	0.155/0.307	0.334/0.664	0.078/0.156	0.032/0.063	0.031/0.062	0.042/0.083
R4 1 st /stream	5.896/13.33	0.218/0.494	0.472/ 1.066	0.111/0.250	0.045/0.102	0.044/0.099	0.059/0.133
R4 2 nd /stream	5.929/10.83	0.220/0.401	0.474/0.866	0.111/0.203	0.045/0.083	0.044/0.081	0.059/0.108

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

zRMS comments:

The PEC/RAC ratio for a.s.-boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in cabbage, strawberry, parsnip and parsley (leafy vegetables, BBCH 15 as worst case) (single/multiple application) except D6 and R4 was below 1 indicated acceptable risk.
Further refinement is needed for D6 and R4 scenario only for chronic risk assessment for fish.

Table 9.5-37: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in cherry (apple early application as worst case, BBCH 60) (single/multiple application)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		EC ₅₀ 2700	NOEC 125	EC ₅₀ 5330	NOEC 1310	EC ₅₀ 1340	NOEC 1000
AF		100	10	100	10	10	10
RAC (µg/L)		27	12.5	53.3	131	134	100
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
	70.71/141.41	2.619/5.237	5.657/11.313	1.327/2.653	0.540/ 1.079	0.528/ 1.055	0.707/ 1.414
Step 2							
S-Europe	25.99/39.51	0.963/ 1.463	2.079/3.161	0.488/0.741	0.198/0.302	0.194/0.295	0.260/0.395
N-Europe	25.99/36.36	0.963/ 1.347	2.079/2.909	0.488/0.682	0.198/0.278	0.194/0.271	0.260/0.364
Step 3							
D3/ditch	20.81/17.97	0.771/0.666	1.665/1.438	0.390/0.337	0.159/0.137	0.155/0.134	0.208/0.180
D4/pond	1.261/2.072	0.047/0.077	0.101/0.166	0.024/0.039	0.010/0.016	0.009/0.015	0.013/0.021
D4/stream	22.05/18.86	0.817/0.699	1.764/1.509	0.414/0.354	0.168/0.144	0.165/0.141	0.221/0.189
D5/pond	1.345/2.323	0.050/0.086	0.108/0.186	0.025/0.044	0.010/0.018	0.010/0.017	0.013/0.023
D5/stream	23.82/20.35	0.882/0.754	1.906/1.628	0.447/0.382	0.182/0.155	0.178/0.152	0.238/0.204
R1/pond	1.261/2.082	0.047/0.077	0.101/0.167	0.024/0.039	0.010/0.016	0.009/0.016	0.013/0.021
R1/stream	16.90/14.43	0.626/0.534	1.352/1.154	0.317/0.271	0.129/0.110	0.126/0.108	0.169/0.144
R2/stream	22.65/19.34	0.839/0.716	1.812/1.547	0.425/0.363	0.173/0.148	0.169/0.144	0.227/0.193
R3/stream	23.65/20.34	0.876/0.753	1.892/1.627	0.444/0.382	0.181/0.155	0.176/0.152	0.237/0.203
R4/stream	16.52/14.42	0.612/0.534	1.322/1.154	0.310/0.271	0.126/0.110	0.123/0.108	0.165/0.144

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

zRMS comments:

The PEC/RAC ratio for a.s.-boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in cherry (apple early application as worst case, BBCH 60) (single/multiple application) except D3, D4, D5 and R1(stream), R2, R3, R4 was below 1 indicated acceptable risk. Further refinement is needed for D3, D4, D5 and R1(stream), R2, R3, R4 scenarios for chronic risk assessment for fish.

Table 9.5-38: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in raspberry, blackcurrant, ornamentals, redcurrant and white currant (vines and apple late application as worst case, BBCH 61) (single/multiple application)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged
Test species		<i>O. mykiss</i>	<i>O. mykiss</i>	<i>D. magna</i>	<i>D. magna</i>	<i>P. subcapitata</i>	<i>C. riparius</i>
Endpoint (µg/L)		EC ₅₀ 2700	NOEC 125	EC ₅₀ 5330	NOEC 1310	EC ₅₀ 1340	NOEC 1000
AF		100	10	100	10	10	10
RAC (µg/L)		27	12.5	53.3	131	134	100
FOCUS Sce- nario	PEC _{gl-max} (µg/L)						
Step 1							
	93.44/186.87	3.461/6.921	7.475/14.950	1.753/3.506	0.713/1.426	0.697/1.395	0.934/1.869
Step 2							
S-Europe	17.28/32.54	0.640/ 1.205	1.382/2.603	0.324/0.611	0.132/0.248	0.129/0.243	0.173/0.325
N-Europe	14.10/26.26	0.522/0.973	1.128/2.101	0.265/0.493	0.108/0.200	0.105/0.196	0.141/0.263
Step 3							
D3/ditch	8.216/7.294	0.304/0.270	0.657/0.584	0.154/0.137	0.063/0.056	0.061/0.054	0.082/0.073
D4/pond	0.294/0.479	0.011/0.018	0.024/0.038	0.006/0.009	0.002/0.004	0.002/0.004	0.003/0.005
D4/stream	7.903/6.985	0.293/0.259	0.632/0.559	0.148/0.131	0.060/0.053	0.059/0.052	0.079/0.070
D6/ditch	8.124/7.391	0.301/0.274	0.650/0.591	0.152/0.139	0.062/0.056	0.061/0.055	0.081/0.074
R1/pond	0.346/0.761	0.013/0.028	0.028/0.061	0.006/0.014	0.003/0.006	0.003/0.006	0.003/0.008
R1/stream	6.038/5.327	0.224/0.197	0.483/0.426	0.113/0.100	0.046/0.041	0.045/0.040	0.060/0.053
R2/stream	8.117/7.161	0.301/0.265	0.649/0.573	0.152/0.134	0.062/0.055	0.061/0.053	0.081/0.072
R3/stream	8.502/7.530	0.315/0.279	0.680/0.602	0.160/0.141	0.065/0.057	0.063/0.056	0.085/0.075
R4/stream	6.055/5.342	0.224/0.198	0.484/0.427	0.114/0.100	0.046/0.041	0.045/0.040	0.061/0.053

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

zRMS comments:

The PEC/RAC ratio for a.s.-boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of CASINO ROYALE in raspberry, blackcurrant, ornamentals, redcurrant and white currant (vines and apple late application as worst case, BBCH 61) (single/multiple application) was below 1 indicated acceptable risk.

Pyraclostrobin: for all intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish as characterised by an LC_{50} for *Oncorhynchus mykiss* of 6 µg a.s./L in connection with an assessment factor of 100) in all FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies.

Metabolites of Pyraclostrobin: for all intended uses, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms. Therefore, no further assessment is necessary.

Boscalid: for all intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish as characterised by a NOEC for *Oncorhynchus mykiss* of 125 µg a.s./L in connection with an assessment factor of 10) in D6 2nd/ditch for bulb vegetables, D6/ditch and R4 1st/stream for leafy vegetables and D3 ditch, D4 stream, D5 stream, R1 stream, R2 stream, R3 stream and R4 stream for apple early application. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies.

Pyraclostrobin

Table 9.5-39: Aquatic organisms: PEC calculation and acceptability of risk ($PEC/RAC < 1$) for Pyraclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE in sugarbeet (single/multiple application)

Intended use		Sugar beet							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 100							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 ditch	0.172/0.144	0.091/0.075	0.062/0.050	0.047/-	-/-	-/-	-/-	-/-
50 %		0.086/0.072	0.046/0.037	0.031/-	-/-	-/-	-/-	-/-	-/-
75 %		0.043/0.036	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	0.178/0.149	0.094/0.077	0.064/0.052	0.049/-	-/-	-/-	-/-	-/-
50 %		0.089/0.074	0.047/0.039	-/-	-/-	-/-	-/-	-/-	-/-
75 %		0.044/0.037	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.153/-	0.081/-	0.079/-	0.079/-	0.153/0.128	0.081/0.067	0.055/0.052	0.042/0.035
50 %		0.079/-	0.079/-	-/-	-/-	0.077/0.096	0.041/0.067	-/-	-/-
75 %		0.079/-	0.079/-	-/-	-/-	0.052/0.096	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	0.215/-	0.114/-	0.085/-	0.085/-	0.215/0.181	0.114/0.094	0.078/0.063	0.059/0.048
50 %		0.108/-	0.085/-	-/-	-/-	0.108/0.090	0.057/0.050	0.039/0.038	-/-
75 %		0.085/-	0.085/-	-/-	-/-	0.055/0.071	-/-	-/-	-/-

Intended use		Sugar beet							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 100							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
90 %		0.085/-	-/-	-/-	-/-	-/0.071	-/-	-/-	-/-
RAC (µg/L)									
0.06									
PEC/RAC ratio									
None	D3 ditch	2.867/2.400	1.517/1.250	1.033/0.833	0.783/-	-/-	-/-	-/-	-/-
50 %		1.433/1.200	0.767/0.617	0.517/-	-/-	-/-	-/-	-/-	-/-
75 %		0.717/0.600	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	2.967/2.483	1.567/1.283	1.067/0.867	0.817/-	-/-	-/-	-/-	-/-
50 %		1.483/1.233	0.783/0.650	-/-	-/-	-/-	-/-	-/-	-/-
75 %		0.733/0.617	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	2.550/-	1.350/-	1.317/-	1.317/-	2.550/2.133	1.350/1.117	0.917/0.867	0.700/0.583
50 %		1.317/-	1.317/-	-/-	-/-	1.283/1.600	0.683/1.117	-/-	-/-
75 %		1.317/-	1.317/-	-/-	-/-	0.867/1.600	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	3.583/-	1.900/-	1.417/-	1.417/-	3.583/3.017	1.900/1.567	1.300/1.050	0.983/0.800
50 %		1.800/-	1.417/-	-/-	-/-	1.800/1.500	0.950/0.833	0.650/0.633	-/-
75 %		1.417/-	1.417/-	-/-	-/-	0.917/1.183	-/-	-/-	-/-
90 %		1.417/-	-/-	-/-	-/-	-/1.183	-/-	-/-	-/-

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

zRMS comment:

Pyraclostrobin- FOCUS STEP4 PEC_{sw} calculation and refined risk assessment

The PEC/RAC < 1 ratio for Pyraclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE **in sugarbeet (single/multiple application)** indicated an acceptable risk when following buffer zone will be applied to surfacewater bodies:

- 5 meter buffer zone +75 % drift reduction nozzels or 15 m drift buffer zone +50% drift reduction nozzels or 20 meter buffer zone for D3 and D4 scenarios
- 15 meter buffer zone +15 meter vegetative buffer strip or 20 meter buffer zone +20 meter vegetative buffer strip for R1 scenario
- 10 meter buffer strip + 10 meter vegetative buffer strip or 20 meter buffer zone +20 meter vegetative buffer strip for R3 scenario

Table 9.5-40: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE in tomato and eggplant (fruiting vegetables and potato, BBCH 12 as worst case) (single/multiple application)

Intended use		Fruiting vegetables and potato, BBCH 12 as worst case							
Active substance		Pyraclostrobin							
Application rate (g/ha)		3 x 100							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 ditch	0.172/0.123	0.091/0.064	0.062/0.044	0.047/-	-/-	-/-	-/-	-/-
50 %		0.086/0.0606	0.046/0.032	0.031/-	-/-	-/-	-/-	-/-	-/-
75 %		0.043/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	0.188/0.134	0.100/0.070	0.068/0.048	0.052/-	-/-	-/-	-/-	-/-
50 %		0.094/0.067	0.050/0.035	0.034/-	-/-	-/-	-/-	-/-	-/-
75 %		0.047/0.033	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch	0.169/0.122	0.090/0.064	0.0613/0.043	-/-	-/-	-/-	-/-	-/-
50 %		0.085/0.0607	0.045/0.032	-/-	-/-	-/-	-/-	-/-	-/-
75 %		0.042/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.150/-	0.092/-	0.092/-	-/-	0.150/0.130	0.080/0.091	0.054/0.071	0.041/-
50 %		0.092/-	0.092/-	-/-	-/-	0.075/0.130	0.042/-	-/-	-/-
75 %		0.092/-	-/-	-/-	-/-	0.060/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 stream	0.202/0.146	0.107/0.077	0.073/0.059	0.056/-	-/-	-/-	-/-	-/-
50 %		0.101/0.073	0.053/0.059	0.037/-	-/-	-/-	-/-	-/-	-/-
75 %		0.051/0.059	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	0.215/-	0.114/-	0.098/-	-/-	0.215/0.154	0.114/0.083	0.078/0.064	0.059/0.044
50 %		0.108/-	0.098/-	-/-	-/-	0.108/0.120	0.057/0.083	0.039/-	-/-
75 %		0.098/-	0.098/-	-/-	-/-	0.064/0.120	-/-	-/-	-/-
90 %		0.098/-	-/-	-/-	-/-	0.064/-	-/-	-/-	-/-
None	R4 stream	0.173/-	0.173/-	-/-	-/-	0.153/0.204	0.081/0.142	0.0605/0.109	0.042/0.074
50 %		0.173/-	-/-	-/-	-/-	0.113/0.204	0.079/0.142	-/-	-/-
75 %		-/-	-/-	-/-	-/-	0.113/-	0.079/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
RAC (µg/L)									

Intended use		Fruiting vegetables and potato, BBCH 12 as worst case							
Active substance		Pyraclostrobin							
Application rate (g/ha)		3 x 100							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
0.06 PEC/RAC ratio									
None	D3 ditch	2.867/2.050	1.517/1.067	1.033/0.733	0.783/-	-/-	-/-	-/-	-/-
50 %		1.433/1.010	0.767/0.533	0.517/-	-/-	-/-	-/-	-/-	-/-
75 %		0.717/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	3.133/2.233	1.667/1.167	1.133/0.800	0.867/-	-/-	-/-	-/-	-/-
50 %		1.567/1.117	0.833/0.583	0.567/-	-/-	-/-	-/-	-/-	-/-
75 %		0.783/0.550	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch	2.817/2.033	1.500/1.067	1.022/0.717	-/-	-/-	-/-	-/-	-/-
50 %		1.417/1.012	0.750/0.533	-/-	-/-	-/-	-/-	-/-	-/-
75 %		0.700/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	2.500/-	1.533/-	1.533/-	-/-	2.500/2.167	1.333/1.517	0.900/1.183	-/0.683
50 %		1.533/-	1.533/-	-/-	-/-	1.250/2.167	0.700/-	-/-	-/-
75 %		1.533/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 stream	3.367/2.433	1.783/1.283	1.217/0.983	0.933/-	-/-	-/-	-/-	-/-
50 %		1.683/1.217	0.883/0.983	0.617/-	-/-	-/-	-/-	-/-	-/-
75 %		0.850/0.983	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	3.583/-	1.900/-	1.633/-	-/-	3.583/2.567	1.900/1.383	1.300/1.067	0.983/0.733
50 %		1.800/-	1.633/-	-/-	-/-	1.800/2.000	0.950/1.383	0.650/-	-/-
75 %		1.633/-	1.633/-	-/-	-/-	1.067/2.000	-/-	-/-	-/-
90 %		1.633/-	-/-	-/-	-/-	1.067/-	-/-	-/-	-/-
None	R4 stream	2.883/-	2.883/-	-/-	-/-	2.550/3.400	1.350/2.367	1.008/1.817	0.700/1.233
50 %		2.883/-	-/-	-/-	-/-	1.883/3.400	1.317/2.367	-/-	-/-
75 %		-/-	-/-	-/-	-/-	1.883/-	1.317/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

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

zRMS comment:

Pyraclostrobin - FOCUS STEP4 PECsw calculations and refined risk assessment

The PEC/RAC < 1 ratio for Pyraclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE in tomato and eggplant (fruiting vegetables and potato, BBCH 12 as worst case) (single/multiple application) indicated an acceptable risk when following buffer zone will be applied to surfacewater bodies:

- 5 meter buffer zone +75 % drift reduction nozzels or 15 m drift buffer zone +50% drift reduction nozzels or 20 meter buffer zone for D3, D4 (stream) and D6 scenarios
- 20 meter buffer zone +20 meter vegetative buffer strip for R1, R2 and R3 scenario
- **An acceptable risk was not indicated for R4 scenario with 20 m DBZ and 10 VBS**

Table 9.5-41: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE in carrots, beetroot, celery root, radish, horseradish, swedes, turnip, chicory roots and salsifies (root vegetables, BBCH 11 as worst case) (single/multiple application)

Intended use		Root vegetables							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 100							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 ditch	0.172/0.144	0.091/0.075	0.062/0.050	0.047/-	-/-	-/-	-/-	-/-
50 %	D3 ditch	0.086/0.072	0.046/0.037	0.031/-	-/	-/-	-/-	-/-	-/-
75 %		0.043/0.036	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch	0.172/0.144	0.091/0.075	0.062/0.051	0.047/-	-/-	-/-	-/-	-/-
50 %	D6 ditch	0.086/0.072	0.046/0.038	0.031/-	-/-	-/-	-/-	-/-	-/-
75 %		0.043/0.036	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.153/-	0.093/-	0.093/-	-/-	0.153/0.128	0.091/0.077	0.055/0.059	0.042/-
50 %	R1 stream	0.093/-	0.093/-	-/-	-/-	0.076/0.111	0.042/0.077	-/-	-/-
75 %		0.093/-	-/-	-/-	-/-	0.061/0.111	-/-	-/-	-/-
None	R2 1 st stream	0.202/0.169	0.107/0.088	0.073/0.062	0.056/0.062	-/0.169	-/0.088	-/0.059	-/0.045
50 %	R2 1 st stream	0.101/0.084	0.054/0.062	0.037/0.062	-/-	-/0.084	-/0.044	-/-	-/-
75 %		0.050/0.062	-/0.062	-/-	-/-	-/0.042	-/-	-/-	-/-
None	R2 2 nd stream	0.205/0.172	0.109/0.089	0.074/0.0602	0.057/-	-/-	-/	-/-	-/-
50 %	R2 2 nd stream	0.103/0.086	0.054/0.045	0.037/-	-/-	-/-	-/-	-/-	-/-
75 %		0.051/0.043	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	0.215/	0.114/-	0.105/-	-/-	0.215/0.179	0.114/0.093	0.078/0.063	0.059/0.047
50 %	R3 stream	0.107/	0.105/-	-/-	-/-	0.107/0.097	0.057/0.068	0.039/0.052	-/-
75 %		0.105/	-/-	-/-	-/-	0.068/0.097	-/0.068	-/-	-/-
None	R4 stream	0.167/	0.167/-	-/-	-/-	0.151/0.180	0.080/0.125	0.058/0.096	0.042/0.066
50 %	R4 stream	0.167/	-/-	-/-	-/-	0.109/0.180	0.076/0.125	-/0.096	-/0.066
75 %		-/-	-/-	-/-	-/-	0.109/-	0.076/-	-/-	-/-
RAC (µg/L)									
0.06									
PEC/RAC ratio									
None	D3 ditch	2.867/2.400	1.517/1.250	1.033/0.833	0.783/-	-/-	-/-	-/-	-/-
50 %	D3 ditch	1.433/1.200	0.767/0.617	0.517/-	-/-	-/-	-/-	-/-	-/-
75 %		0.717/0.600	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch	2.867/2.400	1.517/1.250	1.033/0.850	0.783/-	-/-	-/-	-/-	-/-
50 %	D6 ditch	1.433/1.200	0.767/0.633	0.517/-	-/-	-/-	-/-	-/-	-/-

Intended use		Root vegetables							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 100							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
75 %		0.717/0.600	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	2.550/-	1.550/-	1.550/-	-/-	2.550/2.133	1.517/1.283	0.917/0.983	0.700/-
50 %		1.550/-	1.550/-	-/-	-/-	1.267/1.850	0.700/1.283	-/-	-/-
75 %		1.550/-	-/-	-/-	-/-	1.017/1.850	-/-	-/-	-/-
None	R2 1 st stream	3.367/2.817	1.783/1.467	1.217/1.033	0.933/1.033	-/2.817	-/1.467	-/0.983	-/0.750
50 %		1.683/1.400	0.900/1.033	0.617/1.033	-/-	-/1.400	-/0.733	-/-	-/-
75 %		0.833/1.033	-/1.033	-/-	-/-	-/0.700	-/-	-/-	-/-
None	R2 2 nd stream	3.417/2.867	1.817/1.483	1.233/1.003	0.950/-	-/-	-/-	-/-	-/-
50 %		1.717/1.433	0.900/0.750	0.617/-	-/-	-/-	-/-	-/-	-/-
75 %		0.850/0.717	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	3.583/-	1.900/-	1.750/-	-/-	3.583/2.983	1.900/1.550	1.300/1.050	0.983/0.783
50 %		1.783/-	1.750/-	-/-	-/-	1.783/1.617	0.950/1.133	0.650/0.867	-/-
75 %		1.750/-	-/-	-/-	-/-	1.133/1.617	-/1.133	-/-	-/-
None	R4 stream	2.783/-	2.783/-	-/-	-/-	2.517/3.000	1.333/2.083	0.967/1.600	0.700/1.100
50 %		2.783/-	-/-	-/-	-/-	1.817/3.000	1.267/2.083	-/1.600	-/1.100
75 %		-/-	-/-	-/-	-/-	1.817/-	1.267/-	-/-	-/-

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

zRMS comment:

Pyraclostrobin - FOCUS STEP4 PEC_{sw} calculations and refined risk assessment

The PEC/RAC < 1 ratio for Pyraclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE in carrots, beetroot, celery root, radish, horseradish, swedes, turnip, chicory roots and salsifies (root vegetables, BBCH 11 as worst case) (single/multiple application) indicated an acceptable risk when following buffer zone will be applied to surfacewater bodies:

- 20 meter buffer zone +20 meter vegetative buffer strip for R1 and R2 and R3 scenarios or 10 meter buffer zone +10 meter vegetative buffer strip with 50% drift reduction nozzels

No acceptable risk was not indicated for R4 scenario with 20 m DBZ and 10 VBS

Table 9.5-42: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE in onion, shallot, onion “seven years old and ornamentals (bulb vegetables, BBCH 13 as worst case) (single/multiple application)

Intended use		Bulb vegetables							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 100							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 ditch	0.172/0.144	0.091/0.075	0.062/0.051	0.047/-	-/-	-/-	-/-	-/-
50 %		0.086/0.072	0.046/0.037	0.031/-	-/-	-/-	-/-	-/-	-/-
75 %		0.043/0.036	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	0.175/0.146	0.093/0.076	0.063/0.051	0.048/-	-/-	-/-	-/-	-/-
50 %		0.088/0.073	0.046/0.038	0.032/-	-/-	-/-	-/-	-/-	-/-
75 %		0.044/0.037	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch 1 st	0.173/0.155	0.092/0.080	0.063/0.054	0.048/-	-/-	-/-	-/-	-/-
50 %		0.086/0.077	0.046/0.040	0.031/-	-/-	-/-	-/-	-/-	-/-
75 %		0.043/0.039	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch 2 nd	0.173/0.145	0.092/0.075	0.063/0.051	0.048/-	-/-	-/-	-/-	-/-
50 %		0.087/0.072	0.046/0.038	0.031/-	-/-	-/-	-/-	-/-	-/-
75 %		0.043/0.036	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.150/-	0.092/-	0.092/-	-/-	0.150/0.126	0.080/0.065	0.054/0.049	0.041/-
50 %		0.092/-	0.092/-	-/-	-/-	0.075/0.092	0.042/0.064	-/-	-/-
75 %		0.092/-	-/-	-/-	-/-	0.0601/0.092	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 stream	0.202/0.169	0.107/0.087	0.073/0.059	0.056/-	-/-	-/-	-/-	-/-
50 %		0.101/0.085	0.054/0.048	0.037/-	-/-	-/-	-/-	-/-	-/-
75 %		0.051/0.048	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	0.214/-	0.114/-	0.085/-	0.085/-	0.214/0.180	0.114/0.093	0.078/0.063	0.059/0.048
50 %		0.107/-	0.085/-	0.085/-	-/-	0.107/0.119	0.057/0.048	0.039/0.063	-/-
75 %		0.085/-	0.085/-	-/-	-/-	0.055/0.119	-/-	-/-	-/-
90 %		0.085/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 stream	0.156/-	0.156/-	-/-	-/-	0.152/0.206	0.088/0.143	0.055/0.110	0.042/0.075

Intended use		Bulb vegetables							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 100							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
50 %		0.156/-	-/-	-/-	-/-	0.101/0.206	0.071/0.143	-/-	-/-
75 %		-/-	-/-	-/-	-/-	0.101/-	0.071/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
RAC (µg/L)									
0.06									
PEC/RAC ratio									
None	D3 ditch	2.867/2.400	1.517/1.250	1.033/0.850	0.783/-	-/-	-/-	-/-	-/-
50 %		1.433/1.200	0.767/0.617	0.517/-	-/-	-/-	-/-	-/-	-/-
75 %		0.717/0.600	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	2.917/2.433	1.550/1.267	1.050/0.850	0.800/-	-/-	-/-	-/-	-/-
50 %		1.467/1.217	0.767/0.633	0.533/-	-/-	-/-	-/-	-/-	-/-
75 %		0.733/0.617	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch 1 st	2.883/2.583	1.533/1.333	1.050/0.900	0.800/-	-/-	-/-	-/-	-/-
50 %		1.433/1.283	0.767/0.667	0.517/-	-/-	-/-	-/-	-/-	-/-
75 %		0.717/0.650	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch 2 nd	2.883/2.417	1.533/1.250	1.050/0.850	0.800/-	-/-	-/-	-/-	-/-
50 %		1.450/1.200	0.767/0.633	0.517/-	-/-	-/-	-/-	-/-	-/-
75 %		0.717/0.600	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	2.500/-	1.533/-	1.533/-	-/-	2.500/2.100	1.333/1.083	0.900/0.817	0.683/-
50 %		1.533/-	1.533/-	-/-	-/-	1.250/1.533	0.700/1.067	-/-	-/-
75 %		1.533/-	-/-	-/-	-/-	1.002/1.533	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 stream	3.367/2.817	1.783/1.450	1.217/0.983	0.933/-	-/-	-/-	-/-	-/-
50 %		1.683/1.417	0.900/0.800	0.617/-	-/-	-/-	-/-	-/-	-/-
75 %		0.850/0.800	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	3.567/-	1.900/-	1.417/-	1.417/-	3.567/3.000	1.900/1.550	1.300/1.050	0.983/0.800
50 %		1.783/-	1.417/-	1.417/-	-/-	1.783/1.983	0.950/0.800	0.650/1.050	-/-
75 %		1.417/-	1.417/-	-/-	-/-	0.917/1.983	-/-	-/-	-/-
90 %		1.417/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

Intended use		Bulb vegetables							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 100							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	R4 stream	2.600/-	2.600/-	-/-	-/-	2.533/3.433	1.467/2.383	0.917/1.833	0.700/1.250
50 %		2.600/-	-/-	-/-	-/-	1.683/3.433	1.183/2.383	-/-	-/-
75 %		-/-	-/-	-/-	-/-	1.683/-	1.183/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

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

zRMS comment:

Pyraclostrobin - FOCUS STEP4 PECsw calculations and refined risk assessment

The PEC/RAC < 1 ratio for Pyraclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE in onion, shallot, onion “seven years old and ornamentals (bulb vegetables, BBCH 13 as worst case) (single/multiple application) when following buffer zone will be applied to surfacewater bodies:

- 5 meter buffer zone +75 % drift reduction nozzels or 15 m drift buffer zone +50% drift reduction nozzels or 20 meter buffer zone for D3 , D4 (stream) and D6 (ditch) and R2 scenarios
- 15 meter buffer zone +15 meter vegetative buffer strip or 20 meter buffer zone +20 meter vegetative buffer strip for R1 scenario
- 20 meter buffer zone +20 meter vegetative buffer strip for R3 scenario
- **No safe use for R4 scenario with 20 meter buffer zone +20 meter vegetative buffer strip**

Table 9.5-43: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE in cabbage, strawberry, parsnip and parsley (leafy vegetables, BBCH 15 as worst case) (single/multiple application)

Intended use		Leafy vegetables							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 121							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 1 st ditch	0.208/0.175	0.110/0.091	0.075/0.0611	0.057/-	-/-	-/-	-/-	-/-
50 %		0.104/0.087	0.055/0.045	0.038/-	-/-	-/-	-/-	-/-	-/-
75 %		0.051/0.044	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D3 2 nd ditch	0.207/0.174	0.110/0.090	0.075/0.0608	0.057/-	-/-	-/-	-/-	-/-
50 %		0.104/0.087	0.055/0.045	0.038/-	-/-	-/-	-/-	-/-	-/-
75 %		0.052/0.043	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	0.209/0.179	0.111/0.093	0.076/0.063	0.057/0.047	-/-	-/-	-/-	-/-
50 %		0.104/0.089	0.055/0.046	0.038/0.031	-/-	-/-	-/-	-/-	-/-
75 %		0.052/0.045	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch	0.205/0.173	0.109/0.090	0.074/0.0607	0.057/-	-/-	-/-	-/-	-/-
50 %		0.103/0.087	0.054/0.045	0.037/-	-/-	-/-	-/-	-/-	-/-
75 %		0.051/0.43	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 1 st stream	0.183/-	0.102/-	0.102/-	-/-	0.183/0.153	0.097/0.079	0.066/0.054	0.050/0.040
50 %		0.102/-	0.102/-	-/-	-/-	0.091/0.099	0.048/0.069	0.035/-	-/-
75 %		0.102/-	-/-	-/-	-/-	0.066/0.099	-/0.069	-/-	-/-
90 %		-/-	-/-	-/-	-/-	0.066/-	-/-	-/-	-/-
None	R1 2 nd stream	0.185/-	0.098/-	0.067/-	0.066/-	0.185/0.155	0.098/0.081	0.067/0.054	0.051/0.041
50 %		0.093/-	0.066/-	0.066/-	0.066/-	0.093/0.096	0.049/0.067	0.034/-	-/-
75 %		0.066/-	0.066/-	-/-	-/-	0.046/0.096	-/0.067	-/-	-/-
90 %		0.066/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 1 st stream	0.245/0.205	0.130/0.106	0.089/0.072	0.067/0.054	-/-	-/-	-/-	-/-
50 %		0.122/0.102	0.065/0.053	0.044/0.048	0.034/-	-/-	-/-	-/-	-/-
75 %		0.0612/0.051	0.032/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 2 nd	0.249/0.208	0.132/0.108	0.090/0.073	0.068/0.055	-/-	-/-	-/-	-/-

Intended use		Leafy vegetables							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 121							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
50 %	stream	0.124/0.104	0.066/0.054	0.045/0.036	0.034/-	-/-	-/-	-/-	-/-
75 %	stream	0.062/0.052	0.033/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		0.025/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream 1 st	0.261/-	0.139/-	0.099/-	0.099/-	0.261/0.219	0.139/0.114	0.095/0.077	0.072/0.058
50 %		0.131/-	0.099/-	0.099/-	-/-	0.131/0.133	0.069/0.093	0.047/0.071	0.036/-
75 %		0.099/-	0.099/-	-/-	-/-	0.065/0.133	0.045/0.093	-/-	-/-
90 %		0.099/-	-/-	-/-	-/-	0.065/-	-/-	-/-	-/-
None	R3 stream 2 nd	0.261/-	0.139/-	0.095/-	0.092/-	0.261/0.219	0.139/0.114	0.095/0.077	0.072/0.058
50 %		0.131/-	0.092/-	0.092/-	-/-	0.131/0.112	0.069/0.078	0.047/0.060	0.036/-
75 %		0.092/-	0.092/-	-/-	-/-	0.065/0.112	0.042/0.078	-/-	-/-
90 %		0.092/-	-/-	-/-	-/-	0.060/-	-/-	-/-	-/-
None	R4 stream 1 st	0.185/-	0.164/-	0.164/-	-/-	0.185/0.236	0.098/0.164	0.067/0.126	0.051/0.086
50 %		0.164/-	0.164/-	-/-	-/-	0.107/0.236	0.075/0.164	0.057/-	-/-
75 %		0.164/-	-/-	-/-	-/-	0.107/-	0.075/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 stream 2 nd	0.184/-	0.157/-	0.157/-	-/-	0.184/0.196	0.098/0.137	0.067/0.105	0.051/0.072
50 %		0.157/-	0.157/-	-/-	-/-	0.103/0.196	0.072/0.137	0.055/-	-/-
75 %		0.157/-	-/-	-/-	-/-	0.103/-	0.072/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
RAC (µg/L)									
0.06								PEC/RAC ratio	
None	D3 ditch 1 st	3.467/2.917	1.833/1.517	1.250/1.018	0.950/-	-/-	-/-	-/-	-/-
50 %		1.733/1.450	0.917/0.750	0.633/-	-/-	-/-	-/-	-/-	-/-
75 %		0.850/0.733	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D3 ditch 2 nd	3.450/2.900	1.833/1.500	1.250/1.013	0.950/-	-/-	-/-	-/-	-/-
50 %		1.733/1.450	0.917/0.750	0.633/-	-/-	-/-	-/-	-/-	-/-
75 %		0.867/0.717	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	3.483/2.983	1.850/1.550	1.267/1.050	0.950/0.783	-/-	-/-	-/-	-/-
50 %		1.733/1.483	0.917/0.767	0.633/0.517	-/-	-/-	-/-	-/-	-/-
75 %		0.867/0.750	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

Intended use		Leafy vegetables							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 121							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D6 ditch	3.417/2.883	1.817/1.500	1.233/1.012	0.950/-	-/-	-/-	-/-	-/-
50 %		1.717/1.450	0.900/0.750	0.617/-	-/-	-/-	-/-	-/-	-/-
75 %		0.850/7.167	-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 1 st stream	3.050/-	1.700/-	1.700/-	-/-	3.050/2.550	1.617/1.317	1.100/0.900	0.833/0.667
50 %		1.700/-	1.700/-	-/-	-/-	1.517/1.650	0.800/1.150	0.583/-	-/-
75 %		1.700/-	-/-	-/-	-/-	1.100/1.650	-/1.150	-/-	-/-
90 %		-/-	-/-	-/-	-/-	1.100/-	-/-	-/-	-/-
None	R1 2 nd stream	3.083/-	1.633/-	1.117/-	1.100/-	3.083/2.583	1.633/1.350	1.117/0.900	0.850/0.683
50 %		1.550/-	1.100/-	1.100/-	1.100/-	1.550/1.600	0.817/1.117	0.567/-	-/-
75 %		1.100/-	1.100/-	-/-	-/-	0.767/1.600	-/1.117	-/-	-/-
90 %		1.100/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 1 st stream	4.083/3.417	2.167/1.767	1.483/1.200	1.117/0.900	-/-	-/-	-/-	-/-
50 %		2.033/1.700	1.083/0.883	0.733/0.800	0.567/-	-/-	-/-	-/-	-/-
75 %		1.020/0.850	0.533/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 2 nd stream	4.150/3.467	2.200/1.800	1.500/1.217	1.133/0.917	-/-	-/-	-/-	-/-
50 %		2.067/1.733	1.100/0.900	0.750/0.600	0.567/-	-/-	-/-	-/-	-/-
75 %		1.033/0.867	0.550/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		0.417/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 1 st stream	4.350/-	2.317/-	1.650/-	1.650/-	4.350/3.650	2.317/1.900	1.583/1.283	1.200/0.967
50 %		2.183/-	1.650/-	1.650/-	-/-	2.183/2.217	1.150/1.550	0.783/1.183	0.600/-
75 %		1.650/-	1.650/-	-/-	-/-	1.083/2.217	0.750/1.550	-/-	-/-
90 %		1.650/-	-/-	-/-	-/-	1.083/-	-/-	-/-	-/-
None	R3 2 nd stream	4.350/-	2.317/-	1.583/-	1.533/-	4.350/3.650	2.317/1.900	1.583/1.283	1.200/0.967
50 %		2.183/-	1.533/-	1.533/-	-/-	2.183/1.867	1.150/1.300	0.783/1.000	0.600/-
75 %		1.533/-	1.533/-	-/-	-/-	1.083/1.867	0.700/1.300	-/-	-/-
90 %		1.533/-	-/-	-/-	-/-	1.000/-	-/-	-/-	-/-
None	R4 1 st stream	3.083/-	2.733/-	2.733/-	-/-	3.083/3.933	1.633/2.733	1.117/2.100	0.850/1.433
50 %		2.733/-	2.733/-	-/-	-/-	1.783/3.933	1.250/2.733	0.950/-	-/-
75 %		2.733/-	-/-	-/-	-/-	1.783/-	1.250/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 2 nd	3.067/-	2.617/-	2.617/-	-/-	3.067/3.267	1.633/2.283	1.117/1.750	0.850/1.200

Intended use		Leafy vegetables							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 121							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
50 %	stream	2.617/-	2.617/-	-/-	-/-	1.717/3.267	1.200/2.283	0.917/-	-/-
75 %		2.617/-	-/-	-/-	-/-	1.717/-	1.200/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

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

zRMS comment:

Pyraclostrobin - FOCUS STEP4 PECsw calculations and refined risk assessment

The PEC/RAC < 1 ratio for Pyraclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE in cabbage, strawberry, parsnip and parsley (leafy vegetables, BBCH 15 as worst case) (single/multiple application) when following buffer zone will be applied to surfacewater bodies:

- 5 meter buffer zone +75 % drift reduction nozzels or 15 m drift buffer zone +50% drift reduction nozzels or 20 meter buffer zone for D3, D4 (stream) and D6 (ditch) scenarios
- 20 meter buffer zone +20 meter vegetative buffer strip for R1 scenario
- 20 meter buffer zone + 50% drift reduction nozzels for R2 scenario
- 20 meter buffer zone +20 meter vegetative buffer strip + 50% drift reduction nozzels for R3 scenario
- **No safe use for R4 scenario with 20 meter buffer zone +20 meter vegetative buffer strip**

Table 9.5-44: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE in cherry (apple early application as worst case, BBCH 60) (single/multiple application)

Intended use		Apple early application							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 67							
Nozzl red.	Vegetative strip (m)	None							
	No spray buffer (m)	5	10	15	20	30	40	50	
None	D3 ditch	4.101/3.479	2.519/2.055	1.133/1.128	0.576/0.532	0.220/0.182	0.111/0.085	0.065/0.047	
50 %		2.051/1.739	1.260/1.028	0.567/0.564	0.288/0.266	0.110/0.091	0.055/0.043	0.033/-	

Intended use		Apple early application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 67						
Nozzl red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
75 %		1.026/0.870	0.630/0.514	0.283/0.282	0.144/0.133	0.055/0.046	-/-	-/-
90 %		0.410/0.348	0.252/0.206	0.113/0.113	0.058/0.059	-/-	-/-	-/-
None	D4 pond	0.356/0.562	0.195/0.319	0.103/0.167	0.063/0.096	0.031/0.043	-/-	-/-
50 %		0.178/0.281	0.098/0.159	0.052/0.084	0.032/0.048	-/-	-/-	-/-
75 %		0.089/0.140	0.049/0.080	-/0.042	-/-	-/-	-/-	-/-
90 %		0.036/0.056	-/0.032	-/-	-/-	-/-	-/-	-/-
None	D4 stream	4.755/4.019	2.920/2.374	1.314/1.303	0.668/0.615	0.255/0.211	0.129/0.099	0.075/0.054
50 %		2.377/2.009	1.460/1.187	0.657/0.652	0.334/0.307	0.128/0.106	0.064/0.049	0.038/-
75 %		1.189/1.005	0.730/0.594	0.329/0.326	0.167/0.154	0.064/0.053	0.032/-	-/-
90 %		0.476/0.402	0.292/0.237	0.131/0.130	0.067/0.0615	0.026/-	-/-	-/-
None	D5 pond	0.356/0.532	0.195/0.302	0.103/0.159	0.063/0.091	0.031/0.040	-/-	-/-
50 %		0.178/0.266	0.098/0.151	0.052/0.079	0.032/0.045	-/-	-/-	-/-
75 %		0.089/0.133	0.049/0.075	-/0.040	-/-	-/-	-/-	-/-
90 %		0.036/0.053	-/0.030	-/-	-/-	-/-	-/-	-/-
None	D5 stream	5.135/4.337	3.153/2.561	1.419/1.406	0.721/0.663	0.276/0.228	0.139/0.106	0.081/0.059
50 %		2.567/2.168	1.577/1.281	0.709/0.703	0.361/0.332	0.138/0.114	0.069/0.053	0.041/-
75 %		1.284/1.084	0.788/0.641	0.355/0.352	0.180/0.166	0.069/0.057	0.035/-	-/-
90 %		0.514/0.434	0.315/0.256	0.142/0.141	0.072/0.066	0.028/-	-/-	-/-
None	R1 pond	0.356/0.525	0.195/0.300	0.103/0.159	0.063/0.093	0.031/0.043	-/-	-/-
50 %		0.178/0.264	0.098/0.151	0.052/0.082	0.032/0.048	-/-	-/-	-/-
75 %		0.089/0.134	0.049/0.077	-/0.042	-/-	-/-	-/-	-/-
90 %		0.036/0.055	-/0.033	-/-	-/-	-/-	-/-	-/-
None	R1 stream	3.644/3.074	2.237/1.816	1.007/0.997	0.512/0.470	0.196/0.162	0.099/0.075	0.058/0.054
50 %		1.822/1.537	1.119/0.908	0.503/0.498	0.256/0.235	0.098/0.081	0.052/0.054	-/-
75 %		0.911/0.768	0.559/0.454	0.252/0.249	0.128/0.118	0.052/0.054	-/-	-/-
90 %		0.364/0.307	0.224/0.182	0.101/0.100	0.052/0.054	-/-	-/-	-/-
None	R2 stream	4.884/4.121	2.999/2.434	1.349/1.336	0.686/0.630	0.262/0.217	0.132/0.101	0.077/0.056
50 %		2.442/2.060	1.500/1.217	0.674/0.668	0.343/0.315	0.131/0.108	0.066/0.051	0.039-
75 %		1.221/1.030	0.750/0.609	0.337/0.334	0.171/0.158	0.066/0.054	0.033/-	-/-
90 %		0.488/0.412	0.300/0.243	0.135/0.134	0.069/0.063	0.026/-	-/-	-/-
None	R3 stream	5.099/4.334	3.131/2.560	1.409/1.405	0.716/0.663	0.274/0.228	0.138/0.106	0.081/0.059
50 %		2.549/2.166	1.566/1.280	0.704/0.702	0.358/0.331	0.137/0.114	0.069/0.053	0.040/-
75 %		1.275/1.083	0.783/0.640	0.352/0.351	0.179/0.166	0.068/0.057	0.034/-	-/-

Intended use		Apple early application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 67						
Nozzl red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
90 %		0.510/0.433	0.313/0.256	0.141/0.141	0.072/0.066	0.027/-	-/-	-/-
None	R4 stream	3.561/3.074	2.187/1.185	0.984/0.996	0.500/0.470	0.191/0.162	0.096/0.078	0.056/0.078
50 %		1.780/1.536	1.094/0.908	0.492/0.498	0.250/0.235	0.096/0.081	0.048/0.078	-/-
75 %		0.890/0.768	0.547/0.454	0.246/0.249	0.125/0.118	0.048/0.078	-/-	-/-
90 %		0.356/0.307	0.219/0.182	0.098/0.100	0.050/0.078	-/0.078	-/-	-/-
RAC (µg/L)								
0.06								
PEC/RAC ratio								
None	D3 ditch	68.350/57.983	41.983/34.250	18.883/18.800	9.600/8.867	3.667/3.033	1.850/1.417	1.083/0.783
50 %		34.183/28.983	21.000/17.133	9.450/9.400	4.800/4.433	1.833/1.517	0.917/0.717	0.550/-
75 %		17.100/14.500	10.500/8.567	4.717/4.700	2.400/2.217	0.917/0.767	-/-	-/-
90 %		6.833/5.800	4.200/3.433	1.883/1.883	0.967/0.983	-/-	-/-	-/-
None	D4 pond	5.933/9.367	3.250/5.317	1.717/2.783	1.050/1.600	0.517/0.717	-/-	-/-
50 %		2.967/4.683	1.633/2.650	0.867/1.400	0.533/0.800	-/-	-/-	-/-
75 %		1.483/2.333	0.817/1.333	-/0.700	-/-	-/-	-/-	-/-
90 %		0.600/0.933	-/0.533	-/-	-/-	-/-	-/-	-/-
None	D4 stream	79.250/66.983	48.667/39.567	21.900/21.717	11.133/10.250	4.250/3.517	2.150/1.650	1.250/0.900
50 %		39.617/33.483	24.333/19.783	10.950/10.867	5.567/5.117	2.133/1.767	1.067/0.817	0.633/-
75 %		19.817/16.750	12.167/9.900	5.483/5.433	2.783/2.567	1.067/0.883	0.533/-	-/-
90 %		7.933/6.700	4.867/3.950	2.183/2.167	1.117/1.025	0.433/-	-/-	-/-
None	D5 pond	5.933/8.867	3.250/5.033	1.717/2.650	1.050/1.517	0.517/0.667	-/-	-/-
50 %		2.967/4.433	1.633/2.517	0.867/1.317	0.533/0.750	-/-	-/-	-/-
75 %		1.483/2.217	0.817/1.250	-/0.667	-/-	-/-	-/-	-/-
90 %		0.600/0.883	-/0.500	-/-	-/-	-/-	-/-	-/-
None	D5 stream	85.583/72.283	52.550/42.683	23.650/23.433	12.017/11.050	4.600/3.800	2.317/1.767	1.350/0.983
50 %		42.783/36.133	26.283/21.350	11.817/11.717	6.017/5.533	2.300/1.900	1.150/0.883	0.683/-
75 %		21.400/18.067	13.133/10.683	5.917/5.867	3.000/2.767	1.150/0.950	0.583/-	-/-
90 %		8.567/7.233	5.250/4.267	2.367/2.350	1.200/1.100	0.467/-	-/-	-/-
None	R1 pond	5.933/8.750	3.250/5.000	1.717/2.650	1.050/1.550	0.517/0.717	-/-	-/-
50 %		2.967/4.400	1.633/2.517	0.867/1.367	0.533/0.800	-/-	-/-	-/-
75 %		1.483/2.233	0.817/1.283	-/0.700	-/-	-/-	-/-	-/-
90 %		0.600/0.917	-/0.550	-/-	-/-	-/-	-/-	-/-
None	R1 stream	60.733/51.233	37.283/30.267	16.783/16.617	8.533/7.833	3.267/2.700	1.650/1.250	0.967/0.900
50 %		30.367/25.617	18.650/15.133	8.383/8.300	4.267/3.917	1.633/1.350	0.867/0.900	-/-

