

FINAL REGISTRATION REPORT

Part B

Section 3


Efficacy Data and Information

Concise summary

Product code: SHA 7273 A

Product name: CASINO ROYALE

Chemical active substance:

Boscalid, 267 g/kg 

Pyraclostrobin, 67 g/kg 

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España

Submission date: August 2020

MS Finalisation date: 24/05/2021; 01/2022

Version history

When	What
May 2021	ZRMs evaluated version of dRR submitted by Applicant.
January 2022	Final Registration Report

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3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

Transformation of the dRR (applicant version) into the RR (zRMS version)

The process chosen by the zRMS to transform the dRR into a RR should be explained. Options are to rewrite the document (with track change or not) or to use commenting boxes such as the following:

Comments of zRMS:	Comments of zRMS are presented in commenting boxes at the end of each chapter. The text of dRR was generally not changed or rewritten (small changes in the document are marked by grey colour).
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3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

Comments of zRMS: Overall summaries are not necessary here. It was provided at the end of each chapter of the dRR.

Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. (e)	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: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/synergist per ha (f)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val between applications (days)	kg or L prod- uct / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	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 boscalid + 0.1 pyraclostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	300- 600	14		To be confirmed by cMS.
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 boscalid + 0.1 pyraclostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	300- 600	3		To be confirmed by cMS
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 boscalid + 0.1 pyraclostrobin b) 1.2 boscalid + 0.3 pyraclostrobin	300- 600	3		To be confirmed by cMS
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 boscalid + 0.1 pyraclostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	300- 600	14		To be confirmed by cMS
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 boscalid + 0.1 pyraclostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	300- 600	14		To be confirmed by cMS
Unprotected use in SIGNUM														
6	PL	Cabbage	F	Alternaria, Botrytis cinerea	Spray	BBCH 41-49	a) 1-3 b) 1-3	7	a) 1.0 b) 3.0	a) 0.267 boscalid + 0.067 pyra- clostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	600- 800	14	Unprotected use in SIGNUM	Acceptable

7	PL	Tomatoe in green-houses	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	Acceptable
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	Acceptable
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	Acceptable
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	Acceptable
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 pyraclostrobin b) 0.961 boscalid + 0.241 pyraclostrobin	600-800	3	Unprotected use in SIGNUM	Acceptable
Minor uses according to Article 51 (zonal uses)														
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		Acceptable
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		Acceptable

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 pyra- clostrobin b) 0.400 boscalid + 0.100 pyra- clostrobin	600- 800	14		Acceptable
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		Acceptable
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		Acceptable
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 pyraclostrobin	300- 600	14		Acceptable
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 pyra- clostrobin b) 0.534 boscalid + 0.134 pyra- clostrobin	300- 600	14		Acceptable
19	PL	Turnip	F	<i>Botrytis cinerea</i> , <i>Thanatephorus cu- cumeris</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		Acceptable
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		Acceptable
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 pyra- clostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	300- 600	14		Acceptable
22	PL	Onion	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		Acceptable

23	PL	Aubergines/eggplants	G	<i>Botrytis cinerea</i> , <i>Sclerotinia sclerotiorum</i> <i>Leveillula taurica</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 b) 0.8 boscalid + 0.2 pyraclostrobin	1000	14		Acceptable
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		Acceptable
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		Acceptable
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 pyra- clostrobin b) 0.0534 boscalid + 0.00134 pyra- clostrobin	100	-		Acceptable
27	PL	Ornamentals in field and greenhouses	F/G	<i>Erysiphales</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 pyra- clostrobin b) 0.0962 boscalid + 0.0242 pyra- clostrobin	100	-		Acceptable
28	PL	Ornamentals in field and greenhouses	F/G	<i>Botrytis cinerea</i> , <i>Sclerotinia sclerotiorum</i> <i>Thanatephorus cu- cumeris</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 pyra- clostrobin b) 0.08 boscalid + 0.02 pyraclostrobin	100	-		Acceptable
29	PL	Redcurrant, White currant	F	<i>Drepanopeziza ribis</i> , <i>Drepanopeziza rubric</i> , <i>Botrytis cinerea</i> ,	Spray	BBCH 55-90	a) 1-2 b) 1-2	7-10	a) 1.8 b) 3.6	a) 0.4806 boscalid + 0.1206 pyra- clostrobin b) 0.9612 boscalid + 0.2412 pyra- clostrobin	600- 800	3		Acceptable
30	PL	Salsifies	F	<i>Botrytis cinerea</i> , <i>Sclerotinia sclerotiorum</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 boscalid + 0.1 pyraclostrobin b) 0.8 boscalid + 0.2 pyraclostrobin	300- 600	14		Acceptable

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

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

and non-professional greenhouse use, I: indoor application

Column 15: zRMS conclusion

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

3.2 Efficacy data (KCP 6)

Introduction

This document summarises the information related to the efficacy data of the plant protection product CASINO ROYALE (Boscalid 26.7% + Pyraclostrobin 6.7% WG Product code: SHA 7273 B) containing the active substances boscalid and pyraclostrobin, which were included into Annex I of Council Directive 91/414/EEC and are approved under Regulation 1107/2009.

The SANCO report for boscalid (SANCO/3919/2007 rev 5 – 21 January 2008) and the SANCO report for pyraclostrobin (SANCO/1420/2001-Final - 8 September 2004) are considered to provide the relevant information on the evaluation or a reference to where such information can be found.

For the implementation of the uniform principles of Annex VI, the conclusions of the review reports on the active substance boscalid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008, shall be taken into account. Consideration of active substance for Annex I inclusion does not include an evaluation of efficacy. Therefore, there are no concerns to address arising from the inclusion directive of boscalid relating to efficacy.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on pyraclostrobin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 November 2003 shall be taken into account. Consideration of active substance for Annex I inclusion does not include an evaluation of efficacy. Therefore, there are no concerns to address arising from the inclusion directive of boscalid relating to efficacy.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

The detailed assessment of the individual trial and study data is located in the following report:

Report:	KCP 6.0/001 Biological Assessment Dossier Boscalid 26.7% + Pyraclostrobin 6.7% WG, Central
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Description of active substance boscalid

Boscalid is a member of the class of pyrazine-carboxamide fungicides. Boscalid effectively controls several fungal pathogens belonging to the four major classes of plant pathogenic fungi.

Boscalid has preventative and curative properties. It inhibits spore germination, germ tube elongation, mycelial growth, and sporulation (all major stages of fungal growth and reproduction necessary for disease development). Boscalid is a systemic compound. Depending on the type of formulation, it penetrates into the plant when applied to leaves (or roots), and it is then translocated acropetally.

Description of active substance pyraclostrobin

Pyraclostrobin is a member of the class of methoxy-carbamates fungicides. Pyraclostrobin effectively controls several fungal pathogens belonging to the four major classes of plant pathogenic fungi.

Pyraclostrobin is active against fungal development stages both on the plant surface and within the tissues. Pyraclostrobin has a protective as well as an eradicated/curative action. Pyraclostrobin is selective on a wide range of dicotyledonous and monocotyledonous crop species.

Today, boscalid and pyraclostrobin mixtures as well as straight formulations are registered and commercialised in several formulations around the world.

Uses (from 6 to 30) requested for Boscalid 26.7% + Pyraclostrobin 6.7% WG are identical to those of the reference product Signum (reg nr R-33/2010) registered in POLAND for more than 10 years and, therefore, not in a scope of data protection anymore.

Table 3.2-1: Current approvals of boscalid and pyraclostrobin in the EU Central zone as well as connected EPPO zones where trials were conducted

Country	Product	Active ingredient	Approval number
France	Signum	Boscalid 267 g/kg Pyraclostrobin 67 g/kg	2060084
Germany	Signum	Boscalid 267 g/kg Pyraclostrobin 67 g/kg	025483-00
Greece	Signum	Boscalid 267 g/kg Pyraclostrobin 67 g/kg	60098
Hungary	Signum	Boscalid 267 g/kg Pyraclostrobin 67 g/kg	04.2 / 6869/1/2012
Italy	Signum	Boscalid 267 g/kg Pyraclostrobin 67 g/kg	012869
Spain	Signum	Boscalid 267 g/kg Pyraclostrobin 67 g/kg	25689
United Kingdom	Signum	Boscalid 267 g/kg Pyraclostrobin 67 g/kg	11450
Czech Republic	Signum	Boscalid 267 g/kg Pyraclostrobin 67 g/kg	4738-1
Poland	Signum	Boscalid 267 g/kg Pyraclostrobin 67 g/kg	R-33/2010
Latvia	Signum	Boscalid 267 g/kg Pyraclostrobin 67 g/kg	0269

Mode of action boscalid

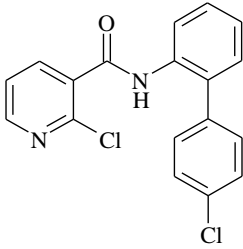
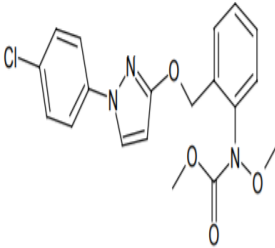
FRAC (Fungicide Resistance Action Committee) presents boscalid as a pyridinecarboxamide in the group of complex II: succinate-dehydrogenase fungicides and is classified in Group 7 by FRAC (FRAC MOA Code: complex II: succinate-dehydrogenase, Group code 7).

Mode of action pyraclostrobin

FRAC (Fungicide Resistance Action Committee) presents boscalid as a methoxy-carbamate in the group of complex III: cytochrome bc1 (ubiquinol oxidase) at Qo site (cyt b gene) and is classified in the Group 11 by FRAC (FRAC MOA Code: complex III: cytochrome bc1 (ubiquinol oxidase) at Qo site (cyt b gene), Group code 11).

Table 3.2-2: Details of the formulation and the active substance

Proposed trade name	CASINO ROYAL
A.S. content:	Boscalid 267 g/kg + Pyraclostrobin 67 g/kg
Formulation type:	WG
Synonyms:	Boscalid 26.7% + Pyraclostrobin 6.7% WG
Active substance	Boscalid
IUPAC name:	2-Chloro-N-(4'-chlorobiphenyl-2-yl)nicotinamide
Chemical group:	pyridinecarboxamide
CIPAC number	673
CAS number	188425-85-6

Structural formula:	
Active substance	Pyraclostrobin
IUPAC name:	methyl N-(2-{[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxymethyl}phenyl) N-methoxy carbamate
Chemical group:	methoxy-carbamate
CIPAC number	657
CAS number	175013-18-0
Structural formula:	

For further physico-chemical properties, please refer to Registration Report Part B Section 1: Identity, physical and chemical properties, other information.

Description of the plant protection product

Boscalid 26.7% + Pyraclostrobin 6.7% WG is a Water Dispersible Granular (WG) formulation containing 267 g/kg boscalid and 67 g/kg pyraclostrobin for use in several crops.

According to the GAP, the proposed application rate of Boscalid 26.7% + Pyraclostrobin 6.7% WG is 1.5 Kg per hectare (kg/ha), with up to three applications per season depending on crop and disease. This will deliver 400 g boscalid and 100 g pyraclostrobin per hectare per application.

The data presented in this dossier fully support the label claim for Boscalid 26.7% + Pyraclostrobin 6.7% WG for the control of a variety of diseases in a wide range of crops.

Not all crops are registered for standard formulation in all Central zone countries. The registered crops for boscalid + pyraclostrobin standard vary depending on countries. For this reason has been included additional standards Azoxystrobin 20% + Difenoconazole 12.5%SC reference product in order to assure one of the formulations is registered for each claimed use.

Table 3.2-3: Simplified table of currently registered uses and requested uses for the product code.