Intended use		Apple early application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 67						
Nozzl red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
75 %		15.183/12.800	9.317/7.567	4.200/4.150	2.133/1.967	0.867/0.900	-/-	-/-
90 %		6.067/5.117	3.733/3.033	1.683/1.667	0.867/0.900	-/-	-/-	-/-
None	R2 stream	81.400/68.683	49.983/40.567	22.483/22.267	11.433/10.500	4.367/3.617	2.200/1.683	1.283/0.933
50 %		40.700/34.333	25.000/20.283	11.233/11.133	5.717/5.250	2.183/1.800	1.100/0.850	0.650/-
75 %		20.350/17.167	12.500/10.150	5.617/5.567	2.850/2.633	1.100/0.900	0.550/-	-/-
90 %		8.133/6.867	5.000/4.050	2.250/2.233	1.150/1.050	0.433/-	-/-	-/-
None	R3 stream	84.983/72.233	52.183/42.667	23.483/23.417	11.933/11.050	4.567/3.800	2.300/1.767	1.350/0.983
50 %		42.483/36.100	26.100/21.333	11.733/11.700	5.967/5.517	2.283/1.900	1.150/0.883	0.667/-
75 %		21.250/18.050	13.050/10.667	5.867/5.850	2.983/2.767	1.133/0.950	0.567/-	-/-
90 %		8.500/7.217	5.217/4.267	2.350/2.350	1.200/1.100	0.450/-	-/-	-/-
None	R4 stream	59.350/51.233	36.450/19.750	16.400/16.600	8.333/7.833	3.183/2.700	1.600/1.300	0.933/1.300
50 %		29.667/25.600	18.233/15.133	8.200/8.300	4.167/3.917	1.600/1.350	0.800/1.300	-/-
75 %		14.833/12.800	9.117/7.567	4.100/4.150	2.083/1.967	0.800/1.300	-/-	-/-
90 %		5.933/5.117	3.650/3.033	1.633/1.667	0.833/1.300	-/1.300	-/-	-/-

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

zRMS comment:

Pyraclostrobin - FOCUS STEP4 PEC_{sw} calculations and refined risk assessment:

The PEC/RAC < 1 ratio for Pyrclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE in cherry (apple early application as worst case, BBCH 60) (single/multiple application) when following buffer zone will be applied to surface water bodies:

- 50 meter buffer zone +50 % drift reduction nozzels for D3 (ditch), D4 (stream) and D5 (stream) scenarios
- 30 meter buffer zone for D5 pond, R1 pond
- 50 meter buffer zone for R1 scenario
- 50 meter buffer zone + 50% drift reduction nozzels for R2 and R3 scenarios
- **No safe use for R4 scenario with 50 meter buffer zone**

Table 9.5-45: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE in raspberry, blackcurrant, ornamentals, redcurrant and white currant (vines late application as worst case, BBCH 61) (single/multiple application)

Intended use		Vines late application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 121						
Nozzl red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
None	D3 ditch	1.250/1.105	0.453/0.397	0.273/0.239	0.159/0.138	0.085/0.074	0.055/0.047	-/-
50 %		0.625/0.553	0.226/0.198	0.137/0.119	0.079/0.069	0.043/0.037	-/-	-/-
75 %		0.313/0.276	0.113/0.099	0.068/0.060	0.040/0.035	-/-	-/-	-/-
90 %		0.125/0.111	0.045/0.040	0.027/-	-/-	-/-	-/-	-/-
None	D4 pond	0.086/0.136	0.047/0.074	-/0.054	-/-	-/-	-/-	-/-
50 %		0.048/0.068	-/0.037	-/-	-/-	-/-	-/-	-/-
75 %		-/0.034	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	1.207/1.064	0.437/0.382	0.264/0.230	0.153/0.133	0.082/0.071	0.053/0.045	-/-
50 %		0.604/0.532	0.219/0.191	0.132/0.115	0.077/0.066	0.041/0.035	-/-	-/-
75 %		0.302/0.266	0.109/0.096	0.066/0.057	0.038/0.033	-/-	-/-	-/-
90 %		0.121/0.106	0.044/0.038	0.026/-	-/-	-/-	-/-	-/-
None	D6 ditch	1.248/1.120	0.452/0.402	0.246/0.217	0.158/0.140	0.085/0.075	0.055/0.048	-/-
50 %		0.624/0.560	0.226/0.201	0.123/0.109	0.079/0.070	0.043/0.036	-/-	-/-
75 %		0.312/0.280	0.113/0.101	0.0614/0.054	0.040/0.035	-/-	-/-	-/-
90 %		0.125/0.112	0.045/0.040	-/-	-/-	-/-	-/-	-/-
None	R1 pond	0.086/0.119	0.047/0.066	-/0.045	-/-	-/-	-/-	-/-
50 %		0.043/0.060	-/0.036	-/-	-/-	-/-	-/-	-/-
75 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	1.107/0.973	0.401/0.350	0.218/0.189	0.141/0.166	0.081/0.166	0.081/-	-/-
50 %		0.553/0.487	0.200/0.175	0.109/0.166	0.081/0.166	0.081/-	-/-	-/-
75 %		0.277/0.244	0.100/0.166	0.081/0.166	0.081/-	-/-	-/-	-/-
90 %		0.111/0.166	0.081/0.166	0.081/-	-/-	-/-	-/-	-/-
None	R2 stream	1.488/1.309	0.539/0.470	0.293/0.254	0.189/0.164	0.102/0.087	0.065/0.056	0.046/-
50 %		0.744/0.655	0.269/0.235	0.146/0.127	0.095/0.082	0.051/0.044	0.033/-	-/-
75 %		0.372/0.327	0.135/0.118	0.073/0.064	0.047/0.041	-/-	-/-	-/-
90 %		0.149/0.131	0.054/0.047	0.029/0.025	-/-	-/-	-/-	-/-

Intended use		Vines late application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 121						
Nozzl red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
None	R3 stream	1.558/1.376	0.564/0.495	0.307/0.267	0.198/0.172	0.106/0.092	0.068/0.059	0.048/
50 %		0.779/0.688	0.282/0.247	0.153/0.134	0.099/0.086	0.053/0.046	0.034/-	-/-
75 %		0.389/0.344	0.141/0.124	0.077/0.067	0.049/0.045	-/-	-/-	-/-
90 %		0.156/0.138	0.056/0.049	0.031/0.045	-/-	-/-	-/-	-/-
None	R4 stream	1.110/0.976	0.402/0.351	0.218/0.190	0.141/0.122	0.076/0.074	0.049/0.074	-/-
50 %		0.555/0.488	0.201/0.175	0.109/0.095	0.070/0.074	0.038/0.074	-/-	-/-
75 %		0.277/0.244	0.101/0.088	0.055/0.074	0.035/0.074	-/-	-/-	-/-
90 %		0.111/0.098	0.040/0.074	-/0.074	-/-	-/-	-/-	-/-
RAC (µg/L)								
0.06								
PEC/RAC ratio								
None	D3 ditch	20.833/18.417	7.550/6.617	4.550/3.983	2.650/2.300	1.417/1.233	0.917/0.783	-/-
50 %		10.417/9.217	3.767/3.300	2.283/1.983	1.317/1.150	0.717/0.617	-/-	-/-
75 %		5.217/4.600	1.883/1.650	1.133/1.000	0.667/0.583	-/-	-/-	-/-
90 %		2.083/1.850	0.750/0.667	0.450/-	-/-	-/-	-/-	-/-
None	D4 pond	1.433/2.267	0.783/1.233	-/0.900	-/-	-/-	-/-	-/-
50 %		0.800/1.133	-/0.617	-/-	-/-	-/-	-/-	-/-
75 %		-/0.567	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	20.117/17.733	7.283/6.367	4.400/3.833	2.550/2.217	1.367/1.183	0.883/0.750	-/-
50 %		10.067/8.867	3.650/3.183	2.200/1.917	1.283/1.100	0.683/0.583	-/-	-/-
75 %		5.033/4.433	1.817/1.600	1.100/0.950	0.633/0.550	-/-	-/-	-/-
90 %		2.017/1.767	0.733/0.633	0.433/-	-/-	-/-	-/-	-/-
None	D6 ditch	20.800/18.667	7.533/6.700	4.100/3.617	2.633/2.333	1.417/1.250	0.917/0.800	-/-
50 %		10.400/9.333	3.767/3.350	2.050/1.817	1.317/1.167	0.717/0.600	-/-	-/-
75 %		5.200/4.667	1.883/1.683	1.023/0.900	0.667/0.583	-/-	-/-	-/-
90 %		2.083/1.867	0.750/0.667	-/-	-/-	-/-	-/-	-/-
None	R1 pond	1.433/1.983	0.783/1.100	-/0.750	-/-	-/-	-/-	-/-
50 %		0.717/1.000	-/0.600	-/-	-/-	-/-	-/-	-/-
75 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	18.450/16.217	6.683/5.833	3.633/3.150	2.350/2.767	1.350/2.767	1.350/-	-/-
50 %		9.217/8.117	3.333/2.917	1.817/2.767	1.350/2.767	1.350/-	-/-	-/-
75 %		4.617/4.067	1.667/2.767	1.350/2.767	1.350/-	-/-	-/-	-/-

Intended use		Vines late application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 121						
Nozzl red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
90 %		1.850/2.767	1.350/2.767	1.350/-	-/-	-/-	-/-	-/-
None	R2 stream	24.800/21.817	8.983/7.833	4.883/4.233	3.150/2.733	1.700/1.450	1.083/0.933	0.767/-
50 %		12.400/10.917	4.483/3.917	2.433/2.117	1.583/1.367	0.850/0.733	0.550/-	-/-
75 %		6.200/5.450	2.250/1.967	1.217/1.067	0.783/0.683	-/-	-/-	-/-
90 %		2.483/2.183	0.900/0.783	0.483/0.417	-/-	-/-	-/-	-/-
None	R3 stream	25.967/22.933	9.400/8.250	5.117/4.450	3.300/2.867	1.767/1.533	1.133/0.983	0.800/-
50 %		12.983/11.467	4.700/4.117	2.550/2.233	1.650/1.433	0.883/0.767	0.567/-	-/-
75 %		6.483/5.733	2.350/2.067	1.283/1.117	0.817/0.750	-/-	-/-	-/-
90 %		2.600/2.300	0.933/0.817	0.517/0.750	-/-	-/-	-/-	-/-
None	R4 stream	18.500/16.267	6.700/5.850	3.633/3.167	2.350/2.033	1.267/1.233	0.817/ 1.233	-/-
50 %		9.250/8.133	3.350/2.917	1.817/1.583	1.167/1.233	0.633/ 1.233	-/-	-/-
75 %		4.617/4.067	1.683/1.467	0.917/ 1.233	0.583/ 1.233	-/-	-/-	-/-
90 %		1.850/1.633	0.667/ 1.233	-/ 1.233	-/-	-/-	-/-	-/-

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

zRMS comment:

Pyraclostrobin - FOCUS STEP4 PEC_{sw} calculations and refined risk assessment:

The PEC/RAC < 1 ratio for Pyraclostrobin based on FOCUS Step 4 calculations and toxicity data for aquatic organisms with mitigation of spray drift and run-off for the use of CASINO ROYALE in raspberry, blackcurrant, ornamentals, redcurrant and white currant (vines late application as worst case, BBCH 61) (single/multiple application) when following buffer zone will be applied to surface water bodies:

- 40 meter buffer zone for D3 (ditch), D4 (stream) and D5 (stream) and D6 scenarios
- 15 meter buffer zone for D4 pond, R1 pond
- 50 meter buffer zone for R1 scenario
- 50 meter buffer zone for R2 and R3 scenarios
- **No safe use for R1 scenario with 50 meter buffer zone**
- **No safe use for R4 scenario with 40 meter buffer zone**

After step 4 calculations, the PEC/RAC ratio calculated were still above the trigger of 1 for:

- R4 stream scenario in fruiting vegetables
- R4 stream scenario in root vegetables
- R4 stream scenario in bulb vegetables
- R4 1st stream and R4 2nd stream scenarios in leafy vegetables
- R4 stream scenario in apple early application
- R1 stream and R4 stream scenarios in vines late application

Therefore, a further refinement was necessary.

Refinement of the risk assessment for the most sensitive group of aquatic organisms: Fish

In the monograph of Pyraclostrobin, acute toxicity laboratory studies of seven different fish species are available for Pyraclostrobin and for the representative formulation BAS 500 00 F (Pyraclostrobin 247.83 g a.s./L) . From this data it appears that the rainbow trout is the most sensitive species, but the carp (species tested in the mesocosm) is not the least sensitive species. The Applicant wishes to consider that the geomean value of LC₅₀ of 24.82 µg a.s./L from these seven different fish species studies with an assessment factor of 100 is more appropriate to use in the refinement of the risk. The value of the RAC obtained is **0.248 µg a.s./L**.

Moreover, together with the assessment using the RAC_{geomean}, new PEC/RAC calculations were included based on the RAC of 0.2 µg/L for chronic risk assessment to fish.

Table 9.5-46: Available LC₅₀ values for pyraclostrobin

Test item	Fish species	LC ₅₀ (mg a.s./L)
Pyraclostrobin	<i>Lepomis macrochirus</i>	0.0196
		0.0335
	<i>Oncorhynchus mykiss</i>	0.00616
Formulated (BAS 500 00 F)	<i>Cyprinus carpio</i>	0.0121
		0.0258
	<i>Oryzias latipes</i>	0.0325
		0.0885
	<i>Pimephales promelas</i>	0.012
		0.0235
	<i>Brachydanio rerio</i>	0.0417
		0.087
	<i>Leuciscus idus melanotus</i>	0.0135
		0.027
	Geomean (µg a.s./L)	24.82

Table 9.5-47: Fish: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and geomean toxicity data for acute fish with mitigation of spray drift and run-off for the use of CASINO ROYALE in sugar beet (single/multiple application)

Intended use		Sugar beet							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 100							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 ditch	0.172/0.144	0.091/0.075	0.062/0.050	0.047/-	-/-	-/-	-/-	-/-
None	D4 stream	0.178/0.149	0.094/0.077	0.064/0.052	0.049/-	-/-	-/-	-/-	-/-
None	R1 stream	0.153/-	0.081/-	0.079/-	0.079/-	0.153/0.128	0.081/0.067	0.055/0.052	0.042/0.035
None	R3 stream	0.215/-	0.114/-	0.085/-	0.085/-	0.215/0.181	0.114/0.094	0.078/0.063	0.059/0.048
RAC (µg/L)									
0.248		PEC/RAC ratio							
None	D3 ditch	0.694/0.581	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	0.718/0.601	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.617/0.000	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	0.867/0.000	-/-	-/-	-/-	-/-	-/-	-/-	-/-
RAC (µg/L)									
0.2		PEC/RAC ratio							
None	D3 ditch	0.860/0.720	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	0.890/0.745	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.765/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	1.075/-	0.570/-	-/-	-/-	1.075/0.905	0.570/0.470	-/-	-/-

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

Table 9.5-48: Fish: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and geomean toxicity data for acute fish with mitigation of spray drift and run-off for the use of CASINO ROYALE in tomato and eggplant (fruiting vegetables and potato, BBCH 12 as worst case) (single/multiple application)

Intended use		Fruiting vegetables and potato, BBCH 12 as worst case							
Active substance		Pyraclostrobin							
Application rate (g/ha)		3 x 100							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 ditch	0.172/0.123	0.091/0.064	0.062/0.044	0.047/-	-/-	-/-	-/-	-/-
None	D4 stream	0.188/0.134	0.100/0.070	0.068/0.048	0.052/-	-/-	-/-	-/-	-/-
None	D6 ditch	0.169/0.122	0.090/0.064	0.0613/0.043	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.150/-	0.092/-	0.092/-	-/-	0.150/0.130	0.080/0.091	0.054/0.071	0.041/-
None	R2 stream	0.202/0.146	0.107/0.077	0.073/0.059	0.056/-	-/-	-/-	-/-	-/-
None	R3 stream	0.215/-	0.114/-	0.098/-	-/-	0.215/0.154	0.114/0.083	0.078/0.064	0.059/0.044
None	R4 stream	0.173/-	0.173/-	-/-	-/-	0.153/0.204	0.081/0.142	0.0605/0.109	0.042/0.074
RAC (µg/L)									
0.248								PEC/RAC ratio	
None	D3 ditch	0.694/0.496	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	0.758/0.540	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch	0.681/0.492	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.605/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 stream	0.815/0.589	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	0.867/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 stream	0.698/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
RAC (µg/L)									
0.2								PEC/RAC ratio	
None	D3 ditch	0.860/0.615	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	0.940/0.670	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch	0.845/0.610	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.750/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 stream	1.010/0.730	0.535/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	1.075/-	0.570/-	-/-	-/-	1.075/0.770	0.570/-	-/-	-/-
None	R4 stream	0.865/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

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

Table 9.5-49: Fish: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and a geomean toxicity data for acute fish with mitigation of spray drift and run-off for the use of CASINO ROYALE in carrots, beetroot, celery root, radish, horseradish, swedes, turnip, chicory roots and salsifies (root vegetables, BBCH 11 as worst case) (single/multiple application)

Intended use		Root vegetables							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 100							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 ditch	0.172/0.144	0.091/0.075	0.062/0.050	0.047/-	-/-	-/-	-/-	-/-
None	D6 ditch	0.172/0.144	0.091/0.075	0.062/0.051	0.047/-	-/-	-/-	-/-	-/-
None	R1 stream	0.153/-	0.093/-	0.093/-	-/-	0.153/0.128	0.091/0.077	0.055/0.059	0.042/-
None	R2 1 st stream	0.202/0.169	0.107/0.088	0.073/0.062	0.056/0.062	-/0.169	-/0.088	-/0.059	-/0.045
None	R2 2 nd stream	0.205/0.172	0.109/0.089	0.074/0.0602	0.057/-	-/-	-/-	-/-	-/-
None	R3 stream	0.215/-	0.114/-	0.105/-	-/-	0.215/0.179	0.114/0.093	0.078/0.063	0.059/0.047
None	R4 stream	0.167/-	0.167/-	-/-	-/-	0.151/0.180	0.080/0.125	0.058/0.096	0.042/0.066
RAC (µg/L)									
0.248		PEC/RAC ratio							
None	D3 ditch	0.694/0.581	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch	0.694/0.581	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.617/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 1 st stream	0.815/0.681	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 2 nd stream	0.827/0.694	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	0.867/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 stream	0.673/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
RAC (µg/L)									
0.2		PEC/RAC ratio							
None	D3 ditch	0.860/0.720	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch	0.860/0.720	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.765/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 1 st stream	1.010/0.845	0.535/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 2 nd stream	1.025/0.860	0.545/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	1.075/-	0.570/-	-/-	-/-	1.075/0.895	0.570/-	-/-	-/-
None	R4 stream	0.835/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

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

Table 9.5-50: Fish: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and a geomean toxicity data for acute fish with mitigation of spray drift and run-off for the use of CASINO ROYALE in onion, shallot, onion “seven years old and ornamentals (bulb vegetables, BBCH 13 as worst case) (single/multiple application)

Intended use		Bulb vegetables							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 100							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 ditch	0.172/0.144	0.091/0.075	0.062/0.051	0.047/-	-/-	-/-	-/-	-/-
None	D4 stream	0.175/0.146	0.093/0.076	0.063/0.051	0.048/-	-/-	-/-	-/-	-/-
None	D6 1 st ditch	0.173/0.155	0.092/0.080	0.063/0.054	0.048/-	-/-	-/-	-/-	-/-
None	D6 2 nd ditch	0.173/0.145	0.092/0.075	0.063/0.051	0.048/-	-/-	-/-	-/-	-/-
None	R1 stream	0.150/-	0.092/-	0.092/-	-/-	0.150/0.126	0.080/0.065	0.054/0.049	0.041/-
None	R2 stream	0.202/0.169	0.107/0.087	0.073/0.059	0.056/-	-/-	-/-	-/-	-/-
None	R3 stream	0.214/-	0.114/-	0.085/-	0.085/-	0.214/0.180	0.114/0.093	0.078/0.063	0.059/0.0
None	R4 stream	0.156/-	0.156/-	-/-	-/-	0.152/0.206	0.088/0.143	0.055/0.110	0.042/0.0
RAC (µg/L)									
0.248									
PEC/RAC ratio									
None	D3 ditch	0.694/0.581	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	0.706/0.589	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 1 st ditch	0.698/0.625	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 2 nd ditch	0.698/0.585	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.605/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 stream	0.815/0.681	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	0.863/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 stream	0.629/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
RAC (µg/L)									
0.2									
PEC/RAC ratio									
None	D3 ditch	0.860/0.720	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	0.875/0.730	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 1 st ditch	0.865/0.775	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 2 nd ditch	0.865/0.725	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.750/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 stream	1.010/0.845	0.535/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	1.070/-	0.570/-	-/-	-/-	1.070/0.900	0.570/-	-/-	-/-
None	R4 stream	0.780/-	-/-	-/-	-/-	0.760/1.030	-/0.715	-/-	-/-

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

Table 9.5-51: Fish: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and a geomean toxicity data for acute fish with mitigation of spray drift and run-off for the use of CASINO ROYALE in cabbage, strawberry, parsnip and parsley (leafy vegetables, BBCH 15 as worst case) (single/multiple application)

Intended use		Leafy vegetables							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 121							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 1 st ditch	0.208/0.175	0.110/0.091	0.075/0.0611	0.057/-	-/-	-/-	-/-	-/-
None	D3 2 nd ditch	0.207/0.174	0.110/0.090	0.075/0.0608	0.057/-	-/-	-/-	-/-	-/-
None	D4 stream	0.209/0.179	0.111/0.093	0.076/0.063	0.057/0.047	-/-	-/-	-/-	-/-
None	D6 ditch	0.205/0.173	0.109/0.090	0.074/0.0607	0.057/-	-/-	-/-	-/-	-/-
None	R1 1 st stream	0.183/-	0.102/-	0.102/-	-/-	0.183/0.153	0.097/0.079	0.066/0.054	0.050/0.040
None	R1 2 nd stream	0.185/-	0.098/-	0.067/-	0.066/-	0.185/0.155	0.098/0.081	0.067/0.054	0.051/0.041
None	R2 1 st stream	0.245/0.205	0.130/0.106	0.089/0.072	0.067/0.054	-/-	-/-	-/-	-/-
None	R2 2 nd stream	0.249/0.208	0.132/0.108	0.090/0.073	0.068/0.055	-/-	-/-	-/-	-/-
50 %		0.124/0.104	0.066/0.054	0.045/0.036	0.034/-	-/-	-/-	-/-	-/-
None	R3 1 st stream	0.261/-	0.139/-	0.099/-	0.099/-	0.261/0.219	0.139/0.114	0.095/0.077	0.072/0.058
50 %		0.131/-	0.099/-	0.099/-	-/-	0.131/0.133	0.069/0.093	0.047/0.071	0.036/-
None	R3 2 nd stream	0.261/-	0.139/-	0.095/-	0.092/-	0.261/0.219	0.139/0.114	0.095/0.077	0.072/0.058
50 %		0.131/-	0.092/-	0.092/-	-/-	0.131/0.112	0.069/0.078	0.047/0.060	0.036/-
None	R4 1 st stream	0.185/-	0.164/-	0.164/-	-/-	0.185/0.236	0.098/0.164	0.067/0.126	0.051/0.086
None	R4 2 nd stream	0.184/-	0.157/-	0.157/-	-/-	0.184/0.196	0.098/0.137	0.067/0.105	0.051/0.072
RAC (µg/L)									
0.248									
PEC/RAC ratio									
None	D3 1 st ditch	0.839/0.706	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D3 2 nd ditch	0.835/0.702	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	0.843/0.722	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch	0.827/0.698	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 1 st stream	0.738/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 2 nd stream	0.746/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 1 st stream	0.988/0.827	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 2 nd stream	1.004/0.839	0.532/-	-/-	-/-	-/-	-/-	-/-	-/-
50 %		0.500/0.419	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 1 st stream	1.052/-	0.560/-	-/-	-/-	-/-	-/-	-/-	-/-
50 %		0.528/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 2 nd stream	1.052/-	0.560/-	-/-	-/-	-/-	-/-	-/-	-/-

Intended use		Leafy vegetables							
Active substance		Pyraclostrobin							
Application rate (g/ha)		2 x 121							
Nozzl red.	Vegetative strip (m)	None				5	10	15	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
50 %		0.528/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 1 st stream	0.746/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 2 nd stream	0.742/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
RAC (µg/L)									
0.2		PEC/RAC ratio							
None	D3 1 st ditch	1.040/0.875	0.550/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D3 2 nd ditch	1.035/0.870	0.550/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	1.045/0.895	0.555/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch	1.025/0.865	0.545/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 1 st stream	0.915/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 2 nd stream	0.925/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 1 st stream	1.225/1.025	0.650/0.530	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 2 nd stream	1.245/1.040	0.660/0.540	-/-	-/-	-/-	-/-	-/-	-/-
50 %		0.620/0.520	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 1 st stream	1.305/-	0.695/-	-/-	-/-	1.305/1.095	0.695/0.570	-/-	-/-
50 %		0.655/-	-/-	-/-	-/-	0.655/0.665	-/-	-/-	-/-
None	R3 2 nd stream	1.305/-	0.695/-	-/-	-/-	1.305/1.095	0.695/0.570	-/-	-/-
50 %		0.655/-	-/-	-/-	-/-	0.655/0.560	-/-	-/-	-/-
None	R4 1 st stream	0.925/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 2 nd stream	0.920/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

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

Table 9.5-52: Fish: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and a geomean toxicity data for acute fish with mitigation of spray drift and run-off for the use of CASINO ROYALE in cherry (apple early application as worst case, BBCH 60) (single/multiple application)

Intended use		Apple early application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 67						
Nozzle red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
None	D3 ditch	4.101/3.479	2.519/2.055	1.133/1.128	0.576/0.532	0.220/0.182	0.111/0.085	0.065/0.047
50 %		2.051/1.739	1.260/1.028	0.567/0.564	0.288/0.266	0.110/0.091	0.055/0.043	0.033/-
75 %		1.026/0.870	0.630/0.514	0.283/0.282	0.144/0.133	0.055/0.046	-/-	-/-
90 %		0.410/0.348	0.252/0.206	0.113/0.113	0.058/0.059	-/-	-/-	-/-
None	D4 pond	0.356/0.562	0.195/0.319	0.103/0.167	0.063/0.096	0.031/0.043	-/-	-/-
50 %		0.178/0.281	0.098/0.159	0.052/0.084	0.032/0.048	-/-	-/-	-/-
75 %		0.089/0.140	0.049/0.080	-/0.042	-/-	-/-	-/-	-/-
90 %		0.036/0.056	-/0.032	-/-	-/-	-/-	-/-	-/-
None	D4 stream	4.755/4.019	2.920/2.374	1.314/1.303	0.668/0.615	0.255/0.211	0.129/0.099	0.075/0.054
50 %		2.377/2.009	1.460/1.187	0.657/0.652	0.334/0.307	0.128/0.106	0.064/0.049	0.038/-
75 %		1.189/1.005	0.730/0.594	0.329/0.326	0.167/0.154	0.064/0.053	0.032/-	-/-
90 %		0.476/0.402	0.292/0.237	0.131/0.130	0.067/0.0615	0.026/-	-/-	-/-
None	D5 pond	0.356/0.532	0.195/0.302	0.103/0.159	0.063/0.091	0.031/0.040	-/-	-/-
50 %		0.178/0.266	0.098/0.151	0.052/0.079	0.032/0.045	-/-	-/-	-/-
75 %		0.089/0.133	0.049/0.075	-/0.040	-/-	-/-	-/-	-/-
90 %		0.036/0.053	-/0.030	-/-	-/-	-/-	-/-	-/-
None	D5 stream	5.135/4.337	3.153/2.561	1.419/1.406	0.721/0.663	0.276/0.228	0.139/0.106	0.081/0.059
50 %		2.567/2.168	1.577/1.281	0.709/0.703	0.361/0.332	0.138/0.114	0.069/0.053	0.041/-
75 %		1.284/1.084	0.788/0.641	0.355/0.352	0.180/0.166	0.069/0.057	0.035/-	-/-
90 %		0.514/0.434	0.315/0.256	0.142/0.141	0.072/0.066	0.028/-	-/-	-/-
None	R1 pond	0.356/0.525	0.195/0.300	0.103/0.159	0.063/0.093	0.031/0.043	-/-	-/-
50 %		0.178/0.264	0.098/0.151	0.052/0.082	0.032/0.048	-/-	-/-	-/-
75 %		0.089/0.134	0.049/0.077	-/0.042	-/-	-/-	-/-	-/-
90 %		0.036/0.055	-/0.033	-/-	-/-	-/-	-/-	-/-
None	R1 stream	3.644/3.074	2.237/1.816	1.007/0.997	0.512/0.470	0.196/0.162	0.099/0.075	0.058/0.054
50 %		1.822/1.537	1.119/0.908	0.503/0.498	0.256/0.235	0.098/0.081	0.052/0.054	-/-
75 %		0.911/0.768	0.559/0.454	0.252/0.249	0.128/0.118	0.052/0.054	-/-	-/-
90 %		0.364/0.307	0.224/0.182	0.101/0.100	0.052/0.054	-/-	-/-	-/-
None	R2 stream	4.884/4.121	2.999/2.434	1.349/1.336	0.686/0.630	0.262/0.217	0.132/0.101	0.077/0.056

Intended use		Apple early application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 67						
Nozzl red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
50 %		2.442/2.060	1.500/1.217	0.674/0.668	0.343/0.315	0.131/0.108	0.066/0.051	0.039-
75 %		1.221/1.030	0.750/0.609	0.337/0.334	0.171/0.158	0.066/0.054	0.033/-	-/-
90 %		0.488/0.412	0.300/0.243	0.135/0.134	0.069/0.063	0.026/-	-/-	-/-
None	R3 stream	5.099/4.334	3.131/2.560	1.409/1.405	0.716/0.663	0.274/0.228	0.138/0.106	0.081/0.059
50 %		2.549/2.166	1.566/1.280	0.704/0.702	0.358/0.331	0.137/0.114	0.069/0.053	0.040/-
75 %		1.275/1.083	0.783/0.640	0.352/0.351	0.179/0.166	0.068/0.057	0.034/-	-/-
90 %		0.510/0.433	0.313/0.256	0.141/0.141	0.072/0.066	0.027/-	-/-	-/-
None	R4 stream	3.561/3.074	2.187/1.185	0.984/0.996	0.500/0.470	0.191/0.162	0.096/0.078	0.056/0.078
50 %		1.780/1.536	1.094/0.908	0.492/0.498	0.250/0.235	0.096/0.081	0.048/0.078	-/-
75 %		0.890/0.768	0.547/0.454	0.246/0.249	0.125/0.118	0.048/0.078	-/-	-/-
90 %		0.356/0.307	0.219/0.182	0.098/0.100	0.050/0.078	-/0.078	-/-	-/-
RAC (µg/L)								
0.248		PEC/RAC ratio						
None	D3 ditch	16.536/14.028	10.157/8.286	4.569/4.548	2.323/2.145	0.887/0.734	-/-	-/-
50 %		8.270/7.012	5.081/4.145	2.286/2.274	1.161/1.073	0.444/0.367	-/-	-/-
75 %		4.137/3.508	2.540/2.073	1.141/1.137	0.581/0.536	-/-	-/-	-/-
90 %		1.653/1.403	1.016/0.831	0.456/0.456	-/-	-/-	-/-	-/-
None	D4 pond	1.435/2.266	0.786/1.286	0.415/0.673	-/-	-/-	-/-	-/-
50 %		0.718/1.133	0.395/0.641	-/-	-/-	-/-	-/-	-/-
75 %		0.359/0.565	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	19.173/16.206	11.774/9.573	5.298/5.254	2.694/2.480	1.028/0.851	0.520/0.399	-/-
50 %		9.585/8.101	5.887/4.786	2.649/2.629	1.347/1.238	0.516/0.427	-/-	-/-
75 %		4.794/4.052	2.944/2.395	1.327/1.315	0.673/0.621	-/-	-/-	-/-
90 %		1.919/1.621	1.177/0.956	0.528/0.524	-/-	-/-	-/-	-/-
None	D5 pond	1.435/2.145	0.786/1.218	0.415/0.641	-/-	-/-	-/-	-/-
50 %		0.718/1.073	0.395/0.609	-/-	-/-	-/-	-/-	-/-
75 %		0.359/0.536	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D5 stream	20.706/17.488	12.714/10.327	5.722/5.669	2.907/2.673	1.113/0.919	0.560/0.427	-/-
50 %		10.351/8.742	6.359/5.165	2.859/2.835	1.456/1.339	0.556/0.460	-/-	-/-
75 %		5.177/4.371	3.177/2.585	1.431/1.419	0.726/0.669	-/-	-/-	-/-
90 %		2.073/1.750	1.270/1.032	0.573/0.569	-/-	-/-	-/-	-/-

Intended use		Apple early application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 67						
Nozzl red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
None	R1 pond	1.435/2.117	0.786/1.210	0.415/0.641	-/-	-/-	-/-	-/-
50 %		0.718/1.065	0.395/0.609	-/-	-/-	-/-	-/-	-/-
75 %		0.359/0.540	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	14.694/12.395	9.020/7.323	4.060/4.020	2.065/1.895	0.790/0.653	-/-	-/-
50 %		7.347/6.198	4.512/3.661	2.028/2.008	1.032/0.948	0.395/0.327	-/-	-/-
75 %		3.673/3.097	2.254/1.831	1.016/1.004	0.516/0.476	-/-	-/-	-/-
90 %		1.468/1.238	0.903/0.734	-/-	-/-	-/-	-/-	-/-
None	R2 stream	19.694/16.617	12.093/9.815	5.440/5.387	2.766/2.540	1.056/0.875	0.532/0.407	-/-
50 %		9.847/8.306	6.048/4.907	2.718/2.694	1.383/1.270	0.528/0.435	-/-	-/-
75 %		4.923/4.153	3.024/2.456	1.359/1.347	0.690/0.637	-/-	-/-	-/-
90 %		1.968/1.661	1.210/0.980	0.544/0.540	-/-	-/-	-/-	-/-
None	R3 stream	20.560/17.476	12.625/10.323	5.681/5.665	2.887/2.673	1.105/0.919	0.556/0.427	-/-
50 %		10.278/8.734	6.315/5.161	2.839/2.831	1.444/1.335	0.552/0.460	-/-	-/-
75 %		5.141/4.367	3.157/2.581	1.419/1.415	0.722/0.669	-/-	-/-	-/-
90 %		2.056/1.746	1.262/1.032	0.569/0.569	-/-	-/-	-/-	-/-
None	R4 stream	14.359/12.395	8.819/4.778	3.968/4.016	2.016/1.895	0.770/0.653	-/-	-/-
50 %		7.177/6.194	4.411/3.661	1.984/2.008	1.008/0.948	0.387/0.327	-/-	-/-
75 %		3.589/3.097	2.206/1.831	0.992/1.004	0.504/0.476	-/-	-/-	-/-
90 %		1.435/1.238	0.883/0.734	-/-	-/-	-/-	-/-	-/-
RAC (µg/L)								
0.2								
PEC/RAC ratio								
None	D3 ditch	20.505/17.395	12.595/10.275	5.665/5.640	2.880/2.660	1.100/0.910	0.555/-	-/-
50 %		10.255/8.695	6.300/5.140	2.835/2.820	1.440/1.330	0.550/0.455	-/-	-/-
75 %		5.130/4.350	3.150/2.570	1.415/1.410	0.720/0.665	-/-	-/-	-/-
90 %		2.050/1.740	1.260/1.030	0.565/0.565	-/-	-/-	-/-	-/-
None	D4 pond	1.780/2.810	0.975/1.595	-/0.835	-/-	-/-	-/-	-/-
50 %		0.890/1.405	-/0.795	-/-	-/-	-/-	-/-	-/-
75 %		0.445/0.700	-/-	-/-	-/-	-/-	-/-	-/-
90 %		0.180/0.280	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	23.775/20.095	14.600/11.870	6.570/6.515	3.340/3.075	1.275/1.055	0.645/0.495	-/-
50 %		11.885/10.045	7.300/5.935	3.285/3.260	1.670/1.535	0.640/0.530	-/-	-/-
75 %		5.945/5.025	3.650/2.970	1.645/1.630	0.835/0.770	-/-	-/-	-/-

Intended use		Apple early application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 67						
Nozzl red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
90 %		2.380/2.010	1.460/1.185	0.655/0.650	-/-	-/-	-/-	-/-
None	D5 pond	1.780/2.660	0.975/ 1.510	-/0.795	-/-	-/-	-/-	-/-
50 %		0.890/ 1.330	-/0.755	-/-	-/-	-/-	-/-	-/-
75 %		0.445/0.665	-/-	-/-	-/-	-/-	-/-	-/-
90 %		0.180/0.265	-/-	-/-	-/-	-/-	-/-	-/-
None	D5 stream	25.675/21.685	15.765/12.805	7.095/7.030	3.605/3.315	1.380/1.140	0.695/0.530	-/-
50 %		12.835/10.840	7.885/6.405	3.545/3.515	1.805/1.660	0.690/0.570	-/-	-/-
75 %		6.420/5.420	3.940/3.205	1.775/1.760	0.900/0.830	-/-	-/-	-/-
90 %		2.570/2.170	1.575/1.280	0.710/0.705	-/-	-/-	-/-	-/-
None	R1 pond	1.780/2.625	0.975/ 1.500	-/0.795	-/-	-/-	-/-	-/-
50 %		0.890/ 1.320	-/0.755	-/-	-/-	-/-	-/-	-/-
75 %		0.445/0.670	-/-	-/-	-/-	-/-	-/-	-/-
90 %		0.180/0.275	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	18.220/15.370	11.185/9.080	5.035/4.985	2.560/2.350	0.980/0.810	-/-	-/-
50 %		9.110/7.685	5.595/4.540	2.515/2.490	1.280/1.175	0.490/0.405	-/-	-/-
75 %		4.555/3.840	2.795/2.270	1.260/1.245	0.640/0.590	-/-	-/-	-/-
90 %		1.820/1.535	1.120/0.910	0.505/-	-/-	-/-	-/-	-/-
None	R2 stream	24.420/20.605	14.995/12.170	6.745/6.680	3.430/3.150	1.310/1.085	0.660/0.505	-/-
50 %		12.210/10.300	7.500/6.085	3.370/3.340	1.715/1.575	0.655/0.540	-/-	-/-
75 %		6.105/5.150	3.750/3.045	1.685/1.670	0.855/0.790	-/-	-/-	-/-
90 %		2.440/2.060	1.500/1.215	0.675/0.670	-/-	-/-	-/-	-/-
None	R3 stream	25.495/21.670	15.655/12.800	7.045/7.025	3.580/3.315	1.370/1.140	0.690/0.530	-/-
50 %		12.745/10.830	7.830/6.400	3.520/3.510	1.790/1.655	0.685/0.570	-/-	-/-
75 %		6.375/5.415	3.915/3.200	1.760/1.755	0.895/0.830	-/-	-/-	-/-
90 %		2.550/2.165	1.565/1.280	0.705/0.705	-/-	-/-	-/-	-/-
None	R4 stream	17.805/15.370	10.935/5.925	4.920/4.980	2.500/2.350	0.955/0.810	-/-	-/-
50 %		8.900/7.680	5.470/4.540	2.460/2.490	1.250/1.175	0.480/0.405	-/-	-/-
75 %		4.450/3.840	2.735/2.270	1.230/1.245	0.625/0.590	-/-	-/-	-/-
90 %		1.780/1.535	1.095/0.910	0.490/-	-/-	-/-	-/-	-/-

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

Table 9.5-53: Fish: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyraclostrobin based on FOCUS Step 4 calculations and a geomean toxicity data for acute fish with mitigation of spray drift and run-off for the use of CASINO ROYALE in raspberry, blackcurrant, ornamentals, redcurrant and white currant (vines late application as worst case, BBCH 61) (single/multiple application)

Intended use		Vines late application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 121						
Nozzl red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
None	D3 ditch	1.250/1.105	0.453/0.397	0.273/0.239	0.159/0.138	0.085/0.074	0.055/0.047	-/-
50 %		0.625/0.553	0.226/0.198	0.137/0.119	0.079/0.069	0.043/0.037	-/-	-/-
75 %		0.313/0.276	0.113/0.099	0.068/0.060	0.040/0.035	-/-	-/-	-/-
90 %		0.125/0.111	0.045/0.040	0.027/-	-/-	-/-	-/-	-/-
None	D4 pond	0.086/0.136	0.047/0.074	-/0.054	-/-	-/-	-/-	-/-
50 %		0.048/0.068	-/0.037	-/-	-/-	-/-	-/-	-/-
75 %		-/0.034	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	1.207/1.064	0.437/0.382	0.264/0.230	0.153/0.133	0.082/0.071	0.053/0.045	-/-
50 %		0.604/0.532	0.219/0.191	0.132/0.115	0.077/0.066	0.041/0.035	-/-	-/-
75 %		0.302/0.266	0.109/0.096	0.066/0.057	0.038/0.033	-/-	-/-	-/-
90 %		0.121/0.106	0.044/0.038	0.026/-	-/-	-/-	-/-	-/-
None	D6 ditch	1.248/1.120	0.452/0.402	0.246/0.217	0.158/0.140	0.085/0.075	0.055/0.048	-/-
50 %		0.624/0.560	0.226/0.201	0.123/0.109	0.079/0.070	0.043/0.036	-/-	-/-
75 %		0.312/0.280	0.113/0.101	0.0614/0.054	0.040/0.035	-/-	-/-	-/-
90 %		0.125/0.112	0.045/0.040	-/-	-/-	-/-	-/-	-/-
None	R1 pond	0.086/0.119	0.047/0.066	-/0.045	-/-	-/-	-/-	-/-
50 %		0.043/0.060	-/0.036	-/-	-/-	-/-	-/-	-/-
75 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	1.107/0.973	0.401/0.350	0.218/0.189	0.141/0.166	0.081/0.166	0.081/-	-/-
50 %		0.553/0.487	0.200/0.175	0.109/0.166	0.081/0.166	0.081/-	-/-	-/-
75 %		0.277/0.244	0.100/0.166	0.081/0.166	0.081/-	-/-	-/-	-/-
90 %		0.111/0.166	0.081/0.166	0.081/-	-/-	-/-	-/-	-/-
None	R2 stream	1.488/1.309	0.539/0.470	0.293/0.254	0.189/0.164	0.102/0.087	0.065/0.056	0.046/-
50 %		0.744/0.655	0.269/0.235	0.146/0.127	0.095/0.082	0.051/0.044	0.033/-	-/-
75 %		0.372/0.327	0.135/0.118	0.073/0.064	0.047/0.041	-/-	-/-	-/-
90 %		0.149/0.131	0.054/0.047	0.029/0.025	-/-	-/-	-/-	-/-

Intended use		Vines late application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 121						
Nozzl red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
None	R3 stream	1.558/1.376	0.564/0.495	0.307/0.267	0.198/0.172	0.106/0.092	0.068/0.059	0.048/
50 %		0.779/0.688	0.282/0.247	0.153/0.134	0.099/0.086	0.053/0.046	0.034/-	-/-
75 %		0.389/0.344	0.141/0.124	0.077/0.067	0.049/0.045	-/-	-/-	-/-
90 %		0.156/0.138	0.056/0.049	0.031/0.045	-/-	-/-	-/-	-/-
None	R4 stream	1.110/0.976	0.402/0.351	0.218/0.190	0.141/0.122	0.076/0.074	0.049/0.074	-/-
50 %		0.555/0.488	0.201/0.175	0.109/0.095	0.070/0.074	0.038/0.074	-/-	-/-
75 %		0.277/0.244	0.101/0.088	0.055/0.074	0.035/0.074	-/-	-/-	-/-
90 %		0.111/0.098	0.040/0.074	-/0.074	-/-	-/-	-/-	-/-
RAC (µg/L)								
0.248								
PEC/RAC ratio								
None	D3 ditch	5.040/4.456	1.827/1.601	1.101/0.964	0.641/0.556	-/-	-/-	-/-
50 %		2.520/2.230	0.911/0.798	-/-	-/-	-/-	-/-	-/-
75 %		1.262/1.113	0.456/0.399	-/-	-/-	-/-	-/-	-/-
90 %		0.504/0.448	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 pond	0.347/0.548	-/-	-/-	-/-	-/-	-/-	-/-
50 %		0.194/0.274	-/-	-/-	-/-	-/-	-/-	-/-
75 %		-/0.137	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	4.867/4.290	1.762/1.540	1.065/0.927	0.617/0.536	-/-	-/-	-/-
50 %		2.435/2.145	0.883/0.770	-/-	-/-	-/-	-/-	-/-
75 %		1.218/1.073	0.440/0.387	-/-	-/-	-/-	-/-	-/-
90 %		0.488/0.427	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch	5.032/4.516	1.823/1.621	0.992/0.875	-/-	-/-	-/-	-/-
50 %		2.516/2.258	0.911/0.810	-/-	-/-	-/-	-/-	-/-
75 %		1.258/1.129	0.456/0.407	-/-	-/-	-/-	-/-	-/-
90 %		0.504/0.452	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 pond	0.347/0.480	-/-	-/-	-/-	-/-	-/-	-/-
50 %		0.173/0.242	-/-	-/-	-/-	-/-	-/-	-/-
75 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	4.464/3.923	1.617/1.411	0.879/0.762	-/-	-/-	-/-	-/-
50 %		2.230/1.964	0.806/0.706	-/-	-/-	-/-	-/-	-/-
75 %		1.117/0.984	0.403/0.669	-/-	-/-	-/-	-/-	-/-

Intended use		Vines late application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 121						
Nozzl red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
90 %		0.448/0.669	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 stream	6.000/5.278	2.173/1.895	1.181/1.024	0.762/0.661	-/-	-/-	-/-
50 %		3.000/2.641	1.085/0.948	0.589/0.512	-/-	-/-	-/-	-/-
75 %		1.500/1.319	0.544/0.476	-/-	-/-	-/-	-/-	-/-
90 %		0.601/0.528	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	6.282/5.548	2.274/1.996	1.238/1.077	0.798/0.694	-/-	-/-	-/-
50 %		3.141/2.774	1.137/0.996	0.617/0.540	-/-	-/-	-/-	-/-
75 %		1.569/1.387	0.569/0.500	-/-	-/-	-/-	-/-	-/-
90 %		0.629/0.556	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 stream	4.476/3.935	1.621/1.415	0.879/0.766	-/-	-/-	-/-	-/-
50 %		2.238/1.968	0.810/0.706	-/-	-/-	-/-	-/-	-/-
75 %		1.117/0.984	0.407/0.355	-/-	-/-	-/-	-/-	-/-
90 %		0.448/0.395	-/-	-/-	-/-	-/-	-/-	-/-
RAC (µg/L)								
0.2								
PEC/RAC ratio								
None	D3 ditch	6.250/5.525	2.265/1.985	1.365/1.195	0.795/0.690	-/-	-/-	-/-
50 %		3.125/2.765	1.130/0.990	0.685/-	-/-	-/-	-/-	-/-
75 %		1.565/1.380	0.565/0.495	-/-	-/-	-/-	-/-	-/-
90 %		0.625/0.555	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 pond	0.430/0.680	-/-	-/-	-/-	-/-	-/-	-/-
50 %		0.240/0.340	-/-	-/-	-/-	-/-	-/-	-/-
75 %		-/0.170	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	D4 stream	6.035/5.320	2.185/1.910	1.320/1.150	0.765/0.665	-/-	-/-	-/-
50 %		3.020/2.660	1.095/0.955	0.660/-	-/-	-/-	-/-	-/-
75 %		1.510/1.330	0.545/0.480	-/-	-/-	-/-	-/-	-/-
90 %		0.605/0.530	-/-	-/-	-/-	-/-	-/-	-/-
None	D6 ditch	6.240/5.600	2.260/2.010	1.230/1.085	0.790/0.700	-/-	-/-	-/-
50 %		3.120/2.800	1.130/1.005	0.615/0.545	-/-	-/-	-/-	-/-
75 %		1.560/1.400	0.565/0.505	-/-	-/-	-/-	-/-	-/-
90 %		0.625/0.560	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 pond	0.430/0.595	-/-	-/-	-/-	-/-	-/-	-/-
50 %		0.215/0.300	-/-	-/-	-/-	-/-	-/-	-/-

Intended use		Vines late application						
Active substance		Pyraclostrobin						
Application rate (g/ha)		2 x 121						
Nozzl red.	Vegetative strip (m)	None						
	No spray buffer (m)	5	10	15	20	30	40	50
75 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
90 %		-/-	-/-	-/-	-/-	-/-	-/-	-/-
None	R1 stream	5.535/4.865	2.005/1.750	1.090/0.945	0.705/-	-/-	-/-	-/-
50 %		2.765/2.435	1.000/0.875	0.545/-	-/-	-/-	-/-	-/-
75 %		1.385/1.220	0.500/0.830	-/-	-/-	-/-	-/-	-/-
90 %		0.555/0.830	-/-	-/-	-/-	-/-	-/-	-/-
None	R2 stream	7.440/6.545	2.695/2.350	1.465/1.270	0.945/0.820	-/-	-/-	-/-
50 %		3.720/3.275	1.345/1.175	0.730/0.635	-/-	-/-	-/-	-/-
75 %		1.860/1.635	0.675/0.590	-/-	-/-	-/-	-/-	-/-
90 %		0.745/0.655	-/-	-/-	-/-	-/-	-/-	-/-
None	R3 stream	7.790/6.880	2.820/2.475	1.535/1.335	0.990/0.860	-/-	-/-	-/-
50 %		3.895/3.440	1.410/1.235	0.765/0.670	-/-	-/-	-/-	-/-
75 %		1.945/1.720	0.705/0.620	-/-	-/-	-/-	-/-	-/-
90 %		0.780/0.690	-/-	-/-	-/-	-/-	-/-	-/-
None	R4 stream	5.550/4.880	2.010/1.755	1.090/0.950	0.705/-	-/-	-/-	-/-
50 %		2.775/2.440	1.005/0.875	0.545/-	-/-	-/-	-/-	-/-
75 %		1.385/1.220	0.505/0.440	-/-	-/-	-/-	-/-	-/-
90 %		0.555/0.490	-/-	-/-	-/-	-/-	-/-	-/-

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

zRMS comments:

It should be noted that according to EFSA ADG, 2009 the SSD approach for acute fish risk assessment is rather recommended than geomean approach for aquatic invertebrates:

In AGD, 2013: „Proposal for the derivation of RACs for aquatic organisms when a limited number of additional single species toxicity tests is available. When applying this approach scientific arguments should be given why the selected toxicity data (on which the Geomean is based) concern the same taxonomic group relevant for the RA. If more data than indicated in the second column (≥ 5 or ≥ 8) are available, the Geomean approach could still be applied, but it is recommended to preferably apply the SSD approach (see section 8.3)”.