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
Sugarbeet	CERCBE	CEU (PL)	2 x 1.5 kg/ha	BBCH 31-39
Tomato	PHYTIN	CEU (PL)	2 x 1.5 kg/ha	BBCH 20-87 (when first symptoms are visible)
	ALTESP		3 x 1.5 kg/ha	BBCH 20-87 (when first symptoms are visible)
Carrot	SEPTAP	CEU (PL)	2 x 1.5 kg/ha	BBCH 41-49 (when first symptoms are visible)
	CERCSP			
	ALTESP			
Onion	PUCAL	CEU (PL)	2 x 1.5 kg/ha	BBCH 41-49 (when first symptoms are visible)
Cabbage	ALTESP	CEU (PL)	3 x 1.0 kg/ha	BBCH 41-49
	BOTRCI			
Tomatoe in greenhouses	PHYTIN	CEU (PL)	2 x 2.0 kg/ha	BBCH 51-85
	BOTRCI			
Strawberry	BOTRCI	CEU (PL)	2 x 1.8 kg/ha	BBCH 60-81
	MYCOFR			
Cherry	MONISP	CEU (PL)	2 x 1.0 kg/ha	BBCH 60-67
Raspberry	BOTRCI	CEU (PL)	2 x 1.8 kg/ha	BBCH 51-90
	DIDYAP			
Blackcurrant	DREPRI	CEU (PL)	2 x 1.8 kg/ha	BBCH 55-90
Beetroot	ERYSB	CEU (PL)	2 x 1.0 kg/ha	BBCH 15-49
Celery root	SCLESC	CEU (PL)	2 x 1.5 kg/ha	BBCH 15-49
Parsnip, Parsley	ALTESP	CEU (PL)	2 x 0.75 kg/ha	BBCH 15-49
	ERYSHE			
Radish	BOTRCI	CEU (PL)	2 x 1.5 kg/ha	BBCH 11-49
	RHIZSO	CEU (PL)	1 x 1.5 kg/ha	BBCH 11-12
Horseradish	PEROSP	CEU (PL)	2 x 1.5 kg/ha	BBCH 15-49
	ALTESP			
	ERYSSP			
Swedes/rutabagas	PEROSP	CEU (PL)	2 x 1.0 kg/ha	BBCH 15-49
	CERCBE			
	ERYSSP			
Turnip	BOTRCI	CEU (PL)	2 x 1.5 kg/ha	BBCH 11-49
	RHIZSO			

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
Chicory roots	ALTECC	CEU (PL)	2 x 1.5 kg/ha	BBCH 13-47
	1PUCCG			
Shallot	PERODE	CEU (PL)	2 x 1.0 kg/ha	BBCH 13-48
	PHYTPO			
	ALTESP			
Onion	PUCCPO	CEU (PL)	2 x 1.5 kg/ha	BBCH 13-47
	PHYTPO			
	ALTESP			
Aubergines/eggplants	BOTRCI	CEU (PL)	2 x 1.5 kg/ha	BBCH 12-89
	SCLESC			
	LEVETA		When first symptoms are visible BBCH 20-87	
	PHYTIN			
	ALTESP			
Ornamentals in field and greenhouses	ALTESP	CEU (PL)	2 x 0.1 kg/ha	BBCH 13-47
Ornamentals in field and greenhouses	1ERYSO		2 x 0.18 kg/ha	
Ornamentals in field and greenhouses	BOTRCI		2 x 0.15 kg/ha	
	SCLESC			
	RHIZSO			
Redcurrant, White currant	BOTRCI	CEU (PL)	2 x 1.8 kg/ha	BBCH 55-90
	DREPRI			
	DREPRR			
Salsifies	BOTRCI	CEU (PL)	2 x 1.5 kg/ha	When first symptoms are visible BBCH 41-49
	SCLESC			
	1RHIZG			

Further details are in the table “All intended uses” in Part B - Section 0.

Description of the target pests

Key targets for this product are ear- and foliar diseases in cereals and oilseed rape. All the listed pests are present throughout or in parts of the Central zone and in relevant EPPO zones. The key targets for this product are described in detail in the Biological Assessment dossier.

Table 3.2-4: Glossary of pests mentioned in the dossier.

EPPO code	Scientific name	Common name
CERCBE	<i>Cercospora beticola</i>	Leaf spot
CERCSP	<i>Cercospora sp.</i>	Leaf spot
PHYTIN	<i>Phytophthora infestans</i>	Late blight

EPPO code	Scientific name	Common name
ALTESP	<i>Alternaria</i> sp.	Early blight
PUCCAL	<i>Puccinia allii</i>	Rust of onion
RAMUBE	<i>Ramularia beticola</i>	Leaf spot of beet
ALTEDA	<i>Alternaria dauci</i>	Leaf blight
SEPTAP	<i>Septoria apiicola</i>	Late blight
MYCOFR	<i>Sphaerotheca macularis</i>	Strawberry mildew
MONISP	<i>Monilinia</i> sp.	
DIDYAP	<i>Didymella applanate</i>	Raspberry spur blight
DREPRI	<i>Drepanopeziza ribis</i>	Leaf spot of gooseberry
ERYSBE	<i>Erysiphe betae</i>	Powdery mildew of beet
SCLESC	<i>Sclerotinia sclerotiorum</i>	Cottony rot
ERYSHE	<i>Erysiphe heraclei</i>	Powdery mildew of carrot
BOTRCI	<i>Botrytis cinerea</i>	Brownish-grey mildew
RHIZSO	<i>Rhizoctonia solani</i>	Areolate leaf spot

Table 3.2-5: Major / minor status of intended uses (for all cMS and zRMS).

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
Sugarbeet	CEU	-	<i>Cercospora beticola</i>	CEU	-
Tomato	-	CEU	<i>Phytophthora infestans</i>	CEU	-
			<i>Alternaria</i> sp.	CEU	-
Carrot	-	CEU	<i>Septoria apiicola</i>	CEU	-
			<i>Cercospora</i> sp.	CEU	-
			<i>Alternaria</i> sp.	CEU	-
Onion	-	CEU	<i>Puccinia allii</i>	CEU	-
Cabbage	-	PL	<i>Alternaria</i>	CEU	-
			<i>Botrytis cinerea</i>		
Tomatoe in greenhouses	-	PL	<i>Botrytis cinerea</i>	CEU	-
			<i>Phytophthora infestans</i>		
Strawberry	-	PL	<i>Botrytis cinerea</i>	CEU	-
			<i>Ramularia grevilleana</i>		
			<i>Sphaerotheca macularis</i>		
Cherry	-	PL	<i>Monilinia</i> sp.	CEU	-
Raspberry	-	PL	<i>Botrytis cinerea</i>	CEU	-
			<i>Didymella applanate</i>		
Blackcurrant	-	PL	<i>Drepanopeziza ribis</i>	CEU	-
			<i>Cronartium ribicola</i>		

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
Beetroot	-	PL	<i>Erysiphe betae</i>	CEU	-
Celery root	-	PL	<i>Sclerotinia sclerotiorum</i>	CEU	-
Parsnip, Parsley	-	PL	<i>Alternaria sp.</i>	CEU	-
			<i>Erysiphe heraclei</i>		
Radish	-	PL	<i>Botrytis cinerea</i>	CEU	-
			<i>Rhizoctonia solani</i>		
Horseradish	-	PL	<i>Peronospora sp.</i>	CEU	-
			<i>Alternaria</i>		
			<i>Erysiphe sp.</i>		
Swedes/rutabagas	-	PL	<i>Peronospora sp.</i>	CEU	-
			<i>Cercospora beticola</i>		
			<i>Erysiphe sp.</i>		
Turnip	-	PL	<i>Botrytis cinerea</i>	CEU	-
			<i>Thanatephorus cucumeris</i>		
Chicory roots	-	PL	<i>Chicory Alternaria</i>	CEU	-
			<i>Chicory Puccinia</i>		
Shallot	-	PL	<i>Peronospora destructor</i>	CEU	-
			<i>Alternaria</i>		
			<i>Stemphylium</i>		
Onion	-	PL	<i>Puccinia porri</i>	CEU	-
			<i>Phytophthora porri</i>		
			<i>Alternaria</i>		
Aubergines/eggplants	-	PL	<i>Botrytis cinerea</i>	CEU	-
			<i>Sclerotinia sclerotiorum</i>		
			<i>Leveillula taurica</i>		
			<i>Phytophthora infestans,</i>		
			<i>Alternaria sp.</i>		
Ornamentals in field and greenhouses	-	PL	<i>Alternaria</i>	CEU	-
			<i>Erysiphales</i>		
			<i>Botrytis cinerea</i>		
			<i>Sclerotinia sclerotiorum</i>		
			<i>Thanatephorus cucumeris</i>		
Redcurrant, White currant	-	PL	<i>Drepanopeziza ribis</i>	CEU	-
			<i>Drepanopeziza rubric</i>		
			<i>Botrytis cinerea</i>		
Salsifies	-	PL	<i>Botrytis cinerea</i>	CEU	-

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
			<i>Sclerotinia sclerotiorum</i>		
			<i>Rhizoctonia</i>		

Since there are no other MS and Poland is the only evaluator country, applicant would like to use data out of protection.

Compliance with the Uniform Principles

Comprehensive field trials were conducted in 2016, 2017 and 2019 in a wide range of European countries the Maritime (i.e. N-France, United Kingdom and Germany) the North-East (i.e. Latvia and Poland) the South-east (i.e. Hungary) and the Mediterranean (i.e. S-France, Greece, Italy and Spain) EPPO zones. The trials followed the corresponding EPPO guidelines. The GEP-requirement and the Uniform Principles are taken care of.

Information on trials submitted (3.1 Efficacy data)

Trials in this dossier were carried out by contractor companies and Official Research institutes, all of which follow the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

On the basis of the EPPO guideline 1/241(1) "Guidance on comparable climates", the trials included in this dossier have been grouped and summarized by EPPO zones. EPPO zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region.

In general, the trials were conducted according to the respective EPPO guidelines.

In support of the current application, conducted in the Maritime (13), in the North-East (14), in the South-East (6) and the Mediterranean (14) EPPO zones. In 47 of these, the level of infestation was high enough for the trials to be considered valid (i.e. PESSEV > 5% and/or PESINC > 5%), whereas in the remaining 36 trials, no disease developed or an extremely high disease pressure i.e. PESSEV > 98% and/or PESINC > 98%) was observed. In the 47 trials considered valid, the level of control obtained by Boscalid 26.7% + Pyraclostrobin 6.7% WG applied in sugarbeet (19), tomato (13), carrot (8) and onion (7), as supportive to the effectiveness of the product) was assessed on the key diseases present in the trials.

Table 3.2-6: Presentation of efficacy trials (efficacy trials, preliminary trials...)

Crop(s) *	Target(s)*	Country	Years	Type of tri- al**	Number of trials (number of valid trials)				GEP, non- GEP, official***	Comments (any other relevant information)
					EPPO zone					
					MAR	MED	S-E	N-E		
BEAVA	CERCBE	France	2016	MED + E	2				GEP	
			2019	MED + E	3				GEP	
		Germany	2016	MED + E	1				GEP	
		UK	2016	MED + E	1				GEP	
		Italy	2016	MED + E		1			GEP	
		Spain	2016	MED + E		2			GEP	
		Hungary	2016	MED + E			2		GEP	
		Poland	2017	MED + E				7	GEP	

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					EPPO zone					
					MAR	MED	S-E	N-E		
LYPES	PHYTIN	Germany	2016	MED + E	1				GEP	
		Italy	2016	MED + E		2			GEP	
		Hungary	2019	MED + E			3		GEP	
	ALTESP	Greece	2016	MED + E		1			GEP	
		Italy	2016	MED + E		2			GEP	
		Spain	2016	MED + E		2			GEP	
		Poland	2016	MED + E				2	GEP	
ALLCE	PUCCAL	France	2016	MED + E	2				GEP	
		Greece	2016	MED + E		1			GEP	
		Italy	2016	MED + E		2			GEP	
		Spain	2016	MED + E		1			GEP	
		Germany	2019	MED + E	1				GEP	
DAUCS	CERCBE	Latvia	2016	MED + E				2	GEP	
		Germany	2019	MED + E	1				GEP	
	ALTESP	Hungary	2019	MED + E			1		GEP	
		Germany	2016	MED + E	1				GEP	
		Latvia	2019	MED + E				2	GEP	
		Poland	2017	MED + E				1	GEP	
					13	14	6	14	-	

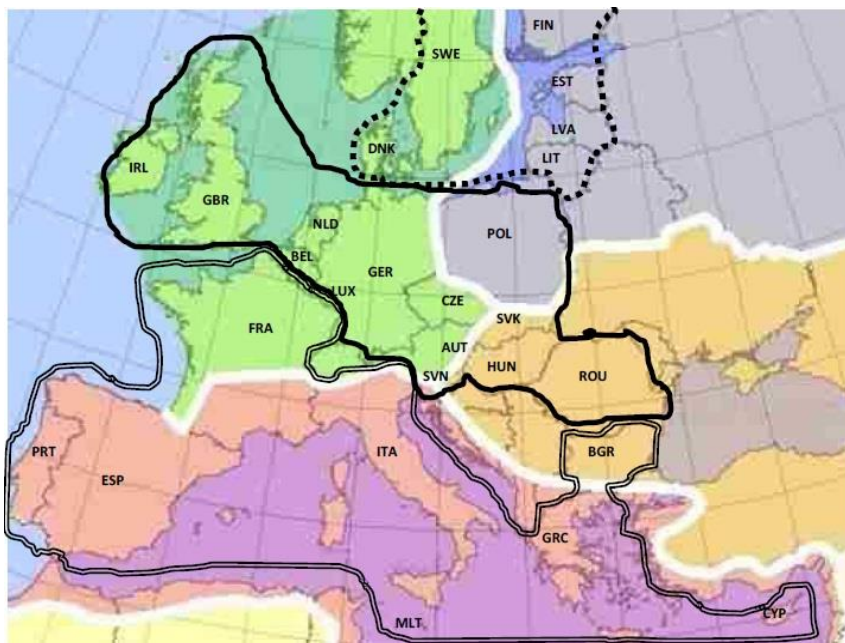
Climatic zones

Europe is divided into four climatic zones, according to EPPO standard PP 1/241 (1). Besides providing guidance in determining comparability of climatic conditions between geographical areas where efficacy evaluation trials are performed, the standard also supports the use of data generated in one country to support registration in another country¹.

Germany, United Kingdom and N-France are located in the EPPO Maritime zone, Poland and Latvia are located in the EPPO North-East zone, Hungary is located in the South-east EPPO zone and Italy, Spain, Greece and S-France are located in the Mediterranean EPPO zone (Figure 3.2-1).

This document prepared to support the submission of Boscalid 26.7% + Pyraclostrobin 6.7% WG throughout the Central Registration zone, therefore data from the the Maritime EPPO zone, the North-east EPPO zone and the South-east EPPO zone are included. Data obtained in Mediterranean EPPO zone has also been added as supporting information, however, the data from each climatic zone is summarised separately.

Figure 3.2-1: Representation of EPPO climatic zones (in colour: EPPO Standard PP1/241, Guidance on comparable climates) superimposed with the 3 European zones (EC Regulation 1107/2009) (Source: EPPO)



Agronomic conditions

Cultural conditions of the different crops and agronomy (e.g. cultivations used, application methods, cultivars, fertilizer regime, relative times of planting and harvest) do not differ significantly between the countries in the central EU.

The same boscalid + Pyraclostrobin containing fungicides are already registered and used in the countries where the trials were conducted to support the current application for registration. Please refer to Table 6.0.3-1 for the registration numbers in the different countries. In all countries, the products are registered for the same use. In each country, these are used at similar application timings when the crops are at similar growth stages.

¹ Development of Comparable Agro-Climatic Zones for the International Exchange of Data on the Efficacy and Crop Safety of Plant Protection Products, E. Bouma, 2005 OEPP/EPPO, Bulletin OEPP/EPPO Bulletin 35, 233-238.

(i) *Pest physiology*

The physiology of individual pathogens presented is common throughout central Europe. Although trials were performed in different countries, sites were selected to exert maximum disease pressure and to exacerbate treatment differences. No difference in the level of control was apparent between the different countries or regions in which the trials were conducted.

(ii) *Site selection*

Although trials were performed throughout the EU, in each country the sites were carefully selected to ensure that for each fungal disease, the level of control was assessed on a range of populations, when treated at the recommended application timings. To exert maximum control pressure and to exacerbate treatment differences in each country this included some trials which contained high infestation levels. No differences in the level of control were apparent between the different countries or regions in which the trials were conducted.

(iii) *Agronomic practices*

Agronomic practices for growing sugarbeet, tomato, onion and carrot are similar throughout the central zone as well as in the countries in the connected EPPO zones where trials were conducted. The levels of inorganic fertilizers and other crop inputs are also generally similar between the countries.

(iv) *Varieties*

Although crop varieties tend to differ between countries, observations on selectivity have not indicated any particular varietal sensitivity. The crop safety of Boscalid 26.7% + Pyraclostrobin 6.7% WG has been tested on a wide range of varieties in the efficacy trial. The results from these trials show that there are no particularly sensitive varieties. Crop tolerance and yield data generated in one country is therefore relevant in another Member state. To increase the probability of high levels of disease in the trials, the varieties chosen in each country were the ones with the least resistance to the selected disease. Therefore, the results from each country can be considered as the worst case.

(v) *Trial methodology*

Similar trial methodology was used in all countries. All trials were conducted to GEP by officially recognized testing organizations and in accordance with relevant EPPO standards.

(vi) *Locations*

Trials were performed in the major crop growing areas in each respective country. These areas have been found to be particularly suitable for the specific crop production due to their innate similarity in terms of soil type and climate.

(vii) *Soil*

It is not expected that a foliar applied fungicide will be affected in any way by soil type and so this factor can be ignored for the purposes of this dossier.

On the basis that the above factors do not influence the overall performance of Boscalid 26.7% + Pyraclostrobin 6.7% WG, it is the applicant's contention that data from Germany, United Kingdom, N-France, Poland, Latvia and Hungary is equally valid in demonstrating the products performance throughout the Central EU zone and the data from Italy, Spain, Greece and S-France are valid as supporting data

Efficacy and crop safety trials were carried out with Boscalid 26.7% + Pyraclostrobin 6.7% WG in comparison to the BASF reference boscalid and pyraclostrobin product (Signum; Boscalid 26.7% + Pyraclostrobin 6.7% WG) in all countries where the efficacy trials were conducted. The trials were carried out on sugarbeet, tomato, carrot and onion.

Table 3.2-7: Presentation of reference standards used in trials (efficacy trials, preliminary trials...)

Trade name	Formulation	Composition	Rates	Country	N° of Trials
Signum	WG	Boscalid 26.7% Pyraclostrobin 6.7 %	3 kg/ha 1.5 kg/ha 1 kg/ha 0.6 kg/ha	HU UK DE IT EL FR ES PL LV	47
Askor Ortiva Top Amistar top	SC	Azoxystrobin 20% Difenoconazole 12.5%	1 L/ha	FR DE IT ES EL HU	37

Comments of zRMS:	<p>This document summarizes the information related to the efficacy of the plant protection product – Casino Royal (product code: SHA 7273 B). The formulation of this product is a water dispersible granules (WG) and it containing two active substances: boscalid (267 g/kg) and pyraclostrobin (67 g/kg). For now this mentioned active substances are on the list of approved active substances.</p> <p>Pyraclostrobin is active against fungal development stages both on the plant surface and within the tissues. Pyraclostrobin has a protective as well as an eradica-tive/curative action. Pyraclostrobin is selective on a wide range of dicotyledonous and monocotyledonous crop species.</p> <p>Boscalid has preventative and curative properties. It inhibits spore germination, germ tube elongation, mycelial growth, and sporulation (all major stages of fungal growth and reproduction necessary for disease development). Boscalid is a sys-temic compound. Depending on the type of formulation, it penetrates into the plant when applied to leaves (or roots), and it is then translocated acropetally.</p> <p>In total, 33 with boscalid and 42 with pyraclostrobin plant protection products are registered in Poland. Both, boscalid and pyraclostrobin is registered in 16 Polish plant protection product.</p> <p>The product – Casino Royal (product code: SHA 7273 B) by Sharda Cropchem España S.L. has not been previously evaluated in any country according to Uni-form Principles. Poland is a ZRMs.</p>
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3.2.1 Preliminary tests (KCP 6.1)

The activity of Boscalid is well known, as it has been marketed since 2001 by BASF to control of *Botrytis Sclerotinia*, *Alternaria* and *Phoma*, in Grape, oilseed rape, peas, beans and other crops, as granular and seed treatment products. The activity of Pyraclostrobin is also well know, as it has been marketed since 2003 by BASF and it has been used applied in foliar spray, to control diseases such as *Colletotrichum gloeosporioides*, *Uromyces phaseoli* or *Puccinia graminis* in barley, apple or potato.

Based on the knowledge about the active substances (+15 years) and the experiences with using Boscalid and Pyraclostrobin in the label claimed crops at the proposed dose rates, the necessary application rates of the mixture to obtain sufficient control of the pest organism are already known. Therefore, preliminary tests in glasshouses and field trials to assess the biological activity of the active substance or dose range for the plant protection product were not deemed necessary.

VComments of zRMS:	No results of the preliminary range-finding tests were submitted by the Applicant.
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	The active substances of Casino Royal (product code: SHA 7273 B) – boscalid (267 g/kg) and pyraclostrobin (67 g/kg), are registered and have been commonly used in agricultural practice for many years (for over 15 years). So, large scale efficacy trials are available to evaluate the effectiveness of products containing these active compounds. Therefore, there was no need for preliminary range-finding tests in the opinion of Evaluator.
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3.2.2 Minimum effective dose tests (KCP 6.2)

Field trials were established to determine the minimum effective dose for the control of the targets claimed in this dossier. In the following, summaries of the performance of Boscalid 26.7% + Pyraclostrobin 6.7% WG on the key disease in sugarbeet, tomato, carrot and onion are presented.

Boscalid 26.7% + Pyraclostrobin 6.7% WG was tested at a range of dose rates, but to demonstrate minimum effective dose rate, the control obtained with Boscalid 26.7% + Pyraclostrobin 6.7% WG applied at different dose rates was evaluated in 19 sugarbeet, 13 tomato, 8 carrot and 7 onion trials. In the 47 trials, Boscalid 26.7% + Pyraclostrobin 6.7% WG was applied at 0.6, 1 and 1.5 kg/ha for the control of *Cercospora beticola* (CERCBE) in sugarbeet, *Phytophthora infestans* (PHYTIN) and *Alternaria* sp. (ALTESP) in tomato, *Septoria apiicola* (SEPTAP), *Cercospora* sp.(CERCSP) and *Alternaria* sp. (ALTESP) in Carrot and *Puccinia allii* (PUCCAL) in onion. The dose rates tested reflects 40% to 67% of the recommended rate of Boscalid 26.7% + Pyraclostrobin 6.7% WG, in accordance with the EPPO guideline PP 1/225(2) “Minimum effective dose”. The dose is selected on the basis of its efficacy performance, product safety parameters and environmental limitations. Efficacy is tested under a range of environmental conditions to fully challenge the product. Data are presented from trials conducted in the Maritime EPPO zone (N-France, Germany and United Kingdom), North-East EPPO zone (Latvia and Poland), South-East EPPO zone (Hungary) and Mediterranean EPPO zone (Italy, S-France, Greece and Spain).

Control of *Cercospora beticola* in Sugarbeet

To prove and to support the proposed dose rates of 1.5 kg/ha Boscalid 26.7% + Pyraclostrobin 6.7% WG [400 g Boscalid and 100 g Pyraclostrobin per hectare, per application] for the control of *Cercospora beticola* (CERCBE) in sugarbeet, the assessment results of 19 efficacy trials performed in the the Maritime EPPO zone (7), the North-east (7), the South-east EPPO zone (2) and the Mediterranean EPPO zone (3) are reported. The trials were conducted in N-France (5), United Kingdom (1), Germany (1), Poland (7), Hungary (2) and Spain (3) in 2016, 2017 and 2019. Boscalid 26.7% + Pyraclostrobin 6.7% WG was included in these trials at 1.5 kg/ha to demonstrate the recommended dose rate as well as two lower dose rates (0.6 kg/ha and 1 kg/ha [160 g Boscalid and 40 g Pyraclostrobin per hectare and 267 g Boscalid and 67 g Pyraclostrobin per hectare respectively, in one application]). In the trials, specifically targeted for this pathogen, two applications were applied, from April to November the first application (BBCH 31-49) and from May to October the second application (BBCH 33-49).

The results obtained with Boscalid 26.7% + Pyraclostrobin 6.7% WG applied for the control of *Cercospora beticola* in sugarbeet are presented in Table 3.2-8, Table 3.2-9, Table 3.2-10 and Table 3.2-11 for results obtained in the the Maritime EPPO zone (four trials, three excluded due to very low infestation), the North-East EPPO zone (two trials), the South-east EPPO zone (two trials) and the Mediterranean EPPO zone (three trials), respectively.