Pyraclostrobin

Based on the geomean approach provided by the applicant it should be noted that RAC_{acute} based on this calculation ($0.248 \mu\text{g a.s./L}$, 7 species tested) is closed to $RAC_{chronic} = 0.2 \mu\text{g/L}$.

In addition, the difference in endpoints of acute toxicity tests is close to the endpoints from chronic tests for the most sensitive species for rainbow trout.

The applicant provided the refined risk assessment based on RAC_{geomean} approach for acute risk assessment. ~~No further refinement was provided for chronic risk.~~

~~In RMS's opinion the slight difference between the refined RAC_{acute} and RAC_{chronic} (Tier1) for fish seems doesn't change the final risk mitigation measures for fish.~~

~~However, for completeness the applicant should provide the relevant calculations based on RAC_{Cof} 0.2 $\mu\text{g/L}$ with STEP 4 PEC_{sw} for chronic risk assessment to long-term fish for request MSs, if relevant, during commenting period.~~

~~Based on the risk assessment the following risk mitigation measures are required:~~

~~Sugar beet, Fruiting vegetables and potato, Root vegetables and Bulb vegetables—Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 5 m to surface water bodies.~~

~~Leafy vegetables—Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 10 m with 5m vegetative strip to surface water bodies.~~

~~Apple (early application)—Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 40 m to surface water bodies OR respect an unsprayed buffer zone of 30 m to surface water bodies with 50% of nozzles reduction OR respect an unsprayed buffer zone of 20 m to surface water bodies with 75% of nozzles reduction OR respect an unsprayed buffer zone of 15 m to surface water bodies with 90% of nozzles reduction.~~

~~Vines (late application)—Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 20 m to surface water bodies OR respect an unsprayed buffer zone of 15 m to surface water bodies with 50% of nozzles reduction OR respect an unsprayed buffer zone of 10 m to surface water bodies with 75% of nozzles reduction OR respect an unsprayed buffer zone of 5 m to surface water bodies with 90% of nozzles reduction.~~

~~It should be noted, that if any of refinement option for a.s. pyraclostrobin (geomean approach for acute risk for fish , chronic risk for fish) for aquatic organism is not accepted by some MSs, they should conclude this issue on MS level.~~

The applicant provided the new calculations of chronic risk assessment during Commenting Period and the final conclusion was updated below:

For completeness reasons, together with the assessment using the RAC_{geomean} , new PEC/RAC calculations were included based on the **RAC of 0.2 $\mu\text{g/L}$ for Pyraclostrobin** for chronic risk assessment to fish. After this refinement, an acceptable risk was obtained **for the worst case scenario for each uses** with the following mitigation measures:

Pyraclostrobin

- Sugar beet: no-spray buffer zone of 10 m
- Fruiting vegetables and potato: no-spray buffer zone of 10 m
- Root vegetables: no-spray buffer zone of 10 m
- Bulb vegetables: no-spray buffer zone of 10 m
- Leafy vegetables: no-spray buffer zone of 10 m
- Apple (early application): no-spray buffer zone of 40 m OR no-spray buffer zone of 30 m + 50% nozzles OR no-spray buffer zone of 20 m + 75% nozzles OR no-spray buffer zone of 15 m + 90% nozzles
- Vines (late application): no-spray buffer zone of 20 m OR no-spray buffer zone of 15 m + 50% nozzles OR no-spray buffer zone of 10 m + 75% nozzles OR no-spray buffer zone of 5 m + 90%

nozzles

In addition, it should be indicated that greenhouse uses are considered acceptable.

Finally, the final risk mitigation measures should be decided at MSs level depen on the relevant scenarios for each countries.

Refinement of the risk assessment for the other aquatic organisms

An aquatic mesocosm study in outdoor consitions (*Dohmen, G.P, 2000*) was submitted in the *Monograph of Pyraclostrobin Annex B.9: Ecotoxicology (2001)*. A large number of different species (approximately 260 taxa) was observed in this mesocosm study at varying abundances during the course of the experiment. The results of a complex mesocosm study show, that BAS 500 F can have effects on few species at concentrations of 24 µg as/L (equivalent to the nine-fold of the 5% drift scenario) and higher. Fish and molluscs may be affected at this concentration, too. For all planktonic species the effects were found to be reversible. No clear effects were observed at 8 µg as/L, which is equivalent to the threefold of a 5% drift scenario in shallow, static water bodies. The multitude of endpoints and species and environmental conditions in this mesocosm study show clearly that at this (8 µg as/L and lower) concentration no adverse effects on aquatic communities can be expected even after multiple applications. The ecologically acceptable concentration (EAC) is thus > 8 µg as/L. Therefore the results obtained were:

NOEC: 8 µg as/L.

LOEC: 24 µg/L

EAC: > 8 µg as/L

The Applicant wishes consider that the use of the derived NOEC value of 8 µg/L from the mesocosm study with an assessment factor of 4 as worst case, according to the EFSA *Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters* (EFSA Journal 2013;11(7):3290). Therefore a RAC of 2 µg/L has been considered for refinement of the risk assessment for other aquatic organisms than fish.

Table 9.5-54: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Pyrclostrobin based on FOCUS Step 2-3 calculations and toxicity data from mesocosm study for the use of CASINO ROYALE

Group		Higher-tier information
Test species		Species sp. (≈260 taxa)
Endpoint (µg/L)		NOEC
AF		8
RAC (µg/L)		4
FOCUS scenario	PEC _{gl-max} (µg/L)	2
Sugar beet, 2 x 100 g a.s./ha		
FOCUS Step2	0.92/0.89	0.46/0.45
Fruiting vegetables and potato, 3 x 100 g a.s./ha		
FOCUS Step2	0.92/2.05	0.46/ 1.03
D6/ditch*	0.624/0.459	0.31/0.23

Group		Higher-tier information
Root vegetables, 2 x 100 g a.s./ha		
FOCUS Step2	0.92/1.50	0.46/0.75
Bulb vegetables, 2 x 100 g a.s./ha		
FOCUS Step2	0.97/1.79	0.49/0.90
Leafy vegetables, 2 x 121 g a.s./ha		
FOCUS Step2	0.92/1.55	0.46/0.78
Apple early application, 2 x 67 g a.s./ha		
FOCUS Step2	6.52/6.32	3.26/3.16
Step 3 D5/stream*	5.977/5.107	2.99/2.55
Step 4 D5 stream (15m buffer, none nozzles)**	1.419/1.406	0.71/0.70
Vines and apple late application, 2 x 121 g a.s./ha		
FOCUS Step2	3.24/3.17	1.62/1.59
Step 3 R3/stream*	2.139/1.894	1.07/0.95
Step 4 R3 stream (5m buffer, none nozzles)**	1.558/1.376	0.78/0.69

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

*Worst FOCUS step 3 scenario.

**Worst FOCUS step 4 scenario.

zRMS comment:

We agree with refinement risk assessment based on RAC of 2 µg a.s./L obtained from mesocosms study evaluated at EU level. The used AF of 4 representing conservative approach is sufficient to cover all uncertainty from one available mesocosm study.

The risk PEC/RAC is below 1 when the risk mitigation measures for the worst case scenario are applied to surface water bodies:

- for D5 scenario 15 meter buffer zone for use in apple early application, 2 x 67 g a.s./ha
- for R3 scenario 5meter buffer zone

The final risk mitigation measures should be applied to surface water bodies at MSs level.

Boscalid

Table 9.5-55: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Boscalid based on FOCUS Step 4 calculations and toxicity data for chronic fish with mitigation of spray drift and run-off for the use of CASINO ROYALE in onion, shallot, onion “seven years old and ornamentals (bulb vegetables, BBCH 13 as worst case) (single/multiple application)

Intended use		Bulb vegetables
Active substance		Boscalid
Application rate (g/ha)		2 x 400
Nozzle reduction	Vegetative strip (m)	None
	No spray buffer (m)	5
None	D6 2 nd ditch	-/19.55
RAC (µg/L)		

Intended use		Bulb vegetables
Active substance		Boscalid
Application rate (g/ha)		2 x 400
Nozzle reduction	Vegetative strip (m)	None
	No spray buffer (m)	5
12.5		PEC/RAC ratio
None	D6 2 nd ditch	-/1.564

Table 9.5-56: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Boscalid based on FOCUS Step 4 calculations and toxicity data for chronic fish with mitigation of spray drift and run-off for the use of CASINO ROYALE in cabbage, strawberry, parsnip and parsley (leafy vegetables, BBCH 15 as worst case) (single/multiple application)

Intended use		Leafy vegetables		
Active substance		Boscalid		
Application rate (g/ha)		2 x 481		
Nozzle reduction	Vegetative strip (m)	None	5	10
	No spray buffer (m)	5	5	10
None	D6 ditch	-/18.81	-/-	-/-
None	R4 1 st stream	-/13.33	-/8.693	-/6.991
RAC (µg/L)				
12.5		PEC/RAC ratio		
None	D6 ditch	-/1.505	-/-	-/-
None	R4 1 st stream	-/1.066	-/0.695	-/0.559

Table 9.5-57: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Boscalid based on FOCUS Step 4 calculations and toxicity data for chronic fish with mitigation of spray drift and run-off for the use of CASINO ROYALE in cherry (apple early application as worst case, BBCH 60) (single/multiple application)

Intended use		Apple early application		
Active substance		Boscalid		
Application rate (g/ha)		2 x 267		
Nozzle reduction	Vegetative strip (m)	None		
	No spray buffer (m)	5	10	15
None	D3 ditch	16.35/13.85	10.04/8.184	-/-
50 %		8.172/6.927	-/-	-/-
None	D4 stream	18.95/16.01	11.63/9.461	-/-
50 %		9.475/8.007	-/-	-/-
None	D5 stream	20.46/17.28	12.56/10.21	5.652/-
50 %		10.23/8.638	6.282/-	-/-
None	R1 stream	14.52/12.25	8.915/-	-/-
50 %		7.261/-	-/-	-/-
None	R2 stream	19.46/16.42	11.95/9.699	-/-
50 %		9.732/8.209	-/-	-/-
None	R3 stream	20.32/17.26	12.48/10.20	-/-
50 %		10.16/8.632	-/-	-/-
None	R4 stream	14.19/12.25	8.714/-	-/-
50 %		7.097/-	-/-	-/-
RAC (µg/L)				
12.5		PEC/RAC ratio		
None	D3 ditch	1.308/1.108	0.803/0.655	-/-
50 %		0.654/0.554	-/-	-/-
None	D4 stream	1.516/1.281	0.930/0.757	-/-
50 %		0.758/0.641	-/-	-/-
None	D5 stream	1.637/1.382	1.005/0.817	0.452/-
50 %		0.818/0.691	0.503/-	-/-
None	R1 stream	1.162/0.980	0.713/-	-/-
50 %		0.581/-	-/-	-/-
None	R2 stream	1.557/1.314	0.956/0.776	-/-
50 %		0.779/0.657	-/-	-/-
None	R3 stream	1.626/1.381	0.998/0.816	-/-
50 %		0.813/0.691	-/-	-/-
None	R4 stream	1.135/0.980	0.697/-	-/-
50 %		0.568/-	-/-	-/-

After step 4 calculations, the PEC/RAC ratio values calculated were below the trigger of 1 for all intended uses. Therefore no further refinement was necessary. However, the PEC/RAC ratio values calculated were still above the trigger of 1 for D6 2nd ditch in bulb vegetables and D6 ditch scenario in leafy vegetables for multiple application. However, D6 scenario is not relevant for CEU countries.

zRMS comment:

Boscalid

After step 4 calculations, the PEC/RAC ratio values calculated were below the trigger of 1 for the following scenarios:

- R4 scenaro in cabbage, strawberry, parsnip and parsley (leafy vegetables, BBCH 15 as worst case) (single/multiple application) when 5 meter buffer zone is applied to surfacewater bodies
- D3, D4, D5, R1, R2, R3 and R4 scenarios when 10 meter buffer zone or 5 meter buffer zone +50% drift reduction nozzels are pplied to surfacewater bodies in cherry (apple early application as worst case, BBCH 60) (single/multiple application)

However, the PEC/RAC ratio values calculated were still above the trigger of 1 for D6 2nd ditch in bulb vegetables and D6 ditch scenario in leafy vegetables for multiple application.

It should be taken into account that the D6 scenario is not relevant for CEU countries.

Greenhouse intended uses

Regarding the intended use of tomatoes, eggplants and ornamentals for greenhouse, CASINO ROYALE is expected to apply in enclosed spaces. These uses are considered to be covered by the assessment in field conditions.

However, the PEC_{sw} and PEC_{sed} have been calculated using TOXSWA v1.2. Please, refer to the B8 core dossier for more information.

Table 9.5-58: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid & Pyraclostrobin and metabolites for each organism group based on TOXSWA v1.2 calculations for the use of CASINO ROYALE in greenhouse (single/multiple applications)

PYRACLOSTROBIN AND METABOLITES			
Group		Mesocosm study	Mesocosm study
Test species		Fish	Planktonic species
Endpoint		LC ₅₀	NOEC
(µg/L)		24.82	8
AF		100	4
RAC (µg/L)		0.248	2
TOXSWA Scenario	PEC _{sw} actual (µg/L)		
NL standard - Spring	0.0611/0.099	0.246/0.399	0.031/0.050
NL standard - Autumn	0.0611/0.063	0.246/0.254	0.031/0.032
BOSCALID			
Group		Fish prolonged	
Test species		<i>O. mykiss</i>	
Endpoint		NOEC	

(µg/L)		125	
AF		10	
RAC (µg/L)		12.5	
TOXSWA Scenario	PEC_{sw} actual (µg/L)		
NL standard - Spring	0.253/0.468	0.020/0.037	
NL standard - Autumn	0.253/0.255	0.020/0.020	

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

zRMS comment:

We agree with the risk assessment provided by the applicant for greenhouse uses with consideration PEC_{sw} values agreed in Section 8.

In addition, it should be noted that greenhouse uses are also covered by field uses.

Risk assessment for the combinations of a.s. in the formulation

Following the dilution and spraying of the formulated product, much of the formulation constituents are likely to be lost by volatilisation. Therefore, shortly after application of a formulated product, aquatic organisms are mainly exposed to the active substance present in the formulation. In addition, as demonstrated in the short-term studies here above there are no indications for interactions of the active substances (no synergisms or additional toxicity occurs due to the co-formulants) given that the formulation does not cause an (unexpected) increased toxicity compared to the active substances. An evaluation of the risk posed by the intact formulation is therefore relevant only for the acute/short-term assessment. The long-term risk was assessed considering data for the active substances in the formulation and no chronic combined risk assessment has been performed.

According to the new EFSA Scientific Opinion (EFSA, 2013) measured and calculated mixture toxicity should be compared to determine synergistic, additive or antagonistic effects of the formulation. In the following the concentration addition (CA) model is used as proposed by EFSA.

To determine the respective formulation effect, EFSA proposed to calculate the model deviation ratio (MDR), which divides the calculated mixture toxicity (LC₅₀/EC₅₀ mix-CA) by the measured mixture toxicity (LC₅₀/EC₅₀ CASINO ROYALE). Ecotoxicity studies are biological test systems which underlie a certain natural biological variability when repeating a study. Hence, a threshold has to be defined when an increased/decreased mixture toxicity effect cannot be seen as only additive any longer. EFSA proposes a factor of 5, *i.e.* if the MDR is between 0.2 and 5 the observed and calculated mixture toxicities are considered in agreement.

Active substance / species	Test system	Endpoint (mg a.s./L)
Pyraclostrobin		
<i>Oncorhynchus mykiss</i>	LC ₅₀ 96h	0.006
<i>Daphnia magna</i>	EC ₅₀ 48h	0.016
<i>P. subcapitata</i>	ErC ₅₀ 72h	0.843
Boscalid		
<i>Oncorhynchus mykiss</i>	LC ₅₀ 96h	2.7
<i>Daphnia magna</i>	EC ₅₀ 48h	5.33
<i>P. subcapitata</i>	EC ₅₀ 96h	1.34

The calculated MDR values are between 0.2 and 5 for each organism except algae (see Table 9.5-59), indicating that the formulation does cause an (unexpected) increased toxicity compared to the active substances for these organisms. No synergisms or additional toxicity occurs due to the co-formulants. The apparent antagonism for algae (toxicity of the formulation lower than expected) can be explained by the fact that endpoints for individual active substances are "higher than" values.

Table 9.5-59: Summary of results obtained in the studies with the formulated product CASINO ROYALE and comparison of calculated and measured mixture toxicity

Test species	Endpoint & Test system	LC ₅₀ / EC ₅₀ [mg/L]			
		Measured toxicity of CASINO ROYALE (LC ₅₀ CASINO ROYALE or EC ₅₀ CASINO ROYALE) (mg/L)	Measured toxicity of CASINO ROYALE (converted to be a.i. based) (LC ₅₀ CASINO ROYALE or EC ₅₀ CASINO ROYALE) (mg a.s./L)	Calculated mixture toxicity ^a LC ₅₀ mix-CA or EC ₅₀ mix-CA	Model deviation ratio (MDR = EC ₅₀ mix-CA / EC ₅₀ CASINO ROYALE)
<i>O. mykiss</i>	LC ₅₀ , acute, 96 h	0.054	0.018	0.030	1.644
<i>D. magna</i>	EC ₅₀ , acute, 48 h	0.254	0.085	0.079	0.929
Algae	EbC ₅₀ , 72 h	28.75	9.603	1.198	0.125

^a The mixture toxicity of the formulation was re-calculated based on the nominal contents of Pyraclostrobin (67 g/Kg) and Boscalid (267 g/Kg) within the formulation.

The calculated factors fall in 0.8-1.2 (see Table 9.5-60), indicating that the mixture composition in the formulation study giving the measured mixture toxicity is similar to the mixture composition at the PEC_{mix}.

Table 9.5-60: Comparison of mixture composition in the formulation study (giving the measured mixture toxicity) and mixture composition at the PEC_{mix}

Test species	Endpoint & Test system	LC ₅₀ / EC ₅₀ [mg/L]		
		Calculated mixture toxicity (a.s. in CASINO ROYALE) LC ₅₀ mix-CA or EC ₅₀ mix-CA	Calculated mixture toxicity (a.s. in PEC _{mix}) ^b LC ₅₀ mix-CA or EC ₅₀ mix-CA at lower exposure tier	Factors (EC ₅₀ mix-CA (a.s. in CASINO ROYALE)/EC ₅₀ mix-CA (a.s. in PEC _{mix})) at lower exposure tier
<i>O. mykiss</i>	LC ₅₀ , acute, 96 h	0.030	0.030	1.000
<i>D. magna</i>	EC ₅₀ , acute, 48 h	0.079	0.079	1.000
Algae	EbC ₅₀ , static, 72 h	1.198	1.198	1.000

^a The mixture toxicity of the formulation was re-calculated based on the nominal contents of Pyraclostrobin (67 g/Kg) and Boscalid (267 g/Kg) within the formulation.

^b The mixture toxicity of the formulation was re-calculated based on the mixture composition at the PEC_{mix} for Pyraclostrobin (0.005977 mg/L at Step 3 (D5/stream) scenario) and Boscalid (0.02382 mg/L at Step 3 for D5/stream scenario).

Table 9.5-61: Comparison of calculated mixture toxicity and toxicity per fraction of a single a.s.

Test species	Endpoint & Test system	LC ₅₀ / EC ₅₀ [mg/L]		
		Calculated mixture toxicity (a.s. in CASINO ROYALE) LC ₅₀ mix-CA or EC ₅₀ mix-CA	Calculated toxicity per fraction of CASINO ROYALE (based on each a.s.) (1/TU _i) ^a	Deviation from mixture toxicity (1-EC _x mix-CA x (1/EC _x mix-CA - TU _i)) [%]
<i>O. mykiss</i>	LC ₅₀ , acute, 96 h	0.030	Pyraclostrobin: 0.030 Boscalid: 3.378	Pyraclostrobin: 99.12% Boscalid: 0.88%
<i>D. magna</i>	EC ₅₀ , acute, 48 h	0.079	Pyraclostrobin: 0.080 Boscalid: 6.667	Pyraclostrobin: 98.82% Boscalid: 1.18%
Algae	E _b C ₅₀ , static, 72 h	1.198	Pyraclostrobin: 4.202 Boscalid: 1.676	Pyraclostrobin: 28.51% Boscalid: 71.49%

^a TU_i is defined as the concentration of the ith a.s. at the EC₅₀ CASINO ROYALE (re-calculated to the sum of a.s.) divided by the respective single-substance toxicity (EC₅₀ a.s.). This is calculated based on the nominal contents of of Pyraclostrobin (67 g/Kg) and Boscalid (267 g/Kg) within the formulation.

With regard to the mixture risk assessment EFSA further states that if the toxicity of the mixture is largely explained by the toxicity of a single active substance, a sufficient protection level might be achieved by simply basing the RA on the toxicity data for that single ‘driver’.

Regarding CASINO ROYALE, Pyraclostrobin is clearly driving the acute risk. The studies performed with the formulated product reflect the toxicity of Pyraclostrobin in fish and daphnids, as the formulation toxicity – endpoint recalculated to each active substance concentrations – come for 90 % (of more) from the toxicity per fraction of a single a.s. (TU_i) (see Table 9.5-61).

Table 9.5-62: Conduct a mixture RA based on calculated mixture toxicity according to 10.3.8 from EFSA AGD in apple (early application) (worst case) for fish

Exposure	Lower exposure tier		Higher exposure tier	
	Pyraclostrobin	Boscalid	Pyraclostrobin	Boscalid
Exposure tier (FOCUS step)	Step 3 (D5/stream)	Step 3 (D5/stream)	Step 4 (R3/stream) - 50 m	Step 4 (D5/stream) - 15 m
PEC _{sw} [mg a.s./L]	0.005977	0.023820	0.000081	0.005652
Relative proportions of the individual mixture components in the environment (pi PEC)	0.201	0.799	0.014	0.986
Total exposure concentration of the mixture (a.s. based) (PEC _{mix}) [mg/L]	0.029797		0.005733	
Calculated mixture toxicity (a.s. in PEC _{mix}) (EC _x mix-CA = ∑ (pi PEC/EC _x i)) [mg a.s./L]	0.030		0.368	
ETR _{mix} = PEC _{mix} /EC _x PPP	1.0050		0.0156	
Trigger	0.01			

Applicability of such approach is justified following the EFSA AGD *Decision scheme for mixture toxicity risk assessment* for fish.

Step	EFSA AGD provisions	Option	Justification	Outcome
1	Are measured toxicity data (ECx) available for the given endpoint (typically chronic data available only for a.s.)?	For both formulation (ECxPPP) and a.s. (ECxa.s.):	Please refer to table 9.5-3	Go to 2
2	Check the plausibility of the measured formulation toxicity (ECxPPP) against the calculated mixture toxicity EC _{xmix} -CA (assuming CA, Equation 13) for exactly the mixture composition of the a.s. in the formulation (ECxPPP) by means of the model deviation ratio (MDR = EC _{xmix} -CA/ECxPPP).	MDR = 0.2–5 (CA approximately holds for the mixture)	Please refer to table 9.5-59	Go to 3
3	Check whether the mixture composition in the formulation study giving the measured mixture toxicity (ECxPPP) in terms of the relative proportions of the individual a.s. is similar to the mixture composition at the PEC _{mix} . As a direct comparison on the basis of the relative proportions of the a.s. at the ECxPPP with the relative proportion at the PEC _{mix} is not informative as such, the comparison is done based on calculated mixture toxicity (assuming CA) for both mixture compositions. Therefore, calculate EC _{xmix} -CA (see Equation 13) for the mixture composition of the a.s. at the PEC _{mix} and compare with the estimate calculated for the formulation (as already done in step 2 above).	EC _x mix-CA (a.s. in product)/EC _x mix-CA (a.s. in PEC _{mix}) is 0.8-1.2	Please refer to table 9.5-60	Go to 4
4	Conduct a mixture RA based on measured mixture toxicity, with the exposure-toxicity ratio (ETR _{mix}) being defined as the PEC _{mix} divided by the measured ECxPPP and compare the outcome with the acceptability criterion (trigger value) decisive for the specific endpoint/exposure scenario combination.	If ETR _{mix} < 0.01 for fish: Low risk	Please refer to table 9.5-62	Not acceptable risk

Table 9.5-63: Conduct a mixture RA based on calculated mixture toxicity according to 10.3.8 from EFSA AGD in apple (early application) (worst case) for *Daphnia*

Exposure	Lower exposure tier		Higher exposure tier	
	Pyraclostrobin	Boscalid	Pyraclostrobin	Boscalid
Exposure tier (FOCUS step)	Step 3 (D5/stream)	Step 3 (D5/stream)	Step 4 (R3/stream) - 50 m	Step 4 (D5/stream) - 15 m
PECsw [mg a.s./L]	0.005977	0.023820	0.000081	0.005652
Relative proportions of the individual mixture components in the environment (pi PEC)	0.201	0.799	0.014	0.986
Total exposure concentration of the mixture (a.s. based) (PECmix) [mg/L]	0.029797		0.005733	
Calculated mixture toxicity (a.s. in PECmix) (ECx mix-CA = $\sum (pi \text{ PEC}/ECx \text{ i})$) [mg a.s./L]	0.079		0.936	
ETRmix = PECmix/ECx PPP	0.3772		0.006	
Trigger	0.01			

Applicability of such approach is justified following the EFSA AGD *Decision scheme for mixture toxicity risk assessment for Daphnia*.

Step	EFSA AGD provisions	Option	Justification	Outcome
1	Are measured toxicity data (ECx) available for the given endpoint (typically chronic data available only for a.s.)?	For both formulation (ECxPPP) and a.s. (ECxa.s.):	Please refer to table 9.5-3	Go to 2
2	Check the plausibility of the measured formulation toxicity (ECxPPP) against the calculated mixture toxicity ECxmix-CA (assuming CA, Equation 13) for exactly the mixture composition of the a.s. in the formulation (ECxPPP) by means of the model deviation ratio (MDR = ECxmix-CA/ECxPPP).	MDR = 0.2–5 (CA approximately holds for the mixture)	Please refer to table 9.5-59	Go to 3
3	Check whether the mixture composition in the formulation study giving the measured mixture toxicity (ECxPPP) in terms of the relative proportions of the individual a.s. is similar to the mixture composition at the PECmix. As a direct comparison on the basis of the relative proportions of the a.s. at the ECxPPP with the relative proportion at the PECmix is not informative as such, the comparison is done based on calculated mixture toxicity (assuming CA) for both mixture compositions. Therefore, calculate ECxmix-CA (see Equation 13) for the mixture composition of the a.s. at the PECmix and compare with the estimate calculated for the formulation (as already done in step 2 above).	ECx mix-CA (a.s. in product)/ECx mix-CA (a.s. in PECmix) is 0.8-1.2	Please refer to table 9.5-60	Go to 4

4	Conduct a mixture RA based on measured mixture toxicity, with the exposure-toxicity ratio (ETR _{mix}) being defined as the PEC _{mix} divided by the measured EC _x PPP and compare the outcome with the acceptability criterion (trigger value) decisive for the specific endpoint/exposure scenario combination.	If ETR _{mix} < 0.01 for fish: Low risk	Please refer to table 9.5-63	Not acceptable risk
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Table 9.5-64: Conduct a mixture RA based on calculated mixture toxicity according to 10.3.8 from EFSA AGD in apple (early application) (worst case) for alga

Exposure	Lower exposure tier		Higher exposure tier	
	Pyraclostrobin	Boscalid	Pyraclostrobin	Boscalid
Exposure tier (FOCUS step)	Step 3 (D5/stream)	Step 3 (D5/stream)	Step 4 (R3/stream) - 50 m	Step 4 (D5/stream) - 15 m
PEC _{sw} [mg a.s./L]	0.005977	0.023820	0.000081	0.005652
Relative proportions of the individual mixture components in the environment (pi PEC)	0.201	0.799	0.014	0.986
Total exposure concentration of the mixture (a.s. based) (PEC _{mix}) [mg/L]	0.029797		0.005733	
Calculated mixture toxicity (a.s. in PEC _{mix}) (EC _x mix-CA = ∑ (pi PEC/EC _x i)) [mg a.s./L]	1.198		1.329	
ETR _{mix} = PEC _{mix} /EC _x PPP	0.025		0.004	
Trigger	0.1			

Applicability of such approach is justified following the EFSA AGD *Decision scheme for mixture toxicity risk assessment* for alga.

Step	EFSA AGD provisions	Option	Justification	Outcome
1	Are measured toxicity data (EC _x) available for the given endpoint (typically chronic data available only for a.s.)?	For both formulation (EC _x PPP) and a.s. (EC _x a.s.):	Please refer to table 9.5-3	Go to 2
2	Check the plausibility of the measured formulation toxicity (EC _x PPP) against the calculated mixture toxicity EC _x mix-CA (assuming CA, Equation 13) for exactly the mixture composition of the a.s. in the formulation (EC _x PPP) by means of the model deviation ratio (MDR = EC _x mix-CA/EC _x PPP).	MDR = <0.2	Please refer to table 9.5-59	Go to 9
9	Carefully recheck the apparent antagonism as observed in the measured mixture toxicity data (EC _x PPP) regarding potential impacts of the default assumption of CA and/or heterogeneous input data used for the CA calculation. Does the apparent antagonism remain and no toxicologically plausible explanation is available (e.g. special feature of the formulation type)?	No (measured mixture toxicity plausible):		Go to 3

3	Check whether the mixture composition in the formulation study giving the measured mixture toxicity (ECx PPP) in terms of the relative proportions of the individual a.s. is similar to the mixture composition at the PECmix. As a direct comparison on the basis of the relative proportions of the a.s. at the ECx PPP with the relative proportion at the PECmix is not informative as such, the comparison is done based on calculated mixture toxicity (assuming CA) for both mixture compositions. Therefore, calculate ECx mix-CA (see Equation 13) for the mixture composition of the a.s. at the PECmix and compare with the estimate calculated for the formulation (as already done in step 2 above).	ECx mix-CA (a.s. in product)/ECx mix-CA (a.s. in PECmix) is 0.8-1.2	Please refer to table 9.5-60	Go to 4
4	Conduct a mixture RA based on measured mixture toxicity, with the exposure-toxicity ratio (ETR _{mix}) being defined as the PECmix divided by the measured ECxPPP and compare the outcome with the acceptability criterion (trigger value) decisive for the specific endpoint/exposure scenario combination.	If ETR _{mix} < 0.1 for fish: Low risk	Please refer to table 9.5-64	Low risk

Refinement with the endpoint from the available microcosm study

Based on the results obtained for mixture risk assessment, a non acceptable risk was observed for fish and *Daphnia*. Therefore, the same refinement criteria for fish and other microorganisms which was followed for pyraclostrobin technical will be followed here, i.e. the use of a reliable mesocosm study, with a LC₅₀ of 24.82 µg a.s./L as endpoint for fish and a derived NOEC value of 8 µg/L from the mesocosm study with an assessment factor of 4 as worst case. Consequently, the trigger value would change to 0.25, considering an Assessment Factor of 4, and the assessment would be as follows:

To determine the respective formulation effect, EFSA proposed to calculate the model deviation ratio (MDR), which divides the calculated mixture toxicity (LC₅₀/EC₅₀ mix-CA) by the measured mixture toxicity (LC₅₀/EC₅₀ CASINO ROYALE). Ecotoxicity studies are biological test systems which underlie a certain natural biological variability when repeating a study. Hence, a threshold has to be defined when an increased/decreased mixture toxicity effect cannot be seen as only additive any longer. EFSA proposes a factor of 5, i.e. if the MDR is between 0.2 and 5 the observed and calculated mixture toxicities are considered in agreement.

Active substance / species	Test system	Endpoint (mg a.s./L)
Pyraclostrobin		
<i>Oncorhynchus mykiss</i> (Mesocosm study)	LC ₅₀ 96h	0.248
<i>Daphnia magna</i> (Mesocosm study)	NOEC	0.002
<i>P. subcapitata</i>	E _r C ₅₀ 72h	0.843
Boscalid		
<i>Oncorhynchus mykiss</i>	LC ₅₀ 96h	2.7
<i>Daphnia magna</i>	EC ₅₀ 48h	5.33
<i>P. subcapitata</i>	EC ₅₀ 96h	1.34

The calculated MDR values are not between 0.2 and 5 for each organism (see Table 9.5-65), indicating that the formulation does not cause an (unexpected) increased toxicity compared to the active substances for these organisms. No synergisms or additional toxicity occurs due to the co-formulants.

Table 9.5-65: Summary of results obtained in the studies with the formulated product CASINO ROYALE and comparison of calculated and measured mixture toxicity

Test species	Endpoint & Test system	LC ₅₀ / EC ₅₀ [mg/L]			
		Measured toxicity of CASINO ROYALE (LC ₅₀ CASINO ROYALE or EC ₅₀ CASINO ROYALE) (mg/L)	Measured toxicity of CASINO ROYALE (converted to be a.i. based) (LC ₅₀ CASINO ROYALE or EC ₅₀ CASINO ROYALE) (mg a.s./L)	Calculated mixture toxicity ^a LC ₅₀ mix-CA or EC ₅₀ mix-CA	Model deviation ratio (MDR = EC ₅₀ mix-CA / EC ₅₀ CASINO ROYALE)
<i>O. mykiss</i>	LC ₅₀ , acute, 96 h	0.054	0.018	0.905	50.179
<i>D. magna</i>	EC ₅₀ , acute, 48 h	0.254	0.085	0.010	0.117
Algae	E _b C ₅₀ , 72 h	28.75	9.603	1.198	0.125

^a The mixture toxicity of the formulation was re-calculated based on the nominal contents of Pyraclostrobin (67 g/Kg) and Boscalid (267 g/Kg) within the formulation.

The calculated factors fall in 0.8-1.2 (see Table 9.5-66), indicating that the mixture composition in the formulation study giving the measured mixture toxicity is similar to the mixture composition at the PEC_{mix}.

Table 9.5-66: Comparison of mixture composition in the formulation study (giving the measured mixture toxicity) and mixture composition at the PEC_{mix}

Test species	Endpoint & Test system	LC ₅₀ / EC ₅₀ [mg/L]		
		Calculated mixture toxicity (a.s. in CASINO ROYALE) LC ₅₀ mix-CA or EC ₅₀ mix-CA	Calculated mixture toxicity (a.s. in PEC _{mix}) ^b LC ₅₀ mix-CA or EC ₅₀ mix-CA at lower exposure tier	Factors (EC ₅₀ mix-CA (a.s. in CASINO ROYALE)/EC ₅₀ mix-CA (a.s. in PEC _{mix})) at lower exposure tier
<i>O. mykiss</i>	LC ₅₀ , acute, 96 h	0.905	0.905	1.000
<i>D. magna</i>	EC ₅₀ , acute, 48 h	0.010	0.010	1.000
Algae	E _b C ₅₀ , static, 72 h	1.198	1.198	1.000

^a The mixture toxicity of the formulation was re-calculated based on the nominal contents of Pyraclostrobin (67 g/Kg) and Boscalid (267 g/Kg) within the formulation.

^b The mixture toxicity of the formulation was re-calculated based on the mixture composition at the PEC_{mix} for Pyraclostrobin (0.005977 mg/L at Step 3 (D5/stream) scenario) and Boscalid (0.02382 mg/L at Step 3 for D5/stream scenario).

Table 9.5-67: Comparison of calculated mixture toxicity and toxicity per fraction of a single a.s.

Test species	Endpoint & Test system	LC ₅₀ / EC ₅₀ [mg/L]		
		Calculated mixture toxicity (a.s. in CASINO ROYALE) LC ₅₀ mix-CA or EC ₅₀ mix-CA	Calculated toxicity per fraction of CASINO ROYALE (based on each a.s.) (1/TU _i) ^a	Deviation from mixture toxicity (1-EC _x mix-CA x (1/EC _x mix-CA - TU _i)) [%]
<i>O. mykiss</i>	LC ₅₀ , acute, 96 h	0.905	Pyraclostrobin: 1.236 Boscalid: 3.378	Pyraclostrobin: 73.20% Boscalid: 26.80%
<i>D. magna</i>	EC ₅₀ , acute, 48 h	0.010	Pyraclostrobin: 0.010 Boscalid: 6.667	Pyraclostrobin: 99.85% Boscalid: 0.15%
Algae	E _b C ₅₀ , static, 72 h	1.198	Pyraclostrobin: 4.202 Boscalid: 1.676	Pyraclostrobin: 28.51% Boscalid: 71.49%

^a TU_i is defined as the concentration of the ith a.s. at the EC₅₀ CASINO ROYALE (re-calculated to the sum of a.s.) divided by the respective single-substance toxicity (EC₅₀ a.s.). This is calculated based on the nominal contents of of Pyraclostrobin (67 g/Kg) and Boscalid (267 g/Kg) within the formulation.

With regard to the mixture risk assessment EFSA further states that if the toxicity of the mixture is largely explained by the toxicity of a single active substance, a sufficient protection level might be achieved by simply basing the RA on the toxicity data for that single ‘driver’.

Regarding CASINO ROYALE, Pyraclostrobin is clearly driving the acute risk. The studies performed with

the formulated product reflect the toxicity of Pyraclostrobin in daphnids, as the formulation toxicity – endpoint recalculated to each active substance concentrations – come for 90 % (of more) from the toxicity per fraction of a single a.s. (TUi) (see Table 9.5-67).

Table 9.5-68: Conduct a mixture RA based on calculated mixture toxicity according to 10.3.8 from EFSA AGD in apple (early application) (worst case) for fish

Exposure	Lower exposure tier		Higher exposure tier	
	Pyraclostrobin	Boscalid	Pyraclostrobin	Boscalid
Exposure tier (FOCUS step)	Step 3 (D5/stream)	Step 3 (D5/stream)	Step 4 (R3/stream) - 40 m	Step 4 (D5/stream) - 15 m
PEC _{sw} [mg a.s./L]	0.005977	0.023820	0.000138	0.005652
Relative proportions of the individual mixture components in the environment (pi PEC)	0.201	0.799	0.024	0.976
Total exposure concentration of the mixture (a.s. based) (PEC _{mix}) [mg/L]	0.029797		0.005790	
Calculated mixture toxicity (a.s. in PEC _{mix}) (EC _x mix-CA = ∑ (pi PEC/EC _x i)) [mg a.s./L]	0.905		2.185	
ETR _{mix} = PEC _{mix} /EC _x PPP	0.0329		0.0026	
Trigger	0.01			

Applicability of such approach is justified following the EFSA AGD *Decision scheme for mixture toxicity risk assessment* for fish.

Step	EFSA AGD provisions	Option	Justification	Outcome
1	Are measured toxicity data (EC _x) available for the given endpoint (typically chronic data available only for a.s.)?	For both formulation (EC _x PPP) and a.s. (EC _x a.s.):	Please refer to table 9.5-3	Go to 2
2	Check the plausibility of the measured formulation toxicity (EC _x PPP) against the calculated mixture toxicity EC _x mix-CA (assuming CA, Equation 13) for exactly the mixture composition of the a.s. in the formulation (EC _x PPP) by means of the model deviation ratio (MDR = EC _x mix-CA/EC _x PPP).	MDR = >5	Please refer to table 9.5-65	Go to 10
10	Carefully recheck the apparent synergism as observed in the measured mixture toxicity data (EC _x PPP) regarding potential impacts of heterogeneous input data (a.s.) and of co-formulants ignored in the CA calculation. Does the apparent synergism remain?	Measured data not available		Go to 8
8	Conduct a mixture RA based on calculated mixture toxicity according to 10.3.8	If ETR _{mix} < 0.01 for fish: Low risk	Please refer to table 9.5-68	Low risk

Table 9.5-69: Conduct a mixture RA based on calculated mixture toxicity according to 10.3.8 from EFSA AGD in apple (early application) (worst case) for *Daphnia*

Exposure	Lower exposure tier		Higher exposure tier	
	Pyraclostrobin	Boscalid	Pyraclostrobin	Boscalid
Exposure tier (FOCUS step)	Step 3 (D5/stream)	Step 3 (D5/stream)	Step 4 (R3/stream) - 40 m	Step 4 (D5/stream) - 15 m
PEC _{sw} [mg a.s./L]	0.005977	0.023820	0.000138	0.005652
Relative proportions of the individual mixture components in the environment (pi PEC)	0.201	0.799	0.024	0.976
Total exposure concentration of the mixture (a.s. based) (PEC _{mix}) [mg/L]	0.029797		0.005790	
Calculated mixture toxicity (a.s. in PEC _{mix}) (EC _x mix-CA = ∑ (pi PEC/EC _x i)) [mg a.s./L]	0.010		0.083	
ETR _{mix} = PEC _{mix} /EC _x PPP	2.980		0.070	
Trigger	0.25			

Applicability of such approach is justified following the EFSA AGD *Decision scheme for mixture toxicity risk assessment for Daphnia*.