Table 3.2-8: Minimum effective dose – Maritime zone: Minimum effective dose of Boscalid 26.7% + Pyraclostrobin 6.7% WG against CERCBE in sugarbeet

		Mean % Control from 4 trials in the Maritime EPPO Zone at a range of doses of Boscalid 26.7% + Pyraclostrobin 6.7% WG							
Target: CERCBE and RAMUBE	No. of trials	Untreated	0.6 kg/ha		1 kg/ha		1.5 kg/ha		
		Mean % PESSEV (range)	Mean	Range	Mean	Range	Mean	Range	
Sugarbeet									

Mean % control, one observation on Leaves per trial, PESSEV at 18-38 days after appl. (CERCBE)	6	21.6	26.3	(6.2-89.6)	37.1	(17.3-91.3)	47.2	(21.4-88.8)
Mean % control, one observation on Leaves per trial, PESSEV at 40 days after appl. (RAMUBE)	1	5.6	50.4	-	41.4	-	61.9	-

Table 3.2-9: Minimum effective dose – North-East zone: Minimum effective dose of Boscalid 26.7% + Pyraclostrobin 6.7% WG against CERCBE in sugarbeet

Target: CERCBE	No. of trials	Mean % Control from 7 trials in the North-east EPPO Zone at a range of doses of Boscalid 26.7% + Pyraclostrobin 6.7% WG						
		Untreated	0.6 kg/ha		1 kg/ha		1.5 kg/ha	
		Mean % PESSEV (range)	Mean	Range	Mean	Range	Mean	Range
Sugarbeet								
Mean % control, one observation on Leave per trial, PESSEV at 39-49 days after appl.	7	29.1 (8.4-58.5)	48.7	(38.3-64.8)	53.6	(44.7-74.5)	69.1	(61.5-88)

Table 3.2-8: Minimum effective dose – South-east zone: Minimum effective dose of Boscalid 26.7% + Pyraclostrobin 6.7% WG against CERCBE in sugarbeet

Target: CERCBE	No. of trials	Mean % Control from 2 trials in the South-east EPPO Zone at a range of doses of Boscalid 26.7% + Pyraclostrobin 6.7% WG						
		Untreated	0.6 kg/ha		1 kg/ha		1.5 kg/ha	
		Mean % PESSEV (range)	Mean	Range	Mean	Range	Mean	Range
Sugarbeet								
Mean % control, one observation on Leave per trial, PESSEV at 11-13 days after appl.	2	10.3 (10.1-10.6)	60.8	(48.3-73.4)	75.2	(65.9-84.5)	76.4	(63.7-89.2)
		Mean % PESINC	Mean	Range	Mean	Range	Mean	Range
Mean % control, one observation on Leave per trial, PESINC at 11-13 days after appl.	1	68.0	44.4	44.4	70.6	70.6	76.9	76.9

Table 3.2-11: Minimum effective dose – Mediterranean zone: Minimum effective dose of Boscalid 26.7% + Pyraclostrobin 6.7% WG against CERCBE in sugarbeet

Target: CERCBE	No. of trials	Mean % Control from 3 trials in the Mediterranean EPPO Zone at a range of doses of Boscalid 26.7% + Pyraclostrobin 6.7% WG						
		Untreated	0.6 kg/ha		1 kg/ha		1.5 kg/ha	
		Mean % PESSEV (range)	Mean	Range	Mean	Range	Mean	Range
Sugarbeet								
Mean % control, one observation on Leaves per trial, PESSEV at 40-45 days after appl.	3	17 (9.4-23.9)	67.2	(54.3-74.2)	68.4	(64.0-73.1)	73.4	(63.4-79.8)
		Mean % PESINC	Mean		Mean		Mean	
Mean % control, one observation on Leaves per trial, PESINC at 40 days after appl.	1	68.4	69.1	-	72.2	-	76.1	-

The data from different EPPO zones proves that the minimum effective dose rate of Boscalid 26.7% + Pyraclostrobin 6.7% WG to control *Cercospora beticola* in sugarbeet is 1.5 kg/ha, with up two applications per season. Furthermore, the data demonstrated that if the application rate is reduced below this, a decrease in control as well as in persistence is observed.

Control of *Phytophthora infestans* in Tomato

To prove and to support the proposed dose rates of 1.5 kg/ha Boscalid 26.7% + Pyraclostrobin 6.7% WG [400 g Boscalid and 100 g Pyraclostrobin per hectare, per application] for the control of *Phytophthora infestans* (PHYTIN) in tomato, the assessment results of six efficacy trials performed in the Maritime EPPO zone (1), Mediterranean EPPO zone (2) and South-East EPPO zone (3) are reported. The trials were conducted in Germany (1), Italy (2), Hungary (3) in 2016 and 2019. Boscalid 26.7% + Pyraclostrobin 6.7% WG was included in these trials at 1.5 kg/ha to demonstrate the recommended dose rate as well as two lower dose rates (0.6 kg/ha and 1 kg/ha [160 g Boscalid and 40 g Pyraclostrobin per hectare and 267 g Boscalid and 67 g Pyraclostrobin per hectare respectively, in one application]). In the trials, specifically targeted for this pathogen, two or three applications were applied, from June to August the first application (BBCH 17-72), from July to August the second application (BBCH 25-81) and from July to August the third application (BBCH 61-72).

The results obtained with Boscalid 26.7% + Pyraclostrobin 6.7% WG applied for the control of *Phy-*

tophthora infestans (PHYTIN) in tomato are presented in Table 3.2-12, Table 3.2-13 and Table 3.2-14 for results obtained in the Mediterranean EPPO zone (two trials), the Maritime EPPO zone (one trial) and the South-east EPPO zone (three trials) respectively.

Table 3.2-12: Minimum effective dose – Maritime zone: Minimum effective dose of Boscalid 26.7% + Pyraclostrobin 6.7% WG against PHYTIN in tomato

Target: PHYTIN		Mean % Control from 1 trial in the Maritime EPPO Zone at a range of doses of Boscalid 26.7% + Pyraclostrobin 6.7% WG							
		Untreated	0.6 kg/ha		1 kg/ha		1.5 kg/ha		
		Mean % PESSEV (range)	Mean		Mean		Mean		
Tomato									
Mean % control, one observation on Leaves per trial, PESSEV at 6 days after appl.		1	85.0	7.4	7.4	11.8	118	26.5	26.5

Table 3.2-13: Minimum effective dose – Mediterranean zone: Minimum effective dose of Boscalid 26.7% + Pyraclostrobin 6.7% WG against PHYTIN in tomato

Target: PHYTIN	No. of trials	Mean % Control from 2 trials in the Mediterranean EPPO Zone at a range of doses of Boscalid 26.7% + Pyraclostrobin 6.7% WG						
		Untreated	0.6 kg/ha		1 kg/ha		1.5 kg/ha	
		Mean % PESSEV (range)	Mean	Range	Mean	Range	Mean	Range
Tomato								
Mean % control, one observation on Leaves per trial, PESSEV at 20 days after appl.	2	12.1 (11.5-12.6)	70.8	(70.8-70.9)	74.14	(73.8-74.4)	78.03	(77.8-78.2)
		Mean % PESINC	Mean	Range	Mean	Range	Mean	Range
Mean % control, one observation on Leaves per trial, PESINC at 20 days after appl.	2	57.6 (55.0-60.2)	70.2	(70.0-70.4)	73.6	(73.1-74.1)	77.1	(77.5-76.6)

Table 3.2-14: Minimum effective dose – South-east zone: Minimum effective dose of Boscalid 26.7% + Pyraclostrobin 6.7% WG against PHYTIN in tomato

Target: PHYTIN		Mean % Control from 2 trials in the Mediterranean EPPO Zone at a range of doses of Boscalid 26.7% + Pyraclostrobin 6.7% WG						
		Untreated	0.6 kg/ha		1 kg/ha		1.5 kg/ha	
		Mean % PESSEV (range)	Mean	Range	Mean	Range	Mean	Range
Tomato								
Mean % control, one observation on Leaves per trial, PESSEV at 14-21 days after appl.	3	13,7 (9.0-16.1)	54.4	(53.1-56.2)	72.2	(69.0-75.0)	90.4	(90.0-90.7)
		Mean % PESINC	Mean	Range	Mean	Range	Mean	Range
Mean % control, one observation on Leaves per trial, PESINC at 14-21 days after appl.	3	-	54.2	(53.2-54.8)	71.8	(68.4-75.1)	90.5	(89.9-91.1)

The data from different EPPO zones proves that the minimum effective dose rate of Boscalid 26.7% + Pyraclostrobin 6.7% WG to control *Phytophthora infestans* in tomato is 1.5 kg/ha, with up two applications per season. Furthermore, the data demonstrated that if the application rate is reduced below this, a decrease in control as well as in persistence is observed.

Control of *Alternaria* spp. in Tomato

To prove and to support the proposed dose rates of 1.5 kg/ha Boscalid 26.7% + Pyraclostrobin 6.7% WG [400 g Boscalid and 100 g Pyraclostrobin per hectare, per application] for the control of *Alternaria* sp. (ALTESO) in tomato, the assessment results of seven efficacy trials performed in the North-East EPPO zone (2) and the Mediterranean EPPO zone (5) are reported. The trials were conducted in Poland (2), Italy (2), Spain (2) and Greece (1) in 2016. Boscalid 26.7% + Pyraclostrobin 6.7% WG was included in these trials at 1.5 kg/ha to demonstrate the recommended dose rate as well as two lower dose rates (0.6 kg/ha and 1 kg/ha [160 g Boscalid and 40 g Pyraclostrobin per hectare and 267 g Boscalid and 67 g Pyraclostrobin per hectare respectively, in one application]). In the trials, specifically targeted for this pathogen, three applications were applied, from June to November and in growth stages ranging from BBCH 21 to BBCH 85 in the first application, from BBCH 28 to BBCH 86 in the second application and from BBCH 52 to BBCH 87 in the third application.

The results obtained with Boscalid 26.7% + Pyraclostrobin 6.7% WG applied for the control of *Alternaria* sp. (ALTESP) in tomato are presented in Table 3.2-15 and Table 3.2-16 for results obtained in the North-East EPPO zone (two trials) and in the Mediterranean EPPO zone (five trials) respectively.

Table 3.2-15: Minimum effective dose – North-East: Minimum effective dose of Boscalid 26.7% + Pyraclostrobin 6.7% WG against ALTESP in tomato.

Target: ALTESO	No. of trials	Mean % Control from 2 trials in the North-east EPPO Zone at a range of doses of Boscalid 26.7% + Pyraclostrobin 6.7% WG						
		Untreated	0.6 kg/ha		1 kg/ha		1.5 kg/ha	
		Mean % PESINC (range)	Mean	Range	Mean	Range	Mean	Range
Tomato								
Mean % control, one observation on Leaves per trial, PESINC at 21 days after appl.	2	20.2 (18.5-21.8)	64.8	(59.5-70.1)	73.4	(67.6-79.3)	75.3	(62.2-88.5)

Table 3.2-16: Minimum effective dose – Mediterranean zone: Minimum effective dose of Boscalid 26.7% + Pyraclostrobin 6.7% WG against ALTESP in tomato.

Target: ALTESP	No. of trials	Mean % Control from 5 trials in the Mediterranean EPPO Zone at a range of doses of Boscalid 26.7% + Pyraclostrobin 6.7% WG						
		Untreated	0.6 kg/ha		1 kg/ha		1.5 kg/ha	
		Mean % PESSEV (range)	Mean	Range	Mean	Range	Mean	Range
Tomato								
Mean % control, one observation on Leaves per trial, PESSEV at 7-30 days after appl.	5	35.2 (17-57.7)	66.9	(57.9-74.9)	70.4	(50.3-78.4)	73.5	(47.4-84.8)
		Mean % PESINC	Mean	Range	Mean	Range	Mean	Range
Mean % control, one observation on Stems per trial, PESINC at 10 days after appl.	2	52.1 (45.0-59.2)	72.4	(72-72.7)	75.8	(75.75-75.9)	79.7	(79.7-79.8)

The data proves that the minimum effective dose rate of Boscalid 26.7% + Pyraclostrobin 6.7% WG to control *Alternaria* spp. in tomato is 1.5 kg/ha, with up three applications per season. Furthermore, the data demonstrated that if the application rate is reduced below this, a decrease in control as well as in persistence is observed.