Step	EFSA AGD provisions	Option	Justification	Outcome
1	Are measured toxicity data (EC _x) available for the given endpoint (typically chronic data available only for a.s.)?	For both formulation (EC _x PPP) and a.s. (EC _x a.s.):	Please refer to table 9.5-3	Go to 2
2	Check the plausibility of the measured formulation toxicity (EC _x PPP) against the calculated mixture toxicity EC _x mix-CA (assuming CA, Equation 13) for exactly the mixture composition of the a.s. in the formulation (EC _x PPP) by means of the model deviation ratio (MDR = EC _x mix-CA/EC _x PPP).	MDR = <0.2	Please refer to table 9.5-65	Go to 9
9	Carefully recheck the apparent antagonism as observed in the measured mixture toxicity data (EC _x PPP) regarding potential impacts of the default assumption of CA and/or heterogeneous input data used for the CA calculation. Does the apparent antagonism remain and no toxicologically plausible explanation is available (e.g. special feature of the formulation type)?	No (measured mixture toxicity plausible)		Go to 3

3	Check whether the mixture composition in the formulation study giving the measured mixture toxicity (ECxPPP) in terms of the relative proportions of the individual a.s. is similar to the mixture composition at the PECmix. As a direct comparison on the basis of the relative proportions of the a.s. at the ECxPPP with the relative proportion at the PECmix is not informative as such, the comparison is done based on calculated mixture toxicity (assuming CA) for both mixture compositions. Therefore, calculate ECxm _{mix} -CA (see Equation 13) for the mixture composition of the a.s. at the PECmix and compare with the estimate calculated for the formulation (as already done in step 2 above).	ECx mix-CA (a.s. in product)/ECx mix-CA (a.s. in PECmix) is 0.8-1.2	Please refer to table 9.5-66	Go to 4
4	Conduct a mixture RA based on measured mixture toxicity, with the exposure-toxicity ratio (ETR _{mix}) being defined as the PECmix divided by the measured ECxPPP and compare the outcome with the acceptability criterion (trigger value) decisive for the specific endpoint/exposure scenario combination.	If ETR _{mix} < 0.25 for fish: Low risk	Please refer to table 9.5-69	Low risk

Table 9.5-70: Conduct a mixture RA based on calculated mixture toxicity according to 10.3.8 from EFSA AGD in apple (early application) (worst case) for alga

Exposure	Lower exposure tier		Higher exposure tier	
	Pyraclostrobin	Boscalid	Pyraclostrobin	Boscalid
Exposure tier (FOCUS step)	Step 3 (D5/stream)	Step 3 (D5/stream)	Step 4 (R3/stream) - 40 m	Step 4 (D5/stream) - 15 m
PEC _{sw} [mg a.s./L]	0.005977	0.023820	0.000138	0.005652
Relative proportions of the individual mixture components in the environment (pi PEC)	0.201	0.799	0.024	0.976
Total exposure concentration of the mixture (a.s. based) (PEC _{mix}) [mg/L]	0.029797		0.005790	
Calculated mixture toxicity (a.s. in PEC _{mix}) (EC _x mix-CA = ∑ (pi PEC/EC _x i)) [mg a.s./L]	1.198		1.321	
ETR _{mix} = PEC _{mix} /EC _x PPP	0.025		0.004	
Trigger	0.1			

Applicability of such approach is justified following the EFSA AGD *Decision scheme for mixture toxicity risk assessment* for alga.

Step	EFSA AGD provisions	Option	Justification	Outcome
1	Are measured toxicity data (ECx) available for the given endpoint (typically chronic data available only for a.s.)?	For both formulation (ECxPPP) and a.s. (ECxa.s.):	Please refer to table 9.5-3	Go to 2

2	Check the plausibility of the measured formulation toxicity (ECxPPP) against the calculated mixture toxicity ECxm _{ix} -CA (assuming CA, Equation 13) for exactly the mixture composition of the a.s. in the formulation (ECxPPP) by means of the model deviation ratio ($MDR = ECxm_{ix}\text{-CA}/ECxPPP$).	$MDR = <0.2$	Please refer to table 9.5-65	Go to 9
9	Carefully recheck the apparent antagonism as observed in the measured mixture toxicity data (ECx PPP) regarding potential impacts of the default assumption of CA and/or heterogeneous input data used for the CA calculation. Does the apparent antagonism remain and no toxicologically plausible explanation is available (e.g. special feature of the formulation type)?	No (measured mixture toxicity plausible):		Go to 3
3	Check whether the mixture composition in the formulation study giving the measured mixture toxicity (ECx PPP) in terms of the relative proportions of the individual a.s. is similar to the mixture composition at the PEC _{mix} . As a direct comparison on the basis of the relative proportions of the a.s. at the ECx PPP with the relative proportion at the PEC _{mix} is not informative as such, the comparison is done based on calculated mixture toxicity (assuming CA) for both mixture compositions. Therefore, calculate ECx mix-CA (see Equation 13) for the mixture composition of the a.s. at the PEC _{mix} and compare with the estimate calculated for the formulation (as already done in step 2 above).	ECx mix-CA (a.s. in product)/ECx mix-CA (a.s. in PEC _{mix}) is 0.8-1.2	Please refer to table 9.5-66	Go to 4
4	Conduct a mixture RA based on measured mixture toxicity, with the exposure-toxicity ratio (ETR _{mix}) being defined as the PEC _{mix} divided by the measured ECxPPP and compare the outcome with the acceptability criterion (trigger value) decisive for the specific endpoint/exposure scenario combination.	If $ETR_{mix} < 0.1$ for fish: Low risk	Please refer to table 9.5-70	Low risk

No unacceptable risk to aquatic organisms is expected from the exposure to the combined active substances following proposed uses of the product and described mitigation measures.

zRMS comment:

The refined the mixture toxicity assessment should be considered at Ms level.

9.5.3 Overall conclusions

Pyraclostrobin

For all intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish as characterised by an LC₅₀ for *Oncorhynchus mykiss* o of 6 µg a.s./L in connection with an assessment factor of 100) in all FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies. For all the intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in R4 stream scenario in fruiting vegetables, R4 stream scenario in root vegetables, R4 stream scenario in bulb vegetables, R4 1st stream and R4 2nd stream

scenarios in leafy vegetables, R4 stream scenario in apple early application and R1 stream and R4 stream scenarios in vines late application. Therefore, a further refinement was necessary. A refinement for fish with RAC value of 0.248 µg a.s./L based on a geomean LC₅₀ from 7 acute toxicity laboratory studies on different fish species available in the monograph of Pyraclostrobin was used. Moreover a refinement for the other aquatic organisms with a RAC value of 2 µg a.s./L based on mesocosms study available in Monograph of the active substance was also used. After the refinement, an acceptable risk was obtained with the following mitigation measures:

- Sugar beet: no-spray buffer zone of 5 m
- Fruiting vegetables and potato: no-spray buffer zone of 5m
- Root vegetables: no-spray buffer zone of 5m
- Bulb vegetables: no-spray buffer zone of 5m
- Leafy vegetables: no-spray buffer zone of 10m
- Apple (early application): no-spray buffer zone of 40m OR no-spray buffer zone of 30m + 50% nozzles OR no-spray buffer zone of 20m + 75% nozzles OR no-spray buffer zone of 15m + 90% nozzles
- Vines (late application): no-spray buffer zone of 20m OR no-spray buffer zone of 15m + 50% nozzles OR no-spray buffer zone of 10m + 75% nozzles OR no-spray buffer zone of 5m + 90% nozzles

Moreover, for completeness reasons, together with the assessment using the RAC_{geomean}, new PEC/RAC calculations were included based on the RAC of 0.2 µg/L for chronic risk assessment to fish. After this refinement, an acceptable risk was obtained with the following mitigation measures:

- Sugar beet: no-spray buffer zone of 10 m
- Fruiting vegetables and potato: no-spray buffer zone of 10 m
- Root vegetables: no-spray buffer zone of 10 m
- Bulb vegetables: no-spray buffer zone of 10 m
- Leafy vegetables: no-spray buffer zone of 10 m
- Apple (early application): no-spray buffer zone of 40 m OR no-spray buffer zone of 30 m + 50% nozzles OR no-spray buffer zone of 20 m + 75% nozzles OR no-spray buffer zone of 15 m + 90% nozzles
- Vines (late application): no-spray buffer zone of 20 m OR no-spray buffer zone of 15 m + 50% nozzles OR no-spray buffer zone of 10 m + 75% nozzles OR no-spray buffer zone of 5 m + 90% nozzles

Metabolites of Pyraclostrobin

For all intended uses, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms. Therefore, no further assessment is necessary.

Boscalid

For all intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish as characterised by a NOEC for *Oncorhynchus mykiss* of 125 µg a.s./L in connection with an assessment factor of 10) in D6 2nd/ditch for bulb vegetables, D6/ditch and R4 1st/stream for leafy vegetables and D3 ditch, D4 stream, D5 stream, R1 stream, R2 stream, R3 stream and R4 stream for apple early application. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies. After step 4 calculations, the PEC/RAC ratio values calculated were below the trigger of 1 for all intended uses. An acceptable risk was obtained with the following mitigation measures:

- Leafy vegetables: no-spray buffer zone of 5m with 5m vegetative strip.
- Apple early application: no-spray buffer zone of 15m OR no-spray buffer zone of 5m + 50% of nozzle reduction.

However, the PEC/RAC ratio values calculated were still above the trigger of 1 for D6 2nd ditch in bulb vegetables and D6 ditch scenario in leafy vegetables for multiple application. However, D6 scenario is not relevant for CEU countries.

Conclusions

Sugar beet, Fruiting vegetables and potato, Root vegetables and Bulb vegetables – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 5 m to surface water bodies.

Leafy vegetables – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 10 m with 5m vegetative strip to surface water bodies.

Apple (early application) – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 40 m to surface water bodies OR respect an unsprayed buffer zone of 30 m to surface water bodies with 50% of nozzles reduction OR respect an unsprayed buffer zone of 20 m to surface water bodies with 75% of nozzles reduction OR respect an unsprayed buffer zone of 15 m to surface water bodies with 90% of nozzles reduction.

Vines (late application) – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 20 m to surface water bodies OR respect an unsprayed buffer zone of 15 m to surface water bodies with 50% of nozzles reduction OR respect an unsprayed buffer zone of 10 m to surface water bodies with 75% of nozzles reduction OR respect an unsprayed buffer zone of 5 m to surface water bodies with 90% of nozzles reduction.

zRMS comments:

Based on the aquatic risk assessment the following risk mitigation measures should be applied to surface water bodies:

~~*Sugar beet, Fruiting vegetables and potato, Root vegetables and Bulb vegetables – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 5 m to surface water bodies.*~~

~~*Leafy vegetables – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 10 m with 5m vegetative strip to surface water bodies.*~~

~~*Apple (early application) – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 40 m to surface water bodies OR respect an unsprayed buffer zone of 30 m to surface water bodies with 50% of nozzles reduction OR respect an unsprayed buffer zone of 20 m to surface water bodies with 75% of nozzles reduction OR respect an unsprayed buffer zone of 15 m to surface water bodies with 90% of nozzles reduction.*~~

~~*Vines (late application) – Spe3: To protect aquatic organisms respect an unsprayed buffer zone of 20 m to surface water bodies OR respect an unsprayed buffer zone of 15 m to surface water bodies with 50% of nozzles reduction OR respect an unsprayed buffer zone of 10 m to surface water bodies with 75% of nozzles reduction OR respect an unsprayed buffer zone of 5 m to surface water bodies with 90% of nozzles reduction.*~~

The applicant provided the new calculations of chronic risk assessment **during Commenting Period** and the final conclusion based on refinement **of both active substances** for the worst case scenarios for each uses was updated below:

- **Sugar beet: no-spray buffer zone of 10 m**
- **Fruiting vegetables and potato: no-spray buffer zone of 10 m**
- **Root vegetables: no-spray buffer zone of 10 m**
- **Bulb vegetables: no-spray buffer zone of 10 m**
- **Leafy vegetables: no-spray buffer zone of 10 m with 5 meter vegetative buffer zone**

- **Apple (early application): no-spray buffer zone of 40 m OR no-spray buffer zone of 30 m + 50% nozzles OR no-spray buffer zone of 20 m + 75% nozzles OR no-spray buffer zone of 15 m + 90% nozzles**
- **Vines (late application): no-spray buffer zone of 20 m OR no-spray buffer zone of 15 m + 50% nozzles OR no-spray buffer zone of 10 m + 75% nozzles OR no-spray buffer zone of 5 m + 90% nozzles**

In addition, it should be indicated that greenhouse uses are considered acceptable.

The final risk mitigation measures for aquatic organism should be decided at MSs level depended on relevant scenarios for each countries.

***Remark zRMS's e- fate expert from Section 8:**

For PEC_{sw/sed} calculations at STEP 4, the values used for reduction in run off volume and flux and erosion mass and flux is 0.5 and 0.8 for 5 meters of vegetative buffer strip according to the Austrian Environmental Agency (AGES) and the values uses for reduction in run off volume and flux and erosion mass and flux were 0.7 and 0.9 respectively for 15 meters of vegetative buffer strip.

In opinion of zRMS-PL, the Step 4 PEC_{sw} calculations are not accepted because of according to Working Document of the Central Zone in the Authorisation of Plant Protection Products (2018), the following approaches for simulating in Step 4 are recommended for the Core Assessment: Landscape And Mitigation Factors In Aquatic Risk Assessment. Volume 1. Extended Summary and Recommendations". Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0. 169 pp and FOCUS (2007) and Working Document of the Central Zone in the Autorisation of Plant Protection Products (Environmental Fate and Behaviour. Ver.1.rev1. 2018).

However, 5 or 15 meters of vegetative buffer strip can be used at national level.

The PEC_{sw} in STEP4 and mitigation measure should be considered by individual MS.

~~In addition, it should be noted, that if any of refinement option for a.s.-pyraclostrobin (geomean approach for acute risk for fish, chronic risk for fish) is not accepted by some MSs, they should conclude this issue on MS level.~~

~~The final risk mitigation measures should be decided at MSs level.~~

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 Pyraclostrobin and Boscalid and their relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents. Effects on bees of Casino Royale were not evaluated as part of the EU assessment of Pyraclostrobin and Boscalid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.6-1: Endpoints and effect values relevant for the risk assessment for bees

Species	Substance	Exposure System	Results	Reference
<i>Apis mellifera</i>	Pyraclostrobin	Oral	LD ₅₀ > 73.1 µg/bee	SANCO/1420/2001-Final.
<i>Apis mellifera</i>	Pyraclostrobin	Contact	LD ₅₀ > 100 µg/bee	SANCO/1420/2001-Final.
<i>Apis mellifera</i>	Boscalid	Oral	LD ₅₀ = 166 µg/bee	SANCO/3919 /2007-rev. 5
<i>Apis mellifera</i>	Boscalid	Contact	LD ₅₀ = 200 µg/bee	SANCO/3919 /2007-rev. 5
<i>Apis mellifera</i>	BAS 510 01 F (Boscalid)	Oral	LD ₅₀ = 100 µg prep./bee	SANCO/3919 /2007-rev. 5
<i>Apis mellifera</i>	BAS 510 01 F (Boscalid)	Contact	LD ₅₀ = 100 µg prep./bee	SANCO/3919 /2007-rev. 5
<i>Apis mellifera</i>	Casino Royale	Oral	LD ₅₀ > 400 µg f.p./bee (> 106.80 µg boscalid/bee + 26.80 µg pyraclostrobin/bee)	KCP 10.3.1.1.1 Glanas, A. 2017, Report No. B/108/16
<i>Apis mellifera</i>	Casino Royale	Contact	LD ₅₀ > 400 µg f.p./bee (> 106.80 µg boscalid/bee + 26.80 µg pyraclostrobin/bee)	KCP 10.3.1.1.2 Glanas, A. 2017, Report No. B/109/16
<i>Apis mellifera</i>	Pyraclostrobin	Adult chronic	LDD ₅₀ = 97.77 µg/bee/day NOEDD = 39.47 µg/bee/day	KCP 10.3.1.2.1 Radha, S., 2020, 5028/2019*
<i>Apis mellifera</i>	Pyraclostrobin	Larvae development	ED ₅₀ = 54.56 µg a.i./larvae NOED = 13.17 µg a.i./larvae	KCP 10.3.1.3.1 Radha, S., 2020, 5029/2019*
<i>Apis mellifera</i>	Boscalid	Adult chronic	LDD ₅₀ = 111.99 µg/bee/day NOEDD = 59.72 µg/bee/day	KCP 10.3.1.2.2 Radha, S., 2020, 5031/2019*
<i>Apis mellifera</i>	Boscalid	Larvae development	ED ₅₀ >100 µg a.i./larvae NOED = 6.25 µg a.i./larvae	KCP 10.3.1.3.2 Radha, S., 2020, 5032/2019*
Higher-tier studies (tunnel test, field studies)				
None				

*Study summaries are included in this dossier (see appendix 2). However, they have not been considered further as they are not relevant to the currently approved risk assessment scheme (SANCO/10329/2002).

9.6.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints. In addition, new acute toxicity studies were performed with the formulation Casino Royale and therefore the resulting endpoints are used in the risk assessment on the product.

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. Here, the assessment for the use group all crops also covers the risk for bees from all other intended uses (see 9.1.4).

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 Casino Royale in all crops (use group all crops)

Intended use	All crops		
Active substance	Pyraclostrobin		
Application rate (g/ha)	2 x 134		
Test design	LD ₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q _{HO} , Q _{HC} criterion: Q _H ≤ 50
Oral toxicity	>73.1	134	<1.83
Contact toxicity	>100		<1.34
Intended use	All crops		
Active substance	Boscalid		
Application rate (g/ha)	2 x 534		
Test design	LD ₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q _{HO} , Q _{HC} criterion: Q _H ≤ 50
Oral toxicity	166	534	3.22
Contact toxicity	200		2.67
Product	Casino Royale		
Application rate (g/ha)	2 × 2000		
Test design	LD ₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q _{HO} , Q _{HC} criterion: Q _H ≤ 50
Oral toxicity	>400	2000	<5.0
Contact toxicity	>400		<5.0

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.

zRMS comments:

The Q_{HO} and Q_{HC} values for boscalid, Pyraclostrobin and the formulation Casino Royale are all below the trigger of 50 and so indicate acceptable acute risk to bees based on the maximum intended use of Casino Royale. According to Reg. 284/2009 the chronic adult and chronic larvae tests for bees should be submitted by the applicant.

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

Not relevant.

9.6.3 Effects on bumble bees

Not relevant.

9.6.4 Effects on solitary bees

Not relevant.

9.6.5 Overall conclusions

First-tier assessments indicate that no unacceptable risk for bees exposed to the product Casino Royale is expected according to the proposed intended uses.

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 Pyraclostrobin and Boscalid and their relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target arthropods of Casino Royale were not evaluated as part of the EU assessment of Pyraclostrobin and Boscalid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.7-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods

Species	Substance	Exposure System	Results	Reference
<i>Typhlodromus pyri</i> (protonymphs)	BAS 500 00 F (Pyraclostrobin 247.83 g/l)	Laboratory test glass plates (2D) 14 d	Mortality (after 1 week): 47.3% at 0.320 kg a.s./ha Fertility (after 4 weeks): 99% at 0.320 kg a.s./ha	SANCO/1420/2001-Final.
<i>Aphidius rhopalosiphi</i> (adults)	BAS 500 00 F (Pyraclostrobin 247.83 g/l)	Laboratory test glass plates (2D) 48 h	Mortality (after 1 week): 30% at 0.320 kg a.s./ha Paratisation (after 4 weeks): 80% at 0.320 kg a.s./ha	SANCO/1420/2001-Final.
<i>Aphidius rhopalosiphi</i> (adults)	BAS 500 00 F (Pyraclostrobin 247.83 g/l)	Extended laboratory test Barley seedlings (2D) 48 h	Mortality (after 1 week): 0% at 0.320 kg a.s./ha Paratisation (after 4 weeks): 0% at 0.320 kg a.s./ha	SANCO/1420/2001-Final.

Species	Substance	Exposure System	Results	Reference
<i>Chrysoperla carnea</i> (larvae)	BAS 500 00 F (Pyraclostrobin 247.83 g/l)	Laboratory test glass plates (2D) 11-18 d	Mortality (after 1 week): 79% at 0.320 kg a.s./ha Fertility (after 4 weeks): 0% at 0.320 kg a.s./ha	SANCO/1420/2001-Final.
<i>Coccinella septempunctata</i> L. (Life cycle)	BAS 500 00 F (Pyraclostrobin 253.95 g/l)	Extended laboratory test Bean seedlings (2D) 63 d	Mortality (after 1 week): 0% at 0.064 kg a.s./ha Fertility (after 4 weeks): 3.1% at 0.064 kg a.s./ha	SANCO/1420/2001-Final.
<i>Coccinella septempunctata</i> L. (larvae)	BAS 500 00 F (Pyraclostrobin 247.83 g/l)	Laboratory test glass plates (2D) Until pupation	Mortality (after 1 week): 100% at 0.320 kg a.s./ha	SANCO/1420/2001-Final.
<i>Chrysoperla carnea</i> (Life cycle)	BAS 500 00 F (Pyraclostrobin 247.83 g/l)	Extended laboratory test Bean leaves (2D) 4-5d (eggs), 14-19d (larvae and pupae), 7d (adults)	Mortality (after 1 week): 27% at 0.160 kg a.s./ha Fertility (after 4 weeks): 80% at 0.160 kg a.s./ha	SANCO/1420/2001-Final.
<i>Chrysoperla carnea</i> (adult)	BAS 500 00 F (Pyraclostrobin 247.83 g/l)	Extended laboratory test Cotton pad (2D) Few minutes	Mortality (after 1 week): 0% at 0.04 kg a.s./ha Fertility (after 4 weeks): 0% at 0.04 kg a.s./ha	SANCO/1420/2001-Final.
<i>Poecilus cupreus</i> (adult)	BAS 500 00 F (Pyraclostrobin 247.83 g/l)	Laboratory test Quartz sand (2D) 14 d	Mortality (after 1 week): 0% at 0.320 kg a.s./ha Fertility (after 4 weeks): 11% at 0.320 kg a.s./ha	SANCO/1420/2001-Final.
<i>Pardosa spp.</i> (adult)	BAS 500 00 F (Pyraclostrobin 247.83 g/l)	Laboratory test Quartz sand (2D) 14 d	Mortality (after 1 week): 0% at 0.320 kg a.s./ha Food uptake (after 4 weeks): 10% at 0.320 kg a.s./ha	SANCO/1420/2001-Final.
<i>Typhlodromus pyri</i> (protonymphs)	BAS 510 01 F (Boscalid 50%)	Laboratory test Glass plates (2D) 14 d	LR ₅₀ > 1800 g a.s./ha	SANCO/3919 /2007-rev. 5
<i>Aphidius rhopalosiphii</i> (imagines)	BAS 510 01 F (Boscalid 50%)	Laboratory test Glass plates (2D) 48 h	LR ₅₀ > 1800 g a.s./ha	SANCO/3919 /2007-rev. 5
<i>Typhlodromus pyri</i> (protonymphs)	BAS 510 01 F (Boscalid 50%)	Extended laboratory test Glass plates (2D) 14 d	Mortality (after 1 week): 0% at 1800 g a.s./ha Fertility (after 4 weeks): 3% at 1800 g a.s./ha	SANCO/3919 /2007-rev. 5
<i>Aphidius rhopalosiphii</i> (imagines)	BAS 510 01 F (Boscalid 50%)	Extended laboratory test Glass plates (2D) 48 h	Mortality (after 1 week): 11% at 1800 g a.s./ha Fertility (after 4 weeks): 34% at 1800 g a.s./ha	SANCO/3919 /2007-rev. 5
Field tests				

Species	Substance	Exposure System	Results	Reference
<i>Typhlodromus pyri</i> (life cycle)	BAS 500 00 F (Pyraclostrobin 247.83 g/l)	Field (overspray + oral) Grapes 146 d	Abundance 1st counting: 0% at 2.64 kg f.p./ha/year (equivalent to 0.65 kg a.s./ha/yer) Abundance 2nd counting: 0% at 2.64 kg f.p./ha/year (equivalent to 0.65 kg a.s./ha/yer)	SANCO/1420/2001- Final.
<i>Typhlodromus pyri</i> (protonymphs)	BAS 500 00 F (Pyraclostrobin 247.83 g/l)	Field (overspray + oral) Grapes 124 d	Abundance 1st counting: 0% at 3.14 kg f.p./ha/year (equivalent to 0.78 kg a.s./ha/yer) Abundance 2nd counting: 12% at 3.14 kg f.p./ha/year (equivalent to 0.78 kg a.s./ha/yer)	SANCO/1420/2001- Final.
<i>Typhlodromus pyri</i> (protonymphs)	BAS 500 00 F (Pyraclostrobin 247.83 g/l)	Field (overspray + oral) Grapes 139 d	Abundance 1st counting: 58% at 12 kg f.p./ha/year (equivalent to 2.97 kg a.s./ha/yer) Abundance 2nd counting: 0% at 12 kg f.p./ha/year (equivalent to 2.97 kg a.s./ha/yer)	SANCO/1420/2001- Final.

Table 9.7-2: Endpoints and effect values relevant for the risk assessment for non-target arthropods – Casino Royale

Species	Substance	Exposure System	Results	Reference
<i>Typhlodromus pyri</i> (protonymphs)	Casino Royale	Laboratory test, glass plate (2D)	LR ₅₀ > 8.10 kg f.p./ha (equivalent to >2162.7 g Boscalid/ha and >542.7 g Pyraclostrobin/ha)	KCP 10.3.2.1-01 Glanas, A. 2018 Study code: B/111/16
<i>Aphidius rhopalosiphi</i> (adults)	Casino Royale	Laboratory test, glass plate (2D)	LR ₅₀ = 3.0 kg f.p./ha (equivalent to 801.2 g Boscalid/ha and 201.2 g Pyraclostrobin/ha)	KCP 10.3.2.1-02 Grzesica, M. 2018 Study code: B/110/16

9.7.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints. New studies were conducted with CASINO ROYALE and the endpoints were considered for the risk assessment.

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. Here, the assessment for the use group all crops also covers the risk for non-target arthropods from all other intended uses (see 9.1.4).

Table 9.7-3: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of Casino Royale in all crops

Intended use	All crops		
Active substance/product	Casino Royale		
Application rate (g/ha)	3 x 1500 g f.p./ha		
MAF	2.3 (foliar)		
Test species Tier I	LR ₅₀ (lab.) (g/ha)	PER _{in-field} (g/ha)	HQ _{in-field} criterion: HQ ≤ 2
<i>Typhlodromus pyri</i>	>8100	3450	<0.43
<i>Aphidius rhopalosiphi</i>	3000		1.15
Intended use	All crops		
Active substance/product	Casino Royale		
Application rate (g/ha)	3 x 1500 g f.p./ha (450* g f.p./ha)		
MAF	2.7 (soil)		
Test species Tier I	LR ₅₀ (lab.) (g/ha)	PER _{in-field} (g/ha)	HQ _{in-field} criterion: HQ ≤ 2
<i>Typhlodromus pyri</i>	>8100	1215	<0.15
<i>Aphidius rhopalosiphi</i>	3000		0.41

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.

*Rate with a 70% of interception at BBCH 20-87. According to the interception values of FOCUS (2012).

zRMS comments:

The risk to non-target arthropods is considered to be from exposure to the formulation Casino Royale . The risk from the formulation Casino Royale based on the results from laboratory studies for indicator species T.pyri and Aphidius rhopalosiphi indicating an acceptable in-field as the HQ-in field values which are <2.

9.7.2.2 Risk assessment for off-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group fruiting vegetables also covers the risk for non-target arthropods from all other intended uses like tomato and aubergines.

Table 9.7-4: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of Casino Royale in fruiting vegetables

Intended use		Fruiting vegetables			
Active substance/product		Casino Royale			
Application rate (g/ha)		3 x 1500 g f.p./ha			
MAF		2.3 (foliar)			
vdf		10 5			
Test species Tier I	LR₅₀ (lab.) (g/ha)	Drift rate	PER_{off-field} (g/ha)	CF	HQ_{off-field} criterion: HQ ≤ 2
<i>Typhlodromus pyri</i>	>8100	0.069	23.81	10	<0.03 <0.06
<i>Aphidius rhopalosiphi</i>	3000		47.61		0.08 0.16

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.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group orchards also covers the risk for non-target arthropods from all other intended uses like cherry.

Table 9.7-5: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of Casino Royale in orchards

Intended use		Orchards			
Active substance/product		Casino Royale			
Application rate (g/ha)		2 x 1000 g f.p./ha			
MAF		1.7 (foliar)			
vdf		10 5			
Test species Tier I	LR₅₀ (lab.) (g/ha)	Drift rate	PER_{off-field} (g/ha)	CF	HQ_{off-field} criterion: HQ ≤ 2
<i>Typhlodromus pyri</i>	>8100	0.1213	20.62	10	0.03
<i>Aphidius rhopalosiphi</i>	3000	0.2563*	43.57		0.053 0.11
			87.14		0.07
					0.145 0.29

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.

*% drift for early application in orchards according to ESCORT 2

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group ornamentals also covers the risk for non-target arthropods from all other intended uses like ornamentals in field.

Table 9.7-6: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of Casino Royale in ornamentals

Intended use		Ornamentals			
Active substance/product		Casino Royale			
Application rate (g/ha)		2 x 180 g f.p./ha			
MAF		1.7 (foliar)			
vdf		10 5			

Test species Tier I	LR ₅₀ (lab.) (g/ha)	Drift rate	PER _{off-field} (g/ha)	CF	HQ _{off-field} criterion: HQ ≤ 2
<i>Typhlodromus pyri</i>	>8100	0.0238	0.728	10	0.001 0.002
<i>Aphidius rhopalosiphi</i>	3000		1.457		0.002 0.005

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.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group small fruits also covers the risk for non-target arthropods from all other intended uses like strawberries, raspberries, blackcurrant, redcurrant and whitecurrant.

Table 9.7-7: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of Casino Royale in small fruits

Intended use		Small fruits			
Active substance/product		Casino Royale			
Application rate (g/ha)		2 x 1800 g f.p./ha			
MAF		1.7 (foliar)			
vdf		10 5			
Test species Tier I	LR ₅₀ (lab.) (g/ha)	Drift rate	PER _{off-field} (g/ha)	CF	HQ _{off-field} criterion: HQ ≤ 2
<i>Typhlodromus pyri</i>	>8100	0.0723	22.12	10	0.03 0.06
<i>Aphidius rhopalosiphi</i>	3000		44.25		0.07 0.15

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.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group field crops also covers the risk for non-target arthropods from all other intended uses like sugarbeet, carrot, onion and cabbage.

Table 9.7-8: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of Casino Royale in field crops

Intended use		Field crops			
Active substance/product		Casino Royale			
Application rate (g/ha)		2 x 1500 g f.p./ha			
MAF		1.7 (foliar)			
vdf		10 5			
Test species Tier I	LR ₅₀ (lab.) (g/ha)	Drift rate	PER _{off-field} (g/ha)	CF	HQ _{off-field} criterion: HQ ≤ 2
<i>Typhlodromus pyri</i>	>8100	0.0238	6.069	10	0.01 0.02
<i>Aphidius rhopalosiphi</i>	3000		12.138		0.02 0.04

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.

zRMS comments:

The risk from the formulation Casino Royale based on the results from laboratory studies for two indicator species indicating an acceptable off-field risk as the HQ off-field values which are <2.

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

The in-field and off-field HQ values calculated for the product Casino Royale for the representative species *Typhlodromus pyri* and *A. rhopalosiphi* are lower than the trigger of 2 for Tier I tests, indicating no risk to non-target arthropods in vegetated off-field areas following application according to the proposed use patterns.

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 Pyraclostrobin and Boscalid and their relevant metabolites. Full details of these studies are provided in the respective EU DAR and related.

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of Casino Royale were not evaluated as part of the EU assessment of Pyraclostrobin and Boscalid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

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
<i>Eisenia fetida</i>	Pyraclostrobin	14 d, acute	LC ₅₀ = 567 mg a.s./kg dw LC _{50, corr} = 283 mg prod./kg dw*	SANCO/1420/2001-Final.
<i>Eisenia fetida</i>	BF 500-6 (metabolite)	14 d, acute	LC ₅₀ > 1000 mg/kg dw LC _{50, corr} > 500 mg prod./kg dw*	SANCO/1420/2001-Final.

Species	Substance	Exposure System	Results	Reference
<i>Eisenia fetida</i>	BF 500-7 (metabolite)	14 d, acute	LC ₅₀ > 1000 mg/kg dw LC_{50, corr} > 500 mg prod./kg dw*	SANCO/1420/2001-Final.
<i>Eisenia fetida</i>	BAS 500 00 F (Pyraclostrobin 250 g/L)	14 d, acute	LC ₅₀ = 282 mg prod./kg dw LC ₅₀ = 35.2 mg a.s./kg dw	SANCO/1420/2001-Final.
<i>Eisenia fetida</i>	BAS 500 00 F (Pyraclostrobin 250 g/L)	Application to soil surface 56 d, chronic	NOEC = 1 L prod./kg dw NOEC_{corr} = 0.443 mg a.s./kg dw*	SANCO/1420/2001-Final.
<i>Eisenia fetida</i>	Boscalid	14 d, acute	LC ₅₀ > 1000 mg a.s./kg dw LC_{50, corr} > 500 mg a.s./kg dw*	SANCO/3919 /2007-rev. 5
<i>Eisenia fetida</i>	BAS 510 01 F (Boscalid 500 g/kg)	14 d, acute	LC ₅₀ > 1000 mg prod./kg dw LC _{50, corr} > 500 mg prod./kg dw*	SANCO/3919 /2007-rev. 5
<i>Eisenia fetida</i>	BAS 510 01 F (Boscalid 500 g/kg)	56 d, chronic	NOEC = 3.6 kg prod./ha NOEC _{corr} = 1.8 kg prod./ha* NOEC_{corr} = 1.197 mg a.s./kg dw*	SANCO/3919 /2007-rev. 5
<i>Folsomia candida</i>	BAS 510 01 F (Boscalid 500 g/kg)	28 d, chronic	NOEC (reproduction) >1000 mg BAS 510 01 F /kg soil (>500 mg a.s./kg soil) NOEC_{corr} >500 mg BAS 510 01 F /kg soil* (>250 mg a.s./kg soil*)	Monograph Boscalid, 2002
<i>Eisenia andrei</i>	CASINO ROYALE	56 d, chronic Mixed into soil sustrate, 5% peat	NOEC = 100 mg f.p./kg dw soil (equivalent to 26.7 mg boscalid/kg dw soil + 6.7 mg pyraclostrobin/kg dw soil) NOEC_{corr} = 50 mg f.p./kg dw soil (equivalent to 13.4 mg boscalid/kg dw soil + 3.4 mg pyraclostrobin/kg dw soil) EC ₁₀ = 121.2 mg f.p./kg dw soil (equivalent to 32.4 mg boscalid/kg dw soil + 8.1 mg pyraclostrobin/kg dw soil)	KCP 10.4.1.1 Weronika, D. 2018 G/203/17

Species	Substance	Exposure System	Results	Reference
<i>Folsomia candida</i>	CASINO ROYALE	28 d, chronic Mixed into soil substrate, 5% peat	NOEC = 308.64 mg f.p./kg dw soil (eq. to 82.41 mg boscalid/kg dw soil + 20.68 mg pyraclostrobin/kg dw soil) NOEC_{corr} = 154.32 mg f.p./kg dw soil (eq. to 41.21 mg boscalid/kg dw soil + 10.34 mg pyraclostrobin/kg dw soil) EC ₁₀ = 589.23 mg f.p./kg dw soil (eq. to 157.32 mg boscalid/kg dw soil + 39.48 mg pyraclostrobin/kg dw soil)	KCP 10.4.2.1-01 Antón, B. 2019 S18-07887
<i>Hypoaspis aculeifer</i>	CASINO ROYALE	14 d, chronic Mixed into soil substrate, 5% peat	NOEC = 600 mg f.p./kg dw soil (eq. to 160.20 mg boscalid/kg dw soil + 40.20 mg pyraclostrobin/kg dw soil) NOEC_{corr} = 300 mg f.p./kg dw soil (eq. to 80.1 mg boscalid/kg dw soil + 20.10 mg pyraclostrobin/kg dw soil) EC ₁₀ > 600.00 mg f.p./kg dw soil (eq. to >160.20 mg boscalid/kg dw soil + >40.20 mg pyraclostrobin/kg dw soil)	KCP 10.4.2.1-02 Lozano, J. 2019 S18-06116

* 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 relevant as there is no deviation to the EU agreed endpoints. New studies were conducted with CASINO ROYALE and the endpoints were considered for the risk assessment.

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, Tables 8.7-3 to 8.7-7. According to the assessment of environmental-fate data, multi-annual accumulation in soil need to be considered for BF 500-6, BF 500-7 and Boscalid.

According to the assessment of environmental-fate data, multi-annual accumulation in soil does not need to

be considered for Pyraclostrobin.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group “onion 7 years old” also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses (see 9.1-2).

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 Casino Royale in onion “7 years old” (worst case)

Intended use	Onion “7 years old”		
Acute effects on earthworms			
Product/active substance	LC ₅₀ (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _a (criterion TER ≥ 10)
Pyraclostrobin	283	0.199	1422.1
BF 500-6	500	0.121*	4132.2
BF 500-7	500	0.048*	10416.7
Boscalid	500	1.033*	484.0
Chronic effects on earthworms			
Product/active substance	NOEC (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{tt} (criterion TER ≥ 5)
Pyraclostrobin	0.443	0.199	2.23
Boscalid	1.197	1.033*	1.16
CASINO ROYALE	50 ¹	3.600 ²	13.89
CASINO ROYALE ³	13.4 ¹	1.033*	12.97
CASINO ROYALE ⁴	3.4 ¹	0.199	17.09
Chronic effects on <i>Folsomia candida</i>			
Product/active substance	NOEC (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{tt} (criterion TER ≥ 5)
Boscalid	250	1.033*	242.0
CASINO ROYALE	154.32 ¹	3.600 ²	42.87
CASINO ROYALE ³	41.21 ¹	1.033*	39.89
CASINO ROYALE ⁴	10.34 ¹	0.199	51.96
Chronic effects on <i>Hypoaspis aculeifer</i>			
Product/active substance	NOEC (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{tt} (criterion TER ≥ 5)
CASINO ROYALE	300 ¹	3.600 ²	83.33
CASINO ROYALE ³	80.1 ¹	1.033*	77.54
CASINO ROYALE ⁴	20.10 ¹	0.199	101.0

TER values shown in bold fall below the relevant trigger.

* PEC_{accumulation} (PEC_{act} + PEC_{soil plateau})

¹The endpoint was divided by 2 since log Kow > 2.

²Worst case of PEC_{soil} for the formulated (please refer to Section 8 of this dossier).

³Risk assessment based on an endpoint expressed as mg Boscalid/kg dw from CASINO ROYALE study.

⁴Risk assessment based on an endpoint expressed as mg Pyraclostrobin/kg dw from CASINO ROYALE study.

The acute TER values for the active substance Pyraclostrobin and the metabolites BAS 500-6 and 500-7, and the active substance Boscalid, were far above the relevant Annex VI trigger of 10. Therefore it is concluded that both active substances and the metabolites do not pose an acute risk to earthworms.

However, the long-term TER values were below the relevant trigger of 5 for both active substances. Therefore a refinement of the long-term risk was necessary.

9.8.2.2 Higher-tier risk assessment

Concerning Pyraclostrobin, two field studies on earthworms in grassland with the representative formulation BAS 500 00 F (Pyraclostrobin 250 g/L) were submitted in the DAR (Krieg, W. 2000 and Ehlers H., 2000). These studies were identical concerning the product and the application rate tested (8 applications with increasing rates obtaining a total dose applied of 0.78 kg a.s./ha and 0.39 kg s.a./ha). The application rate tested covers the maximum annual application rate according to the proposal GAP ($3 \times 100 \text{ g a.s./ha} = 300 \text{ g a.s./ha}$). In the first field test (Krieg, W. 2000) no reduction of either abundance or biomass in time was observed in comparison to control. In most application dates an increase in numbers was observed in comparison to control. In the second field test (Ehlers H., 2000), there was a significant reduction in abundance of about 35 % compared to control after the third application of 0.06 kg as/ha. Two weeks after the last application there was still a reduction of about 28 %, which was not significant. One year after study start the population densities of this treatment were comparable to the control values. The application rate of 0.03 kg as/also showed some reduction after the third application (about 24 %), which was not significant. Two weeks after the last application the abundance was comparable to control values. According to the DAR: *“The differences between the outcome in the two field studies may be partly explained by a different precipitation regime. The second study yielded a higher precipitation, therefore exposure might have been higher. As with the lower rate - which takes into account that vegetation cover is given during application and that therefore not the whole applied amount will reach the soil surface – no longlasting effects occurred in both studies, it is concluded that no long-lasting effect on earthworm populations will probably occur.”* Moreover, a third field study in wheat field (Krieg, W. 2000) with the representative formulation BAS 500 01 F (Pyraclostrobin 250 g/L) was tested with a rate of $2 \times 1 \text{ L formulation}$ (corresponding to $2 \times 0.25 \text{ kg as/ha}$). No longlasting effects on earthworm populations were observed in this study. Therefore, according to the Monograph of Pyraclostrobin and the application rate if the proposal GAP, can be concluded that no unacceptable long-term risk on earthworm populations is expected for this Pyraclostrobin.

Regarding Boscalid, two field studies on earthworms in grassland with the representative formulation BAS 510 01 F (Boscalid 500 g/Kg) were submitted in the DAR (Krieg, W. 2001 and Ehlers H., 2001). These studies were identical concerning the product and the application rate tested (3 applications with 1.2 kg BAS 510 01 F/ha, equivalent to 0.6 kg a.s./ha, and 3 applications with 0.6 kg BAS 510 01 F/ha, equivalent to 0.3 kg a.s./ha). According to the DAR and considering the statistical evaluation of the Krieg, W. (2001) study using Williams' and Dunnett's tests to detect significant differences to controls, a potential risk to earthworms can be excluded only for the lower treatment ($3 \times 0.6 \text{ kg BAS 510 01 F/ha}$ respectively 0.9 kg as/ha). The maximum application rate according to the proposal GAP is $3 \times 400 \text{ g a.s./ha}$ for tomato and eggplant, however the applicant wishes to refer that an interception of 70 % (based on the *Generic guidance for Focus groundwater scenario*) should be considered for tomato and eggplant at BBCH 20-87 hence a maximum of 30% of the dose will reach the soil. Considering the real dose that reaches the ground, an application rate of $3 \times 120 \text{ g a.s./ha} = 360 \text{ g a.s./ha}$ should be considered. This annual real dose is lower than the dose without effects from the field study submitted in DAR (900 g a.s./ha). In addition, when the field study application is translated to a PECsoil value (assuming a soil bulk density of 1500 kg/m^3 , depth 5 cm) then for boscalid the application rate of 900 g a.s./ha results in a PEC of $1.20 \text{ mg a.s./kg dw soil}$. These values are higher than the maximum PECs accumulated of 0.691 mg a.s./kg .

Therefore, a low long-term risk to earthworms can be expected when applied according to the proposed use rates.

zRMS comments:

The risk assessment for earthworms and other soil macro-organism was accepted by zRMS.
The risk assessment provided by the zRMS considered PECs agreed at Section 8 by e-fate expert.
The long-term TER values were below the relevant trigger of 5 for both active substances. Therefore, a refinement of the long-term risk was necessary. Higher tier study for earthworms for both active substances were evaluated at EU level. Based on these results it can be concluded that no unacceptable long-term risk on earthworm populations is expected for this Pyraclostrobin and Boscalid.
The long-term risk assessment from exposure from ppp Casino Royale for all proposed uses in the GAP is considered as acceptable.

9.8.3 Overall conclusions

All the TERa values on earthworms for both active substances are higher than the Annex VI trigger value of 10, indicating that Casino Royale poses low acute risk to earthworms when applied according to the proposed use rates. The TERlt values on earthworms, *Folsomia* and *Hypoaspis* were higher than the Annex VI trigger value of 5, indicating low risk for non-target soil organisms with the application of Casino Royale.

However, TERlt values on earthworms for both active substances are lower than the Annex VI trigger value of 5, being necessary a further refinement. After refinement considering the field studies submitted in DAR for both active substances, a low long-term risk is expected indicating that Casino Royale poses low long-term risk to earthworms and other non-target soil organisms when applied according to the proposed use rates.

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 Pyraclostrobin and Boscalid and their relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on soil microorganisms of Casino Royale were not evaluated as part of the EU assessment of Pyraclostrobin and Boscalid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.9-1: Endpoints and effect values relevant for the risk assessment for soil microorganisms

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	BAS 500 00 F (Pyraclostrobin 250 g/L)	28 d, aerobic Silty sand	No effect up to 10 L prod./ha Respective 2.5 kg a.s./ha (equivalent to 3.33 mg a.s/kg dry soil)	SANCO/1420/2001-Final.
N-mineralisation	BAS 500 00 F (Pyraclostrobin 250 g/L)	28 / 49 d, aerobic Loamy silt	No effect up to 10 L prod./ha Respective 2.5 kg a.s./ha (equivalent to 3.33 mg a.s/kg dry soil)	SANCO/1420/2001-Final.
N-mineralisation	BAS 500-6 (metabolite)	28 d, aerobic Loamy sand (72.4% sand)	No effect up to 750 g/ha (equivalent to 1 mg a.s/kg dry soil)	SANCO/1420/2001-Final.
N-mineralisation	BAS 500-7 (metabolite)	28 d, aerobic Loamy sand (72.4% sand)	No effect up to 375 g/ha (equivalent to 0.5 mg a.s/kg dry soil)	SANCO/1420/2001-Final.
N-mineralisation	BAS 500-6 (metabolite)	28 / 77 d, aerobic Loamy sand (57.7% sand)	No effect up to 750 g/ha (equivalent to 1 mg a.s/kg dry soil)	SANCO/1420/2001-Final.
N-mineralisation	BAS 500-7 (metabolite)	28 / 77 d, aerobic Loamy sand (57.7% sand)	No effect up to 375 g/ha (equivalent to 0.5 mg a.s/kg dry soil)	SANCO/1420/2001-Final.
C-mineralisation	BAS 500 00 F (Pyraclostrobin 250 g/L)	28 d, aerobic Silty sand	No effect up to 10 L prod./ha Respective 2.5 kg a.s./ha (equivalent to 3.33 mg a.s/kg dry soil)	SANCO/1420/2001-Final.
C-mineralisation	BAS 500 00 F (Pyraclostrobin 250 g/L)	28 d, aerobic Loamy sand	No effect up to 10 L prod./ha Respective 2.5 kg a.s./ha (equivalent to 3.33 mg a.s/kg dry soil)	SANCO/1420/2001-Final.
C-mineralisation	BAS 500-6 (metabolite)	28 d, aerobic Loamy sand (72.4% sand)	No effect up to 750 g/ha (equivalent to 1 mg a.s/kg dry soil)	SANCO/1420/2001-Final.
C-mineralisation	BAS 500-7 (metabolite)	28 d, aerobic Loamy sand (72.4% sand)	No effect up to 375 g/ha (equivalent to 0.5 mg a.s/kg dry soil)	SANCO/1420/2001-Final.
C-mineralisation	BAS 500-6 (metabolite)	28 / 77 d, aerobic Loamy sand (57.7% sand)	No effect up to 750 g/ha (equivalent to 1 mg a.s/kg dry soil)	SANCO/1420/2001-Final.
C-mineralisation	BAS 500-7 (metabolite)	28 / 77 d, aerobic Loamy sand (57.7% sand)	No effect up to 375 g/ha (equivalent to 0.5 mg a.s/kg dry soil)	SANCO/1420/2001-Final.

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	BAS 510 01 F (Boscalid 500 g/kg)	28 d, aerobic Loamy sand	No effect up to 12 kg prod./ha Equivalent to 6 kg a.s./ha or 8 mg a.s./kg soil	SANCO/3919 /2007-rev. 5
N-mineralisation	BAS 510 01 F (Boscalid 500 g/kg)	28 d, aerobic Loamy silt	No effect up to 12 kg prod./ha Equivalent to 6 kg a.s./ha or 8 mg a.s./kg soil	SANCO/3919 /2007-rev. 5
C-mineralisation	BAS 510 01 F (Boscalid 500 g/kg)	28 d, aerobic Loamy silt	No effect up to 12 kg prod./ha Equivalent to 6 kg a.s./ha or 8 mg a.s./kg soil	SANCO/3919 /2007-rev. 5
C-mineralisation	BAS 510 01 F (Boscalid 500 g/kg)	28 d, aerobic Loamy silt	No effect up to 12 kg prod./ha Equivalent to 6 kg a.s./ha or 8 mg a.s./kg soil	SANCO/3919 /2007-rev. 5
N-mineralisation	CASINO ROYALE	28 d, aerobic agricultural soil	Effects <25% at 6 mg of the test item/kg soil (1.6 mg boscalid + 0.4 mg pyraclostrobin/kg soil) Effects <25% at 30 mg of the test item/kg soil (8.0 mg boscalid + 2.0 mg pyraclostrobin/kg soil)	KCP 10.5.1 Weronika, D. 2018 G/202/17
C-mineralisation	CASINO ROYALE	28 d, aerobic agricultural soil	Effects <25% at 6 mg of the test item/kg soil (1.6 mg boscalid + 0.4 mg pyraclostrobin/kg soil) Effects <25% at 30 mg of the test item/kg soil (8.0 mg boscalid + 2.0 mg pyraclostrobin/kg soil)	KCP 10.5.2 Weronika, D. 2018 G/201/17

9.9.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints. New studies were conducted with CASINO ROYALE and the endpoints were considered for the risk assessment.

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, Tables 8.7-3 to 8.7-7 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. Here, the assessment for the use group “onion 7 years old” also covers the risk for the soil microorganisms from all other intended uses (see 9.1-2).

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of Casino Royale in onion “7 years old “ (worst case)

Intended use	Onion “7 years old “		
N-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC _{soil} (mg/kg dw)	Risk acceptable?
Pyraclostrobin	3.33 (at 28 d)	0.199	yes
BF 500-6	1 (at 28 d)	0.121*	yes
BF 500-7	0.5 (at 28 d)	0.048*	yes
Boscalid	8.0 (at 28 d)	1.033*	yes
CASINO ROYALE	30 (at 28 d)	3.600 ¹	yes
CASINO ROYALE ²	8.0 (at 28d)	1.033*	yes
CASINO ROYALE ³	2.0 (at 28 d)	0.199	yes
C-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC _{soil} (mg/kg dw)	Risk acceptable?
Pyraclostrobin	3.33 (at 28 d)	0.199	yes
BF 500-6	1 (at 28 d)	0.121*	yes
BF 500-7	0.5 (at 28 d)	0.048*	yes
Boscalid	8.0 (at 28 d)	1.033*	yes
CASINO ROYALE	30 (at 28d)	3.600 ¹	yes
CASINO ROYALE ²	8.0 (at 28d)	1.033*	yes
CASINO ROYALE ³	2.0 (at 28 d)	0.199	yes

* $PEC_{accumulation}$ ($PEC_{act} + PEC_{soil}$ plateau)

¹Worst case of PEC_{soil} for the formulated (please refer to Section 8 of this dossier).

²Risk assessment based on an endpoint expressed as mg Boscalid/kg dw from CASINO ROYALE study.

³Risk assessment based on an endpoint expressed as mg Pyraclostrobin/kg dw from CASINO ROYALE study.

zRMS comments:

The risk assessment for soil micro-organism after exposure of both active substances and their metabolites was accepted by the zRMS with consideration PECs values agreed by e-fate experts in Section 8.

The effects on the nitrogen transformations are acceptable (<25%) at concentration which is higher than the maximum relevant PECs soil for the maximum application rate of active substances and the product Casino Royale.

9.9.3 Overall conclusions

Risk assessments conducted with relevant PEC_{soil} for Casino Royale indicate a low risk to soil microorganisms when applied according to the proposed use rates.

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 Pyraclostrobin and Boscalid and their relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target terrestrial plants of Casino Royale were not evaluated as part of the EU assessment of Pyraclostrobin and Boscalid. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.10-1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants regarding Boscalid and Pyraclostrobin

Species	Substance	Exposure System	Results					Reference
			160 g as/ha ¹	480 g as/ha ¹	160 g as/ha ²	480 g as/ha ²	Effects	
<i>Daucus carota</i> _d ¹⁾ <i>Brassica napus</i> _d ²⁾ <i>Pisum sativum</i> _d ³⁾ <i>Zea mays</i> _m ⁴⁾ <i>Avena sativa</i> _m ⁵⁾ <i>Allium cepa</i> _m ⁶⁾	BAS 500 00 F	14 d Vegetative vigour	¹⁾ 0 ²⁾ 3 ³⁾ 6 ⁴⁾ 0 ⁵⁾ 0 ⁶⁾ 0	¹⁾ 5 ²⁾ 7 ³⁾ 6 ⁴⁾ 0 ⁵⁾ 0 ⁶⁾ 0	¹⁾ 120.3 ²⁾ 85.4 ³⁾ 95.0 ⁴⁾ 98.6 ⁵⁾ 95.6 ⁶⁾ 99.9	¹⁾ 111.1 ²⁾ 93.3 ³⁾ 100.7 ⁴⁾ 98.1 ⁵⁾ 97.8 ⁶⁾ 104.5	No significant effects on weight. No effects on phytotoxicity of more than 10 %.	DAR pyraclostrobin, 2001
Species	Substance	Exposure System	Results					Reference
			1.2 kg as/ha ¹	3.6 kg as/ha ¹	1.2 kg as/ha ²	3.6 kg as/ha ²	Effects	
<i>Daucus carota</i> _d ¹⁾ <i>Brassica oleracea</i> _d ²⁾ <i>Pisum sativum</i> _d ³⁾ <i>Zea mays</i> _m ⁴⁾ <i>Avena sativa</i> _m ⁵⁾ <i>Allium cepa</i> _m ⁶⁾	BAS 510 01 F	14 d Vegetative vigour	¹⁾ 2.5 ²⁾ 0 ³⁾ 0 ⁴⁾ 0 ⁵⁾ 0 ⁶⁾ 0	¹⁾ 5 ²⁾ 0 ³⁾ 0 ⁴⁾ 0 ⁵⁾ 0 ⁶⁾ 0	¹⁾ 109.4 ²⁾ 100.2 ³⁾ 91.2 ⁴⁾ 101.9 ⁵⁾ 105.7 ⁶⁾ 108.2	¹⁾ 110.6 ²⁾ 98.9 ³⁾ 97.5 ⁴⁾ 103.5 ⁵⁾ 99.5 ⁶⁾ 113.6	No significant effects on weight. No effects on phytotoxicity of more than 5 %.	Monograph Boscalid, 2002

m: monocotyledonous; d: dicotyledonous

¹ Mean phytotoxicity (% control)

² Mean fresh weight (% control)
BAS 500 00 F = Pyraclostrobin 250 g/L
BAS 510 01 F = Boscalid 500 g/kg

Table 9.10-2: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants regarding CASINO ROYALE

Species	Substance	Exposure System	Results	Reference
Sunflower (<i>Helianthus annuus</i>) _d Cabbage (<i>Brassica oleracea</i> var. <i>capitata</i>) _d Pea (<i>Pisum sativum</i>) _d Carrot (<i>Daucus carota</i>) _d Onion (<i>Allium cepa</i>) _m Oats (<i>Avena sativa</i>) _m	CASINO ROYALE	14 d, seedling emergence and seedling growth	ER ₅₀ >4500 g f.p./ha (eq. to > 1201.5 g boscalid/ha + 301.5 g pyraclostrobin/ha)	KCP 10.6.2-01 Weronika, D. 2018 G/206/17
Sunflower (<i>Helianthus annuus</i>) _d Cabbage (<i>Brassica oleracea</i> var. <i>capitata</i>) _d Pea (<i>Pisum sativum</i>) _d Carrot (<i>Daucus carota</i>) _d Onion (<i>Allium cepa</i>) _m Oats (<i>Avena sativa</i>) _m	CASINO ROYALE	21 d, vegetative vigour	ER ₅₀ >4500 g f.p./ha (eq. to > 1201.5 g boscalid/ha + 301.5 g pyraclostrobin/ha)	KCP 10.6.2-02 Weronika, D. 2018 G/207/17

m: monocotyledonous; d: dicotyledonous

9.10.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints. New studies were conducted with CASINO ROYALE and the endpoints were considered for the risk assessment.

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. Here, the assessment for the use group fruiting vegetables also covers the risk for non-target terrestrial plants from all other intended uses like tomato and aubergines.

Table 9.10-3: Assessment of the risk for non-target plants due to the use of Casino Royale in fruiting vegetables

Intended use		Fruting vegetables		
Active substance/product		Pyraclostrobin		
Application rate (g/ha)		3 × 100		
MAF		2.3		
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
<i>Daucus carota</i> <i>Brassica napus</i> <i>Pisum sativum</i> <i>Zea mays</i> <i>Avena sativa</i> <i>Allium cepa</i>	>480	0.069	15.87	>30.25
Active substance/product		Boscalid		
Application rate (g/ha)		3 × 400		
MAF		2.3		
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
<i>Daucus carota</i> <i>Brassica oleracea</i> <i>Pisum sativum</i> <i>Zea mays</i> <i>Avena sativa</i> <i>Allium cepa</i>	>3600	0.069	63.48	>56.71
Active substance/product		Casino Royale		
Application rate (g/ha)		3 × 1500		
MAF		2.3		
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
<i>Helianthus annuus</i> <i>Brassica oleracea</i> <i>var. capitata</i> <i>Pisum sativum</i> <i>Daucus carota</i> <i>Allium cepa</i> <i>Avena sativa</i>	>4500	0.069	238.05	>18.90

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group orchards also covers the risk for non-target terrestrial plants from all other intended uses like cherry.

Table 9.10-4: Assessment of the risk for non-target plants due to the use of Casino Royale in orchards

Intended use		Orchards		
Active substance/product		Pyraclostrobin		
Application rate (g/ha)		2 × 67		
MAF		1.7		
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
<i>Daucus carota</i> <i>Brassica napus</i> <i>Pisum sativum</i> <i>Zea mays</i> <i>Avena sativa</i> <i>Allium cepa</i>	>480	0.1213 29.20	13.82 19.56	>34.7 >24.53
Active substance/product		Boscalid		
Application rate (g/ha)		2 × 267		
MAF		1.7		
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
<i>Daucus carota</i> <i>Brassica oleracea</i> <i>Pisum sativum</i> <i>Zea mays</i> <i>Avena sativa</i> <i>Allium cepa</i>	>3600	0.1213 29.20	55.06 77.96	>65.4 >46.17
Active substance/product		Casino Royale		
Application rate (g/ha)		2 × 1000		
MAF		1.7		
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
<i>Helianthus annuus</i> <i>Brassica oleracea</i> <i>var. capitata</i> <i>Pisum sativum</i> <i>Daucus carota</i> <i>Allium cepa</i> <i>Avena sativa</i>	>4500	0.1213 29.20	206.2 292	>21.8 >15.41

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group ornamentals also covers the risk for non-target terrestrial plants from all other intended uses like ornamentals in field.

Table 9.10-5: Assessment of the risk for non-target plants due to the use of Casino Royale in ornamentals

Intended use		Ornamentals		
Active substance/product		Pyraclostrobin		
Application rate (g/ha)		2 × 12.1		
MAF		1.7		
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
<i>Daucus carota</i> <i>Brassica napus</i> <i>Pisum sativum</i> <i>Zea mays</i> <i>Avena sativa</i> <i>Allium cepa</i>	>480	0.0238	0.49	>980.5
Intended use		Ornamentals		
Active substance/product		Boscalid		
Application rate (g/ha)		2 × 48.1		
MAF		1.7		
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
<i>Daucus carota</i> <i>Brassica oleracea</i> <i>Pisum sativum</i> <i>Zea mays</i> <i>Avena sativa</i> <i>Allium cepa</i>	>3600	0.0238	1.95	>1849.8
Intended use		Ornamentals		
Active substance/product		Casino Royale		
Application rate (g/ha)		2 × 180		
MAF		1.7		
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
<i>Helianthus annuus</i> <i>Brassica oleracea</i> <i>var. capitata</i> <i>Pisum sativum</i> <i>Daucus carota</i> <i>Allium cepa</i> <i>Avena sativa</i>	>4500	0.0238	7.28	>617.9

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group small fruits also covers the risk for non-target terrestrial plants from all other intended uses like strawberries, raspberries, blackcurrant, redcurrant and whitecurrant.

Table 9.10-6: Assessment of the risk for non-target plants due to the use of Casino Royale in small fruits

Intended use		Small fruits		
Active substance/product		Pyraclostrobin		
Application rate (g/ha)		2 × 121		
MAF		1.7		
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
<i>Daucus carota</i> <i>Brassica napus</i> <i>Pisum sativum</i> <i>Zea mays</i> <i>Avena sativa</i> <i>Allium cepa</i>	>480	0.0723	14.87	>32.3
Intended use		Small fruits		
Active substance/product		Boscalid		
Application rate (g/ha)		2 × 481		
MAF		1.7		
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
<i>Daucus carota</i> <i>Brassica oleracea</i> <i>Pisum sativum</i> <i>Zea mays</i> <i>Avena sativa</i> <i>Allium cepa</i>	>3600	0.0723	59.12	>60.9
Intended use		Small fruits		
Active substance/product		Casino Royale		
Application rate (g/ha)		2 × 1800		
MAF		1.7		
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
<i>Helianthus annuus</i> <i>Brassica oleracea</i> <i>var. capitata</i> <i>Pisum sativum</i> <i>Daucus carota</i> <i>Allium cepa</i> <i>Avena sativa</i>	>4500	0.0723	221.2	>20.3

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group field crops also covers the risk for non-target terrestrial plants from all other intended uses like sugarbeet, carrot, onion and cabbage.

Table 9.10-7: Assessment of the risk for non-target plants due to the use of Casino Royale in field crops

Intended use		Field crops		
Active substance/product		Pyraclostrobin		
Application rate (g/ha)		2 × 100		
MAF		1.7		
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
<i>Daucus carota</i> <i>Brassica napus</i> <i>Pisum sativum</i> <i>Zea mays</i> <i>Avena sativa</i> <i>Allium cepa</i>	>480	0.0238	4.05	>118.6
Intended use		Field crops		
Active substance/product		Boscalid		
Application rate (g/ha)		2 × 400		
MAF		1.7		
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
<i>Daucus carota</i> <i>Brassica oleracea</i> <i>Pisum sativum</i> <i>Zea mays</i> <i>Avena sativa</i> <i>Allium cepa</i>	>3600	0.0238	16.18	>222.4
Intended use		Field crops		
Active substance/product		Casino Royale		
Application rate (g/ha)		2 × 1500		
MAF		1.7		
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
<i>Helianthus annuus</i> <i>Brassica oleracea</i> <i>var. capitata</i> <i>Pisum sativum</i> <i>Daucus carota</i> <i>Allium cepa</i> <i>Avena sativa</i>	>4500	0.0238	60.69	>74.2

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

zRMS comment:

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. The deterministic risk based on the ER₅₀ of 4500 g formulation/L and PER_{off}- field values, the risk is considered acceptable. However it should be noted that applicant should use the MAF of 1 to calculate the PER_{off} field. Generally speaking in zRMS’s opinion due to the fact that it stated worst case in comparison to MAF of 1 the risk is considered acceptable.
No risk mitigation measures are required.

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

Risk assessment conducted with relevant toxicity data on non-target terrestrial plants for Casino Royale shows that the Annex VI trigger value of 5 is not exceeded, indicating that Casino Royale poses a low risk to non-target terrestrial plants when applied according to the proposed use rates.

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

No additional data are available.

9.12 Monitoring data (KCP 10.8)

Not relevant.

9.13 Classification and Labelling

	Casino Royale
Common Name	Boscalid 26.7% + Pyraclostrobin 6.7% WG
Classification and proposed labelling	
With regard to ecotoxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: Aquatic Acute Category 1 Aquatic Chronic Category 1 Code(s) for hazard pictogram(s): GHS 09 Signal word: Warning Hazard statement(s):

	Casino Royale
	H410: Very toxic to aquatic life with long lasting effects Precautionary statement: P273 , P391, P501

Pyraclostrobin is classified as Aquatic Acute 1, H400 (M = 100) and Chronic Category 1, H410 (M = 10). CASINO ROYALE contains $100 \times 6.87 \geq 25\%$ and $10 \times 6.87 \geq 25\%$ [$M \times \text{Acute } 1 \geq 25\%$ and $M \times \text{Chronic } 1 \geq 25\%$] of this active substance, therefore hazard statement H400 and H410, with pictogram GHS09 and signal word “Warning” is proposed.

zRMS comment:

We agree with labelling and classification provided by the applicant.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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 10.1.1.2-01	Łukaszewski, K.	2019	Magnitude of the residue of pyraclostrobin + boscalid in tomato (Raw Agricultural Commodity) after two application of Pyraclostrobin 6.7% + Boscalid 26.7% WG – two harvest trials and one decline curve trial in Poland – 2018 Report No. 18SGS18. SGS Polska Sp. Z o.o. GLP. Unpublished	N	Sharda Cropchem Limited
KCP 10.1.1.2-02	Iszak, P.	2020	Determination of the residues of Boscalid + Pyraclostrobin in/on tomato (outdoor) after two applications of Boscalid 26.7% + Pyraclostrobin 6.7% WG in Northern Europe – Hungary in 2019 Report No. 034SRHU19R27. CPR Europe Kft. GLP. Unpublished	N	Sharda Cropchem Limited
KCP 10.2.1-01	xxxxf	2018	Pyraclostrobin 6.7% + Boscalid 26.7% WG Rainbow Trout, Acute Toxicity Test Report No. W/140/17 xxx GLP. Unpublished	Y	Sharda Cropchem Limited
KCP 10.2.1-02	Kulec-Płoszczyca, E.	2018	Pyraclostrobin 6.7% + Boscalid 26.7% WG <i>Daphnia magna</i> , acute immobilisation test Report No. W/142/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP. Unpublished	N	Sharda Cropchem Limited
KCP 10.2.1-03	Kulec-Płoszczyca, E.	2018	Pyraclostrobin 6.7% + Boscalid 26.7% WG <i>Raphidocelis subcapitata</i> SAG 61.81 (formerly <i>Pseudokirchneriella subcapitata</i>) Growth inhibition test Report No. W/141/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP. Unpublished	N	Sharda Cropchem Limited

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 10.2.1-04	Kulec-Ploszczycza, E.	2018	Pyraclostrobin 6.7% + Boscalid 26.7% WG <i>Lemna gibba</i> CPCC 310, Growth inhibition test Report No. W/143/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP. Unpublished	N	Sharda Cropchem Limited
KCP 10.3.1.1.1	Glanas, A.	2017	Boscalid 26.7% + Pyraclostrobin 6.7% WG Honeybees (<i>Apis mellifera</i> L.), Acute Oral Toxicity Test Report No. B/108/16 Institute of Industrial Organic Chemistry Branch Pszczyna GLP. Unpublished	N	Sharda Cropchem Limited
KCP 10.3.1.1.2	Glanas, A.	2017	Boscalid 26.7% + Pyraclostrobin 6.7% WG. Honeybees (<i>Apis mellifera</i> L.), Acute Contact Toxicity Test Report No. B/109/16 Institute of Industrial Organic Chemistry Branch Pszczyna GLP. Unpublished	N	Sharda Cropchem Limited
KCP 10.3.1.2.1	Radha, S.	2020	Chronic oral toxicity study of Pyraclostrobin Technical on adult honey bee (<i>Apis mellifera</i>). Report No. 5028/2019 Bioscience Research Foundation GLP. Unpublished	N	Sharda Cropchem Limited
KCP 10.3.1.3.1	Radha, S.	2020	Effect of Pyraclostrobin Technical on larvae of honey bee, <i>Apis mellifera</i> (L.) following repeated exposure. Report No. 5029/2019 Bioscience Research Foundation GLP. Unpublished	N	Sharda Cropchem Limited
KCP 10.3.1.2.2	Radha, S.	2020	Chronic oral toxicity study of Boscalid Technical on adult honey bee (<i>Apis mellifera</i>) Report No. 5031/2019 Bioscience Research Foundation GLP. Unpublished	N	Sharda Cropchem Limited
KCP 10.3.1.3.2	Radha, S.	2020	Effect of Boscalid Technical on larvae of honey bee, <i>Apis mellifera</i> (L.) following repeated exposure. Report No. 5032/2019 Bioscience Research Foundation GLP. Unpublished	N	Sharda Cropchem Limited

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 10.3.2.1-01	Glanas, A.	2018	A laboratory test for evaluating the effects of Boscalid 26.7% + Pyraclostrobin 6.7% WG on the predatory mite, <i>Typhlodromus pyri</i> (Sch.) Report No. B/111/16 Institute of Industrial Organic Chemistry Branch Pszczyna GLP. Unpublished	N	Sharda Cropchem Limited
KCP 10.3.2.1-02	Grzesica, M.	2018	A laboratory test for evaluating the effects of Boscalid 26.7% + Pyraclostrobin 6.7% WG on the parasitic wasp, <i>Aphidius rhopalosiphi</i> (De Stefani - Perez) Report No. B/110/16 Institute of Industrial Organic Chemistry Branch Pszczyna GLP. Unpublished	N	Sharda Cropchem Limited
KCP 10.4.1.1	Weronika, D.	2018	Boscalid 26.7% + Pyraclostrobin 6.7% WG Earthworm Reproduction Test (<i>Eisenia andrei</i>) Report No. G/203/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP. Unpublished	N	Sharda Cropchem Limited
KCP 10.4.2.1-01	Antón, B.	2019	Pyraclostrobin 6.7 % + Boscalid 26.7 % WG Effects on the Reproductive Output of the Springtail <i>Folsomia candida</i> Willem (Collembola, Isotomidae) in Artificial Soil Report No. S18-07887 TRIALCAMP S.L.U. GLP. Unpublished	N	Sharda Cropchem Limited
KCP 10.4.2.1-02	Lozano, J.	2019	Pyraclostrobin 6.7% + Boscalid 26.7% WG: Effects on the Reproductive Output of the Predatory Soil Mite <i>Hypoaspis</i> (<i>Geolaelaps</i>) <i>aculeifer</i> Canestrini (Acari: Laelapidae) in Artificial Soil Report No. S18-06116 TRIALCAMP S.L.U. GLP. Unpublished	N	Sharda Cropchem Limited
KCP 10.5.1	Weronika, D.	2018	Boscalid 26.7% + Pyraclostrobin 6.7% WG Soil Microorganisms: Nitrogen Transformation Test Report No. G/202/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP. Unpublished	N	Sharda Cropchem Limited
KCP 10.5.2	Weronika, D.	2018	Boscalid 26.7% + Pyraclostrobin 6.7% WG Soil Microorganisms: Carbon Transformation Test Report No. G/201/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP. Unpublished	N	Sharda Cropchem Limited

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 10.6.2-01	Weronika, D.	2018	Boscalid 26.7% + Pyraclostrobin 6.7% WG Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Report No. G/206/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP. Unpublished	N	Sharda Cropchem Limited
KCP 10.6.2-02	Weronika, D.	2018	Boscalid 26.7% + Pyraclostrobin 6.7% WG Terrestrial Plant Test: Vegetative Vigour Test Report No. G/207/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP. Unpublished	N	Sharda Cropchem Limited

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

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

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

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

Comments of zRMS:	The study was evaluated in Residue section and was considered as acceptable.
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Reference: KCP 10.1.1.2-01

Report Magnitude of the residue of pyraclostrobin + boscalid in tomato (Raw Agricultural Commodity) after two application of Pyraclostrobin 6.7% + Boscalid 26.7% WG – two harvest trials and one decline curve trial in Poland – 2018, K. Łukaszewski, Report No. 18SGS18

Guideline(s): Yes

- Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
- Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue trials, July 22, 1997
- OECD Environmental Health and Safety Publications, Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 1 OECD Principles of Good Laboratory Practice, 1997.
- SANCO/825/00 rev. 8.1
- SANCO/3029/99 rev. 4

Deviations: No

GLP: Yes

Acceptability: Yes

Three field trials were established on tomato in three different locations. The sites were representative for tomato production, grown in a typical way in the test countries. Each trial consisted of on untreated plot U and on treated plot T. Plots were of sufficient size to generate the desired specimen quantities. Around the treated and untreated plots a buffer zone of at least 10 m was set up. Tomato was cultivated according to normal local agronomic practises.

The application equipment consisted of boom sprayer. The foliar applications closely simulated commercial-type treatments. Pyraclostrobin 6.7% + Boscalid 26.7% WG was only mixed with water. No adjuvant was added to the spray mixture. The target dose rate of the test item was 1.5 kg/ha of formulated product per application, equivalent to 100.5 g as/ha Pyraclostrobin and 400.6 g as/ha Boscalid.

Applications were made at a target water volume of 500-1000 litres per hectare of mixture according to GAP.

In all study trials (harvest trials – HS and decline curve trials – DCS), RAC specimens were collected following the target schedule:

Trial type	Number of sampling events	Timing of sampling events
HS	1	3 DALA
DCS	1	0 DALA
	2	1 DALA
	3	3 DALA

Reference: KCP 8.3.2.4

Report Magnitude of the residue of pyraclostrobin + boscalid in tomato (raw agricultural commodity) after two applications of pyraclostrobin 6.7% + boscalid 26.7% WG – two harvest trials and one decline curve trial in Poland – 2018. – analytical phase report. Zofia Hordyjewicz-Baran, 2019. Study No. 22/2019

Guideline(s): Yes

- Council Regulation (EC) No 440/2008, ICSO Procedure BA-AB/SPO-1 and research method No. BA-AB/MS/MB-5 and BA-AB/MS/MB-6
- Directive 2004/10/EC of the European Parliament and of the Council of 11th February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of the applications for test on chemical substances.
- The Minister of Health Regulations of 22nd May 2013 on Good Laboratory Practice and performance of studies in compliance with the principles of GLP (Dz. U. Z 2013 poz. 665)
- Act of 25th February 2011 on the chemical substances and their mixtures (The Republic of Poland Journal of Law of 2011, No. 63, item 322 with subsequent amendments)
- OECD Environmental Health and Safety Publications, Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 1 OECD Principles of Good Laboratory Practice, 1997.
- SANCO/825/00 rev. 8.1
- SANCO/3029/99 rev. 4

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods:

During the growing season of 2018, a total of three trials were conducted in tomato in Northern Europe (Poland) to determine the magnitude of harvest residues of Pyraclostrobin and Boscalid in or on raw agricultural commodities (RAC).

The determination of Pyraclostrobin and Boscalid residues has been performed by liquid chromatography, and consists in an separation on a reversed-phase column and detection by tandem mass spectrometry (MS/MS) by electrospray (ESI) operating with optimized conditions.

The characteristics of the analytical method was as follows:

Preparation of Stock Standard Solutions

Preparation of stock solution of Pyraclostrobin for calibration

Reference Item	Purity of reference item* (%)	Weighed amount of reference item (mg)	Amount of analyte corrected for purity (mg)	Final volume (mL)	Solvent used for dilution	Equivalent conc. (mg/mL)	Reference of standard solution produced
Pyraclostrobin	99.9	20.04	20	10	Acetonitrile	2	1S1

Preparation of stock solution of Boscalid for calibration

Reference Item	Purity of reference item* (%)	Weighed amount of reference item (mg)	Amount of analyte corrected for purity (mg)	Final volume (mL)	Solvent used for dilution	Equivalent conc. (mg/mL)	Reference of standard solution produced
Boscalid	99.5	20.21	20	10	Acetonitrile	2	1S2

Preparation of Working, Fortification and Stability Testing Standard Solutions

Preparation of working solutions of Pyraclostrobin

Reference of standard solution used	Concentration Pyraclostrobin (µg/mL)	Volume taken (mL)	Final volume (mL)	Equivalent concentration (µg/mL)	Reference of standard solution produced (mixture)
1S1	2000	0.5	50	20	1SW1
1SW1	20	2	10	4	1SW2
1SW1	20	1	10	2	1SW3
1SW1	20	0.5	10	1	1SW4
1SW1	20	0.2	10	0.4	1SW5
1SW1	20	0.1	10	0.2	1SW6
1SW3	2	0.5	10	0.1	1SW7
1SW3	2	0.2	10	0.04	1SW8
1SW3	2	0.1	10	0.02	1SW9

Preparation of working solutions of Boscalid

Reference of standard solution used	Concentration Boscalid (µg/mL)	Volume taken (mL)	Final volume (mL)	Equivalent concentration (µg/mL)	Reference of standard solution produced (mixture)
1S2	2000	0.5	50	20	1SW1
1SW1	20	2	10	4	1SW2
1SW1	20	1	10	2	1SW3
1SW1	20	0.5	10	1	1SW4
1SW1	20	0.2	10	0.4	1SW5
1SW1	20	0.1	10	0.2	1SW6
1SW3	2	0.5	10	0.1	1SW7
1SW3	2	0.2	10	0.04	1SW8
1SW3	2	0.1	10	0.02	1SW9

Sample preparation

Preparation of Sample Matrix

- A. Portion of dry ice was added to a homogenizer apparatus (Laboratory mill). Subsequent appropriate amount of sample was added to the apparatus in small portions. Sample was blended after each addition until a homogeneous mixture was obtained.
- B. Contents of the apparatus were poured into polyethylene bags, and stored in a freezer until the last traces of dry ice have sublimed.

Sample Extraction

- A. 10.00 g ± 0.1 g of homogenized matrix was weighed into a 50 mL PP centrifuge tube. Sample weight was recorded.
- B. If necessary fortification of the concurrent recovery sample(s) by aliquoting the fortification standard of Pyraclostrobin and Boscalid mixture onto the matrix was carried out at this step. Fortification details are given below:

Fortification level	Standard dilution	Concentration of individual standard (µg/mL)	Volume used (µL)
LOQ (0.01 mg/kg)	1SW3	2	50

- C. For extraction using an automatic pipette 10 mL of acetonitrile was added.
- D. The PP centrifuge tube was closed tightly and shake for 1 min automatically.

Liquid-Liquid Partition

A. Buffer-salt mixture ($4 \text{ g} \pm 0.2 \text{ g}$ of magnesium sulfate anhydrous, $1 \text{ g} \pm 0.05 \text{ g}$ of sodium chloride, $0.5 \text{ g} \pm 0.03 \text{ g}$ NaCitrate dibasic sesquihydrate, $1 \text{ g} \pm 0.05 \text{ g}$ NaCitrate tribasic dehydrate) was added and the centrifuge tube was closed and shaken by vortex for 1 min.

B. The extract was centrifuged at $>3000 \text{ g}$ for 5 min.

Sample purification

A. Using an automatic pipette 6 ml of sample extract supernatant was transferred to Dispersive SPE 12 ml centrifuge tubes containing 150 mg Supelclean PSA and 900 mg MgSO_4 . The tube was shaken automatically for 30 sec.

Sample Dilution

A. An aliquot of 0.5 mL of purified sample extract was transferred to new Eppendorf safe-lock tube and subsequently diluted with 0.4 mL of Water, 0.05 mL acetonitrile (+1% Vol. formic acid) and 0.05 mL of acetonitrile.

B. Content was vortex gently and filtered through the $0.22 \text{ }\mu\text{m}$ Teflon filter attached to a syringe direct into amber HPLC vial.

C. Vial was labelled so that it may be identified.

Final Determination

A. Final determination was performed using LC-MS/MS.

Results:

No residue above the LOD were detected in the control samples. The analytical results in mg per kg are summarized in Table A.2:

Table 1: Summary of the study

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment	Stage at last treatment	Portion analyzed	Residues (mg/kg)		PHI (d)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./ hl				Pyra-clos-trobin	Bos-calid		
(a)	(b)	(b)				(c)					(d)	(e)
18SGS18 PL01/ Poland / NEU / 2018	Tomato/ Asterix	29/05/2018 25/06-28/07/2018 07/09/2018	A1: 106.93 + 426.13 A2: 93.47 + 372.47	745 651	-	2 27/08/2018 94/09/2018	BBCH 85-87	Fruits	0.065	0.558	3	Analytical phase report: 22/2019 LOD Pyraclostrobin = 0.002 mg/kg (tomato) LOD Boscalid = 0.002 mg/kg (tomato) Time between harvest and extraction: 160 days
18SGS18 PL02/ Poland / NEU / 2018	Tomato/ Dyno F1	30/04/2018 14/06-12/08/2018 01/08-15/09/2018	A1: 98.09 + 390.89 A2: 103.31 + 411.71	683.3 720	-	2 14/08/2018 21/08/2018	BBCH 82-85	Fruits	0.040	0.252	3	Analytical phase report: 22/2019 LOD Pyraclostrobin = 0.002 mg/kg (tomato) LOD Boscalid = 0.002 mg/kg (tomato) Time between harvest and extraction: 173 days
18SGS18 PL03/ Poland / NEU / 2018	Tomato/ Babinicz	05/05/2018 01//06- 25/06/2018 07/09/2018	A1: 102.18 + 407.18 A2: 98.89 + 394.09	610 590.6	-	2 28/08/2018 04/09/2018	BBCH 83-85	Fruits Fruits Fruits	0.043 0.028 0.016	0.216 0.163 0.076	0 1 3	Analytical phase report: 22/2019 LOD Pyraclostrobin = 0.002 mg/kg (tomato) LOD Boscalid = 0.002 mg/kg (tomato) Time between harvest and extraction: 162 days

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS: The study was evaluated in Residue section and was considered as acceptable.

Reference: KCP 10.1.1.2-02

Report Determination of the residues of Boscalid + Pyraclostrobin in/on tomato (outdoor) after two applications of Boscalid 26.7% + Pyraclostrobin 6.7% WG in Northern Europe – Hungary in 2019. P. Iszak, Report No. 034SRHU19R27

Guideline(s): Yes

- Regulations (EU) No. 283/2013 and 284/2013 implementing Regulation (EC) No. 1107/2009 of the European Parliament.

- "Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997.

- OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)

Deviations: No

GLP: Yes

Acceptability: Yes

Three trials were conducted in Hungary in 2019. The field phase was performed in Kőszeg (SRHU19-192-034FR), in Vép (SRHU19-193-034FR), and in Szatymaz (SRHU19-194-034FR).

Two applications (8 days interval) of the formulated product Boscalid 26.7% + Pyraclostrobin 6.7% WG were applied at a target rate of 1.5 kg formulated product/ha to tomato, using conventional sprayer equipment, under open field condition, with the last application done 3 days before commercial harvest.

Specimens (fruits) were collected at 0, 1 and 3 days after application, frozen and shipped deep frozen to analytical facility.

Reference: KCP 8.3.2.6

Report Determination of the residue of boscalid + pyraclostrobin in/on tomato (outdoor) after two foliar application of Boscalid 26.7% + Pyraclostrobin 6.7% WG in northern Europe – Hungary in 2019, M. Zarębska, Report No. 173/2019

Guideline(s): Yes

- Council Regulation (EC) No 440/2008, ICSO Procedure BA-AB/SPO-1 and research method No. BA-AB/MS/MB-5 and BA-AB/MS/MB-6
- Directive 2004/10/EC of the European Parliament and of the Council of 11th February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of the applications for test on chemical substances.
- The Minister of Health Regulations of 22nd May 2013 on Good Laboratory Practice and performance of studies in compliance with the principles of GLP (Dz. U. Z 2013 poz. 665)
- Act of 25th February 2011 on the chemical substances and their mixtures (The Republic of Poland Journal of Law of 2011, No. 63, item 322 with subsequent amendments)
- OECD Environmental Health and Safety Publications, Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 1 OECD Principles of Good Laboratory Practice, 1997.
- SANCO/825/00 rev. 8.1
- SANCO/3029/99 rev. 4

Deviations: No

GLP: Yes

Acceptability: Yes

The objective of this study was to determine the residues of Pyraclostrobin and Boscalid in raw agricultural commodities of tomatoes after application of Pyraclostrobin 6.7 + Boscalid 26.7% WG.

Materials

Mobile phase A: 0.1% (v/v) Formic acid in Water

1000 mL volumetric flask was half filled with water and 1 mL of formic acid was added. Volumetric flask was filled up to the mark with water, closed tightly and mixed by inverting several times. Solvent was transferred to amber HPLC solvent reservoir.

Mobile phase B: 0.1% (v/v) Formic acid in Acetonitrile

1000 mL volumetric flask was half filled with acetonitrile and 1 mL of formic acid was added. Volumetric flask was filled up to the mark with acetonitrile, closed tightly and mixed by inverting several times. Solvent was transferred to amber HPLC solvent reservoir.

Preparation of Sample Matrix

Portion of dry ice was added to a homogenizer apparatus (laboratory mill). Subsequent appropriate amount of sample was added to the apparatus in small portions. Sample was blended after each addition until a homogeneous mixture was obtained.

Contents of the apparatus were poured into polyethylene bags, and stored in a freezer until the last traces of dry ice have sublimed.

Sample extraction

10 g of homogenized matrix was weighed into a 50 mL PP centrifuge tube. Sample weight was recorded. If necessary fortification of the concurrent recovery sample by aliquoting the fortification standard of Pyraclostrobin and Boscalid mixture onto the matrix was carried out at this step.

Fortification level	Standard dilution	Concentration of individual standard (µg/mL)	Volume used (µL)
LOQ (0.01 mg/kg)	1SW3	2	50
10LOQ (0.1 mg/kg)	1SW1	20	50

For extraction using an automatic pipette 10 mL of acetonitrile was added
The PP centrifuge tube was closed tightly and shake for 1 min automatically/

Liquid-Liquid Partition

Buffer-salt mixture (4 g +/- 0.2 g of magnesium sulfate anhydrous, 1 g of sodium chloride, 0.5 g NaCitrate dibasic sesquihydrate, 1 g NaCitrate tribasic dehydrate) was added and the centrifuge tube was closed and shaken by vortex for 1 min. The extract was centrifuged for 5 min.

ACCURACY and PRECISION

Analyte	Matrix	Fortification level (mg/kg)	Mean Recovery (%)	RSD (%)	n
Pyraclostrobin	Ion Mass Transition m/z 388 → 194 (Quantification)				
	Tomatoes	0.01	108	1.1	3
		0.1	109	0.8	3
	Ion Mass Transition m/z 388 → 163 (Confirmation)				
	Tomatoes	0.01	106	1.4	3
		0.1	105	2.3	3
Boscalid	Ion Mass Transition m/z 343 → 307 (Quantification)				
	Tomatoes	0.01	109	2.0	3
		0.1	106	3.6	3
	Ion Mass Transition m/z 343 → 140 (Confirmation)				
	Tomatoes	0.01	104	0.6	3
		0.1	106	2.2	3

Table 1: Summary of the study

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment €	Stage at last treatment	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial €
			g a.s./ ha	Water (l/ha)	g a.s./ hl				Pyra-clos-trobin	Boscalid		
SHRU19-192-034FR/ Hungary NEU / 2019	Tomato/ Kecskeméti 549	31/05/2019 07/2019 08/2019	A1: 399.63 + 99.91 A2: 393.59 + 98.4	749 738	-	2 06/08/2019 14/08/2019	BBCH 81 BBCH 85	Fruits Fruits Fruits	0.11 0.09 0.006	0.078 0.046 0.052	0 1 3	Analytical phase report: 173/2019 LOD Pyraclostrobin = 0.002 mg/kg (tomato) LOD Boscalid = 0.002 mg/kg (tomato) Time between harvest and extraction: 7 monrhs
SHRU19-193-034FR/ Hungary NEU / 2019	Tomato/ Kecskeméti 549	03/07/2019 07/2019 08/2019	A1: 406.4 + 101.6 A2: 386.1 + 96.5	762 724	-	2 06/08/2019 14/08/2019	BBCH 83 BBCH 85	Fruits Fruits Fruits	0.049 0.034 0.011	0.278 0.170 0.075	0 1 3	Analytical phase report: 173/2019 LOD Pyraclostrobin = 0.002 mg/kg (tomato) LOD Boscalid = 0.002 mg/kg (tomato) Time between harvest and extraction: 7 monrhs
SHRU19-194-034FR/ Hungary NEU / 2019	Tomato/ Kecskeméti jubileum	31/05/2019 07/2019 08/2019	A1: 411.8 + 102.9 A2: 391.8 + 97.95	772 735	-	2 06/08/2019 14/08/2019	BBCH 83 BBCH 85	Fruits Fruits Fruits	0.027 0.006 0.017	0.138 0.025 0.090	0 1 3	Analytical phase report: 173/2019 LOD Pyraclostrobin = 0.002 mg/kg (tomato) LOD Boscalid = 0.002 mg/kg (tomato) Time between harvest and extraction: 7 monrhs

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

Comments of zRMS:	<p>The study is considered acceptable. All validity criteria were met.</p> <ul style="list-style-type: none"> The mortality in the control was 0% at exposure termination (should not exceed 10% or 1 fish if less than 10 fish are used) Dissolved oxygen concentrations were within the range of 91 – 99% of air saturation value (obligatory above 60% of air saturation value) <p>Agreed endpoints: The 96h LC_{50} = 0.054 mg/L (nominal test item concentrations). The 96h LC_{50} = 0.0036 mg/L (nominal concentrations of pyraclostrobin). The 96h LC_{50} = 0.0144 mg/L (nominal concentrations of boscalid).</p>
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Reference:	KCP 10.2.1 - 01
Report	“Pyraclostrobin 6.7% + Boscalid 26.7% WG Rainbow Trout, Acute Toxicity Test”. xxx, 2018, W/140/17. xxx.
Guideline(s):	OECD Guideline No. 203 (1992)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	Yes

Materials and methods

Test item:	<p>Description: Pyraclostrobin 6.7% + Boscalid 26.7% WG</p> <p>Production batch: SCL-65489</p> <p>A.i. content: 6.7% w/w of pyraclostrobin; 26.7% w/w of boscalid</p>
Test system:	<p>Species: Rainbow trout (<i>Oncorhynchus mykiss</i> Walb.)</p> <p>Strain: -</p> <p>Age: approximately 3 months, average weight: 0.87 g ± 0.39 g; average body length: 4.25 cm ± 0.32 cm</p> <p>Source: ‘The Culture of Salmonidae Fish in Zawoja’, Poland</p> <p>Acclimation period: 7 days</p> <p>Diet: The fish were not fed during the test</p>
Experimental conditions:	<p>Temperature: 13.8 – 14.8°C</p> <p>Dissolved O₂: 90 – 99%</p> <p>Hardness: 41 mg CaCO₃/dm³</p> <p>pH: 7.65 – 7.95</p> <p>Light and photoperiod: 16h light and 8h dark.</p> <p>Loading: 0.61 g fish/L test solution. Each aquarium comprised 7 fish and 10 L test solution.</p> <p>Test procedure: -</p>

Experimental period: 96h

Test design and treatment

Semi-static system (96 hours) with one renewal after 48 h of exposure (one replicate of each test item concentration and the control. Seven fish were introduced into each aquarium.).

The following nominal test item concentrations were used: 0.1, 0.05, 0.025, 0.013, 0.006 mg/L plus control. The fish were observed for mortality and intoxication symptoms after 3, 6, 24, 48, 72 and 96 h of exposure.

The concentrations of pyraclostrobin and boscalid were chemically determined using a validated liquid chromatographic method with DAD detection. The concentrations of pyraclostrobin and boscalid were chemically determined in samples of all fresh test item concentration and the control collected at exposure initiation and fresh samples of test item concentrations 0.05, 0.025, 0.013, and 0.006 mg/L during the renewal. Moreover, samples of all spent test item concentrations and the control collected at the renewal and samples of test item concentrations 0.05, 0.025, 0.013, and 0.006 mg/L at exposure termination were chemically analyzed.

The determined concentrations of pyraclostrobin in fresh samples were in the range of 89.2 – 110.0% of the nominal concentration. The determined concentrations of boscalid in fresh samples were in the range of 82.8 – 98.5% of the nominal concentration. The results confirm correct preparation of the test item concentrations.