Control of *Alternaria dauci* in Carrot

In support of the proposed dose rates of 1.5 kg/ha Boscalid 26.7% + Pyraclostrobin 6.7% WG [400 g Boscalid and 100 g Pyraclostrobin per hectare, per application] on the claimed crops, results for the con-

trol of *Alternaria dauci* (ALTEDA) in carrot, of five efficacy trials performed in the Maritime EPPO zone (1), South-East EPPO zone (1) and the North-east (3) EPPO zones are reported. The trials were conducted in Germany (1), Hungary (1), Poland (1) and Latvia (2) in 2016, 2017 and 2019. Boscalid 26.7% + Pyraclostrobin 6.7% WG was included in these trials at 1.5 kg/ha to demonstrate the recommended dose rate as well as two lower doses rate (0.6 kg/ha and 1 kg/ha [160 g Boscalid and 40 g Pyraclostrobin per hectare and 267 g Boscalid and 67 g Pyraclostrobin per hectare respectively, in one application]). In the trials, specifically targeted for this pathogen, the two applications were applied in August for one trial and in November for the other one (BBCH 41-47).

The results obtained with Boscalid 26.7% + Pyraclostrobin 6.7% WG applied for the control of *Alternaria dauci* (ALTEDA) in carrot are presented in Table 3.2-17, Table 3.2-18 and Table 3.2-19 for results obtained in the Maritime EPPO zone (one trial, one excluded because of the extremely low disease pressure) South-East EPPO zone (one trial) and North-East EPPO zone (three trials), respectively.

Table 3.2-17: Minimum effective dose – Maritime zone: Minimum effective dose of Boscalid 26.7% + Pyraclostrobin 6.7% WG against ALTEDA in carrot.

Target: ALTEDA	No. of trials	Mean % Control from 1 trial in the Maritime EPPO Zone at a range of doses of Boscalid 26.7% + Pyraclostrobin 6.7% WG						
		Untreated	0.6 kg/ha		1 kg/ha		1.5 kg/ha	
		Mean % PESSEV	Mean		Mean		Mean	
Carrot								
Mean % control, one observation on Stems per trial, PESSEV at 14 days after appl.	1	41.4	57.6	-	60.1	-	79.5	-

Table 3.2-18: Minimum effective dose – South-east zone: Minimum effective dose of Boscalid 26.7% + Pyraclostrobin 6.7% WG against ALTEDA in carrot.

Target: ALTEDA	No. of trials	Mean % Control from 3 trials in the North-east EPPO Zone at a range of doses of Boscalid 26.7% + Pyraclostrobin 6.7% WG						
		Untreated	0.6 kg/ha		1 kg/ha		1.5 kg/ha	
		Mean % PESSEV	Mean		Mean		Mean	
Carrot								
Mean % control, one observation on Leaves per trial, PESINC at 14 days after appl.	1	98.5	26.7	-	49.2	-	61.9	-
		Mean % PESINC	Mean	Range	Mean	Range	Mean	Range
Mean % control, one observation on Leaves per trial, PESSEV at 14 days after appl.	1	19.1	55.6	-	78.7	-	92.1	-

Table 3.2-9: Minimum effective dose – North-East: Minimum effective dose of Boscalid 26.7% + Pyraclostrobin 6.7% WG against ALTEDA in carrot.

Target: ALTEDA	No. of trials	Mean % Control from 3 trials in the North-east EPPO Zone at a range of doses of Boscalid 26.7% + Pyraclostrobin 6.7% WG						
		Untreated	0.6 kg/ha		1 kg/ha		1.5 kg/ha	
		Mean % PESSEV	Mean		Mean		Mean	
Carrot								
Mean % control, one observation on Leaves per trial, PESINC at 28-43 days after appl.	2	5.7 (5.3-6.0)	54	45.8- 62.2	27.9	12.5- 43.4	4.7	0.0-9.4
		Mean %	Mean	Range	Mean	Range	Mean	Range

		PESINC						
Mean % control, one observation on Leaves per trial, PESSEV at 8-14 days after appl.	3	11.3 (6.3-20.3)	86.8	(82.9- 89.4)	86.8	(76.1- 98.2)	86.9	(70.5-100)

The data from trial proves that the minimum effective dose rate of Boscalid 26.7% + Pyraclostrobin 6.7% WG to control of *Alternaria dauci* in carrot is 1.5 kg/ha, with up to two applications per season. Furthermore, the data demonstrated that if the application rate is reduced below this, a decrease in control as well as in persistence is observed.

Control of *Cercospora carotae* in Carrot.

In support of the proposed dose rates of 1.5 kg/ha Boscalid 26.7% + Pyraclostrobin 6.7% WG [400 g Boscalid and 100 g Pyraclostrobin per hectare, per application] on the claimed crops, results for the control of *Cercospora carotae* (CERCCA) in carrot, of three efficacy trials performed in the North-East EPPO zone (2) and Maritime EPPO zone (1) are reported. The trials were conducted in Latvia (2) and Germany (1) in 2016 and 2019 Boscalid 26.7% + Pyraclostrobin 6.7% WG was included in these trials at 1.5 kg/ha to demonstrate the recommended dose rate as well as two lower doses rate (0.6 kg/ha and 1 kg/ha [160 g Boscalid and 40 g Pyraclostrobin per hectare and 267 g Boscalid and 67 g Pyraclostrobin per hectare respectively, in one application]). In the trials, specifically targeted for this pathogen, the two applications were applied in August for one trial and in November for the other one (BBCH 43-47).

The results obtained with Boscalid 26.7% + Pyraclostrobin 6.7% WG applied for the control of *Cercospora carotae* (CERCCA) in carrot are presented in Table 3.2-20 and Table 3.2-21 for results obtained in the Maritime EPPO zone (one trial) and the North-East EPPO zone (two trials).

Table 3.2-20: Minimum effective dose – Maritime: Minimum effective dose of Boscalid 26.7% + Pyraclostrobin 6.7% WG against CERCCA in carrot.

Mean % Control from 1 trials in the Maritime EPPO Zone at a range of doses of Boscalid 26.7% + Pyraclostrobin 6.7% WG								
Target: CERCCA	No. of trials	Untreated	0.6 kg/ha		1 kg/ha		1.5 kg/ha	
		Mean % PESSEV	Mean		Mean		Mean	
Carrot								
Mean % control, one observation on Stems per trial, PESINC at 28 - 21days after appl.	1	20.0	25.0	-	25.0	-	50.0	-
Mean % control, one observation on Stems per trial, PESSEV at days after appl.	1	18.8	46.7	-	46.7	-	60.0	-

Table 3.2-21: Minimum effective dose – North-East: Minimum effective dose of Boscalid 26.7% + Pyraclostrobin 6.7% WG against CERCCA in carrot.

Mean % Control from 1 trials in the Maritime EPPO Zone at a range of doses of Boscalid 26.7% + Pyraclostrobin 6.7% WG								
Target: CERCCA	No. of trials	Untreated	0.6 kg/ha		1 kg/ha		1.5 kg/ha	
		Mean % PESSEV	Mean		Mean		Mean	
Carrot								
Mean % control, one observation on Stems per trial, PESINC at 28 - 21days after appl.	2	19.6	76.5	71.9-81.1	90.3	84.5-96.2	86.7	97.6-75.7
Mean % control, one observation on Stems per trial, PESSEV at days after appl.	1	31.1	10.8	-	7.8	-	8.2	-

The data from trial proves that the minimum effective dose rate of Boscalid 26.7% + Pyraclostrobin 6.7% WG to control of *Cercospora carotae* in carrot is 1.5 kg/ha, with up to two applications per season. Fur-

thermore, the data demonstrated that if the application rate is reduced below this, a decrease in control as well as in persistence is observed.

Control of *Puccinia allii* in Onion

To prove and to support the proposed dose rates of 1.5 kg/ha Boscalid 26.7% + Pyraclostrobin 6.7% WG [400 g Boscalid and 100 g Pyraclostrobin per hectare, per application] for the control of *Puccinia allii* (PUCCAL) in onion, the assessment results of 7 efficacy trials performed in the Maritime EPPO zone (2) and the Mediterranean EPPO zone (5) are reported. The trials were conducted in France (2), Germany (1), Greece (1), Italy (2) and Spain (1) in 2016 and 2019. Boscalid 26.7% + Pyraclostrobin 6.7% WG was included in these trials at 1.5 kg/ha to demonstrate the recommended dose rate as well as two lower dose rates (0.6 kg/ha and 1 kg/ha [160 g Boscalid and 40 g Pyraclostrobin per hectare and 267 g Boscalid and 67 g Pyraclostrobin per hectare respectively, in one application]). In the trial, specifically targeted for this pathogen, the two applications were applied in from February to August at growth stage BBCH 15-45 in the first application, at the BBCH 41-47 in the second application.

The results obtained with Boscalid 26.7% + Pyraclostrobin 6.7% WG applied for the control of *Puccinia allii* (PUCCAL) in onion are presented in Table 3.2-22 and Table 3.2-23 for results obtained in the Maritime EPPO zone (one trial, two trials excluded because of no target disease or extremely low pressure) and the Mediterranean EPPO zone (five trials), respectively. No results are reported for the South-east EPPO zone because of no target pest in the trial.

Table 3.2-22: Minimum effective dose – Mediterranean zone: Minimum effective dose of Boscalid 26.7% + Pyraclostrobin 6.7% WG against PUCCAL in onion

Target: PUCCAL	No. of trials	Mean % Control from 5 trials in the Mediterranean EPPO Zone at a range of doses of Boscalid 26.7% + Pyraclostrobin 6.7% WG						
		Untreated	0.6 kg/ha		1 kg/ha		1.5 kg/ha	
		Mean % PESSEV (range)	Mean	Range	Mean	Range	Mean	Range
Onion								
Mean % control, one observation on Leaves per trial, PESSEV at 12-14 days after appl.	5	16.3 (7.9-20.7)	64.7	(20.09-80.5)	70.8	(24.3-100.0)	75.2	(32.1-84.8)
		Mean % PESINC	Mean	Range	Mean	Range	Mean	Range
Mean % control, one observation on Leaves per trial, PESINC at 12-14 days after appl.	2	44.8 (41.9-47.8)	68.9	(68.7-69.0)	72.3	(72.2-72.5)	76.3	(76.1-76.5)

Table 3.2-23: Minimum effective dose – Maritime zone: Minimum effective dose of Boscalid 26.7% + Pyraclostrobin 6.7% WG against PUCCAL in onion

Target: PUCCAL	No. of trials	Mean % Control from 1 trial in the Maritime EPPO Zone at a range of doses of Boscalid 26.7% + Pyraclostrobin 6.7% WG			
		Untreated	0.6 kg/ha	1 kg/ha	1.5 kg/ha
		Mean % PESSEV (range)	Mean	Mean	Mean
Onion					
Mean % control, one observation on Leaves per trial, PESSEV at 12-14 days after appl.	2	25.6	37.9	36.4	41.6

The data from the different EPPO zones proves that the minimum effective dose rate of Boscalid 26.7% + Pyraclostrobin 6.7% WG to control *Puccinia allii*, in onion it is 1.5 kg / ha, with up to three applications by season. In addition, the data showed that if the application rate is reduced below this, a decrease in control as well as persistence is observed.

Summary and conclusions on the minimum effective dose

In summary, reducing the application rate from the proposed dose rates of 1.5 kg/ha to 40% or 67% of that rate, showed a decrease in the efficacy against *Cercospora beticola* (CERCBE) in sugarbeet, *Phytophthora infestans* (PHYTIN) and *Alternaria* sp.(ALTESP) in tomato, *Septoria apiicola* (SEPTAP), *Cercospora* sp.(CERCSP) and *Alternaria* sp. (ALTESP) in Carrot and *Puccinia allii* (PUCCAL) in onion.

According to the presented results, the dose of 1.5 kg/ha of Boscalid 26.7% + Pyraclostrobin 6.7% WG provided the optimum overall control and should be considered as effective against the diseases, for which activity Boscalid 26.7% + Pyraclostrobin 6.7% WG is claimed. A control may be obtained with lower than recommended dose rates, if treating susceptible disease under optimal conditions (pre-infection/low infestation and good weather conditions), but as diseases often occur as complexes of several pathogens throughout a season, two or three applications of Boscalid 26.7% + Pyraclostrobin 6.7% WG at 1.5 kg/ha per application should be used to efficiently control all pathogens claimed on the label's crops.

A strong dataset was presented to demonstrate the efficiency of the tested product in a wide range of crops and target diseases. Therefore, for any label claims not adequately supported for one crop type, the applicant requests that the evaluators reads across to the data on the other crop types.

This BAD clearly demonstrates – as will be demonstrated in the following section – that the efficacy and crop safety of Boscalid 26.7% + Pyraclostrobin 6.7% WG is equivalent to that of the standard boscalid and pyraclostrobin reference product to which it was compared. Therefore, the applicant wishes to cite the original registrant's data on boscalid and pyraclostrobin now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Comments of zRMS:	<p>In order to provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least one lower dose(s) (for example 60–80% of the recommended dose) to that which would be recommended. It is utilized to achieve the desired effect.</p> <p>During field tests Applicant used different doses of tested fungicide: 0,6 kg/ha (0,4 N); 1,0 kg/ha (0,67N) and 1,5 kg/ha (N-recommended). So, in the appropriate researches of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance to EPPO 1/225 (2). All of the trials submitted followed the appropriate EPPO standard and were conducted in accordance with GEP. Appropriate evidence and certificates of GEP have been provided for the organisations that conducted the trials. The appropriate reference products were used.</p> <p>According to the presented results, the dose of 1.5 kg/ha of Boscalid 26.7% + Pyraclostrobin 6.7% WG provided the optimum overall control and should be considered as effective against the diseases, for which activity Boscalid 26.7% + Pyraclostrobin 6.7% WG is claimed.</p> <p>Also, the applicant wishes to cite the original registrant's data on boscalid and pyraclostrobin now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data. Decision about extrapolation those results is left to each CMS.</p>
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3.2.3 Efficacy tests (KCP 6.2)

Efficacy data are presented from 47 efficacy trials where the level of infestation was sufficient high for the trial to be claimed valid, to support the label claims and recommendations on efficacy and selectivity in the EU Central Registration zone. The trials were carried out in 2016, 2017 and 2019 in the the Maritime EPPO zone (i.e. France (7), Germany (5) and the United Kingdom (1)), the North-East EPPO zone (i.e. Latvia (4) and Poland (10)), the South-east EPPO zone (i.e. Hungary (6)) and Mediterranean EPPO

zone (i.e. Italy (7), Greece (2) and Spain (5)). Efficacy was assessed on *Cercospora beticola* (CERCBE), *Phytophthora infestans*. (PHYTIN), *Alternaria* spp. (ALTESP), *Puccinia allii* (PUCCAL), and *Alternaria dauci* (ALTEDA). Data from each zone has been summarized separately.

In the trials used to assess the level of control obtained with Boscalid 26.7% + Pyraclostrobin 6.7% WG, a different number of assessments were conducted during the course of the trial. In some trials, a single assessment was conducted on the specific plant part and in others, two or more assessments were conducted. Therefore, not to bias the data from any trial with more than one assessment, the summary tables contain the data from one assessment per plant part per trial. An assessment is only considered valid for evaluation if the level of pest severity (PESSEV) is minimum 5% in the untreated check or if pest incidence (PESINC) is minimum 5% in the untreated check. The data selected from each trial is either the final assessment timing on each plant part or the assessment after the last of the max recommended number of applications.

In the efficacy trials, the performance of Boscalid 26.7% + Pyraclostrobin 6.7% WG was measured against a commercial standard formulation currently on the market in Central Europe (Signum; Boscalid 26.7% + Pyraclostrobin 6.7% WG). . Since Signum is not registered in all Central zone countries for these uses and additional formulation (Askor, Ortiva Top, Amistar Top, Azoxystrobin 20% + Difenconazole 12.5%SC) has been included to give support for those countries. The trials were carried out on sugarbeet, tomato, carrot and onion.

Table 3.2-10: Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/152 (4), PP 1/181 (4), PP 1/135(4)
	Specific guidelines	EPPO PP PP 1/1(4), PP 1/2(4), PP 1/057(3), 1/120(2) PP 1/214(3), PP 1/225/(2), PP 1 /239(2), PP 1/241(2), PP 1/271(2), PP 1/278(1), PP 1/65(3), PP 1/121(2), PP 1/124(2), PP 1/263(1), PP 1/137(2), PP 1/124(1), PP 1/226(2), CEB M221
Experimental design	Plot design	RCBD (4)
	Plot size	2.5 - 36 m ²
	Number of replications	4
Crop	Trials per crop	sugarbeet (19), tomato (13), onion (7), carrot (8)
	Varieties per crop	Sugarbeet: Altares, Bison, Contenta, Dragon, FD Schelem, Hannibal, Harmonia, Jadeit, Lavenda, Polanin, Rainette, Sanlúcar, Shubert, Springbok, Tapir, Telimena Tomato: Guarapo, Patriarca, Vulcan F1, Benito F1, Defender F1, Hoffmanns, Impact F1, Rallijs, Stratos F1, Sultan F1, Tolstoj Onion: Dalila, Hamasodachi 950, Nevada, Vares, White Lisbon Carrot: Rote Riesen 2, Laguna F1, Maestro, Nates Forto, Nerac, Volcano

	Sowing period	<p>Sugarbeet:</p> <ul style="list-style-type: none"> • 20/11/2015 • 20/02/2016-15/04/2016 • 31/03/2017-15/04/2017 • 26/03/2019 <p>Tomato:</p> <ul style="list-style-type: none"> • 04/05/2016-07/06/2016 • 16/05/2019 <p>Onion:</p> <ul style="list-style-type: none"> • 20/10/2015 • 17/02/2016-20/04/2016 • 27/02/2019 <p>Carrot:</p> <ul style="list-style-type: none"> • 25/04/2016-09/05/2016 • 16/05/2017 • 26/04/2019-29/05/2019
Application	Crop stage (BBCH)* at application	<p>Sugarbeet; 1. Appl BBCH 31-49 Sugarbeet; 2 Appl BBCH 33-49 Tomato; 1 Appl BBCH 17-85 Tomato; 2 Appl BBCH 25-86 Tomator 3 Appl BBCH 52-87 Onion; 1 Appl BBCH 15-47 Onion; 2 Appl BBCH 16-47 Carrot; 1 Appl BBCH 41-45 Carrot; 2 Appl BBCH 42-47</p>
	Timing Pest stage at appl. (1)	Please refer to detailed summary tables in Appenix 5.
	Spray volumes	<p>Sugarbeet: 150-1000 L/ha (19 trials) Tomato: 200-1400 L/ha (13 trials) Carrot: 250-600 L/ha (8 trials) Onion: 150-1000 L/ha (7 trials)</p>
Assessment	Assessment types	<p>- Visual estimation of Pest severity, compared to 'untreated' ('untreated' = 0 % control); total control = 100 % control) – based on the assessment of attacked plant area, as compared to the untreated check.</p> <p>- Visual estimation of Pest incidence, compared to 'untreated' ('untreated' = 0 % control); total control = 100 % control) – based on the percentage of attacked plants or plant parts on a sample of a defined number of plants/plant parts per plot, as compared to the untreated check.</p> <p>- Visual estimation of crop injury and crop stand reduction (thinning) compared to 'untreated' ('untreated' = 0% crop injury; 100% crop injury = total crop destruction). Where appropriate this overall score was substituted or supplemented by assessments of individual symptoms.</p>
	Assessment dates	Between one and six weeks
Other relevant information	Soil type	Light to heavy soils
	Natural / artificial inoculation...	Natural
	Field / Greenhouse...	Field

Control of *Cercospora beticola* in Sugarbeet

Crop	Sugarbeet
Use rate	1.5 kg/ha Boscalid 26.7% + Pyraclostrobin 6.7% WG
Use frequency	2 (8-10 days interval)
Application timing	BBCH 31-39
Target disease	<i>Cercospora beticola</i>

In the trials, Boscalid 26.7% + Pyraclostrobin 6.7% WG was tested alongside EU approved boscalid + pyraclostrobin formulation, i.e. Signum (Boscalid 26.7% + Pyraclostrobin 6.7% WG) and azoxystrobin + difenoconazole, i.e. Askor, Ortiva top, Amistar top (Azoxystrobin 20% + Difenconazole 12.5%SC)...

Table 3.2-21: Effective dose - Maritime zone: Mean efficacy of Boscalid 26.7% + Pyraclostrobin 6.7% WG and boscalid + pyraclostrobin reference products and azoxystrobin + difenoconazole reference products against CERCBE (18-40 days after application; mean and variation in % control as compared to untreated check)

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with			No. of trials where Boscalid 26.7% + Pyraclostrobin 6.7% WG at 400 and 100 g ai/ha is >, < or =, compared to the boscalid Ref. product at 400 and 100 g ai/ha and azoxystrobin + difenoconazole Ref. product at 200 and 125 g ai/ha = : ± 5% control			
				Boscalid 26.7% + Pyraclostrobin 6.7% WG	Boscalid + Pyraclostrobin WG ref. prod. at	Azoxystrobin + difenoconazole ref. prod. at				Overall
				Mean (min-max)						
				400 and 100 g ai/ha	400 and 100 g ai/ha	200 and 125 g ai/ha	>	=	<	
Pest severity CERCBE				PESSEV						

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with			No. of trials where Boscalid 26.7% + Pyraclostrobin 6.7% WG at 400 and 100 g ai/ha is >, < or =, compared to the boscalid Ref. product at 400 and 100 g ai/ha and azoxystrobin + difenoconazole Ref. product at 200 and 125 g ai/ha = : ± 5% control			Overall		
				Boscalid 26.7% + Pyraclostrobin 6.7% WG	Boscalid + Pyraclostrobin WG ref. prod. at	Azoxystrobin + difenoconazole ref. prod. at						
				Mean (min-max)								
				400 and 100 g ai/ha	400 and 100 g ai/ha	200 and 125 g ai/ha	>	=	<			
Leaves	15-40 DAT	6	21.6 (9.5-33.8)	45.1 (8.2-88.8)	36.4 (6.0-98.3)	59.3 (15.7-92.9)	1	0	5	<		
Pest severity RAMUBE				PESSEV								
Leaves	40 DAT	1	5.6	61.9	63.3	55.7	0	1	0	=		

Table 3.2-22: Effective dose – North-East zone: Mean efficacy of Boscalid 26.7% + Pyraclostrobin 6.7% WG and boscalid + pyraclostrobin reference products against CERCBE (39-49 days after application; mean and variation in % control as compared to untreated check)

Part assessed	Days after Treat ment.	No. x (DAT	No. of trials	Mean infestation level (%)	Efficacy obtained with			No. of trials where Boscalid 26.7% + Pyraclostrobin 6.7% WG at 400 and 100 g ai/ha is >, < or =, compared to the boscalid Ref. product at 400 and 100 g ai/ha and azoxystrobin + difenoconazole Ref- product at 200 and 125 g ai/ha = : ± 5% control			Overall		
					Boscalid 26.7% + Pyraclostrobin 6.7% WG	Boscalid + Pyraclostrobin WG ref. prod. at	Azoxystrobin + difenoconazole ref. prod. at						
					Mean (min-max)								
					400 and 100 g ai/ha	400 and 100 g ai/ha	200 and 125 g ai/ha	>	=	<			
Pest severity CERCBE				PESSEV									
Leaves	16-49	7	29.1	69.1 (60.9-88.0)	64.4 (55.8-81.0)	63.6 (51.7-92.5)	5	2		>			

Table 3.2-23: Effective dose – South-East zone: Mean efficacy of Boscalid 26.7% + Pyraclostrobin 6.7% WG and boscalid + pyraclostrobin reference products and azoxystrobin + difenoconazole reference products against CERCBE (11-13 days after application; mean and variation in % control as compared to untreated check)

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with			No. of trials where Boscalid 26.7% + Pyraclostrobin 6.7%WG at 400 and 100 g ai/ha is >, < or =, compared to the boscalid Ref. product at 400 and 100 g ai/ha and azoxystrobin + difenoconazole Ref- product at 200 and 125 g ai/ha = : ± 5% control			Overall		
				Boscalid 26.7% + Pyraclostrobin 6.7% WG	Boscalid + Pyraclostrobin WG ref. prod. at	Azoxystrobin + difenoconazole ref. prod. at						
				Mean (min-max)								
				400 and 100 g ai/ha	400 and 100 g ai/ha	200 and 125 g ai/ha	>	=	<			
Pest severity				PESSEV								
Leaves	11-13 DAT2	2	10.3 (10.1-10.6)	76.4 (63.7-89.2)	74.4 (64.5-84.2)	71.7 (59.5-83.9)		2	0	=		
Pest incidence				PESINC								
Leaves	13 DAT2	2	68.0	76.9	72.3	60.4	0	1	0	=		

Table 3.2-24: Effective dose - Mediterranean zone: Mean efficacy of Boscalid 26.7% + Pyraclostrobin 6.7% WG and boscalid + pyraclostrobin reference products and azoxystrobin + difenoconazole reference products against CERCBE (40-45 days after application; mean and variation in % control as compared to untreated check)

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with			No. of trials where Boscalid 26.7% + Pyraclostrobin 6.7% WG at 400 and 100 g ai/ha is >, < or =, compared to the boscalid Ref. product at 400 and 100 g ai/ha and azoxystrobin + difenoconazole Ref- product at 200 and 125 g ai/ha = : ± 5% control			Overall
				Boscalid 26.7% + Pyraclostrobin 6.7% WG	Boscalid + Pyraclostrobin WG ref. prod. at	Azoxystrobin + difenoconazole ref. prod. at				
				Mean (min-max)						
				400 and 100 g ai/ha	400 and 100 g ai/ha	200 and 125 g ai/ha	>	=	<	
Pest severity				PESSEV						
Leaves	40-45 DAT2	3	17.0 (9.4-23.9)	73.4 (63.4-79.8)	74.9 (68.2-79.1)	80.3 (75.1-86.3)	0	2	1	=
Pest incidence				PESINC						
Leaves	40 DAT2	1	68.4	76.1	76.5	78.8	0	1	0	=

Control of *Phytophthora infestans* in Tomato.