The determined concentrations of pyraclostrobin in spent samples were in the range of 80.3 – 101.2% of the nominal concentration. The determined concentrations of boscalid in spent samples were in the range of 80.0 – 99.3% of the nominal concentration. Therefore, concentrations of pyraclostrobin and boscalid were stable under the test conditions. The Limit of Quantification (LoQ) for pyraclostrobin and boscalid analyzed in water is -5 mg/L and Limit of Detection (LoD) is -15 mg/L.

Calculations with the probit method analysis by The Bartlett test Procedure on Variance Homogeneity and Student-t test for Homogeneous Variances with Bonferroni-Holm Adjustment. were made.

Results

In the control and in the test item concentrations of 0.006, 0.013, and 0.025 mg/L neither mortality of fish nor symptoms of intoxication were observed during exposure. In test item concentration of 0.05 mg/L, nontypical swimming and respiratory problems for three fish were observed after 6 h of exposure. After 24 h of exposure, one fish was dead, nontypical swimming, and respiratory problems for two fish were observed. After 48 h of exposure, two fish were dead, nontypical swimming, and respiratory problems for three fish were observed. After 72 and 96 h of exposure, two fish were dead, nontypical swimming for one fish and respiratory problems for three fish were observed.

In the test item concentration of 0.1 mg/L, loss of balance and nontypical swimming for two fish as well as respiratory problems for seven fish were observed after 3 h of exposure. After 6 h of exposure, two fish were dead, loss of balance and nontypical swimming for three fish as well as respiratory problems for five fish were observed. After 24 h of exposure, five fish were dead and loss of balance, nontypical swimming, respiratory problems as well as pigmentation change for two fish were observed. After 48 h of exposure, all fish were dead.

The endpoint values determined on the basis of the nominal test item concentrations and mortality of fish are given below:

The LC₅₀ value after 96 h of exposure is 0.054 mg/L.

The LOEC/96 h value is 0.050 mg/L.

The NOEC/96 h value is 0.025 mg/L.

The endpoint values determined on the basis of the nominal concentrations of pyraclostrobin and mortality of fish:

The LC₅₀/96 h value is 0.0036 mg/L.
The LOEC/96 h value is 0.0034 mg/L.
The NOEC/96 h value is 0.0017 mg/L.

The endpoint values determined on the basis of the nominal concentrations of boscalid and mortality of fish:

The LC₅₀/96 h value is 0.0144 mg/L.
The LOEC/96 h value is 0.0134 mg/L.
The NOEC/96 h value is 0.0067 mg/L.

Validity criteria

The following validity criteria specified in the OECD Guideline No. 203 (1992) were met:

The mortality in the control was 0% at exposure termination (should not exceed 10% or 1 fish if less than 10 fish are used);
Dissolved oxygen concentrations were within the range of 91 – 99% of air saturation value (obligatory above 60% of air saturation value).

Conclusion

The 96h LC₅₀ value: 0.054 mg/L (nominal test item concentrations).
The 96h LC₅₀ value: 0.0036 mg/L (nominal concentrations of pyraclostrobin).
The 96h LC₅₀ value: 0.0144 mg/L (nominal concentrations of boscalid).
The 96h No-Observed Effect Concentration (NOEC): 0.025 mg/L (nominal test item concentrations); 0.0017 mg/L (nominal concentrations of pyraclostrobin); 0.0067 mg/L (nominal concentrations of boscalid).

Comments of zRMS:	<p>The study is considered acceptable. All validity criteria were met.</p> <ul style="list-style-type: none"> The immobilization of <i>Daphnia magna</i> in the control was 0% (criterion: not more than 10%). The dissolved oxygen concentrations in the test vessels were within the range of 8.2 – 9.1 mg/L (criterion: not less than 3 mg/L). <p>Agreed endpoints:</p> <p><u>The endpoint values determined based on nominal test item concentrations:</u> The EC₅₀/48 h = 0.254 mg/L (95% confidence interval: 0.212 – 0.303). The LOEC/48 h = 0.25 mg/L. The NOEC/48 h = 0.125 mg/L.</p> <p><u>The endpoint values based on the nominal concentrations of pyraclostrobin in the test item:</u> The EC₅₀/48 h = 0.017 mg/L (95% confidence interval: 0.014 – 0.020). The LOEC/48 h = 0.0168 mg/L. The NOEC/48 h = 0.0084 mg/L.</p> <p><u>The endpoint values based on the nominal concentrations of boscalid in the test</u></p>
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	<p><u>item:</u></p> <p>The EC₅₀/48 h =0.068 mg/L (95% confidence interval: 0.057 – 0.081).</p> <p>The LOEC/48 h =0.0688 mg/L.</p> <p>The NOEC/48 h =0.0334 mg/L.</p>
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Reference:	KCP 10.2.1-02
Report	“Pyraclostrobin 6.7% + Boscalid 26.7% WG. <i>Daphnia magna</i> , acute immobilisation test”, Elżbieta Kulec-Płoszczyca (2018), Report No. W/142/17. Institute of Industrial Organic Chemistry Branch Pszczyna.
Guideline(s):	OECD Guideline No. 202 (2004)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	Not relevant

Materials and methods

Immobilisation of *Daphnia magna* (< 24 hours old) exposed to the test item Pyraclostrobin 6.7% + Boscalid 26.7% WG (batch No. SCL-65489) was investigated during a 48-hour static test. Five test item concentrations: 1.0, 0.5, 0.25, 0.125 and 0.0625 mg/L plus the control were used. Four replicates per each test item concentration and the control with five daphnids per replicate were used. The *Daphnia magna* were observed for immobilisation after 24 and 48 h of exposure.

The concentrations of pyraclostrobin and boscalid were determined using a validated liquid chromatographic method. Samples of each test item concentration and the control collected at exposure initiation and at exposure termination were chemically determined. At exposure initiation, the determined concentration of pyraclostrobin was in the range of 94.7 – 105.1% of the nominal concentration and the determined concentration of boscalid was in the range of 102.7 – 110.2% of the nominal concentration. The results confirm that the test item concentrations were prepared correctly. At exposure termination, the determined concentration of pyraclostrobin was in the range of 88.7 – 109.6% of the nominal concentration and the determined concentration of boscalid was in the range of 89.2 – 108.9% of the nominal concentration. Therefore, the concentrations of pyraclostrobin and boscalid were stable under test conditions.

Results

Preliminary test

In the preliminary test, the test item concentrations of 100, 10, 1.0, 0.1, 0.01 mg/L plus the control were used. After 24 hours of exposure, the immobilisation of *Daphnia magna* was 100, 100, 95, 5, 0 and 0, respectively. After 48 hours of exposure, the immobilisation of *Daphnia magna* was 100, 100, 100, 5, 0 and 0, respectively.

Definitive test

In the definitive test *Daphnia magna* was exposed to the test item concentrations 1.0, 0.5, 0.25, 0.125 and 0.0625 mg/L plus the control (with spacing factor of 2) for 48 hours in a static system. The results are summarized in the table below.

Table 10.2.1-02-01

Immobilization of *Daphnia magna*, definitive test

Nominal test item concentration [mg/L]	Number of <i>Daphnia magna</i>	Number of immobilized <i>Daphnia magna</i>								Total of immobilised <i>Daphnia magna</i> [%]	
		24 h				48 h					
		Replicates									
		A	B	C	D	A	B	C	D	24 h	48 h
Control (0.0)	20	0	0	0	0	0	0	0	0	0	0
0.0625	20	0	0	0	0	0	0	0	0	0	0
0.125	20	0	0	0	1	0	0	0	1	5	5
0.25	20	1	2	2	3	1	2	2	3	40	40
0.5	20	3	3	3	4	5	5	5	5	65	100
1.0	20	4	5	5	5	5	5	5	5	95	100

Validity criteria

In the definitive test, the following validity criteria specified in the OECD Guideline No. 202 (2004) were met:

The immobilization of *Daphnia magna* in the control was 0% (criterion: not more than 10%).

The dissolved oxygen concentrations in the test vessels were within the range of 8.2 – 9.1 mg/L (criterion: not less than 3 mg/L).

Conclusion

The endpoint values determined based on nominal test item concentrations:

The EC₅₀/48 h is 0.254 mg/L (95% confidence interval: 0.212 – 0.303).

The LOEC/48 h value is 0.25 mg/L.

The NOEC/48 h value is 0.125 mg/L.

The endpoint values based on the nominal concentrations of pyraclostrobin in the test item:

The EC₅₀/48 h is 0.017 mg/L (95% confidence interval: 0.014 – 0.020).

The LOEC/48 h value is 0.0168 mg/L.

The NOEC/48 h value is 0.0084 mg/L.

The endpoint values based on the nominal concentrations of boscalid in the test item:

The EC₅₀/48 h is 0.068 mg/L (95% confidence interval: 0.057 – 0.081).

The LOEC/48 h value is 0.0688 mg/L.

The NOEC/48 h value is 0.0334 mg/L.

Comments of zRMS:	<p>The study is considered acceptable. All validity criteria were met.</p> <ul style="list-style-type: none"> The biomass in the control increased by a factor of 114.4 within the 72-hour test period (criterion: at least a 16-fold growth). The coefficient of variation of the mean specific growth rate after the 72-hour test period (exposure initiation – exposure termination) in the control culture was 1.6% (criterion: it must not exceed 7%). The mean coefficient of variation for the section-by-section growth rate in the control culture was 28.3% (criterion: it must not exceed 35%). <p>Agreed endpoints:</p> <p><u>The endpoint values based on the nominal test item concentrations:</u></p> <p>The E_rC₅₀/72 h = 28.75 mg/L (95% confidence interval: 24.56 – 33.65).</p> <p>The E_yC₅₀/72 h = 2.74 mg/L (95% confidence interval: 2.57 – 2.92).</p> <p>The LOEC/72 h e for growth rate and yield ≤1.23 mg/L, and the NOEC/72 h value for growth rate and yield ≤1.23 mg/L.</p>
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	<p><u>The endpoint values based on the nominal concentrations of pyraclostrobin in the test item:</u></p> <p>The $E_rC_{50}/72 = 1.926$ mg/L (95% confidence interval: 1.645 – 2.254). The $E_yC_{50}/72$ h = 0.183 mg/L (95% confidence interval: 0.172 – 0.195). The LOEC/72 h value for growth rate and yield ≤ 0.082 mg/L, and the NOEC/72 h value for growth rate and yield ≤ 0.082 mg/L.</p> <p><u>The endpoint values based on the nominal concentrations of boscalid in the test item:</u></p> <p>The $E_rC_{50}/72$ h = 7.675 mg/L (95% confidence interval: 6.557 – 8.983) The $E_yC_{50}/72$ h = 0.731 mg/L (95% confidence interval: 0.687 – 0.779). The LOEC/72 h for growth rate and yield ≤ 0.328 mg/L, and the NOEC/72 h value for growth rate and yield ≤ 0.328 mg/L.</p> <p><u>The endpoint values based on geometric means of determined concentrations of pyraclostrobin:</u></p> <p>The $E_rC_{50}/72$ h = 1.928 mg/L (95% confidence interval: 1.634 – 2.275). The $E_yC_{50}/72$ h = 0.158 mg/L (95% confidence interval: 0.147 – 0.169). The LOEC/72 h value for growth rate and yield ≤ 0.063 mg/L, and the NOEC/72 h value for growth rate and yield ≤ 0.063 mg/L.</p> <p><u>The endpoint values based on geometric means of determined concentrations of pyraclostrobin converted into the test item:</u></p> <p>The $E_rC_{50}/72$ h = 28.78 mg/L (95% confidence interval: 24.50 – 34.19). The $E_yC_{50}/72$ h = 2.35 mg/L (95% confidence interval: 2.19 – 2.52). The LOEC/72 h value for growth rate and yield ≤ 0.95 mg/L, and the NOEC/72 h value for growth rate and yield ≤ 0.95 mg/L.</p>
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Reference: KCP 10.2.1-03

Report “Pyraclostrobin 6.7% + Boscalid 26.7% WG. *Raphidocelis subcapitata* SAG 61.81, Growth inhibition test”, Elżbieta Kulec-Płoszczyca (2018), Report No. W/141/17. Institute of Industrial Organic Chemistry Branch Pszczyna.

Guideline(s): OECD Guideline No. 201 (2006)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) Not relevant

Materials and methods

The growth of the green algae *Raphidocelis subcapitata* (formerly *Pseudokirchneriella subcapitata*) exposed to the test item, Pyraclostrobin 6.7% + Boscalid 26.7% WG (batch No. SCL-65489) was investigated during a 72-hour test. The test was performed in glass flasks with a capacity of 250 mL containing 100 mL of either test item concentration or the control per replicate. The initial density of the algae was 1×10^4 cells/mL. The following test item concentrations were used: 100, 33, 11, 3.7, 1.23 mg/L plus the control. Three replicates were used for each test item concentration, whereas six replicates were used for control. The concentrations of pyraclostrobin and boscalid were determined using a validated

liquid chromatographic method. Samples of each test item concentration and the control collected at exposure initiation, after 24, 48 and 72 h of exposure were chemically determined.

At exposure initiation, the determined concentration of pyraclostrobin was in the range of 92.6 – 105.1% of the nominal concentration and the determined concentration of boscalid was in the range of 92.1 – 101.0% of the nominal concentration. The results confirm that the test item concentrations were prepared correctly.

After 24 h of exposure, the determined concentration of pyraclostrobin was in the range of 86.3 – 108.1% of the nominal concentration and the determined concentration of boscalid was in the range of 90.8 – 99.5% of the nominal concentration.

After 48 h of exposure, the determined concentration of pyraclostrobin was in the range of 78.0 – 105.3% of the nominal concentration and the determined concentration of boscalid was in the range of 91.5 – 105.2% of the nominal concentration.

At exposure termination, the determined concentration of pyraclostrobin was in the range of 49.3 – 100.1% of the nominal concentration and the determined concentration of boscalid was in the range of 83.7 – 105.4% of the nominal concentration.

Therefore, the concentration of boscalid was stable under test conditions. Since the concentration of pyraclostrobin was below 80% of the nominal concentration, it can be concluded that the concentration of pyraclostrobin was not stable under test conditions.

The limit of quantification (LoQ) for pyraclostrobin and boscalid analyzed in water is -5 mg/L and Limit of Detection (LoD) is -15 mg/L.

The endpoint values were determined based on the nominal test item concentrations, nominal concentrations of pyraclostrobin and boscalid in the test item, geometric mean of determined concentrations of pyraclostrobin and geometric mean of determined concentrations pyraclostrobin converted into the test item.

Results

Preliminary test

The test was performed using five test item concentrations: 100, 10, 1.0, 0.1, 0.01 mg/L and the control. The inhibition of growth rate and yield estimated in comparison to the control after 72 hours of exposure are given in the table below.

Table 10.2.1-03.1 Growth rate and yield inhibition, preliminary test (non-GLP)

Nominal test item concentration [mg/L]	% inhibition after 72 h of exposure (growth rate)	% inhibition after 72 h of exposure (yield)
Control	0.00	0.00
0.01	-2.97*	-14.68*
0.1	-2.21*	-10.14*
1.0	1.62	8.88
10	44.31	90.12
100	74.05	98.28

*Inhibition is lower than 0.00%, which means that the algal cell density at exposure termination was higher than in the control.

Definitive test

In the definitive test, the algae, *Pseudokirchneriella subcapitata*, with an initial cell density of 1×10^4 cells/mL were exposed to the test item concentrations: 100, 33, 11, 3.7 and 1.23 mg/L (with a separation factor of 3) plus control for 72 hours in a static test design. The results are summarized in the table below.

Table 10.2.1-03.2 Growth rate and yield inhibition, definitive test

Nominal test item concentration [mg/L]	% inhibition after 72 h of exposure (growth rate)	% inhibition after 72 h of exposure (yield)
Control	0.00	0.00

1.23	5.4	23.0
3.7	23.5	67.2
11	32.2	78.6
33	54.9	93.0
100	68.0	96.8

Validity criteria

In the definitive test, the following validity criteria specified in OECD Guideline No. 201 (2006) were met:

The biomass in the control increased by a factor of 114.4 within the 72-hour test period (criterion: at least a 16-fold growth).

The coefficient of variation of the mean specific growth rate after the 72-hour test period (exposure initiation – exposure termination) in the control culture was 1.6% (criterion: it must not exceed 7%).

The mean coefficient of variation for the section-by-section growth rate in the control culture was 28.3% (criterion: it must not exceed 35%).

Conclusion

The endpoint values based on the nominal test item concentrations:

The $E_rC_{50}/72$ h value is 28.75 mg/L (95% confidence interval: 24.56 – 33.65).

The $E_yC_{50}/72$ h value is 2.74 mg/L (95% confidence interval: 2.57 – 2.92).

The LOEC/72 h value for growth rate and yield is lower than or equal to 1.23 mg/L, and the NOEC/72 h value for growth rate and yield is lower than 1.23 mg/L.

The endpoint values based on the nominal concentrations of pyraclostrobin in the test item:

The $E_rC_{50}/72$ h value is 1.926 mg/L (95% confidence interval: 1.645 – 2.254).

The $E_yC_{50}/72$ h value is 0.183 mg/L (95% confidence interval: 0.172 – 0.195).

The LOEC/72 h value for growth rate and yield is lower than or equal to 0.082 mg/L, and the NOEC/72 h value for growth rate and yield is lower than 0.082 mg/L.

The endpoint values based on the nominal concentrations of boscalid in the test item:

The $E_rC_{50}/72$ h value is 7.675 mg/L (95% confidence interval: 6.557 – 8.983)

The $E_yC_{50}/72$ h value is 0.731 mg/L (95% confidence interval: 0.687 – 0.779).

The LOEC/72 h value for growth rate and yield is lower than or equal to 0.328 mg/L, and the NOEC/72 h value for growth rate and yield is lower than 0.328 mg/L.

The endpoint values based on geometric means of determined concentrations of pyraclostrobin:

The $E_rC_{50}/72$ h value is 1.928 mg/L (95% confidence interval: 1.634 – 2.275).

The $E_yC_{50}/72$ h value is 0.158 mg/L (95% confidence interval: 0.147 – 0.169).

The LOEC/72 h value for growth rate and yield is lower than or equal to 0.063 mg/L, and the NOEC/72 h value for growth rate and yield is lower than 0.063 mg/L.

The endpoint values based on geometric means of determined concentrations of pyraclostrobin converted into the test item:

The $E_rC_{50}/72$ h value is 28.78 mg/L (95% confidence interval: 24.50 – 34.19).

The $E_yC_{50}/72$ h value is 2.35 mg/L (95% confidence interval: 2.19 – 2.52).

The LOEC/72 h value for growth rate and yield is lower than or equal to 0.95 mg/L, and the NOEC/72 h value for growth rate and yield is lower than 0.95 mg/L.

Comments	The study is considered acceptable. All validity criteria were met.
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of zRMS:	<ul style="list-style-type: none"> - The doubling time of frond number in the control was 2.2 days, criterion: less than 2.5 days (the factor of frond number in the control between 0 and 7 day was 9.2). - The average specific growth rate in the control between day 0 and day 7 was 0.316 d⁻¹ (minimum requirement: higher than 0.275 d⁻¹). 			
	Agreed endpoints:			
	The endpoint values based on the nominal test item concentrations			
	Yield inhibition based on the frond number	Growth rate inhibition based on the frond number	Yield inhibition based on the dry weight	Growth rate inhibition based on the dry weight
	17.25 (13.81 – 21.53)	79.56 (65.38 – 96.81)	12.15 (9.90 – 14.91)	167.26 (144.69 – 193.35)
	2.59 (1.80 – 3.73)	9.30 (6.95 – 12.45)	1.57 (1.11 – 2.23)	17.08 (14.28 – 20.43)
	0.96 (0.59 – 1.58)	3.03 (2.00 – 4.59)	< 0.9	5.18 (3.96 – 6.78)
	3.0	3.0	9.5	3.0
	0.9	0.9	3.0	0.9
	The endpoint values based on the nominal concentrations of pyraclostrobin			
	Yield inhibition based on the frond number	Growth rate inhibition based on the frond number	Yield inhibition based on the dry weight	Growth rate inhibition based on the dry weight
	1.155 (0.923 – 1.446)	5.331 (4.407 – 6.551)	0.814 (0.661 – 0.999)	11.207 (9.756 – 13.057)
	0.174 (0.115 – 0.241)	0.623 (0.450 – 0.813)	0.105 (0.071 – 0.144)	1.145 (0.945 – 1.355)
	0.065 (0.036 – 0.100)	0.203 (0.127 – 0.295)	< 0.06	0.347 (0.259 – 0.445)
	0.201	0.201	0.637	0.637
	0.060	0.060	0.201	0.201
	The endpoint values based on the nominal concentrations of boscalid			
	Yield inhibition based on the frond number	Growth rate inhibition based on the frond number	Yield inhibition based on the dry weight	Growth rate inhibition based on the dry weight
	4.604 (3.678 – 5.763)	21.242 (17.561 – 26.102)	3.244 (2.635 – 3.982)	44.659 (38.877 – 52.030)
	0.693 (0.457 – 0.960)	2.484 (1.794 – 3.240)	0.419 (0.282 – 0.576)	4.561 (3.764 – 5.397)
	0.257 (0.145 – 0.397)	0.809 (0.505 – 1.174)	< 0.24	1.384 (1.033 – 1.775)
	0.801	0.801	2.537	2.537
	0.240	0.240	0.801	0.801

Reference: KCP 10.2.1 - 04

Report: “Pyraclostrobin 6.7% + Boscalid 26.7% WG. *Lemna gibba* CPCC 310, Growth Inhibition Test”. Elżbieta Kulec-Płoszczyca, 2018, W/143/17. Institute of Industrial Organic Chemistry Branch Pszczyna.

Guideline(s): OECD Guideline No. 221 (2006)

Deviations: No
GLP: Yes
Acceptability: Yes
Duplication No
(if vertebrate study)

Materials and methods

Test item:

Description: Pyraclostrobin 6.7% + Boscalid 26.7% WG
 Batch number: SCL-65489
 A.i. content: pyraclostrobin: 6.7% w/w; boscalid: 26.7% w/w

Test system:

Species: *Lemna gibba* L. CPCC 310
 Strain: -
 Age: -
 Source: Canadian Phycological Culture Centre (CPCC), Department of Biology, University of Waterloo, Ontario, Canada
 Medium: 20X AAP

Experimental conditions:

Temperature: 22.7 – 24.2°C
 pH values: 7.45 – 9.35
 Mean light intensity: 7640 – 7895 lux, constant illumination
 Test vessels: Glass crystallizers containing 150 mL of a given test item concentration or control
 Initial frond number: 9 (i.e. 3 plants per 3 fronds)

Experimental period:

7 d

Test design:

Semi-static system with three renewals; three replicates for each test item concentration and six replicates for control.
 The test item concentrations in definitive test were: 312.5, 97.7, 30.5, 9.5, 3.0, 0.9 mg/L plus the control. The concentrations of pyraclostrobin and boscalid were determined using a validated liquid chromatographic method with DAD detection.

Samples of all fresh test item concentrations and the control collected at exposure initiation and at each renewal, and all spent test item concentrations and the control collected at each renewal and at exposure termination were chemically determined.

In fresh samples the determined concentration of pyraclostrobin was in the range of 86.1 – 105.4% of nominal concentration and the determined concentration of boscalid was in the range of 85.0 – 107.3% of nominal concentration. The results confirm that the test item concentrations were prepared correctly.

In spent samples the determined concentration of pyraclostrobin was in the range of 81.6 – 110.2% of nominal concentration and the determined concentration of boscalid was in the range of 80.2 – 109.3% of nominal concentration. Therefore, the concentrations of pyraclostrobin and boscalid were stable under test conditions

between renewals.

The preliminary growth inhibition tests (non-GLP) and definitive test were performed under semi-static test design.

The total number of fronds in each test vessel was counted twice during exposure (day 2 and 4) and at exposure termination. The observations of plant development, i.e. size of fronds, necrosis, chlorosis, colony break-up, gibbosity, changes in the appearance of roots were performed at the same time. Growth of plant cultures in the test item concentrations was compared with that of the control. The dry weight of the representative sample of the duckweed culture used as the inoculum was measured after exposure initiation. The dry weight of all plants from each test vessel was measured after exposure termination

In both tests, the pH values were measured in fresh test item concentrations and the control before splitting up into replicates at exposure initiation and at each renewal. The pH values were also measured in spent test item concentrations and the control at each renewal and at exposure termination in pooled replicates

Statistics: Probit method calculations and analysis by Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Stepdown Jonckheere-Terpstra test procedure, Multiple sequentially-rejective Welsh-t-test after Bonferroni-Holm, Williams Multiple Sequential t-test Procedure.

Results: In the growth inhibition test on *Lemna gibba*, the endpoint values were determined on the basis of the nominal test item concentrations and the nominal concentrations of pyraclostrobin and nominal concentrations of boscalid in the test item. Results are summarized in the table below:

The endpoint values based on the nominal test item concentrations				
	Yield inhibition based on the frond number	Growth rate inhibition based on the frond number	Yield inhibition based on the dry weight	Growth rate inhibition based on the dry weight
EyC ₅₀ /7d/ ErC ₅₀ /7d (mg/l)	17.25 (13.81 – 21.53)	79.56 (65.38 – 96.81)	12.15 (9.90 – 14.91)	167.26 (144.69 – 193.35)
EyC ₂₀ /7d/ ErC ₂₀ /7d (mg/l)	2.59 (1.80 – 3.73)	9.30 (6.95 – 12.45)	1.57 (1.11 – 2.23)	17.08 (14.28 – 20.43)
EyC ₁₀ /7d/ ErC ₁₀ /7d (mg/l)	0.96 (0.59 – 1.58)	3.03 (2.00 – 4.59)	< 0.9	5.18 (3.96 – 6.78)
LOEC/7d (mg/l)	3.0	3.0	9.5	3.0
NOEC/7d (mg/l)	0.9	0.9	3.0	0.9
The endpoint values based on the nominal concentrations of pyraclostrobin				
	Yield inhibition based on the frond number	Growth rate inhibition based on the frond number	Yield inhibition based on the dry weight	Growth rate inhibition based on the dry weight
EyC ₅₀ /7d/ ErC ₅₀ /7d (mg/l)	1.155 (0.923 – 1.446)	5.331 (4.407 – 6.551)	0.814 (0.661 – 0.999)	11.207 (9.756 – 13.057)
EyC ₂₀ /7d/ ErC ₂₀ /7d (mg/l)	0.174 (0.115 – 0.241)	0.623 (0.450 – 0.813)	0.105 (0.071 – 0.144)	1.145 (0.945 – 1.355)
EyC ₁₀ /7d/ ErC ₁₀ /7d (mg/l)	0.065 (0.036 – 0.100)	0.203 (0.127 – 0.295)	< 0.06	0.347 (0.259 – 0.445)

LOEC/7d (mg/l)	0.201	0.201	0.637	0.637
NOEC/7d (mg/l)	0.060	0.060	0.201	0.201
The endpoint values based on the nominal concentrations of boscalid				
	Yield inhibition based on the frond number	Growth rate inhibition based on the frond number	Yield inhibition based on the dry weight	Growth rate inhibition based on the dry weight
EyC ₅₀ /7d/ ErC ₅₀ /7d (mg/l)	4.604 (3.678 – 5.763)	21.242 (17.561 – 26.102)	3.244 (2.635 – 3.982)	44.659 (38.877 – 52.030)
EyC ₂₀ /7d/ ErC ₂₀ /7d (mg/l)	0.693 (0.457 – 0.960)	2.484 (1.794 – 3.240)	0.419 (0.282 – 0.576)	4.561 (3.764 – 5.397)
EyC ₁₀ /7d/ ErC ₁₀ /7d (mg/l)	0.257 (0.145 – 0.397)	0.809 (0.505 – 1.174)	< 0.24	1.384 (1.033 – 1.775)
LOEC/7d (mg/l)	0.801	0.801	2.537	2.537
NOEC/7d (mg/l)	0.240	0.240	0.801	0.801

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

Comments of zRMS:	<p>The study is considered acceptable. All validity criteria were met.</p> <ul style="list-style-type: none"> - The average mortality for the control was 0.0% at the end of the experiment (criterion: it must not exceed 10%). - The 24-hour LD₅₀ of the reference item (dimethoate) was 0.10 µg/bee (criterion: 0.10 - 0.35 µg a.i./bee) <p>Agreed endpoints: LD₅₀/48h ≥ 400.0 µg/honeybee (106.80 µg Boscalid/bee, 26.80 µg Pyraclostrobin/bee).</p>
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Reference:	KCP 10.3.1.1.1
Report	“Boscalid 26.7% + Pyraclostrobin 6.7% WG. Honeybees (<i>Apis mellifera</i> L.), Acute Oral Toxicity Test”. Aneta Glanas, 2017, Study code B/108/16. Institute of Industrial Organic Chemistry Branch Pszczyna
Guideline(s):	OECD Guideline for the Testing of Chemicals No. 213 (1998) and the EU Method C.16. (2008)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The acute oral toxicity study of Boscalid 26.7% + Pyraclostrobin 6.7% WG (batch number: SCL-20604) was conducted to determine the LD₅₀ values for honeybees. Five doses of the test item were used. These included: 25.0, 50.0, 100.0, 200.0 and 400.0 µg/honeybee (i.e. (6.68, 1.68 µg a.i./bee; 13.35, 3.35 µg a.i./bee; 26.70, 6.70 µg a.i./bee; 53.40, 13.40 µg a.i./bee; and 106.80 µg Boscalid/bee, 26.80 µg Pyraclostrobin/bee) and a control (0.0 µg/bee)). The range of doses was selected on the basis of the preliminary test results. Each group of 10 bees (3 replicates containing 10 bees each) was fed with 100 µL of a 50% sucrose solution, containing the test item at the doses enumerated above, using a micropipette. During the entire experiment, the insects were caged in groups of 10.

The general condition of the test honeybees and the reliability of the test conducted on them were controlled using the recommended reference item - dimethoate.

After the administration, the insects were observed for mortality and other signs of toxicity. These observations were made 4 hours after the beginning of the treatment and then every 24 hours after the beginning of the treatment. The acute oral toxicity test ended after the 48-hour exposure.

Results

Table 10.3.1.1.1-01: Acute oral toxicity on honeybees (*Apis mellifera* L.)

Dose			N° of tested bees	Mortality after 48 h		LD ₅₀		
				Total				
[µg /bee] ^a	[µg a.i./bee] ^b			[no.]	[%]	[µg /bee] ^a	[µg a.i./bee] ^b	
	a.i. ^c	a.i. ^d					a.i. ^c	a.i. ^d
0.0 (Control)				30	0	0.0	>400.0	>106.80
25.0	6.68	1.68	30	0	0.0			
50.0	13.35	3.35	30	0	0.0			
100.0	26.70	6.70	30	0	0.0			
200.0	53.40	13.40	30	0	0.0			
400.0	106.80	26.80	30	0	0.0			

a: µg test item/ bee

b: µg active ingredient /bee

c: boscalid

d: pyraclostrobin

Findings

- The mortality in the test item treatments after 48 hours was lower than 50% when compared to the control.

- The median lethal doses of Boscalid 26.7% + Pyraclostrobin 6.7% WG (LD₅₀) after 24 and 48 hours of the exposure are higher than the highest dose used in the study, i.e. 400 µg test item/bee.
- No sublethal toxicity effects (behavioural abnormalities) such as excitement (uncoordinated movement, increased activity, intensive cleaning) or any signs of paralysis with respect to the test item and the control were observed over the 48 hours exposure.
- The reduction in food consumption (sucrose solution) during 48 h ranged from (- 20.6) to 39.1 % when compared to the control. The negative values show that the treated groups consumed more than the control group.

Validity criteria

The following validity criteria were met during the test:

- The average mortality for the control was 0.0% at the end of the experiment (criterion: it must not exceed 10%).
- The 24-hour LD₅₀ of the reference item (dimethoate) was 0.10 µg/bee (criterion: 0.10 - 0.35 µg a.i./bee)

Conclusion

The median lethal doses (LD₅₀/24 h and LD₅₀/48 h ~~contact-oral~~) are higher than the highest dose used in the test, i.e. 400.0 µg/honeybee (106.80 µg Boscalid/bee, 26.80 µg Pyraclostrobin/bee).

With respect to the test results, it can be concluded that the test item, Boscalid 26.7% + Pyraclostrobin 6.7% WG had no adverse effect on mortality of honeybees (*Apis mellifera* L.).

No behavioural abnormalities or any signs of paralysis with respect to the test item and the control were observed over the 48 hours exposure.

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Comments of zRMS:	<p>The study is considered acceptable. All validity criteria were met.</p> <ul style="list-style-type: none"> • The average mortality for the total number of controls was 0.0% after 48 h (criterion: it must not exceed 10%). • The 24 hour LD₅₀ of the reference item (dimethoate) was 0.21 µg a.i./bee (criterion: 0.10 - 0.30 µg a.i./bee). • <p>Agreed endpoints: LD₅₀/48h ≥ 400.0 µg/honeybee (106.80 µg Boscalid/bee, 26.80 µg Pyraclostrobin/bee).</p>
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Reference: KCP 10.3.1.1.2

Report “Boscalid 26.7% + Pyraclostrobin 6.7% WG. Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test”, Aneta Glanas, 2017, Study code B/109/16. Institute of Industrial Organic Chemistry Branch Pszczyna.

Guideline(s): OECD Guideline for the Testing of Chemicals No. 214 (1998) and the EU Method C.17. (2008)

Deviations: Yes. In definitive test as a reference item Danadim 400 EC was used (in the

Study Plan a reference item was Bi 58 Nowy 400 EC). Danadim 400 EC has got the same content of dimethoat as Bi 58 Nowy 400 EC.

GLP: Yes

Acceptability: Yes

Materials and methods

The acute contact toxicity study of Boscalid 26.7% + Pyraclostrobin 6.7% WG (batch No. SCL-20604) was conducted to determine the effects on honeybees. Five doses of the test item were used. These included: 25.0, 50.0, 100.0, 200.0 and 400.0 µg/honeybee (6.68, 1.68 µg a.i./bee; 13.35, 3.35 µg a.i./bee; 26.70, 6.70 µg a.i./bee; 53.40, 13.40 µg a.i./bee; and 106.80 µg Boscalid/bee, 26.80 µg Pyraclostrobin/bee). The range of doses was selected on the basis of the preliminary test results.

The test item was diluted in distilled water and applied to the dorsal part of thorax using a microapplicator. The volume was 1 µL/bee. During the entire experiment, the insects were caged in groups of 10 under controlled conditions of the temperature and the humidity.

The recommended reference item, i.e. dimethoate was used to verify the sensitivity of the honeybees and the precision of the test procedure.

After the application, the insects were observed for mortality and signs of toxicity. These observations were made 4, 24, and 48 hours after the beginning of the treatment. The acute contact toxicity test finished after the 48-hour observation.

Results

Table 10.3.1.1.2-01: Acute contact toxicity on honeybees (*Apis mellifera* L.)

Dose			N° of tested bees	Mortality after 48 h		LD ₅₀		
				Total				
[µg /bee] ^a	[µg a.i./bee] ^b			[no.]	[%]	[µg /bee] ^a	[µg a.i./bee] ^b	
	a.i. ^c	a.i. ^d					a.i. ^c	a.i. ^d
0.0 (Control)				30	0	0.0	>400.0	>106.80
25.0	6.68	1.68	30	0	0.0			
50.0	13.35	3.35	30	0	0.0			
100.0	26.70	6.70	30	0	0.0			
200.0	53.40	13.40	30	0	0.0			
400.0	106.80	26.80	30	0	0.0			

a: µg test item/ bee

b: µg active ingredient /bee

c: boscalid

d: pyraclostrobin

Findings

- Mortality of the control group after 48 hours of exposure was 0%.
- Mortality of the treated groups was lower than 50% when compared to the control.
- No sublethal toxicity effects (behavioural abnormalities) such as excitement (uncoordinated movement, increased activity, intensive cleaning) or any signs of paralysis with respect to the test item and the control were observed over the 48 hours exposure.

Validity criteria

The following validity criteria were met during the test:

- The average mortality for the total number of controls was 0.0% after 48 h (criterion: it must not exceed 10%).
- The 24 hour LD₅₀ of the reference item (dimethoate) was 0.21 µg a.i./bee (criterion: 0.10 - 0.30 µg a.i./bee).

Conclusion

The median lethal doses (LD₅₀/24 h and LD₅₀/48 h contact) are higher than the highest dose used in the test, i.e. 400.0 µg/honeybee (106.80 µg Boscalid/bee, 26.80 µg Pyraclostrobin/bee).

With respect to the test results, it can be concluded that the test item, Boscalid 26.7% + Pyraclostrobin 6.7% WG had no adverse effect on mortality of honeybees (*Apis mellifera* L.).

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

Comments of zRMS:	<p>The study is considered acceptable. All validity criteria were met.</p> <ul style="list-style-type: none"> The mean mortality in the control was $\leq 15\%$ at the end of the test (actual 0.00 and 0.00 % for control and control solvent respectively). The mean mortality in the reference item group was $\geq 50\%$ at the end of the test (actual 86.7 %) <p>Agreed endpoints:</p> <p>The actual mean concentrations of Pyraclostrobin in test item feeding solutions were in the range of 98 to 101.5 % of the nominal concentrations; therefore results are based on nominal.</p> <p>The 10-day NOEC = 1481.5 mg a.s./kg feeding solution.</p> <p>The 10-day NOED = 39.47 µg a.s./bee/day.</p> <p>The 10-day LC₅₀ = 4094.97 ± 159.80 mg a.s./kg feeding solution.</p> <p>The 10-day LDD₅₀ = 97.77 ± 3.26 µg a.s./bee/day.</p>
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Reference:	KCP 10.3.1.2.1
Report	“Chronic Oral Toxicity Study of Pyraclostrobin Technical on adult Honey Bee (<i>Apis mellifera</i>)”, S. Radha, 2020, Study code 5028/2019
Guideline(s):	Yes, OECD OECD test No. 245 Guideline for the Testing of Chemicals: Honey bee (<i>Apis mellifera</i> L.), Chronic Oral Toxicity Test – 10 Day Feeding (9 October 2017).
Deviations:	Deviation from Study Plan: The study finished in March 2020, not in January 2020, as it had been planned. This deviation did not affect the study results.
GLP:	Yes
Acceptability:	Yes

Materials and methods

The aim of the study was to determine the effects of the test item Pyraclostrobin Technical (Batch SCL-395601) on the honey bee *Apis mellifera* L. from chronic feeding exposure, the median Lethal Concentration (LC₅₀) and the median Lethal Dietary Dose (LDD₅₀) after 10 days of exposure, as well as the No Observed Effect Concentration and the No Observed Effect Dietary Dose (NOEC/NOEDD) were determined.

The test species was honey bee (*Apis mellifera* L.), young adult worker bees (not older than 48 hours) originating from bee hive maintained at BRF test facility.

The test was conducted as a dose-response test with an exposure phase duration of 10 days. Two control groups (a negative control and a solvent control), six test item groups and a toxic reference item group were used. Six different concentrations of Pyraclostrobin Technical were applied to the bees in the test item groups, and one single concentration of the reference item was applied to the bees in the toxic reference group. The analyzed content of Pyraclostrobin was considered for calculation of the test item

doses and dimethoate for the reference item dose. Control groups and treated groups were exposed concurrently to identical conditions.

The test concentrations were: 1 control group, 6 test item groups with 1481.5, 2222.2, 3333.3, 5000, 7500 and 11250 mg a.s/kg diet, equivalent to 29.6, 44.4, 66.6, 100, 150 and 225 µg a.s./bee/day; 1 reference item group with 0.016 µg dimethoate/bee/day. Three replicates of 10 bees each were used for each group. Mortality and behavioural abnormalities were assessed daily over the 10 days test period.

The test conditions were: Air temperature: Min / Max: 34.3/ 34.8 °C, Relative air humidity: Min / Max: 51 % / 63 % RH, Exposure to light: Constant darkness except during observations.

Results and discussions

Table 2.3.1.1.2-1: Cumulative mortality, overall mean consumption of feeding solution, dietary dose (DD), accumulated mean uptake, NOEC, NOEDD, LC₅₀ and LDD₅₀

Treatment	10-day cumulative mortality	Overall mean consumption of feeding solution	Dietary dose (based on actual measured consumption of feeding solution)	Mean accumulated uptake of test item during the test period
	[%]	[µg/bee/day]	[µg a.s./bee/day]	[µg a.s./bee]
Control				
C (0)	0.00	-	-	-
C _s (0)	0.00	-	-	-
Reference item: dimethoate [µg a.s./bee]				
R (0.016)	86.6	0.016	0.009	0.09
Test item: Pyraclostrobin Technical [mg a.s./kg feeding solution]				
T1 (1481.5)	3.3	29.6	39.47	394.7
T2 (2222.2)	16.7	44.4	59.58	595.8
T3 (3333.3)	46.6	66.6	81.45	814.5
T4 (5000)	60.0	100	117.1	1171
T5 (7500)	73.3	150	160.8	1608
T6 (11250)	100.0	225	236.25	2362.5
NOEC	1481.5 mg a.s./kg feeding solution			
NOEDD	39.47 µg a.s./bee/day			
LC₅₀ [95 % IC]	4094.97 ± 159.80 mg a.s./kg feeding solution			
LDD₅₀ [95 % IC]	97.77 ± 3.26 µg a.s./bee/day			

Findings:

- The actual mean concentrations of pyraclostrobin in all test item feeding solutions were in the range from 98.0 to 101.5 % of the nominal concentrations; therefore results are based on nominal.
- In control groups fed with pure 50 % (w/v) aqueous sucrose solution and 50 % (w/v) aqueous sucrose solution containing 5 % acetone, 0.00 and 0.00 % mortality was observed at the final assessment after 10 days.
- The maximum mortality which was observed in the highest test item treatment concentration, 11250 mg a.s./kg feeding solution was 100.00 % after 10 days.
- At the concentrations of 1481.5, 2222.2, 3333.3, 5000, 7500 and 11250 mg a.s./kg feeding solution 3.3, 16.7, 46.6, 60.0, 73.3 and 100.00 % mortality (was observed).
- At the end of 10 days exposure bees treated with control and treatment group were appeared normal and no toxic sign was observed.
- The overall mean daily consumption of feeding solutions (i.e. the average consumption/bee over 10 days) in the test item concentrations of 1481.5, 2222.2, 3333.3, 5000, 7500 and 11250 mg a.s./kg feeding solution was 29.6, 44.4, 66.6, 100, 150 and 225 µg/bee/day, respectively.
- After 10 days of continuous exposure, the mean accumulated uptake of acetamiprid at the test item concentrations of 1481.5, 2222.2, 3333.3, 5000, 7500 and 11250 mg a.s./kg feeding solution was 394.7, 595.8, 814.5, 1171, 1608 and 2362.5 µg a.s./bee, respectively. The corresponding average daily dose (DD) was therefore 39.47, 59.58, 81.45, 117.1, 160.8 and 236.25 µg a.s./bee/day.
- The NOEC for mortality after 10 days of continuous exposure was determined to be 1481.5 mg a.s./kg feeding solution. The corresponding NOEDD, based on the actual consumption of the feeding solutions, was determined to be 39.47 µg a.s./bee/day.
- After 10 days of continuous exposure, the LC₅₀ with 95 % confidence intervals was determined to be 4094.97 ± 159.80 mg a.s./kg feeding solution. The corresponding LDD₅₀ with 95 % confidence intervals, based on the actual consumption of the feeding solutions, was determined to be 97.77 ± 3.26 µg a.s./bee/day.

The following validity criteria were met during the test:

- The mean mortality in the control was $\leq 15\%$ at the end of the test (actual 0.00 and 0.00 % for control and control solvent respectively).
- The mean mortality in the reference item group was $\geq 50\%$ at the end of the test (actual 86.7 %)

Conclusion

The chronic toxicity of Pyraclostrobin Technical to honey bees was tested under laboratory conditions over a period of 10 days.

The actual mean concentrations of Pyraclostrobin in test item feeding solutions were in the range of 98 to 101.5 % of the nominal concentrations; therefore results are based on nominal.

The 10-day NOEC was determined to be 1481.5 mg a.s./kg feeding solution.

The 10-day NOEDD was determined to be 39.47 µg a.s./bee/day.

The 10-day LC₅₀ with 95 % confidence intervals was determined to be 4094.97 ± 159.80 mg a.s./kg feeding solution.

The 10-day LDD₅₀ with 95 % confidence intervals was determined to be 97.77 ± 3.26 µg a.s./bee/day.

Comments of zRMS:	<p>The study is considered acceptable. All validity criteria were met.</p> <ul style="list-style-type: none"> • The mean mortality in the control was $\leq 15\%$ at the end of the test (actual 0.00 and 0.00 % for control and control solvent respectively). • The mean mortality in the reference item group was $\geq 50\%$ at the end of the test (actual 86.7 %) <p>Agreed endpoints:</p> <p>The actual mean concentrations of Boscalid in test item feeding solutions were in the range of 98.1 to 101.9 % of the nominal concentrations; therefore results are based on nominal.</p> <p>The 10-day NOEC = 2222.2 mg a.s./kg feeding solution.</p> <p>The 10-day NOED = 59.72 µg a.s./bee/day.</p> <p>The 10-day LC₅₀ = 4768.70 ± 210.86 mg a.s./kg feeding solution.</p> <p>The 10-day LDD₅₀ = 111.99 ± 4.20 µg a.s./bee/day.</p>
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Reference:	KCP 10.3.1.2.2
Report	“Chronic Oral Toxicity Study of Boscalid Technical on adult Honey Bee (<i>Apis mellifera</i>)”, S. Radha, 2020, Study code 5031/2019
Guideline(s):	Yes, OECD OECD test No. 245 Guideline for the Testing of Chemicals: Honey bee (<i>Apis mellifera</i> L.), Chronic Oral Toxicity Test – 10 Day Feeding (9 October 2017).
Deviations:	<p>Deviation from Study Plan:</p> <p>The study finished in March 2020, not in November 2019, as it had been planned. This deviation did not affect the study results.</p>
GLP:	Yes
Acceptability:	Yes

Materials and methods

The aim of the study was to determine the effects of the test item Boscalid Technical (Batch SCL-45612) on the honey bee *Apis mellifera* L. from chronic feeding exposure, the median Lethal Concentration (LC50) and the median Lethal Dietary Dose (LDD50) after 10 days of exposure, as well as the No Observed Effect Concentration and the No Observed Effect Dietary Dose (NOEC/NOEDD) were determined.

The test species was honey bee (*Apis mellifera* L.), young adult worker bees (not older than 48 hours) originating from bee hive maintained at BRF test facility.

The test was conducted as a dose-response test with an exposure phase duration of 10 days. Two control groups (a negative control and a solvent control), six test item groups and a toxic reference item group were used. Six different concentrations of Boscalid Technical were applied to the bees in the test item groups, and one single concentration of the reference item was applied to the bees in the toxic reference group. The analyzed content of Boscalid was considered for calculation of the test item doses and dimethoate for the reference item dose. Control groups and treated groups were exposed concurrently to identical conditions.

The test concentrations were: 1 control group, 6 test item groups with 1481.5, 2222.2, 3333.3, 5000, 7500 and 11250 mg a.s/kg diet, equivalent to 29.6, 44.4, 66.6, 100, 150 and 225 µg a.s./bee/day; 1 reference item group with 0.016 µg dimethoate/bee/day. Three replicates of 10 bees each were used for each group. Mortality and behavioural abnormalities were assessed daily over the 10 days test period.

The test conditions were: Air temperature: Min / Max: 34.3/ 34.8 °C, Relative air humidity: Min / Max: 51 % / 63 % RH, Exposure to light: Constant darkness except during observations.

Results and discussions

Table 2.3.1.1.2-1: Cumulative mortality, overall mean consumption of feeding solution, dietary dose (DD), accumulated mean uptake, NOEC, NOEDD, LC₅₀ and LDD₅₀

Treatment	10-day cumulative mortality	Overall mean consumption of feeding solution	Dietary dose (based on actual measured consumption of feeding solution)	Mean accumulated uptake of test item during the test period
	[%]	[µg/bee/day]	[µg a.s./bee/day]	[µg a.s./bee]
Control				
C (0)	0.00	-	-	-
C _s (0)	0.00	-	-	-
Reference item: dimethoate [µg a.s./bee]				
R (0.016)	86.6	0.016	0.009	0.09
Test item: Boscalid Technical [mg a.s./kg feeding solution]				
T1 (1481.5)	6.7	29.6	40.09	400.9
T2 (2222.2)	20.0	44.4	59.72	597.2
T3 (3333.3)	30.0	66.6	82.42	824.2
T4 (5000)	46.7	100	117.9	1179
T5 (7500)	60.0	150	163.05	1630.5
T6 (11250)	100.0	225	231.3	2313
NOEC	2222.2 mg a.s./kg feeding solution			
NOEDD	59.72 µg a.s./bee/day			
LC₅₀ [95 % IC]	4768.70 ± 210.86 mg a.s./kg feeding solution			
LDD₅₀ [95 % IC]	111.99 ± 4.20 µg a.s./bee/day			

Findings:

- The actual mean concentrations of boscalid in all test item feeding solutions were in the range

from 98.1 to 101.9 % of the nominal concentrations; therefore results are based on nominal.

- In control groups fed with pure 50 % (w/v) aqueous sucrose solution and 50 % (w/v) aqueous sucrose solution containing 5 % acetone, 0.00 and 0.00 % mortality was observed at the final assessment after 10 days.
- The maximum mortality which was observed in the highest test item treatment concentration, 11250 mg a.s./kg feeding solution was 100.00 % after 10 days.
- At the concentrations of 1481.5, 2222.2, 3333.3, 5000, 7500 and 11250 mg a.s./kg feeding solution 6.7, 20, 30, 46.7, 60 and 100.00 % mortality (was observed).
- At the end of 10 days exposure bees treated with control and treatment group were appeared normal and no toxic sign was observed.
- The overall mean daily consumption of feeding solutions (i.e. the average consumption/bee over 10 days) in the test item concentrations of 1481.5, 2222.2, 3333.3, 5000, 7500 and 11250 mg a.s./kg feeding solution was 29.6, 44.4, 66.6, 100, 150 and 225 µg/bee/day, respectively.
- After 10 days of continuous exposure, the mean accumulated uptake of boscalid at the test item concentrations of 1481.5, 2222.2, 3333.3, 5000, 7500 and 11250 mg a.s./kg feeding solution was 400.9, 597.2, 824.2, 1179, 1630.5 and 2313 µg a.s./bee, respectively. The corresponding average daily dose (DD) was therefore 40.09, 59.72, 82.42, 117.9, 163.05 and 231.3 µg a.s./bee/day.
- The NOEC for mortality after 10 days of continuous exposure was determined to be 2222.2 mg a.s./kg feeding solution. The corresponding NOEDD, based on the actual consumption of the feeding solutions, was determined to be 59.72 µg a.s./bee/day.
- After 10 days of continuous exposure, the LC₅₀ with 95 % confidence intervals was determined to be 4768.70 ± 210.86 mg a.s./kg feeding solution. The corresponding LDD₅₀ with 95 % confidence intervals, based on the actual consumption of the feeding solutions, was determined to be 111.99 ± 4.20 µg a.s./bee/day.

The following validity criteria were met during the test:

- The mean mortality in the control was ≤ 15 % at the end of the test (actual 0.00 and 0.00 % for control and control solvent respectively).
- The mean mortality in the reference item group was ≥50 % at the end of the test (actual 86.7 %)

Conclusion

The chronic toxicity of Boscalid Technical to honey bees was tested under laboratory conditions over a period of 10 days.

The actual mean concentrations of Boscalid in test item feeding solutions were in the range of 98.1 to 101.9 % of the nominal concentrations; therefore results are based on nominal.

The 10-day NOEC was determined to be 2222.2 mg a.s./kg feeding solution.

The 10-day NOEDD was determined to be 59.72 µg a.s./bee/day.

The 10-day LC₅₀ with 95 % confidence intervals was determined to be 4768.70 ± 210.86 mg a.s./kg feeding solution.

The 10-day LDD₅₀ with 95 % confidence intervals was determined to be 111.99 ± 4.20 µg a.s./bee/day.

A 2.3.1.3 KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

Comments of zRMS:	<p>The study is considered acceptable. All validity criteria were met.</p> <ul style="list-style-type: none"> • The cumulative larval mortality from day 3 (D3) to the day 8 (D8) was $\leq 15\%$ across all replicates in control group and control solvent group (actual values 0.0% and 2.78 % respectively). • On day 22 (D22) the adult emergence rate was $\geq 70\%$ across all control replicates (actual value 91.67 and 88.89 %, respectively). • The cumulative larval mortality was $\geq 50\%$ across all reference replicates between D3 and D8(actual 72.22%). <p>Agreed endpoints: The 22-Day NOEC =85.60 mg a.s./kg diet. The 22-Day NOED =13.17 μg a.s./larva. The 22-Day EC_{50} =354.64 \pm 22.82 mg a.s./kg diet. The 22-Day ED_{50} =54.56 \pm 3.51μg a.s./larva. The 22-Day > 650 mg a.s./kg diet. The 22-Day ED_{20} > 100 μg a.s./larva. The 22-Day EC_{10} > 650 mg a.s./kg diet. The 22-Day ED_{10} > 100 μg a.s./larva.</p>
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Reference:	KCP 10.3.1.3.1
Report	“Effect of Pyraclostrobin Technical on larvae of Honey Bee, <i>Apis mellifera</i> (L.) following Repeated Exposure”, S. Radha, 2020, Study code 5029/2019
Guideline(s):	Yes, ENV/JM/MONO (2016) 34: Guidance Document on Honey bee (<i>Apis mellifera</i>) Larval Toxicity Test, Following Repeated Exposure, Series on Testing and Assessment (OECD 239 (2016)).
Deviations:	Deviation from Study Plan: The study finished in March 2020, not in January 2020, as it had been planned. This deviation did not affect the study results.
GLP:	Yes
Acceptability:	Yes

Materials and methods

The objective of this study was to determine the effects of Pyraclostrobin Technical (batch SCL-395601 on the honey bee larvae, *Apis mellifera* L., from repeated feeding exposure in an 22 day *in vitro* test and to determine the No Observed Effect Dose/Concentration (NOED, NOEC) and the corresponding Median Effect Dose/Concentration (ED_{50} , EC_{50}) and any ED_x/EC_x for day 22, where possible.

The test species was honey bee (*Apis mellifera* L.), synchronized first instar (L1) larvae originating from bee hive maintained at BRF test facility.

The test was conducted as a dose response test with a duration of 22 days from grafting on day 1 (D1) to the final assessment on day 22 (D22); from day 3 (D3) until day 6 (D6) of the test, test item (Pyraclostrobin Technical) and reference item (dimethoate) were dissolved in the appropriate larval diet

and provided to larvae once a day. The analysed Pyraclostrobin content was used to calculate the test item doses and dimethoate content was used to calculate the reference item dose.

The experimental groups were: 1 untreated control group, 1 untreated control solvent group, 6 test item groups and 1 reference item group. The control groups and treated groups were exposed for the same period of time under identical conditions. Each treatment group consisted of 3 replicates and 12 larvae per replication. Mortality assessments were performed on day 4 (D4), day 5 (D5), day 6 (D6), day 7 (D7), day 8 (D8), day 15 (D15) and day 22 (D22); the presence of uneaten food was qualitatively recorded on day 8 (D8).

The test concentrations were: 1 control group, 1 control solvent group (acetone 0.5 %), 6 test item groups with 85.60, 128.40, 192.59, 288.89, 433.33 and 650 mg a.s./kg diet, equivalent to cumulative doses of 13.17, 19.75, 29.63, 44.44, 66.67 and 100 µg a.s./larva; 1 reference item group with 48.00 mg dimethoate/kg diet, equivalent to a cumulative dose of 7.6 µg dimethoate/larva.

The test conditions were: Air temperature: D1-D8: 34.3-34.7°C, D3-D8: 34.3-34.7°C, D8-D15: 34.2-34.7°C; Relative air humidity: D1-D8: 80-86%, D3-D8: 80-86%, D8-D15: 80-87% Exposure to light: constant darkness except during observations.

The NOED/NOEC was determined by one-way ANOVA test using Graph Pad Prism 8.2, the value obtained was ≥ 100 µg a.i./larva. The data did not allow to determine ED₁₀, ED₂₀ and ED₅₀ (22)

Results and discussions

Table 2.3.1.1.2-1: Cumulative mortality, overall mean consumption of feeding solution, dietary dose (DD), accumulated mean uptake, NOEC, NOEDD, LC₅₀ and LDD₅₀

Endpoint	µg a.s./larva
22-Day NOED	13.17
22-Day ED ₁₀ [95 % I.C.]	>100
22-Day ED ₂₀ [95 % I.C.]	>100
22-Day ED ₅₀ [95 % I.C.]	54.56 ± 3.51
Endpoint	mg a.s./kg diet
22-Day NOEC	85.60
22-Day EC ₁₀ [95 % I.C.]	>650
22-Day EC ₂₀ [95 % I.C.]	>650
22-Day EC ₅₀ [95 % I.C.]	354.64 ± 22.82

Findings:

- In control and control solvent groups, cumulative larval mortality from day 4 (D4) until day 8 (D8) was 0.00 and 2.78 % respectively. On day 22 (D22), the adult emergence rate in control and control solvent groups was 91.67 % and 88.89% of the initial grafted larvae, respectively. Cumulative mortality in the Reference Item treatment group was 72.22 % by D8. Therefore, the validity criteria were met.
- At day 8 (D8) of the test in the test item doses of 13.17, 19.75, 29.63, 44.44, 66.67 and 100 µg a.s./larva, the cumulative mean mortality were; 5.56, 8.33, 11.11, 19.44, 30.56 and 69.44 % respectively.

- At day 15 (D15) of the test in the test item doses of 13.17, 19.75, 29.63, 44.44, 66.67 and 100 µg a.s./larva, the cumulative mean mortality were 11.11, 11.11, 13.89, 22.22, 38.89 and 80.56 % respectively.
- In the test item doses of 13.17, 19.75, 29.63, 44.44, 66.67 and 100 µg a.s./larva, the cumulative mean mortalities at 22 days (D22) after grafting were 16.67, 16.67, 22.22, 30.56, 47.22 and 88.89 % respectively. In consequence the mean emergence rates were 83.33, 83.33, 77.78, 69.44, 52.78 and 11.11 % respectively. No affected emerged bees were recorded on day 22 (D22).
- The NOEC for mortality at 22 days (D22) after grafting was determined to be 85.60 mg a.s./kg diet. The corresponding NOED was determined to be 13.17 µg a.s./larva.
- The 22-Day EC₅₀ was calculated to be 354.64 ± 22.82 mg a.s./kg diet.
The 22-Day ED₅₀ was calculated to be 54.56 ± 3.51 µg a.s./larva.
The 22-Day EC₂₀ was calculated to be > 650 mg a.s./kg diet.
The 22-Day ED₂₀ was calculated to be > 100 µg a.s./larva.
The 22-Day EC₁₀ was calculated to be > 650 mg a.s./kg diet.
The 22-Day ED₁₀ was calculated to be > 100 µg a.s./larva

The following validity criteria were met during the test:

- The cumulative larval mortality from day 3 (D3) to the day 8 (D8) was ≤ 15% across all replicates in control group and control solvent group (actual values 0.0% and 2.78 % respectively).
- On day 22 (D22) the adult emergence rate was ≥ 70% across all control replicates (actual value 91.67 and 88.89 %, respectively).
- The cumulative larval mortality was ≥ 50 % across all reference replicates between D3 and D8(actual 72.22%).

Conclusion

The repeated exposure of Pyraclostrobin Technical to honey bee larval was tested under laboratory conditions over a period of 22 days.

The 22-Day NOEC was determined to be 85.60 mg a.s./kg diet.

The 22-Day NOED was determined to be 13.17 µg a.s./larva.

The 22-Day EC₅₀ was calculated to be 354.64 ± 22.82 mg a.s./kg diet.

The 22-Day ED₅₀ was calculated to be 54.56 ± 3.51 µg a.s./larva.

The 22-Day EC₂₀ was calculated to be > 650 mg a.s./kg diet.

The 22-Day ED₂₀ was calculated to be > 100 µg a.s./larva.

The 22-Day EC₁₀ was calculated to be > 650 mg a.s./kg diet.

The 22-Day ED₁₀ was calculated to be > 100 µg a.s./larva.

The study was deemed valid since all validity criteria were met.

Comments of zRMS:	<p>The study is considered acceptable. All validity criteria were met.</p> <ul style="list-style-type: none"> • The cumulative larval mortality from day 3 (D3) to the day 8 (D8) was ≤ 15% across all replicates in control group and control solvent group (actual values 5.56 % and 11.11 % respectively). • On day 22 (D22) the adult emergence rate was ≥ 70% across all control replicates (actual value 86.11 and 80.56 %, respectively). • The cumulative larval mortality was ≥ 50 % across all reference replicates between D3 and D8(actual 77.78%). <p>Agreed endpoints: The 22-Day NOEC =40.625 mg a.s./kg diet. The 22-Day NOED =6.25 µg a.s./larva. The 22-Day EC₅₀ >650 mg a.s./kg diet. The 22-Day ED₅₀ >100 µg a.s./larva.</p>
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Reference:	KCP 10.3.1.3.2
Report	“Effect of Boscalid Technical on larvae of Honey Bee, <i>Apis mellifera</i> (L.) following Repeated Exposure”, S. Radha, 2020, Study code 5032/2019
Guideline(s):	Yes, ENV/JM/MONO (2016) 34: Guidance Document on Honey bee (<i>Apis mellifera</i>) Larval Toxicity Test, Following Repeated Exposure, Series on Testing and Assessment (OECD 239 (2016)).
Deviations:	Deviation from Study Plan: The study finished in March 2020, not in November 2019, as it had been planned. This deviation did not affect the study results.
GLP:	Yes
Acceptability:	Yes

Materials and methods

The objective of this study was to determine the effects of Boscalid Technical (batch SCL-45612 on the honey bee larvae, *Apis mellifera* L., from repeated feeding exposure in an 22 day in vitro test and to determine the No Observed Effect Dose/Concentration (NOED, NOEC) and the corresponding Median Effect Dose/Concentration (ED₅₀, EC₅₀) and any ED_x/EC_x for day 22, where possible.

The test species was honey bee (*Apis mellifera* L.), synchronized first instar (L1) larvae originating from bee hive maintained at BRF test facility.

The test was conducted as a dose response test with a duration of 22 days from grafting on day 1 (D1) to the final assessment on day 22 (D22); from day 3 (D3) until day 6 (D6) of the test, test item (Boscalid Technical) and reference item (dimethoate) were dissolved in the appropriate larval diet and provided to larvae once a day. The analysed Boscalid content was used to calculate the test item doses and dimethoate content was used to calculate the reference item dose.

The experimental groups were: 1 untreated control group, 1 untreated control solvent group, 5 test item groups and 1 reference item group. The control groups and treated groups were exposed for the same period of time under identical conditions. Each treatment group consisted of 3 replicates and 12 larvae per replication. Mortality assessments were performed on day 4 (D4), day 5 (D5), day 6 (D6), day 7 (D7), day 8 (D8), day 15 (D15) and day 22 (D22); the presence of uneaten food was qualitatively recorded on day 8 (D8).

The test concentrations were: 1 control group, 1 control solvent group (acetone 0.5 %), 6 test item groups with 40.625, 81.25, 162.5, 325 and 650 mg a.s./kg diet, equivalent to cumulative doses of 6.25, 12.5, 25, 50 and 100 µg a.s./larva; 1 reference item group with 48.00 mg dimethoate/kg diet, equivalent to a cumulative dose of 7.6 µg dimethoate/larva.

The test conditions were: Air temperature: D1-D8: 34.1-34.5°C, D3-D8: 34.1-34.5°C, D8-D15: 34.2-34.8°C; Relative air humidity: D1-D8: 90-95%, D3-D8: 90-95%, D8-D15: 80-94% Exposure to light: constant darkness except during observations.

The NOED/NOEC was determined by one-way ANOVA test using Graph Pad Prism 8.2, the value obtained was $\geq 100 \mu\text{g a.i./larva}$. The data did not allow to determine ED₁₀, ED₂₀ and ED₅₀ (22)

Results and discussions

Table 2.3.1.1.2-1: Cumulative mortality, overall mean consumption of feeding solution, dietary dose (DD), accumulated mean uptake, NOEC, NOEDD, LC₅₀ and LDD₅₀

Endpoint	$\mu\text{g a.s./larva}$
22-Day NOED	6.25
22-Day ED ₁₀ [95 % I.C.]	-
22-Day ED ₂₀ [95 % I.C.]	-
22-Day ED ₅₀ [95 % I.C.]	>100
Endpoint	mg a.s./kg diet
22-Day NOEC	40.625
22-Day EC ₁₀ [95 % I.C.]	-
22-Day EC ₂₀ [95 % I.C.]	-
22-Day EC ₅₀ [95 % I.C.]	>650

Findings:

- In control and control solvent groups, cumulative larval mortality from day 4 (D4) until day 8 (D8) was 5.56 and 11.11 % respectively. On day 22 (D22), the adult emergence rate in control and control solvent groups was 86.11 % and 80.56% of the initial grafted larvae, respectively. Cumulative mortality in the Reference Item treatment group was 77.78 % by D8. Therefore, the validity criteria were met.
- At day 8 (D8) of the test in the test item doses of 6.25, 12.5, 25, 50 and 100 $\mu\text{g a.s./larva}$, the cumulative mean mortality were; 13.89, 13.89, 16.67, 19.44 and 22.22 % respectively.
- At day 15 (D15) of the test in the test item doses of 6.25, 12.5, 25, 50 and 100 $\mu\text{g a.s./larva}$, the cumulative mean mortality were 16.67, 19.44, 22.22, 25.00 and 30.56 % respectively.
- In the test item doses of 6.25, 12.5, 25, 50 and 100 $\mu\text{g a.s./larva}$, the cumulative mean mortalities at 22 days (D22) after grafting were 25.00, 27.78, 30.56, 33.33 and 38.89 % respectively. In consequence the mean emergence rates were, 75.00, 72.22, 69.44, 66.67 and 61.11 % respectively. No affected emerged bees were recorded on day 22 (D22).
- The NOEC for mortality at 22 days (D22) after grafting was determined to be 40.625 mg a.s./kg diet. The corresponding NOED was determined to be 6.25 $\mu\text{g a.s./larva}$.
- The 22-Day EC₅₀ was calculated to be >650 mg a.s./kg diet.
The 22-Day ED₅₀ was calculated to be >100 $\mu\text{g a.s./larva}$.

The following validity criteria were met during the test:

- The cumulative larval mortality from day 3 (D3) to the day 8 (D8) was $\leq 15\%$ across all replicates in control group and control solvent group (actual values 5.56 % and 11.11 % respectively).
- On day 22 (D22) the adult emergence rate was $\geq 70\%$ across all control replicates (actual value 86.11 and 80.56 %, respectively).
- The cumulative larval mortality was $\geq 50 \%$ across all reference replicates between D3 and D8(actual 77.78%).

Conclusion

The repeated exposure of Boscalid Technical to honey bee larval was tested under laboratory conditions over a period of 22 days.

The 22-Day NOEC was determined to be 40.625 mg a.s./kg diet.

The 22-Day NOED was determined to be 6.25 $\mu\text{g a.s./larva}$.

The 22-Day EC₅₀ was calculated to be >650 mg a.s./kg diet.

The 22-Day ED₅₀ was calculated to be >100 µg a.s./larva.
The study was deemed valid since all validity criteria were met.

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

zRMS comments: The study is considered acceptable. All validity criteria were met.

- mortality of the control group was 5.0% on day 7 of exposure (criterion: a maximum of 20%),
- corrected mortality of the mites exposed to the reference item at the rate of 9.0 mL/ha was 85.96% on day 7 of exposure (criterion: from 50 to 100%),
- the mean number of eggs per female in the control group was 5.1 (required: ≥ 4 eggs per female).

Agreed endpoints:

Study group Application rate			Parameter (endpoint)									
			Mortality					Reproduction				
Test item			Total [%]	Corre-cted*	LR ₅₀			Mean n°eggs/fem (Rr)	Rep. reduction Pr [%]	ER ₅₀		
[hg/ha] ^a	[g.a.i./ha] ^b				[kg/ha] ^a	[g a.i./ha] ^b				[kg/ha] ^a	[g a.i./ha] ^b	
	a.i ^e	a.i ^f				a.i ^e	a.i ^f				a.i ^e	a.i ^f
Control (0.0)			5.0	-	-			5.1	-	-		
2.03	540.7	135.7	6.67	1.75	>8.10	>2162.7	>542.7	3.5	34.45	5.48** (2.81-7.64)	1462.63	367.03
4.05	1081.4	271.4	10.0	5.26				3.6	29.91			
8.10	2162.7	542.7	8.33	3.51				1.5	70.11			
NOER _{mortality}				≥8.10 kg/ha ^g				NOER _{reproduction}		< 2.03 kg/ha ^h		
Reference item			-									
[ml/ha] ^c	[g a.i./ha] ^d											
9.0	3.6		86.67	85.96	Not determined			Not assessed				

^a: [kg test item/ha]

^b: [g active ingredient/ha test item]

^c: [mL reference item/ha]

^d: [g active ingredient/ha reference item]

^e: Boscalid

^f: Pyraclostrobin

^g: ≥ 2162.7g boscalid/ha + 542.7g pyraclostrobin/ha

^h: < 540 g boscalid/ha + 135.7g pyraclostrobin/ha

^{*}: mortality corrected using the formula of Abbott

^{**}: ER₅₀ with 95%- confidence limits

Reference: KCP 10.3.2.1-01

Report “A laboratory test for evaluating the effects of Boscalid 26.7% + Pyra-

clostrobilin 6.7% WG on the predatory mite, *Typhlodromus pyri* (Sch.)".
Aneta Glanas, MSc B/111/16. Institute of Industrial Organic Chemistry
Branch Pszczyna.

Guideline(s): ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Blümel S. et al., 2000)

Deviations: Yes, delay in the study completion date.
The deviation has no negative impact on the overall outcome of the study

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) Not relevant

Materials and methods

The aim of the laboratory test was to evaluate the effects of the test item, Boscalid 26.7% + Pyraclostrobin 6.7% WG (batch number: SCL- 20604) on mortality and reproduction of the predatory mite, *T. pyri* (Sch.).

The mites, *T. pyri* at the protonymphal stage (24 hours old) were exposed to the test item applied to discs. The mites were fed with pine pollen (*Pinus sp.*). Mortality observations were made after 7 days of the treatment. Observations of reproduction of the control group and all groups treated with the test item were made after 10, 12, and 14 days of the treatment.

On the basis of the preliminary test results, it was decided to use three rates of the test item in the definitive test. These were 2.03, 4.05 and 8.1 kg/ha (i.e. 540.7 g boscalid/ha + 135.7 g pyraclostrobin/ha, 1081.4 g boscalid/ha + 271.4 g pyraclostrobin/ha and 2162.7 g boscalid/ha + 542.7g pyraclostrobin/ha). To verify the sensitivity of the mites and the precision of the test procedure, an insecticide, Danadim 400 EC (400 g dimethoate/L) was used as a reference item. The rate of the reference item was 9.0 mL/ha (3.6 g a.i./ha). The control group was treated with distilled water.

Each treatment group included 3 replicates containing 20 mites *T.pyri*. Mortality of *T.pyri* after 7 days of the treatment and the reproduction reduction (Pr) after 14 days of the treatment were test endpoints.

Results

Table10.3.2.1-01-1 Mortality and reproduction of *T. pyri* in the laboratory test

Study group Application rate			Parameter (endpoint)									
			Mortality					Reproduction				
Test item			Total [%]	Cor- re- cted*	LR ₅₀			Mean n°eggs /fem (Rr)	Rep. reduc- tion Pr [%]	ER ₅₀		
[hg/ha] ^a	[g.a.i./ha] ^b				[kg/ ha] ^a	[g a.i./ha] ^b				[kg/ha] ^a	[g a.i./ha] ^b	
	a.i ^e	a.i ^f				a.i ^e	a.i ^f				a.i ^e	a.i ^f
Control (0.0)			5.0	-	-			5.1	-	-		
2.03	540.7	135.7	6.67	1.75	>8.1 0	>2162.7	>542.7	3.5	34.45	5.48** (2.81- 7.64)	1462.63	367.03
4.05	1081.4	271.4	10.0	5.26				3.6	29.91			
8.10	2162.7	542.7	8.33	3.51				1.5	70.11			
NOER _{mortality}					≥8.10 kg/ha ^g			NOER _{reproduction}		< 2.03 kg/ha ^h		
Reference item			-									
[ml/ha] ^c	[g a.i./ha] ^d											
9.0	3.6		86.67	85.96	Not determined			Not assessed				

^a: [kg test item/ha]

^b: [g active ingredient/ha test item]

^c: [mL reference item/ha]

^d: [g active ingredient/ha reference item]

^e: Boscalid

^f: Pyraclostrobin

^g: $\geq 2162.7 \text{ g boscalid/ha} + 542.7 \text{ g pyraclostrobin/ha}$

^h: $< 540 \text{ g boscalid/ha} + 135.7 \text{ g pyraclostrobin/ha}$

^{*}: mortality corrected using the formula of Abbott

^{**}: ER50 with 95%- confidence limits

Findings

In the definitive test, mortality of the control group after 7 days of exposure was 5.0%. After 7 days of exposure to Boscalid 26.7% + Pyraclostrobin 6.7% WG at the rates of 2.03, 4.05, 8.10 kg/ha (i.e. 540.7 g boscalid/ha + 135.7 g pyraclostrobin/ha, 1081.4 g boscalid/ha + 271.4 g pyraclostrobin/ha and 2162.7 g boscalid/ha + 542.7 g pyraclostrobin/ha), the percentages of mortality of *T. pyri*, corrected using the formula of Abbott, were 1.8, 5.3 and 3.5%, respectively.

There were no statistically significant differences in mortality between the groups treated with the test item at the rates of 2.03, 4.05, 8.10 kg/ha (i.e. 540.7 g boscalid/ha + 135.7 g pyraclostrobin/ha, 1081.4 g boscalid/ha + 271.4 g pyraclostrobin/ha and 2162.7 g boscalid/ha + 542.7 g pyraclostrobin/ha) and the control group (Step-down Cochran-Armitage Test Procedure, $p > 0.05$).

On the basis of the obtained mortality results, the LR50 value is higher than 8.10 kg/ha (i.e. $> 2162.7 \text{ g boscalid/ha} + 542.7 \text{ g pyraclostrobin/ha}$) and NOERMortality is higher than or equal to 8.10 kg/ha (i.e. $\geq 2162.7 \text{ g boscalid/ha} + 542.7 \text{ g pyraclostrobin/ha}$).

After 7 days of exposure to Danadim 400 EC at the rate of 9.0 mL/ha (3.6 g a.i./ha), mortality of the mites, corrected using the formula of Abbott, was 85.96 %. Therefore, the validity criterion specified in the Method description was met. The results obtained in the reference item group showed that the test organisms were sensitive to dimethoate.

The mean reproduction rate (Rr) in the control group was 5.1 eggs/female. The mean reproduction rates after 14 days of exposure to Boscalid 26.7% + Pyraclostrobin 6.7% WG at the rates of 2.03, 4.05, 8.10 kg/ha (i.e. 540.7 g boscalid/ha + 135.7 g pyraclostrobin/ha, 1081.4 g boscalid/ha + 271.4 g pyraclostrobin/ha and 2162.7 g boscalid/ha + 542.7 g pyraclostrobin/ha) were 3.5, 3.6 and 1.5 eggs/female, respectively.

Validity criteria

The following validity criteria were met during the study:

- mortality of the control group was 5.0% on day 7 of exposure (criterion: a maximum of 20%),
- corrected mortality of the mites exposed to the reference item at the rate of 9.0 mL/ha was 85.96% on day 7 of exposure (criterion: from 50 to 100%),
- the mean number of eggs per female in the control group was 5.1 (required: ≥ 4 eggs per female).

Conclusion

On the basis of the obtained results it can be concluded that Boscalid 26.7% + Pyraclostrobin 6.7% WG at the rates of 2.03, 4.05 and 8.10 kg/ha (i.e. 540.7 g boscalid/ha + 135.7 g pyraclostrobin/ha, 1081.4 g boscalid/ha + 271.4 g pyraclostrobin/ha and 2162.7 g boscalid/ha + 542.7 g pyraclostrobin/ha) has no adverse effect on mortality of the mites. However at the all rates: 2.03, 4.05 and 8.10 kg/ha (i.e. 540.7 g boscalid/ha + 135.7 g pyraclostrobin/ha, 1081.4 g boscalid/ha + 271.4 g pyraclostrobin/ha and 2162.7 g boscalid/ha + 542.7 g pyraclostrobin/ha) effect on reproduction of the mites is observed.

Comments of zRMS:	The study is considered acceptable. All validity criteria were met.								
	– after 48 hours mortality of the control group was 5.0% (criterion: a maximum of 13.0%),								
	– after 24 hours the Abbott corrected mortality of the group treated with the reference item at the rate of 0.1 mL/ha was 73.68% (criterion: from 75 to 100%),								
	– the mean number of mummies per female in the control group was 34.93 (criterion: a minimum of 5.0 mummies/female),								
	– all wasps in the control group gave offspring (criterion: a maximum of 2 females giving no offspring).								
	Agreed endpoints:								
	Study group (application rate)	Parameter (endpoint)							
		Mortality after 48h of exposure				Fecundity			
	Test item	Total (%)	Corre-Ted ^c (%)	LR ₅₀		Mean n°of Mummies/ female	Fecundity reduction Pr (%)	ER ₅₀	
	(kg/ha)			(Kg ti/ha)	(g a.i./ha)			(kg t.i/ha)	(g a.i./ha)
	Control (0.0)	5.0	-	-		34.9	-	-	
	0.68	0.00	(-5.26)**	3.0 (1.6-5.6)	801.2 ^a +201.2 ^b	22.5+	35.7	1.2 (0.1-14.2)	320 ^a +80.4 ^b
	1.35	12.50	7.89			15.3+	31.8		
	2.70	60.00	57.89 ⁺			10.7+	30.4		
	5.40	75.00	73.68 ⁺			Not assessed			
	NOER _{mortality}			1.35(kg t.i./ha) (360.5a+90.80b g a.i./ha)		NOER _{fecundity}		<068(kg t.i./ha) [<(181.6 ^a +45.6 ^b) g a.i./ha]	
	Reference item								
	(ml/ha)	Mortality after 24h of exposure				Not assessed			
Total (%)		Corrected ^c (%)							
0.1	75.00		73.68						
^a boscalid									
^b pyraclostrobin									
^c : mortality corrected according to the formula of Abbott [8]									
** negative values indicate that mortality in the treated groups was lower than in the control									
+ statistically significant difference									

Reference: KCP 10.3.2.1-02

Report: A laboratory test for evaluating the effects of Boscalid 26.7% + Pyraclostrobin 6.7% WG on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani - Perez) Mateusz Grzesica, MSc B/110/16. Institute of Industrial Organic Chemistry Branch Pszczyna.

Guideline(s): ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2001) guidance documents and the guidelines developed by the Joint Initiative of IOBC, BART, and EPPO

(Mead-Briggs M.A. et al., 2000; Mead-Briggs M.A. et al., 2010)

Deviations: None
GLP: Yes
Acceptability: Yes
Duplication (if vertebrate study): No

Materials and methods

Test item:

Description: Boscalid 26.7% + Pyraclostrobin 6.7% WG

Batch number: SCL-20604

Test system:

Species: *Aphidius rhopalosiphi* (De Stefani-Perez).
 Strain: Hymenoptera: Braconidae, Aphidinae.
 Age: Adult females (24 - 48 hours after emerging from mummies)
 Source: A laboratory culture at the Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was obtained from Katz Biotech AG (Baruth, Germany)

Plant material:

Species: The barley, *Hordeum L*, variety: "Kucyk"
 Development stage: 7days old, 20 seedlings
 Source: A laboratory culture at the institute of Industrial Organic Chemistry, Branch Pszczyna

Experimental conditions:

Temperature: 19 - 21 °C
 Relative air humidity: 68 – 75 %
 Photoperiod: 16 h light (mortality assessment and ovoposition: 1198 lx: fecundity assessment: 4351 lx): 8 hours dark.

Test units: Transparent PMMA cylinder (isolator) with a diameter of 11 cm and a height of 20 cm put on a plastic pot with a diameter of 12 cm.
 Mortality: pots contained 7-day old barley seedlings (8 seedlings per pot).
 Fecundity: approximately 20 seedlings of 7-day-old barley infested with the bird cherry-oat aphid, *Rhopalosiphum padi* (> 100 aphids per pot). Apex of each cylinder and two longitudinal openings on its two sides are covered with fine metal netting to provide ventilation. A hole was used to introduce the wasps and to place a cotton wool bung soaked with a 1:3 v/v solution of honey in water.

Endpoints:

- Wasp mortality after 48 hours of exposure
- Reduction of fecundity (Pr) of the surviving female wasps exposed to Boscalid 26.7%+Pyraclostrabin 6.7% WG, 12 days after the ovoposition period.

Test design:

The study was divided into a non-GLP preliminary range-finding test and a definitive test. The non-GLP preliminary test was conducted to determine the range of rates to be used in the definitive test. The preliminary test involved only the assessment of the impact of Boscalid 26.7%+Pyraclostrabin 6.7% WG on wasp mortality. It was done on one control group and five test item groups. Two replicates of each group were used. There were ten wasps in each replicate.

The definitive test was done on one control group, four test item groups (0.68, 1.35, 2.70 and 5.4 kg/ha of Boscalid 26.7%+Pyraclostrabin 6.7% WG) and one reference group (0.1 ml/ha of Danadim 400 EC). Four replicates of each group were used. There were ten wasps in each replicate.

The glass plates were sprayed using the potter laboratory spray tower (model: standard; version manual-load; manufacture: Burkard Scientific, England).

After the calibration, the plates were sprayed with distilled water, suspension of Boscalid 26.7 % + Pyraclostrabin 6.7 % WG or an aqueous emulsion of Danadim 400 EC at the rate of 0.1 ml/ha. Before the plates were sprayed with the reference item, the Potter spray tower had been cleaned and flushed several times with distilled water and acetone.

After 48 hours of exposure, 15 females from the control group and 15 females from the group treated with Boscalid 26.7%+Pyraclostrabin 6.7% WG at the rates of 0.68, 1.35, 2.70 and 5.4 kg/ha (mortality: < 50%) were individually introduced into the fecundity units containing barley plants infested with the aphid, *R. padi*. The aim was to allow the parasitisation process (oviposition) lasting 24 hours. After the oviposition, all surviving wasps were removed from the fecundity units, whereas the parasitized aphids were left for 12 days to allow the development of mummies (a pupal stage of a wasp in the aphid body). The impact of the reference item on fecundity of the wasps was not evaluated.

The temperature and the relative air humidity during the experimental phase were continuously recorded throughout the trial with a thermo hygrograph. The light intensity was measured once per phase with a luxmeter.

Statistics:

Data on mortality were analyzed using the log-probit method in order to determine the LR₅₀ value. To determine the NOER_{mortality}, and the significance of differences in mortality between treated groups and the control, chi² 2x2 Table test with Bonferroni Correction was used.

Mortality and fecundity results were statistically analyzed using the ToxRate Professional 3.2.1 statistical software.

Results:

The test item at the rates of 2.70 and 5.4 kg/ha had adverse effects on mortality of *Aphidius rhopalosiphi*; the test item at the rates of 0.68, 1.35 and 2.70 kg/ha had adverse effects on fecundity of *Aphidius rhopalosiphi*. The effects of the test item on mortality and fecundity of *A. rhopalosiphi* under laboratory conditions are summarized below:

Table10.3.2.1-02-1 Mortality and reproduction of *A. rhopalosiphi* in the laboratory test

Table 12.1. 5.2. 1. Mortality and reproduction of <i>R. mupulosign</i> in the laboratory test								
Study group (application rate)		Parameter (endpoint)						
		Mortality after 48h of exposure				Fecundity		
Test item	Total (%)	Corre-Ted ^c (%)	LR ₅₀		Mean n°of Mummies/ female	Fecundity reduction Pr (%)	ER ₅₀	
(kg/ha)			(Kg ti/ha)	(g a.i./ha)			(kg t.i/ha)	(g a.i./ha)
Control (0.0)	5.0	-	-		34.9	-	-	
0.68	0.00	(-5.26)**	3.0 (1.6-5.6)	801.2 ^a + 201.2 ^b	22.5+	35.7	1.2 (0.1-14.2)	320 ^a +80.4 ^b
1.35	12.50	7.89			15.3+	31.8		
2.70	60.00	57.89 ⁺			10.7+	30.4		
5.40	75.00	73.68 ⁺			Not assessed			
NOER _{mortality}			1.35(kg t.i./ha) (360.5a+90.80b g a.i./ha)		NOER _{fecundity}		<068(kg t.i./ha) [<(181.6 ^a +45.6 ^b) g a.i./ha]	
Reference item								
(ml/ha)	Mortality after 24h of exposure				Not assessed			
	Total (%)		Corrected ^c (%)					
0.1	75.00		73.68					

^a boscalid

^b pyraclostrobin

^c: mortality corrected according to the formula of Abbott [8]

** negative values indicate that mortality in the treated groups was lower than in the control

+ statistically significant difference

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

Comments of zRMS:	<p>The study is considered acceptable. All validity criteria were met.</p> <ul style="list-style-type: none"> Each replicate produced 44.8 juveniles (mean) at the end of the experiment (criterion: ≥ 30 juveniles by the end of the experiment) The coefficient of variation of reproduction was 18.3% (criterion: $\leq 30\%$) Adult mortality over the initial 4 weeks of the experiment was 6.3% (criterion: $\leq 10\%$) <p>Agreed endpoints: EC₁₀ =121.2 mg/kg dry weight of artificial soil (32.4 mg of boscalid + 8.1 mg of pyraclostrobin/kg dry weight of artificial soil). EC₂₀=142.7 mg/kg dry weight of artificial soil (38.1 mg of boscalid + 9.6 mg of pyraclostrobin/kg dry weight of artificial soil). EC₅₀ =195.0 mg/kg dry weight of artificial soil (52.1 mg of boscalid + 13.1 mg of pyraclostrobin/kg dry weight of artificial soil). NOEC=100 mg/kg dry weight of artificial soil (26.7 mg of boscalid + 6.7 mg of pyraclostrobin/kg dry weight of artificial soil). LOEC =180 mg/kg dry weight of artificial soil (48.1 mg of boscalid + 12.1 mg of pyraclostrobin/kg dry weight of artificial soil).</p>
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Reference: KCP 10.4.1.1

Report “Boscalid 26.7% + Pyraclostrobin 6.7% WG. Earthworm Reproduction Test (*Eisenia andrei*)”, Weronika Dec (2018), Study code: G/203/17. Institute of Industrial Organic Chemistry Branch Psczyna.

Guideline(s): OECD Guideline No. 222 (2016)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) Not relevant

Materials and methods

The aims of the study were to assess the impact of Boscalid 26.7% + Pyraclostrobin 6.7% WG (SCL-65489) on reproduction of the earthworm, *Eisenia andrei* and to determine the EC₁₀, EC₂₀, EC₅₀, and NOEC.

The test item in the form of an aqueous solution was mixed with a suitable amount of the artificial soil. The concentrations of the test item were 5.6, 10, 18, 32, 56, 100, 180, 320, and 560 mg/kg dry weight of

the artificial soil. Each of them was divided into four replicates. There were also untreated control group (with deionised water and without test item) divided into eight replicates. The experiment lasted 8 weeks. After 4 weeks, all adult earthworms were removed from the test containers and observed. All changes in their behavior and morphology were recorded. The number of earthworms and their body weights were also determined

The impact of the test item on reproduction was evaluated after an additional 4-week period on the basis of the number of juveniles hatched from cocoons during the experiment.

Results and discussions

❖ *Observation of the earthworms*

After 4 weeks of the experiment, the treated earthworms did not exhibit any changes in appearance and behaviour.

❖ *Mortality data*

The impact of the test item on mortality of the earthworms is presented in the table below.

Table 10.4.1.1-1 Mortality of the adult earthworms (*Eisenia andrei*) after 4 weeks of the experiment.

Concentration [mg/kg dry weight of the artificial soil]	Number of tested earthworms [no.]	Total Mortality	
		No.	%
0 (control)	80	5	6.3
5.6	40	5	12.5
10	40	3	7.5
18	40	6	15.0
32	40	7	17.5
56	40	6	15.0
100	40	6	15.0
180	40	6	15.0
320	40	7	17.5
560	40	8	20.0

❖ *Body weight*

Table 10.4.1.1-2 Body weight change in the adult earthworms (*Eisenia andrei*) after 4 weeks.

Concentration [mg/kg dry weight of the artificial soil]	Number of tested earthworms [no.]	Mean body weight increase	
		mg	%
0 (control)	80	64.5	20.3
5.6	40	71.0	22.5
10	40	58.8	19.1
18	40	65.0	19.0
32	40	79.6	24.2
56	40	60.4	18.0
100	40	72.3	23.1
180	40	45.3	14.3
320	40	44.3	14.2
560	40	11.6	3.7

❖ *Impact of the test item on reproduction of the earthworms*

The results concerning the impact of the test item on reproduction are shown in the table below.

Table 10.4.1.1-3 Number of juvenile worms (*Eisenia andrei*) after 8 weeks of the experiment

Concentration [mg/kg dry weight of the artificial soil]	Mean \pm SD	Comparison to the control [%]	CV* [%]
0 (control)	44.8 \pm 8.2	-	18.3
5.6	46.0 \pm 11.3	102.8	24.5
10	47.0 \pm 9.2	105.0	19.6
18	42.3 \pm 6.9	94.4	16.4
32	45.0 \pm 6.4	100.6	14.2
56	44.0 \pm 6.8	98.3	15.4
100	43.0 \pm 8.2	96.1	19.2
180	26.3 ⁺ \pm 8.3	58.7	31.8
320	4.0 ⁺ \pm 2.3	8.9	57.7
560	0.0 ⁺ \pm 0.0	0.0	-

* - coefficient of variation

+ - statistically significant difference between the control and the treatment group (Williams Multiple Sequential t-test Procedure, significance level = 0.05, one-sided smaller)

Validity criteria

The results are considered valid because the following criteria were satisfied in the controls:

- Each replicate produced 44.8 juveniles (mean) at the end of the experiment - (criterion: ≥ 30 juveniles by the end of the experiment)
- The coefficient of variation of reproduction was 18.3% (criterion: $\leq 30\%$)
- Adult mortality over the initial 4 weeks of the experiment was 6.3% (criterion: $\leq 10\%$)

Conclusion

After 4 weeks, at the control group there was mortality of adult earthworm noticed and it was equal to 6.3%. At concentrations ranging from 5.6 to 560 mg of the test item/kg dry weight of artificial soil, after 4 weeks of exposure to the test item, mortality of the adult earthworms was ranging from 7.5 to 20.0%.

After the application of the test item at the concentrations ranging from 5.6 to 560 mg/kg dry weight of artificial soil, the body weight increase was between 3.7 to 24.2%. As for the control group, it was equal to 20.3%.

After the application of the test item at the concentrations ranging from 5.6 to 560 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 0.0 – 47.0 per replicate. The mean number of juveniles in the control group was equal to 44.8 per replicate.

After 8 weeks of the experiment, it was concluded that **Boscalid 26.7% + Pyraclostrobin 6.7% WG** had statistically significant impact on reproduction of the earthworms at the concentrations between 180 - 560 mg/kg dry weight of artificial soil.

The concentration of the test item causing a 10% reduction in the number of juveniles produced within the exposure period (**EC₁₀**) is equal to **121.2 mg/kg dry weight of artificial soil** (32.4 mg of boscalid + 8.1 mg of pyraclostrobin/kg dry weight of artificial soil).