The efficacy trials were conducted to prove the following label claims:

Crop	Tomato
Use rate	1.5 kg/ha Boscalid 26.7% + Pyraclostrobin 6.7% WG
Use frequency	2 (8-10 days interval)
Application timing	BBCH 20-87 (when first symptoms are visible)
Target disease	<i>Phytophthora infestans</i>

The effectiveness of applying Boscalid 26.7% + Pyraclostrobin 6.7% WG against *Phytophthora infestans* was evaluated in 6 tomato trials, assessed for pest severity and pest incidence. These trials were carried out in 2016, 2019 in the Maritime EPPO zone (i.e. Germany (1)) in the Mediterranean EPPO zone (i.e. Italy (2)), in the South-east EPPO zone (i.e. Hungary (3)). The objective was to confirm the performance of Boscalid 26.7% + Pyraclostrobin 6.7% WG at 1.5 kg/ha (i.e. 400 g Boscalid and 100 g Pyraclostrobin per hectare, per application). In the trials specifically targeted for this pathogen, two application were applied, from June to August the first application (BBCH 17-71) and from July to August the second application (BBCH 25-81).

In the trials, Boscalid 26.7% + Pyraclostrobin 6.7% WG was tested alongside EU approved boscalid + pyraclostrobin formulation, i.e. Signum (Boscalid 26.7% + Pyraclostrobin 6.7% WG) and azoxystrobin + difenoconazole, i.e. Askor, Ortiva top, Amistar top (Azoxystrobin 20% + Difenoconazole 12.5%SC).

The results obtained with Boscalid 26.7% + Pyraclostrobin 6.7% WG applied for the control of *Phytophthora infestans* in tomato are presented in Table 3.2.-25, Table 3.2-26 and Table 3.2-27 for results obtained in the the Maritime EPPO zone (one trial), the the Maritime EPPO zone (three trials) and the Mediterranean EPPO zone (two trial), respectively.

Table 3.2-25: Effective dose Maritime zone: Mean efficacy of Boscalid 26.7% + Pyraclostrobin 6.7% WG and boscalid + pyraclostrobin reference products and azoxystrobin + difenoconazole reference products against PHYTIN (6 days after application; mean and variation in % control as compared to untreated check)

Part	Days after	No.	Mean	Efficacy obtained with	No. of trials where
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assessed	Treatment. No. x (DATx)	of trials	infestation level (%)	Boscalid 26.7% + Pyraclostrobin 6.7% WG	Boscalid + Pyraclostrobin WG ref. prod. at	Azoxystrobin + difenoconazole ref. prod. at	Boscalid 26.7% + Pyraclostrobin 6.7% WG at 400 and 100 g ai/ha is >, < or =, compared to the boscalid Ref. product at 400 and 100 g ai/ha and azoxystrobin + difenoconazole Ref- product at 200 and 125 g ai/ha = : ± 5% control			Overall
				Mean (min-max)						
				400 and 100 g ai/ha	400 and 100 g ai/ha	200 and 125 g ai/ha	>	=	<	
Pest severity PHYTIN PESSEV										
Leaves	6 DAT	1	85.0	26.5	14.7	30.9	1	1	0	>

Table 3.2-26: Effective dose Mediterranean zone: Mean efficacy of Boscalid 26.7% + Pyraclostrobin 6.7% WG and boscalid + pyraclostrobin reference products and azoxystrobin + difenoconazole reference products against PHYTIN (20 days after application; mean and variation in % control as compared to untreated check)

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with			No. of trials where Boscalid 26.7% + Pyraclostrobin 6.7% WG at 400 and 100 g ai/ha is >, < or =, compared to the boscalid Ref. product at 400 and 100 g ai/ha and azoxystrobin + difenoconazole Ref- product at 200 and 125 g ai/ha = : ± 5% control			Overall
				Boscalid 26.7% + Pyraclostrobin 6.7% WG	Boscalid + Pyraclostrobin WG ref. prod. at	Azoxystrobin + difenoconazole ref. prod. at				
				Mean (min-max)						
				400 and 100 g ai/ha	400 and 100 g ai/ha	200 and 125 g ai/ha	>	=	<	
Pest severity PESSEV										
Leaves	20 DAT2	2	12.1 (11.5-12.6)	78.4 (77.8-78.2)	78.5 (78.2-78.8)	80.9 (80.8-81.1)	0	2	0	=
Pest incidence PESINC										
Leaves	20 DAT2	2	57.6 (55.0-60.2)	77.1 (77.1-79.0)	77.6 (77.2-77.9)	79.8 (79.3-80.3)	0	2	0	=

Table 3.2-27: Effective dose South-east zone: Mean efficacy of Boscalid 26.7% + Pyraclostrobin 6.7% WG and boscalid + pyraclostrobin reference products and azoxystrobin reference products against PHYTIN (14-21 days after application; mean and variation in % control as compared to untreated check)

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with			No. of trials where Boscalid 26.7% + Pyraclostrobin 6.7% WG at 400 and 100 g ai/ha is >, < or =, compared to the azoxystrobin Ref- product at 250 g ai/ha and 188 g ai/ha = : ± 5% control			
				Boscalid 26.7% + Pyraclostrobin 6.7% WG	Azoxystrobin ref. prod. at 0.75 L/ha	Azoxystrobin ref. prod. at 1 L/ha				Overall
				Mean (min-max)						
				400 and 100 g ai/ha	400 and 100 g ai/ha	200 and 125 g ai/ha	>	=	<	
Pest severity				PESSEV						
Leaves	14-21 DAT2	3	13.7 (9.0-16.1)	90.4 (90.0-90.7)	57.2 (53.2-64.1)	72.6 (60.9-78.6)	3	0	0	=
Pest incidence				PESINC						
Leaves	14-21 DAT2	3	-	90.5 (89.9-91.1)	56.7 (52.7-64.0)	72.2 (60.4-78.3)	3	0	0	=

Control of *Alternaria* spp. in Tomato

The efficacy trials were conducted to prove the following label claims:

Crop	Tomato
Use rate	1.5 kg/ha Boscalid 26.7% + Pyraclostrobin 6.7% WG
Use frequency	3 (8-10 days interval)
Application timing	BBCH 20-87 (when first symptoms are visible)
Target disease	<i>Alternaria</i> sp.

The effectiveness of applying Boscalid 26.7% + Pyraclostrobin 6.7% WG against *Alternaria* sp. was evaluated in seven tomato trials, assessed for pest severity and pest incidence. These trials were carried out in 2016 in the North-East EPPO zone (i.e. Poland (2)) and in the Mediterranean EPPO zone (i.e. Italy (2), Spain (2) and Greece (1)). The objective was to confirm the performance of Boscalid 26.7% + Pyraclostrobin 6.7% WG at 1.5 kg/ha (i.e. 400 g Boscalid and 100 g Pyraclostrobin per hectare, per application). In the trials specifically targeted for this pathogen, three applications were applied from June to November and in growth stages ranging from BBCH 21 to BBCH 85 in the first application, from BBCH 28 to BBCH 86 in the second application and from BBCH 52 to BBCH 87 in the third application.

In the trials, Boscalid 26.7% + Pyraclostrobin 6.7% WG was tested alongside EU approved boscalid + pyraclostrobin formulation, i.e. Signum (Boscalid 26.7% + Pyraclostrobin 6.7% WG) and azoxystrobin + difenoconazole, i.e. Askor, Ortiva top, Amistar top (Azoxystrobin 20% + Difenoconazole 12.5%SC).

The results obtained with Boscalid 26.7% + Pyraclostrobin 6.7% WG applied for the control of *Alternaria* sp. in tomato are presented in the Table 3.2-28 and Table 3.2-29 for results obtained in the North-East EPPO zone (two trials) and Mediterranean EPPO zone (five trials), , respectively.

Table 3.2-28: Effective dose North-East zone: Mean efficacy of Boscalid 26.7% + Pyraclostrobin 6.7% WG and boscalid + pyraclostrobin reference products and azoxystrobin + difenoconazole reference products against ALTESP and ALTESO (10 days after application; mean and variation in % control as compared to untreated check).

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Boscalid 26.7% + Pyraclostrobin 6.7%WG at 400 and 100 g ai/ha is >, < or =, compared to the boscalid Ref. product at 400 and 100 g ai/ha = : ± 5% control			Overall
				Boscalid 26.7% + Pyraclostrobin 6.7% WG	Boscalid + Pyraclostrobin WG ref. prod. at				
				Mean (min-max)					
				400 and 100 g ai/ha	400 and 100 g ai/ha	>	=	<	
Pest incidence									
PESINC									
Leaves	10 DAT3	2	51.8 (18.5-21.8)	75.3 (88.5-62.2)	68.0 (48.6-87.4)			2	<

Table 3.2-29: Effective dose Mediterranean zone: Mean efficacy of Boscalid 26.7% + Pyraclostrobin 6.7% WG and boscalid + pyraclostrobin reference products and azoxystrobin + difenoconazole reference products against ALTESP and ALTESO (7-30 days after application; mean and variation in % control as compared to untreated check).

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with			No. of trials where Boscalid 26.7% + Pyraclostrobin 6.7% WG at 400 and 100 g ai/ha is >, < or =, compared to the boscalid Ref. product at 400 and 100 g ai/ha and azoxystrobin + difenoconazole Ref- product at 200 and 125 g ai/ha = : ± 5% control			Overall
				Boscalid 26.7% + Pyraclostrobin 6.7% WG	Boscalid + Pyraclostrobin WG ref. prod. at	Azoxystrobin + difenoconazole ref. prod. at				
				Mean (min-max)			>	=	<	
				400 and 100 g ai/ha	400 and 100 g ai/ha	200 and 125 g ai/ha				
Pest severity PESSEV										
Leaves	7-30	5	35.2	73.5	72.0		1	4	0	=

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with			No. of trials where Boscalid 26.7% + Pyraclostrobin 6.7% WG at 400 and 100 g ai/ha is >, < or =, compared to the boscalid Ref. product at 400 and 100 g ai/ha and azoxystrobin + difenoconazole Ref- product at 200 and 125 g ai/ha = : ± 5% control			Overall
				Boscalid 26.7% + Pyraclostrobin 6.7% WG	Boscalid + Pyraclostrobin WG ref. prod. at	Azoxystrobin + difenoconazole ref. prod. at				
				Mean (min-max)			>	=	<	
				400 and 100 g ai/ha	400 and 100 g ai/ha	200 and 125 g ai/ha				
	DAT2		(17.0-57.7)	(47.4-84.8)	(50.0-87.3)	74.7 (57.4-84.6)				
Pest incidence PESINC										
Leaves	10 DAT2	2	52.1 (45.0-59.2)	79.7 (79.7-79.8)	80.1 (79.9-80.3)	82.6 (82.1-83.1)	0	2	0	=

Control of *Alternaria dauci* in Carrot

Crop	Carrot
Use rate	1.5 kg/ha Boscalid 26.7% + Pyraclostrobin 6.7% WG
Use frequency	2 (8-10 days interval)
Application timing	BBCH 41-49 (when first symptoms are visible)
Target disease	<i>Alternaria</i> sp

The effectiveness of applying Boscalid 26.7% + Pyraclostrobin 6.7% WG against *Alternaria* sp. was evaluated in 5 carrot trials, assessed for pest severity and pest incidence. These trials were carried out in 2016, 2017, 2019 in the Maritime EPPO zone (i.e. Germany (1)), in the South-east EPPO zone (i.e. Hungary (1)) and in the North-East EPPO zone (i.e. Poland (1) and Latvia (2)). The objective was to confirm the performance of Boscalid 26.7% + Pyraclostrobin 6.7% WG at 1.5 kg/ha (i.e. 400 g Boscalid and 100 g Pyraclostrobin per hectare, per application). In the trials specifically targeted for this pathogen, two applications were applied from July to October and in growth stages ranging from BBCH 41 to BBCH 45 in the first application and from BBCH 42 to BBCH 47 in the second application.