The concentration of the test item causing a 20% reduction in the number of juveniles produced within the exposure period (**EC₂₀**) is equal to **142.7 mg/kg dry weight of artificial soil** (38.1 mg of boscalid + 9.6 mg of pyraclostrobin/kg dry weight of artificial soil).

The concentration of the test item causing a 50% reduction in the number of juveniles produced within the exposure period (**EC₅₀**) is equal to **195.0 mg/kg dry weight of artificial soil** (52.1 mg of boscalid + 13.1 mg of pyraclostrobin/kg dry weight of artificial soil).

The highest concentration at which the test item is observed to have no statistically significant effects on reproduction (**NOEC**) is equal to **100 mg/kg dry weight of artificial soil** (26.7 mg of boscalid + 6.7 mg of pyraclostrobin/kg dry weight of artificial soil).

The lowest concentration at which the test item is observed to have a statistically significant effect on reproduction (**LOEC**) is equal to **180 mg/kg dry weight of artificial soil** (48.1 mg of boscalid + 12.1 mg of pyraclostrobin/kg dry weight of artificial soil).

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

Comments of zRMS:	The study is considered acceptable. All validity criteria were met.														
	<table><tr><th>Parameter</th><th>Required</th><th>Observed</th></tr><tr><td>Mean mortality of adults</td><td>≤ 20 %</td><td>1.25 %</td></tr><tr><td>Mean number of juveniles per vessel</td><td>≥ 100</td><td>793.50</td></tr><tr><td>Coefficient of variation of reproductive output</td><td><30 %</td><td>9.14 %</td></tr></table>			Parameter	Required	Observed	Mean mortality of adults	≤ 20 %	1.25 %	Mean number of juveniles per vessel	≥ 100	793.50	Coefficient of variation of reproductive output	<30 %	9.14 %
	Parameter	Required	Observed												
	Mean mortality of adults	≤ 20 %	1.25 %												
	Mean number of juveniles per vessel	≥ 100	793.50												
Coefficient of variation of reproductive output	<30 %	9.14 %													
Agreed endpoints:															
<p>The NOEC and LOEC of the test item for adult mortality =555.56 mg test item/kg soil dry weight and as 1000.00 mg test item/kg soil dry weight; equivalent to 37.22 and 67.00 mg Pyraclostrobin/kg soil dry weight and equivalent to 148.33 and 267.00 mg Boscalid/kg soil dry weight, respectively.</p>															
<p>The NOEC and LOEC of test item regarding reproductive output of <i>Folsomia candida</i> =308.64 mg test item/kg soil dry weight and as 555.56 mg test item/kg soil dry weight; equivalent to 20.68 and 37.22 mg Pyraclostrobin/kg soil dry weight and equivalent to 82.41 and 148.33 mg Boscalid/kg soil dry weight, respectively.</p>															
<p>EC₁₀ =589.23 mg test item/kg soil dry weight, equivalent to 39.48 mg Pyraclostrobin and 157.32 mg Boscalid/kg soil dry weight, (ratio upper/lower 95 % confidence limits: 1.81)</p>															
<p>EC₂₀ = 897.89 mg test item/kg soil dry weight, equivalent to 60.16 mg Pyraclostrobin and 239.74 mg Boscalid/kg soil dry weight (ratio upper/lower 95 % confidence limits: 1.37)</p>															
<p>EC₅₀ > 1000 mg test item/kg soil dry weight, equivalent to > 67.00 mg Pyraclostrobin/kg soil dry weight and > 267.00 mg Boscalid/kg soil dry weight.</p>															

Reference:	KCP 10.4.2.1 - 01
Report	“Pyraclostrobin 6.7 % + Boscalid 26.7 % WG Effects on the Reproductive Output of the Springtail <i>Folsomia candida</i> Willem (Collembola, Isotomidae) in Artificial Soil.” Beatriz Antón, 2019, S18-07887. Trialcamp S.L.U.
Guideline(s):	OECD Guideline No. 232 (2016)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Pyraclostrobin 6.7 % + Boscalid 26.7 % WG'; Batch code: SCL-65489; expiry date: 10th January 2020; active ingredients (a.i.): Pyraclostrobin and Boscalid; content of a.i. analysed: 6.7 % w/w Pyraclostrobin; 26.7 % w/w Boscalid
Test species:	<i>Folsomia candida</i> from in-house culture, 10 to 11 days old female juveniles.
Soil:	Artificial soil with 5 % sphagnum peat content
Study design:	28-day exposure in treated artificial soil; the test item solutions were mixed homogeneously into the soil, deionised water was added for the control group and the treated soil was filled in glass vessels before the springtails were introduced on top of the soil. 8 test item groups with 4 replicates each; 1 control group with 8 replicates; 10 juvenile springtails per replicate.
Application rates:	Assessment of mortality and reproductive output after 28 days of exposure Control (deionised water), 16.33, 29.40, 52.92, 95.26, 171.47, 308.64, 555.56 and 1000.00 mg test item/kg soil dry weight
Test conditions:	Soil pH 5.95 to 6.22 at test initiation (target: 6.0 ± 0.5) and pH 6.20 to 6.43 at test termination; water content 18.61 % of soil dry weight (45% of WHC), temperature during exposure: 19.81 to 21.32 °C (target: 20 ± 2 °C); 16:08 light-dark cycles, 442 to 686 lux (target: 400 to 800 lux).
Statistical analysis:	Calculation of treatment means and standard deviations. Adult mortality (arcsine-transformed) and reproductive output data were tested for normality and homoscedasticity using Shapiro-Wilk test and Levene's test. The Williams Multiple Sequential t-test (sig. 95%, one-sided) was used for hypothesis testing of mortality and reproduction, since a monotone response was observed. The EC10 and EC20 values were calculated by Logit analysis using maximum likelihood regression. The EC50 was estimated according to the results.
Endpoints:	LOEC (Lowest Observed Effect Concentration for reproductive output and additionally mortality) and NOEC (No Observed Effect Concentration for reproductive output and additionally mortality); LC ₅₀ (Lethal Concentration for 50 % adults mortality); EC ₁₀ , EC ₂₀ and EC ₅₀ (Effect Concentration for 10, 20, 50 % effect on reproductive output), where possible

Findings

No pathological or behavioural abnormalities of the individuals were detected.

Compared to the control group, a statistically significant increase in mortality of *Folsomia candida* was detected at the test item concentration 1000.00 mg test item/kg soil dry weight, after 28 days of exposure.

Accordingly, the NOEC and LOEC for mortality were determined as 555.56 mg test item/kg soil dry weight and as 1000.00 mg test item/kg soil dry weight, respectively. The LC_{50} was estimated to be $LC_{50} > 1000.00$ mg test item/kg soil dry weight, according to the corrected mortalities.

A statistically significant reduction in the number of juveniles compared to the contro group was found at the test item concentrations 555.56 and 1000.00 mg test item/k soil dry weight. Accordingly, the NOEC and LOEC for reproduction were determine as 308.64 mg test item/kg soil dry weight and as 555.56 mg test item/kg soil dr weight, respectively.

EC_{10} EC_{20} and EC_{50} for reproductive output were determined as 589.23, 897.89 and > 1000 mg test item/kg soil dry weight, respectively.

Results of mortality and reproductive output of *Folsomia candida* summarised:

Treatment group	Test item concentration	Mean mortality ^a	Corrected mortality ^b	Mean number of juveniles per replicate ^c	Reproductive output CV	Reduction relative to control ^d	Offspring output (relative to control)
	[mg/kg sdw]	[%]	[%]		[%]	[%]	[%]
Control	0	1.25	--	793.50	9.14	--	100.00
T1	16.33	2.50	1.27	832.25	3.27	-4.88	104.88
T2	29.40	2.50	1.27	805.00	7.22	-1.45	101.45
T3	52.92	0.00	-1.27	846.00	4.79	-6.62	106.62
T4	95.26	2.50	1.27	768.00	11.07	3.21	96.79
T5	171.47	0.00	-1.27	847.25	5.14	-6.77	106.77
T6	308.64	2.50	1.27	820.25	7.87	-3.37	103.37
T7	555.56	2.50	1.27	716.50 ^c	9.91	9.70	90.30
T8	1000.00	12.50 ^a	11.39	608.00 ^c	10.29	23.38	76.62

Endpoints	[mg test item/kg sdw]	[mg a.i./kg sdw] ^e		Ratio 95% CL ^f
		Pyraclostrobin	Boscalid	
LOEC _{mortality}	1000.00	67.00	267.00	--
NOEC _{mortality}	555.56	37.22	148.33	--
LC ₅₀	LC ₅₀ > 1000.00	> 67.00	> 267.00	--
LOEC _{reproductive output}	555.56	37.22	148.33	--
NOEC _{reproductive output}	308.64	20.68	82.41	--
EC ₁₀ (upper / lower CL)	589.23 (702.39 / 387.11)	39.48 (47.06 / 25.94)	157.32 (187.54 / 103.36)	1.81
EC ₂₀ (upper / lower CL)	897.89 (1060.07 / 771.20)	60.16 (71.02 / 51.67)	239.74 (283.04 / 205.91)	1.37
EC ₅₀	> 1000.00	> 67.00	> 267.00	--

sdw: soil dry weight; CV: coefficient of variation; a.i.: active ingredient

^a statistically significantly different compared to the control group (Williams t-test, sig. 95%, one-sided)

^b corrected mortality according to the Abbott's formula. Negative value indicates lower adult mortality compared to the control

^c statistically significantly different compared to the control group (Williams t-test, sig. 95%, one-sided)

^d negative value indicates higher offspring output compared to the control

^e active ingredients concentrations are indicated according to the analytical content from the certificate of analysis and rounded to 2 decimals: Pyraclostrobin: 6.7 % w/w; Boscalid: 26.7 % w/w.

^f ratio upper/lower 95 % confidence limits

Reference

The toxic reference item Boric Acid was tested in a separate study (S18-06179) done in September-October 2018. The EC50 for reproductive output was determined as 80.98 mg test substance/kg soil dry

weight. This is within the target of about 100 mg/kg soil dry weight given by the OECD guideline 232 (2016) and also within the expected range according to historical facility data.

Conclusions

In the control group, 1.25 % mortality (< 20 %) and an acceptable reproductive capacity with a mean of 793.50 juveniles per replicate (> 100 juveniles per vessel) were observed at the end of the test. Furthermore, the coefficient of variation for the number of juveniles was 9.14 %, less than 30 %. So, the validity criteria were fulfilled and the study is considered valid.

Concentrations of the test item “Pyraclostrobin 6.7 % + Boscalid 26.7 % WG”, resulted in corrected mortality of less than 10 % at concentrations up to and including 555.56 mg test item/kg soil dry weight. The LC50 (concentration that would cause 50 % of adult mortality) was estimated as > 1000.00 mg test item/kg soil dry weight, according to the obtained results.

The NOEC and LOEC of the test item for adult mortality were determined as 555.56 mg test item/kg soil dry weight and as 1000.00 mg test item/kg soil dry weight; equivalent to 37.22 and 67.00 mg Pyraclostrobin/kg soil dry weight and equivalent to 148.33 and 267.00 mg Boscalid/kg soil dry weight, respectively.

The NOEC and LOEC of test item regarding reproductive output of *Folsomia candida* were determined as 308.64 mg test item/kg soil dry weight and as 555.56 mg test item/kg soil dry weight; equivalent to 20.68 and 37.22 mg Pyraclostrobin/kg soil dry weight and equivalent to 82.41 and 148.33 mg Boscalid/kg soil dry weight, respectively.

EC₁₀ was calculated in 589.23 mg test item/kg soil dry weight, equivalent to 39.48 mg Pyraclostrobin and 157.32 mg Boscalid/kg soil dry weight, (ratio upper/lower 95 % confidence limits: 1.81)

EC₂₀ was calculated in 897.89 mg test item/kg soil dry weight, equivalent to 60.16 mg Pyraclostrobin and 239.74 mg Boscalid/kg soil dry weight (ratio upper/lower 95 % confidence limits: 1.37)

EC₅₀ was estimated as > 1000 mg test item/kg soil dry weight, equivalent to > 67.00 mg Pyraclostrobin/kg soil dry weight and > 267.00 mg Boscalid/kg soil dry weight.

Comments of zRMS:														
The study is considered acceptable. All validity criteria were met.														
	<table> <tr> <th>Parameter</th><th>Required</th><th>Observed</th></tr> <tr> <td>Mean mortality of adult females</td><td>≤ 20 %</td><td>8.75 %</td></tr> <tr> <td>Mean number of juveniles per replicate</td><td>≥ 50</td><td>119.13</td></tr> <tr> <td>Coefficient of variation of reproductive output</td><td>≤ 30 %</td><td>19.41 %</td></tr> </table>	Parameter	Required	Observed	Mean mortality of adult females	≤ 20 %	8.75 %	Mean number of juveniles per replicate	≥ 50	119.13	Coefficient of variation of reproductive output	≤ 30 %	19.41 %	
Parameter	Required	Observed												
Mean mortality of adult females	≤ 20 %	8.75 %												
Mean number of juveniles per replicate	≥ 50	119.13												
Coefficient of variation of reproductive output	≤ 30 %	19.41 %												
Agreed endpoints: LOEC for mortality could not be determined and was estimated to be greater than 600.00 mg test item/kg soil dry weight; equivalent to 40.20 mg Pyraclostrobin/kg soil dry weight and 160.20 mg Boscalid/kg soil dry weight according to the analysed content. The NOEC for mortality =600.00 mg test item/kg soil dry weight; equivalent to 40.20 mg Pyraclostrobin/kg soil dry weight and 160.20 mg Boscalid/kg soil dry weight according to the analysed content. LOEC for reproductive output could not be determined and was estimated to														

	<p>be greater than 600.00 mg test item/kg soil dry weight; equivalent to 40.20 mg Pyraclostrobin/kg soil dry weight and 160.20 mg Boscalid/kg soil dry weight according to the analysed content.</p> <p>The NOEC for reproductive = 600.00 mg test item/kg soil dry weight; equivalent to 40.20 mg Pyraclostrobin/kg soil dry weight and 160.20 mg Boscalid/kg soil dry weight according to the analysed content.</p> <p>Since no statistically significant concentration/response was found, the EC10, EC20 and EC50 for reproductive output could not be calculated.</p> <p>The EC10, EC20 and EC50 for reproductive > 600.00 mg test item/kg soil dry weight; equivalent to 40.20 mg Pyraclostrobin/kg soil dry weight and 160.20 mg Boscalid/kg soil dry weight according to the analysed content.</p>
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Reference:	KCP 10.4.2.1-02
Report	“Pyraclostrobin 6.7% + Boscalid 26.7% WG: Effects on the Reproductive Output of the Predatory Soil Mite <i>Hypoaspis (Geolaelaps) aculeifer</i> Canestrini (Acari: Laelapidae) in Artificial Soil.” Josep Lozano, 2019, S18-06116. Trialcamp S.L.U.
Guideline(s):	OECD Guideline for the Testing of Chemicals No. 226 (2016)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Pyraclostrobin 6.7% + Boscalid 26.7% WG; Batch code: SCL-65489; a.i.1: Pyraclostrobin, content: 6.7 % (w/w) and a.i.2: Boscalid, content: 26.7 % (w/w) (content of active ingredients according to the certificate of analysis); expiry date: 10 Jan 2020
Test species:	<i>Hypoaspis aculeifer</i> Canestrini (Acari, Laelapidae), from in-house culture, adult mites (32 days after the start of the egg-laying for synchronisation).
Soil:	Artificial soil with 5 % sphagnum peat content
Study design:	Adult females were exposed to the test item in artificial soil. After 14 days, the surviving individuals were extracted from the test units. The number of juveniles per test unit and, additionally, the number of surviving adult females were determined. The reproductive output and the mortality in each test item group were compared to that of the control group. A concentration-response test with 8 different test item concentrations and 4 replicates each as well as a water control (without test item) with eight replicates; 10 adult females were exposed per replicate.
Application rates:	0 (control), 9.80, 17.64, 31.75, 57.16, 102.88, 185.19, 333.33 and 600.00 mg test item/kg soil dry weight. Equivalent to: 0.66, 1.18, 2.13, 3.83, 6.89, 12.41, 22.33 and 40.20 mg Pyraclostrobin/kg soil dry weight and 2.62, 4.71, 8.48, 15.26, 27.47, 49.44, 89.00 and 160.20 mg Boscalid/kg soil dry weight
Test conditions:	Soil pH 6.11 to 6.21 at test initiation and pH 6.03 to 6.20 at test termination;

	water content at test initiation 20.25 % to 21.05 % (corresponding to 48.97 – 50.90 % of the WHCmax), 19.76 – 20.04 % (corresponding to 47.78 – 48.44 % of the WHCmax) at test termination; temperature during exposure: 19.7 °C to 20.3 °C; 16:8 light:dark cycles (long day conditions), and light intensity 563 lux to 757 lux.
Statistical analysis:	Calculation of treatment means and standard deviations. Level of significance $\alpha = 0.05$ for the statistical final comparison tests. After performing a qualitative trend analysis by contrasts using proportions (monotonicity of concentration/response), the mortality data was analysed using the Chi ² 2×2 table test with Bonferroni correction (one-sided greater, $\alpha = 0.05$). The reproductive output was pre-tested with Shapiro-Wilk's test for normality of data distribution and with Levene's test for homoscedasticity. After performing a trend analysis by contrasts (monotonicity of concentration/response), the reproductive output was analysed using Dunnett's multiple t-test procedure (one-sided smaller, $\alpha = 0.05$). The EC ₁₀ , 20, 50 for reproductive output could not be calculated. Statistical calculations were performed with ToxRat Professional 3.2.1 and Microsoft Office Excel-2010® v.14.0.
Endpoints:	LOEC (lowest observed effect concentration) and NOEC (no observed effect concentration) for mortality and reproductive output; EC ₁₀ , 20, 50 effect concentration of 10, 20, 50 %) for reproductive output, where possible

Findings

No statistically significant increase in mortality of *Hypoaspis aculeifer* was detected at any of the test item concentrations as compared to the control group after 14 days of exposure. Accordingly the LOEC for mortality could not be determined and was estimated to be greater than 600.00 mg test item/kg soil dry weight. The NOEC for mortality was determined as 600.00 mg test item/kg soil dry weight.

No behavioural abnormalities or any pathological symptoms of the test organisms could be observed in the control group and in any of the test item groups.

No statistically significant reduction in the number of juveniles was detected at any of the test item concentrations as compared to the control group after 14 days of exposure. Accordingly, the LOEC for reproductive output could not be determined and was estimated to be greater than 600.00 mg test item/kg soil dry soil. The NOEC for reproductive output was determined as 600.00 mg test item/kg soil dry weight.

Since no statistically significant concentration/response was found, the EC₁₀, EC₂₀ and EC₅₀ for reproductive output could not be calculated. The EC₁₀, EC₂₀ and EC₅₀ for reproductive output are assumed as > 600.00 mg test item/kg soil dry weight. The toxic reference item BAS 152 11 I (a.i. dimethoate) was tested in a separate study (S18-06178, issued: 24 Dec 2018). The EC₅₀ for reproductive output was determined to be 3.46 mg a.i./kg soil dry weight (95 %-confidence interval: 3.03 –3.95 mg a.i./kg soil dry weight). This is within the target range of 3.0 to 7.0 m a.i./kg soil dry weight given by the OECD guideline 226 (2016) and, hence acceptable sensitivity of the test system was assured.

Mortality and reproductive output of *Hypoaspis aculeifer* after 14 days exposure to artificial soil treated with Pyraclostrobin 6.7% + Boscalid 26.7% WG:

Treatment group	Test item concentration [mg TI/kg sdw]	Mean mortality [%]	Mean number of juveniles per replicate	Coefficient of variation [%]	Reduction in reproductive output [%] ^a
Control group	0	8.75	119.13	19.41	-
Pyraclostrobin 6.7% + Boscalid 26.7% WG	9.80	5.00	108.50	20.14	8.92
	17.64	15.00	134.00	30.88	-12.49
	31.75	5.00	119.50	29.50	-0.31
	57.16	2.50	131.50	16.45	-10.39
	102.88	10.00	114.00	24.78	4.30
	185.19	5.00	122.50	40.35	-2.83
	333.33	15.00	119.25	35.10	-0.10
	600.00	12.50	113.00	15.99	5.14
Endpoints			[mg TI/kg sdw]	[mg a.i.1/kg sdw]	[mg a.i.2/kg sdw]
NOEC _{mortality}			600.00	40.20	160.20
LOEC _{mortality}			>600.00	>40.20	>160.20
NOEC _{reproductive output}			600.00	40.20	160.20
LOEC _{reproductive output}			>600.00	>40.20	>160.20
EC _{10, 20 and 50}			>600.00	>40.20	>160.20

TI: test item; sdw: soil dry weight and a.i.: active ingredient (a.i.1: Pyraclostrobin and a.i.2: Boscalid)
a negative values indicate higher reproduction compared to control group.

Conclusions

All validity criteria were met and the sensitivity of the test organisms was confirmed. Accordingly, the study was deemed valid.

Survival and reproduction output of *Hypoaspis aculeifer* were not negatively affected by any of the assayed test item concentration after 14 days of exposure.

Under the conditions of this study, the LOEC for mortality could not be determined and was estimated to be greater than 600.00 mg test item/kg soil dry weight; equivalent to 40.20 mg Pyraclostrobin/kg soil dry weight and 160.20 mg Boscalid/kg soil dry weight according to the analysed content. The NOEC for mortality was determined as 600.00 mg test item/kg soil dry weight; equivalent to 40.20 mg Pyraclostrobin/kg soil dry weight and 160.20 mg Boscalid/kg soil dry weight according to the analysed content.

Under the conditions of this study, the LOEC for reproductive output could not be determined and was estimated to be greater than 600.00 mg test item/kg soil dry weight; equivalent to 40.20 mg Pyraclostrobin/kg soil dry weight and 160.20 mg Boscalid/kg soil dry weight according to the analysed content. The NOEC for reproductive output was determined as 600.00 mg test item/kg soil dry weight; equivalent to 40.20 mg Pyraclostrobin/kg soil dry weight and 160.20 mg Boscalid/kg soil dry weight according to the analysed content.

Since no statistically significant concentration/response was found, the EC₁₀, EC₂₀ and EC₅₀ for reproductive output could not be calculated. The EC₁₀, EC₂₀ and EC₅₀ for reproductive output are assumed as > 600.00 mg test item/kg soil dry weight; equivalent to 40.20 mg Pyraclostrobin/kg soil dry weight and 160.20 mg Boscalid/kg soil dry weight according to the analysed content.

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

A 2.5 KCP 10.5.1 Effects on soil nitrogen transformation

Comments of zRMS:	<p>The study is considered acceptable. All validity criteria were met.</p> <ul style="list-style-type: none"> The coefficients of variation (CV) in the control group were 14.3, 5.4, 4.3 and 6.0%, after 0, 7, 14, and 28 days of incubation. The validity criterion was met, because the variation between replicate control samples is less than $\pm 15\%$ <p>Agreed endpoints: On the basis of the results, it was concluded that at the concentration corresponding to the PEC: 6 mg test item/kg soil (1.6 mg boscalid/ kg soil + 0.4 mg pyraclostrobin/kg soil) and 5 x PEC: 30 mg the test item/kg soil (8.0 mg boscalid/ kg soil + 2.0 mg pyraclostrobin/ kg soil), Boscalid 26.7% + Pyraclostrobin 6.7% WG did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.</p>
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Reference:	KCP 10.5.1
Report	“Boscalid 26.7% + Pyraclostrobin 6.7% WG. Soil Microorganisms: Nitrogen Transformation Test” Weronika Dec, 2018, G/202/17. Institute of Industrial Organic Chemistry Branch Pszczyna.
Guideline(s):	OECD Guideline No. 216 (2000) / EU Method C.21.
Deviations:	<p>Yes.</p> <p>1. According the Guideline, the soil extraction should be conducted at 150 rpm for 60 min. However, in this study, the extraction was performed at 90 rpm for 24 hours. The modification resulted from the optimization of the nitrate extraction which showed that the extraction was more effective when the shaking rate was lower and the extraction lasted longer.</p> <p>2. the upper tested concentration should not exceed ten times the maximum single application rate. In this study, the second concentration (5 x PEC) is the single application rate multiplied by fifteen.</p> <p>The deviations did not affect the results of the study.</p>
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods

Test item:	
Description:	Boscalid 26.7% + Pyraclostrobin 6.7% WG
Production batch:	SCL- 65489
Active ingredients content:	boscalid – 26.7% (w/w) pyraclostrobin – 6.7% (w/w)

Vehicle and control:	Distilled water
Test system:	
Species:	Microorganisms
Source:	Agricultural soil collected from a place belonging to the Institute of Industrial Organic Chemistry, Branch Pszczyna.
Experimental conditions:	
Temperature:	19.5 – 22°C
Humidity:	52.2% – 57.8% MWHC incubation in darkness.

Study design and methods

Test design and treatment:	Three portions of soil (3 x 1500 g), i.e. one control group and two treated groups. Every portion was divided into three replicates (3 x 500g). The soil was enriched with the organic substrate, i.e. lucerne at dose of 5 g/kg dry weight of soil. Test duration: 28 days. Concentrations of the test item: control, PEC: 6 mg test item/kg soil (1.6 mg boscalid/ kg soil + 0.4 mg pyraclostrobin/kg soil), 5 x PEC: 30 mg the test item/kg soil (8.0 mg boscalid/ kg soil + 2.0 mg pyraclostrobin/ kg soil).
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Results

The difference in the nitrates formation rate between the control soil and the one treated with the test item at the concentration corresponding to the PEC: 6 mg test item/kg soil (1.6 mg boscalid/ kg soil + 0.4 mg pyraclostrobin/kg soil) and 5 x PEC: 30 mg the test item/kg soil (8.0 mg boscalid/ kg soil + 2.0 mg pyraclostrobin/ kg soil) did not exceed 25% on 28 day of analysis.

Deviations from the control based on nitrates formation rate for selected time interval [%]:

Time interval [d]	PEC 6 mg of the test item/kg of soil (1.6 mg boscalid + 0.4 mg pyraclostrobin/kg soil)	5 x PEC 30 mg of the test item/kg of soil (8.0 mg boscalid + 2.0 mg pyraclostrobin/kg soil)
0 - 7	0.3	1.7
0 - 14	0.3	0.9
0 - 28	1.2	4.9

Validity

The coefficients of variation (CV) in the control group were 14.3, 5.4, 4.3 and 6.0%, after 0, 7, 14, and 28 days of incubation. The validity criterion was met, because the variation between replicate control samples is less than $\pm 15\%$

Conclusion

On the basis of the results, it was concluded that at the concentration corresponding to the PEC: 6 mg test item/kg soil (1.6 mg boscalid/ kg soil + 0.4 mg pyraclostrobin/kg soil) and 5 x PEC: 30 mg the test item/kg soil (8.0 mg boscalid/ kg soil + 2.0 mg pyraclostrobin/ kg soil), Boscalid 26.7% + Pyraclostrobin 6.7% WG did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

A 2.6

KCP 10.5.2 Effects on soil carbon transformation

Comments of zRMS:	<p>The study is considered acceptable. All validity criteria were met.</p> <p>Agreed endpoints: On the basis of the results, it was concluded that Boscalid 26.7% + Pyraclostrobin 6.7% WG at the concentrations corresponding to the PEC: 6 mg test item/kg soil (1.6 mg boscalid/ kg soil + 0.4 mg pyraclostrobin/kg soil) and 5 x PEC: 30 mg the test item/kg soil (8.0 mg boscalid/ kg soil + 2.0 mg pyraclostrobin/ kg soil), did not have any long-term adverse effects on the process of carbon transformation in aerobic surface soils.</p>
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Reference:	KCP 10.5.2
Report	“Boscalid 26.7% + Pyraclostrobin 6.7% WG. Soil Microorganisms: Carbon Transformation Test. Weronika Dec, 2018, G/201/17. Institute of Industrial Organic Chemistry Branch Pszczyna.
Guideline(s):	OECD Guideline No. 217 (2000) / EU Method C.22
Deviations:	According to OECD Guideline No. 217 and EU Method C.22., the upper tested concentration should not exceed ten times the maximum single application rate. In this study, the second concentration (5 x PEC) is the single application rate multiplied by fifteen.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	-

Materials and methods

Materials

Test item:

Description:	Boscalid 26.7% + Pyraclostrobin 6.7% WG
Production batch:	SCL- 65489
Active ingredients content:	boscalid – 26.7% (w/w) pyraclostrobin – 6.7% (w/w)

Test system:

Species:	Microorganisms
Source:	Agricultural soil taken from the area belonging to the Institute of Industrial Organic Chemistry, Branch Pszczyna.

Experimental conditions:

Temperature:	19.5 – 22°C
Humidity:	51.9 – 57.5% of MWHC
Air changes:	-
Light and photoperiod:	Dark (24/24h)

Study design and methods

Test design and treatment:	3 portions of soil: one control group and two groups containing the test item weighing 1500 g each. Every portion was divided into three replicates weighing 500 g each. Test duration: 28 days. Concentrations of the test material: Control; PEC: 6 mg test item/kg soil (1.6 mg boscalid/ kg soil + 0.4 mg pyraclostrobin/kg soil), 5 x PEC: 30 mg the test item/kg soil (8.0 mg boscalid/ kg soil + 2.0 mg pyraclostrobin/ kg soil).
Statistics:	In order to determine significance of differences between the control and the treated groups, the Shapiro-Wilk's Test on Normal Distribution, the Levene's Test on Variance Homogeneity and Williams Multiple Sequential t-test Procedure were used.

Results

The difference in the soil respiration rate between the control soil and the one treated with the test item at the concentrations corresponding to the PEC: 6 mg test item/kg soil (1.6 mg boscalid/ kg soil + 0.4 mg pyraclostrobin/kg soil) and 5 x PEC: 30 mg the test item/kg soil (8.0 mg boscalid/ kg soil + 2.0 mg pyraclostrobin/ kg soil) did not exceed 25% on any day of analysis.

Oxygen (O₂) consumption - deviations from the control [%]:

Day	PEC 6 mg of the test item/kg soil (1.6 mg boscalid + 0.4 mg pyraclostrobin/kg soil)	5 x PEC 30 mg of the test item/kg soil (8.0 mg boscalid + 2.0 mg pyraclostrobin/kg soil)
0	1.1	9.7
7	-6.8	-8.2
14	-3.9	-6.2
28	-1.4	8.4

“-“ the value of the oxygen consumption higher than the one obtained for the control group

Conclusion

On the basis of the results, it was concluded that Boscalid 26.7% + Pyraclostrobin 6.7% WG at the concentrations corresponding to the PEC: 6 mg test item/kg soil (1.6 mg boscalid/ kg soil + 0.4 mg pyraclostrobin/kg soil) and 5 x PEC: 30 mg the test item/kg soil (8.0 mg boscalid/ kg soil + 2.0 mg pyraclostrobin/ kg soil), did not have any long-term adverse effects on the process of carbon transformation in aerobic surface soils.

A 2.7 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.8 KCP 10.6.1 Summary of screening data

A 2.8.1 KCP 10.6.2 Testing on non-target plants

Comments of zRMS:	The study is considered acceptable. All validity criteria were met.
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<p>- the seedling emergence in the control (validity criterion: at least 70%) was as follows:</p> <p>85.7% - sunflower, 81.0% - cabbage, 90.5% - pea, 90.0% – carrot, 75.0% – onion, 100.0% – oats,</p> <p>- the mean survival of the emerged control seedlings was 100% for all tested species (validity criterion: at least 90%);</p> <p>- the control seedlings did not exhibit any visible phytotoxic effects;.</p> <p>- environmental conditions for all plants of the same species were identical.</p>						
Agreed endpoints:						
	Sunflower <i>Helianthus annuus</i>	Cabbage <i>Brassica oleracea var. capitata</i>	Pea <i>Pisum sativum</i>	Carrot <i>Daucus carota</i>	Onion <i>Allium cepa</i>	Oats <i>Avena sativa</i>
Plant number at the end of the experiment						
ER₅₀	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
NOER	≥ 4500	≥ 4500	≥ 4500	≥ 4500	≥ 4500	≥ 4500
Shoot length (plants without roots)						
ER₅₀	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
NOER	≥ 4500	≥ 4500	≥ 4500	≥ 4500	≥ 4500	≥ 4500
Plant dry weight (plants without roots)						
ER₅₀	n.d.	n.d.	n.d.	n.d.	n.d.	> 4500
NOER	≥ 4500	≥ 4500	≥ 4500	≥ 4500	≥ 4500	1800
<p>* value determined out of the range of the tested application rates</p> <p>n.d. – not determined</p>						

Reference: KCP 10.6.2-01

Report “Boscalid 26.7% + Pyraclostrobin 6.7% WG. Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test”. Weronika Dec. 2018. Study code: G/206/17. Institute of Industrial Organic Chemistry Branch Pszczyna

Guideline(s): OECD Guideline No. 208 (2006)

Deviations: Yes. According to OECD Guideline No. 208 (2006), the light intensity should be $350 \pm 50 \mu\text{E}/\text{m}^2/\text{s}$. 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 $55.0 - 105.4 \mu\text{E}/\text{m}^2/\text{s}$. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing.

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Materials and methods

Test item:	Boscalid 26.7% + Pyraclostrobin 6.7% WG; batch no: SCL- 65489; active substances: boscalid – 26.7% (w/w) pyraclostrobin – 6.7% (w/w)
Test species:	Carrot (<i>Daucus carota</i>), sunflower (<i>Helianthus annuus</i>), abbage (<i>Brassica oleracea</i> var. <i>capitata</i>), Pea (<i>Pisum sativum</i>), onion (<i>Allium cepa</i>), and oats (<i>Avena sativa</i>)
Soil:	sandy loam
Study design:	number of rates: five application rates + control; number of replicates: 4 or 7 replicates/rate. The total number of plants per application rate – 20 or 21. test termination: 14 days after the emergence of 50% of the control seedlings.
Application rates:	a control, 115.2, 288, 720, 1800, and 4500 g test item/ha in cultivation of all tested species
Test conditions:	volume of deionised water used to prepare the highest rate: 300 L water/ha Temperature: 17.0 – 32.0°C; humidity: 45.0 – 94.6%; lighting: 16 hours light and 8 hours dark; light intensity: 55.0 – 105.4 $\mu\text{E}/\text{m}^2/\text{s}$; carbon dioxide concentration: 340 – 355 ppm.
Statistical analysis:	ER ₁₀ , ER ₂₅ , ER ₅₀ – probit analyses NOER – the Shapiro-Wilk's Test on Normal Distribution, the Levene's Test on Variance Homogeneity (with Residuals), the Williams Multiple Sequential t-test Procedure, or the Welch-t test for Inhomogeneous Variances with Bonferroni-Holm Adjustment
Endpoints:	ER ₁₀ , ER ₂₅ , ER ₅₀ , and NOER.

Results and Conclusions

The ER₅₀ and NOER values determined on the basis plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as g of test item/ha for all test species are given below.

	Sunflower <i>Helianthus annuus</i>	Cabbage <i>Brassica oleracea</i> var. <i>capitata</i>	Pea <i>Pisum sativum</i>	Carrot <i>Daucus carota</i>	Onion <i>Allium cepa</i>	Oats <i>Avena sativa</i>
Plant number at the end of the experiment						
ER ₅₀	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
NOER	≥ 4500	≥ 4500	≥ 4500	≥ 4500	≥ 4500	≥ 4500
Shoot length (plants without roots)						
ER ₅₀	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
NOER	≥ 4500	≥ 4500	≥ 4500	≥ 4500	≥ 4500	≥ 4500
Plant dry weight (plants without roots)						
ER ₅₀	n.d.	n.d.	n.d.	n.d.	n.d.	> 4500
NOER	≥ 4500	≥ 4500	≥ 4500	≥ 4500	≥ 4500	1800

* value determined out of the range of the tested application rates
n.d. – not determined

The ER₅₀ and NOER values determined on the basis plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as g of boscalid + pyraclostrobin/ha for all test species are given below.

	Sunflower <i>Helianthus annuus</i>	Cabbage <i>Brassica oleracea</i> <i>var. capitata</i>	Pea <i>Pisum sativum</i>	Carrot <i>Daucus carota</i>	Onion <i>Allium cepa</i>	Oats <i>Avena sativa</i>
Plant number at the end of the experiment						
ER₅₀	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
NOER	≥ 1201.5 + 301.5	≥ 1201.5 + 301.5	≥ 1201.5 + 301.5	≥ 1201.5 + 301.5	≥ 1201.5 + 301.5	≥ 1201.5 + 301.5
Shoot length (plants without roots)						
ER₅₀	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
NOER	≥ 1201.5 + 301.5	≥ 1201.5 + 301.5	≥ 1201.5 + 301.5	≥ 1201.5 + 301.5	≥ 1201.5 + 301.5	≥ 1201.5 + 301.5
Plant dry weight (plants without roots)						
ER₅₀	n.d.	n.d.	n.d.	n.d.	n.d.	> 1201.5 + 301.5
NOER	≥ 1201.5 + 301.5	≥ 1201.5 + 301.5	≥ 1201.5 + 301.5	≥ 1201.5 + 301.5	≥ 1201.5 + 301.5	480.6 + 120.6

* value determined out of the range of the tested application rates
n.d. – not determined

The test item, i.e. Boscalid 26.7% + Pyraclostrobin 6.7% WG applied at rates ranging from 115.2 to 4500 g/ha had no impact on the growth and seedling emergence of sunflower, pea, and carrot. The test item slightly impacted the growth of cabbage, onion, and oats.

Plants of all analyzed species emerged at all of analyzed concentrations. After the application of the test item at the rates ranging from 115.2 to 4500 g/ha, the emergence of all tested plants was not delayed in comparison to the control groups.

There was no mortality observed for all tested species.

On the basis of NOER, ER₁₀, ER₂₅ and ER₅₀ values determined from the plant number and the shoot length at the end of the experiment, it was observed that the test item did not inhibit the process of growth of all tested plants.

On the basis of NOER, ER₁₀, ER₂₅ and ER₅₀ values determined from the shoot dry weight, it was proved that the test item slightly inhibited the process of growth of cabbage, onion, and oats.

No phytotoxic symptoms for sunflower, cabbage, pea, carrot, and onion were observed after 7 and 14 days of the exposure, whereas, for oats one phytotoxic symptom, i.e. wilting was observed after 14 days of the exposure.

The following order of the test plant sensitivity was noticed:
oats > onion > cabbage > sunflower, pea, carrot.

Comments of zRMS:	The study is considered acceptable. All validity criteria were met.						
	- the seedling emergence (validity criterion: at least 70%) was as follows:						
	83.3 – 92.9 – sunflower,						
	83.3 – 95.2 – cabbage,						
	85.7 – 97.6 – pea,						
	82.5 – 90.0 – carrot,						
	80.0 – 87.5 – onion,						
	87.5 – 95.0 – oats,						
	- the mean survival of the emerged control seedlings was 100% (validity criterion: at least 90%),						
	- the control seedlings did not exhibit any visible phytotoxic symptoms,						
- environmental conditions for all plants belonging to the same species were identical.							
Agreed endpoints:							
	Sunflower <i>Helianthus annuus</i>	Cabbage <i>Brassica oleracea</i> var. <i>capitata</i>	Pea <i>Pisum sativum</i>	Carrot <i>Daucus carota</i>	Onion <i>Allium cepa</i>	Oats <i>Avena sativa</i>	
Plant number at the end of the experiment							
ER ₅₀	> 4500	> 4500	> 4500	> 4500	> 4500	> 4500	
NOER	> 4500	> 4500	> 4500	> 4500	> 4500	> 4500	
Shoot length (plants without roots)							
ER ₅₀	> 4500	> 4500	> 4500	> 4500	> 4500	> 4500	
NOER	≥ 4500	≥ 4500	≥ 4500	1800	720	≥ 4500	
Plant dry weight (plants without roots)							
ER ₅₀	> 4500	> 4500	> 4500	4042.3*	> 4500	> 4500	
NOER	≥ 4500	≥ 4500	≥ 4500	1800	≥ 4500	≥ 4500	
* value determined out of the range of the tested application rates							

Reference: KCP 10.6.2-02

Report “Boscalid 26.7% + Pyraclostrobin 6.7% WG Terrestrial Plant Test: Vegetative Vigour Test”. Weronika Dec. 2018. Study code: G/207/17. Institute of Industrial Organic Chemistry Branch Pszczyna

Guideline(s): OECD Guideline No. 227 (2006)

Deviations: Yes. According to OECD Guideline No. 227 (2006), the light intensity should be $350 \pm 50 \mu\text{E}/\text{m}^2/\text{s}$. 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 $61.7 - 138.4 \mu\text{E}/\text{m}^2/\text{s}$.
Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing.

GLP: Yes

Acceptability: Yes

Duplication No

(if vertebrate study)

Materials and methods

Test item:	Boscalid 26.7% + Pyraclostrobin 6.7% WG; Batch Number SCL- 65489; active substance: boscalid – 26.7% (w/w) pyraclostrobin – 6.7% (w/w)
Test species:	Pea (<i>Pisum sativum</i>), sunflower (<i>Helianthus annuus</i>), cabbage (<i>Brassica oleracea</i> var. <i>capitata</i>), carrot (<i>Daucus carota</i>), onion (<i>Allium cepa</i>) and oats (<i>Avena sativa</i>)
Soil:	Sandy loam
Study design:	Number of rates: 5 application rates + control; number of replicates: 4 or replicates/rate; The total number of plants per application rate – 20 or 21; exposure duration: 21 days after the spraying
Application rates:	a control, 115.2, 288, 720, 1800, and 4500 g test item/ha in cultivation of all tested species. volume of distilled water used to prepare the highest rate: 300 L water/ha
Test conditions:	Temperature: 17.0 – 32.0°C; humidity: 45.0 – 94.6 %; lighting: 16 hours light: 8 hours dark; light intensity: 61.7 – 138.4 µE/m ² /s; carbon dioxide concentration: 340 – 360 ppm.
Statistical analysis:	ER ₁₀ , ER ₂₅ , ER ₅₀ – probit analyses NOER – Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure or Dunnett's Multiple t-test Procedure.
Endpoints:	ER ₁₀ , ER ₂₅ , ER ₅₀ , NOER

Results and Conclusions

The ER₅₀ and NOER values determined on the basis plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as g of test item / ha for all test species are given below.

	Sunflower <i>Helianthus annuus</i>	Cabbage <i>Brassica oleracea</i> var. <i>capitata</i>	Pea <i>Pisum sativum</i>	Carrot <i>Daucus carota</i>	Onion <i>Allium cepa</i>	Oats <i>Avena sativa</i>
Plant number at the end of the experiment						
ER ₅₀	> 4500	> 4500	> 4500	> 4500	> 4500	> 4500
NOER	> 4500	> 4500	> 4500	> 4500	> 4500	> 4500
Shoot length (plants without roots)						
ER ₅₀	> 4500	> 4500	> 4500	> 4500	> 4500	> 4500
NOER	≥ 4500	≥ 4500	≥ 4500	1800	720	≥ 4500
Plant dry weight (plants without roots)						
ER ₅₀	> 4500	> 4500	> 4500	4942.3*	> 4500	> 4500
NOER	≥ 4500	≥ 4500	≥ 4500	1800	≥ 4500	≥ 4500

* value determined out of the range of the tested application rates

The ER₅₀ and NOER values determined on the basis plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as g of boscalid + pyraclostrobin/ ha for all test species are given below.

	Sunflower <i>Helianthus annuus</i>	Cabbage <i>Brassica oleracea</i> var. <i>capitata</i>	Pea <i>Pisum sativum</i>	Carrot <i>Daucus carota</i>	Onion <i>Allium cepa</i>	Oats <i>Avena sativa</i>
Plant number at the end of the experiment						
ER ₅₀	> 1201.5 + 301.5	> 1201.5 + 301.5	> 1201.5 + 301.5	> 1201.5 + 301.5	> 1201.5 + 301.5	> 1201.5 + 301.5
NOER	> 1201.5 + 301.5	> 1201.5 + 301.5	> 1201.5 + 301.5	> 1201.5 + 301.5	> 1201.5 + 301.5	> 1201.5 + 301.5
Shoot length (plants without roots)						
ER ₅₀	> 1201.5 + 301.5	> 1201.5 + 301.5	> 1201.5 + 301.5	> 1201.5 + 301.5	> 1201.5 + 301.5	> 1201.5 + 301.5
NOER	≈ 1201.5 + 301.5	≈ 1201.5 + 301.5	≈ 1201.5 + 301.5	480.6 + 120.6	192.2 + 48.2	≈ 1201.5 + 301.5
Plant dry weight (plants without roots)						
ER ₅₀	> 1201.5 + 301.5	> 1201.5 + 301.5	> 1201.5 + 301.5	1319.6 + 331.1*	> 1201.5 + 301.5	> 1201.5 + 301.5
NOER	≈ 1201.5 + 301.5	≈ 1201.5 + 301.5	≈ 1201.5 + 301.5	480.6 + 120.6	≈ 1201.5 + 301.5	≈ 1201.5 + 301.5

* value determined out of the range of the tested application rates

The test item, i.e. Boscalid 26.7% + Pyraclostrobin 6.7% WG applied at rates ranging from 115.2 to 4500 g/ha had a varied impact on vegetative vigour of the test plant species. The impact depended on the rate and species. There was no mortality observed for all tested species at rates ranged from 115.2 to 4500 g/ha. On the basis of NOER, ER₁₀, ER₂₅ and ER₅₀ values determined from the plant number at the end of the experiment, the shoot length and shoot dry weight, it was observed that the test item caused slightly inhibition of growth of pea, carrot and onion. Some phototoxic symptoms were observed after 21 days of the exposure: stunted growth (onion), wilting (pea, carrot, onion).

In case of sunflower, cabbage, and oats no phytotoxic symptoms were observed. The following order of the test plant sensitivity was noticed: carrot > onion > pea > sunflower, cabbage, oats.

A 2.8.2 KCP 10.6.3 Extended laboratory studies on non-target plants

A 2.9 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

A 2.10 KCP 10.8 Monitoring data