In the trials, Boscalid 26.7% + Pyraclostrobin 6.7% WG was tested alongside EU approved boscalid + pyraclostrobin formulation, i.e. Signum (Boscalid 26.7% + Pyraclostrobin 6.7% WG) and azoxystrobin + difenoconazole, i.e. Askor (Azoxystrobin 20% + Difenoconazole 12.5%SC).

The results obtained with Boscalid 26.7% + Pyraclostrobin 6.7% WG applied for the control of *Alternaria dauci* (ALTEDA) in carrot are presented in Table 3.2-30, Table 3.2-31 and Table 3.2.-32 for results obtained in the Maritime EPPO zone (one trial), South-East EPPO zone (one trial) and North-East EPPO zone (three trial), respectively.

Table 3.2-30: Effective dose Maritime zone: Mean efficacy of Boscalid 26.7% + Pyraclostrobin 6.7% WG and boscalid + pyraclostrobin reference products and azoxystrobin + difenoconazole reference products against ALTEDA (14 days after application; mean and variation in % control as compared to untreated check).

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with			No. of trials where Boscalid 26.7% + Pyraclostrobin 6.7% WG at 400 and 100 g ai/ha is >, < or =, compared to the boscalid+ pyraclostrobin and azoxystrobin + difenoconazole Ref. product at 400 and 100 g ai/ha = : ± 5% control			Overall
				Boscalid 26.7% + Pyraclostrobin 6.7% WG	Boscalid + Pyraclostrobin WG ref. prod. at	Azoxystrobin + difenoconazole SC ref. prod at				
				Mean (min-max)			>	=	<	
				400 and 100 g ai/ha	400 and 100 g ai/ha	200 and 125 g ai/ha				
Pest incidence PESINC										
Leaves	14 DAT2	1	41.4	79.5	78.8	84.3		1		1

Table 3.2-31: Effective dose South-East: Mean efficacy of Boscalid 26.7% + Pyraclostrobin 6.7% WG and boscalid + pyraclostrobin reference products against ALTEDA (14 days after application; mean and variation in % control as compared to untreated check).

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with			No. of trials where Boscalid 26.7% + Pyraclostrobin 6.7% WG at 400 and 100 g ai/ha is >, < or =, compared to the boscalid+ pyraclostrobin Ref. product at 400 and 100 g ai/ha and azoxystrobin Ref. product at 250 g ai/ha = : ± 5% control			Overall
				Boscalid 26.7% + Pyraclostrobin 6.7% WG	Boscalid + Pyraclostrobin WG ref. prod. at 1Kg/ha	Boscalid + Pyraclostrobin WG ref. prod. at 0.6 Kg/ha				
				Mean (min-max)						
				400 and 100 g ai/ha	400 and 100 g ai/ha	200 and 125 g ai/ha	>	=	<	
Pest incidence				PESSEV						
Leaves	14 DAT2	1	19.1	92.1	60.6	81.5	1			1

Table 3.2-32: Effective dose North-East: Mean efficacy of Boscalid 26.7% + Pyraclostrobin 6.7% WG and boscalid + pyraclostrobin reference products and azoxystrobin + difenoconazole reference products against ALTEDA (14-43 days after application; mean and variation in % control as compared to untreated check).

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Boscalid 26.7% + Pyraclostrobin 6.7%WG at 400 and 100 g ai/ha is >, < or =, compared to the boscalid Ref. product at 400 and 100 g ai/ha = : ± 5% control			Overall
				Boscalid 26.7% + Pyraclostrobin 6.7% WG	Boscalid + Pyraclostrobin WG ref. prod. at				
				Mean (min-max)					
				400 and 100 g ai/ha	400 and 100 g ai/ha	>	=	<	
Pest incidence				PESINC					
Leaves	8-14 DAT2	2	5.6	4.7	11.5		2		=
Pest severity				PESSEV					
Leaves	28-43 DAT2	3	11.3	86.9	84.3		3		=

Control of *Cercospora carotae* in Carrot

Crop	Carrot
Use rate	1.5 kg/ha Boscalid 26.7% + Pyraclostrobin 6.7% WG
Use frequency	2 (8-10 days interval)
Application timing	BBCH 41-49 (when first symptoms are visible)
Target disease	<i>Cercospora carotae</i>

The effectiveness of applying Boscalid 26.7% + Pyraclostrobin 6.7% WG against *Cercospora carotae* was evaluated in 3 carrot trials, assessed for pest severity and pest incidence. These trials were carried out in 2016, 2019 in the Maritime EPPO zone (i.e. Germany (1)) and in the North-East EPPO zone (i.e. Latvia (2)). The objective was to confirm the performance of Boscalid 26.7% + Pyraclostrobin 6.7% WG at 1.5 kg/ha (i.e. 400 g Boscalid and 100 g Pyraclostrobin per hectare, per application). In the trials specifically targeted for this pathogen, two applications were applied from July to October and in growth stages ranging from BBCH 42 to BBCH 45 in the first application and from BBCH 42 to BBCH 47 in the second application.

In the trials, Boscalid 26.7% + Pyraclostrobin 6.7% WG was tested alongside EU approved boscalid + pyraclostrobin formulation, i.e. Signum (Boscalid 26.7% + Pyraclostrobin 6.7% WG).

The results obtained with Boscalid 26.7% + Pyraclostrobin 6.7% WG applied for the control of *Cercospora carotae* (CERCCA) in carrot are presented in Table 3.2-33 and Table 3.2-34 for results obtained in the North-East EPPO Zone. No results are reported for Maritime EPPO zone because of the extremely low disease pressure.

Table 3.2-33: Effective dose Maritime: Mean efficacy of Boscalid 26.7% + Pyraclostrobin 6.7% WG and boscalid + pyraclostrobin and azoxystrobin reference products against CERCCA (13 days after application; mean and variation in % control as compared to untreated check).

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with			No. of trials where Boscalid 26.7% + Pyraclostrobin 6.7% WG at 400 and 100 g ai/ha is >, < or =, compared to the boscalid+ pyraclostrobin Ref. product at 400 and 100 g ai/ha and azoxystrobin Ref. product at 250 g ai/ha = : ± 5% control			Overall
				Boscalid + Pyraclostrobin WG at 1.5 Kg/ha	Boscalid + Pyraclostrobin WG ref. prod. at 1.5 Kg/ha	Azoxystrobin ref. prod at 1 L/ha				
				Mean	Mean					
				333 g ai/ha	333 g ai/ha	259 g ai/ha	>	=	<	
Pest incidence				PESINC						
Leaves	13 DAT2	1	20.0	50.0	50.0	50.0		1		=
Pest severity				PESSEV						
Leaves	13 DAT2	1	18.8	60.0	73.3	66.7	1			>

Table 3.2-34: Effective dose North-East: Mean efficacy of Boscalid 26.7% + Pyraclostrobin 6.7% WG and boscalid + pyraclostrobin reference products against CERCCA (14-43 days after application; mean and variation in % control as compared to untreated check).

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Boscalid 26.7% + Pyraclostrobin 6.7% WG at 400 and 100 g ai/ha is >, < or =, compared to the boscalid Ref. product at 400 and 100 g ai/ha = : ± 5% control			Overall
				Boscalid 26.7% + Pyraclostrobin 6.7% WG	Boscalid + Pyraclostrobin WG ref. prod. at				
				Mean (min-max)					
				400 and 100 g ai/ha	400 and 100 g ai/ha	>	=	<	
Pest incidence				PESINC					
Leaves	28-21 DAT3	2	19.6	86.7	88.6		2		=
Pest severity				PESSEV					
Leaves	28-43 DAT3	1	26.3	78.2	80.3		1		=

Control of *Puccinia allii* in Onion

The efficacy trials were conducted to prove the following label claims:

Crop	Onion
Use rate	1.5 kg/ha Boscalid 26.7% + Pyraclostrobin 6.7% WG
Use frequency	2 (8-14 days interval)
Application timing	BBCH 41-49 (when first symptoms are visible)
Target disease	<i>Puccinia allii</i>

The effectiveness of applying Boscalid 26.7% + Pyraclostrobin 6.7% WG against *Puccinia allii* was evaluated in seven onion trials, assessed for pest severity and pest incidence. These trials were carried out in 2016 in the Maritime EPPO Zone (France (2) Germany (1)) and in the Mediterranean EPPO zone (i.e. Greece (1), Italy (2) and Spain (1)). The objective was to confirm the performance of Boscalid 26.7% + Pyraclostrobin 6.7% WG at 1.5 kg/ha (i.e. 400 g Boscalid and 100 g Pyraclostrobin per hectare, per application). In the trials, specifically targeted for this pathogen, two applications (eight trials) or three applications (one trial) were applied from February to August at growth stage BBCH 15-45 in the first application, at the BBCH 41-47 in the second application and at the BBCH 47 in the third application.

In the trials, Boscalid 26.7% + Pyraclostrobin 6.7% WG was tested alongside EU approved boscalid + pyraclostrobin formulation, i.e. Signum (Boscalid 26.7% + Pyraclostrobin 6.7% WG) and azoxystrobin + difenoconazole, i.e. Askor/Ortiva Top (Azoxystrobin 20% + Difenconazole 12.5%SC).

The results obtained with Boscalid 26.7% + Pyraclostrobin 6.7% WG applied for the control of *Puccinia*

allii (PUCCAL) in onion are presented in Table 3.2-35 and Table 3.2-36 for results obtained in the Maritime EPPO zone (one trial, two trials excluded because of no target disease or extremely low pressure) and the Mediterranean EPPO zone (five trials), respectively. No results are reported for the South-east EPPO zone because of no target pest in the trial.

Table 3.2-35: Effective dose Maritime zone: Mean efficacy of Boscalid 26.7% + Pyraclostrobin 6.7% WG and boscalid + pyraclostrobin reference products against PUCCAL and (6-14 days after application; mean and variation in % control as compared to untreated check).

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with			No. of trials where Boscalid 26.7% + Pyraclostrobin 6.7% WG at 400 and 100 g ai/ha is >, < or =, compared to the boscalid + pyraclostrobin and azoxystrobin + difenoconazole Ref. product at 400 and 100 g ai/ha = : ± 5% control			Overall
				Boscalid 26.7% + Pyraclostrobin 6.7% WG	Boscalid + Pyraclostrobin WG ref. prod. at	Azoxystrobin + difenoconazole SC ref. prod. at				
				Mean (min-max)						
				400 and 100 g ai/ha	400 and 100 g ai/ha	200 and 125 g ai/ha	>	=	<	
Pest severity				PESSEV						
Leaves	6-14 DAT2	2	25.6	42.9	40.5	75.8	0	1	1	=

Table 3.2-36: Effective dose Mediterranean zone: Mean efficacy of Boscalid 26.7% + Pyraclostrobin 6.7% WG and boscalid + pyraclostrobin reference products against PUCCAL and (12-14 days after application; mean and variation in % control as compared to untreated check).

Part assessed	Days after Treatment. No. x (DATx)	No. of trials	Mean infestation level (%)	Efficacy obtained with			No. of trials where Boscalid 26.7% + Pyraclostrobin 6.7% WG at 400 and 100 g ai/ha is >, < or =, compared to the boscalid + pyraclostrobin and azoxystrobin+ difenoconazole Ref. product at 400 and 100 g ai/ha = : ± 5% control			Overall
				Boscalid 26.7% + Pyraclostrobin 6.7% WG	Boscalid + Pyraclostrobin WG ref. prod. at	Azoxystrobin + Difenoconazole SC ref. prod. at				
				Mean (min-max)						
				400 and 100 g ai/ha	400 and 100 g ai/ha	200 and 125 g ai/ha	>	=	<	
Pest severity				PESSEV						
Leaves	12-14 DAT2	2	16.3 (7.9-20.7)	75.2 (32.1-100)	76.5 (78.7-100)	79.1 (78.8-79.5)	0	2	0	=
Pest incidence				PESINC						
Leaves	14 DAT2	5	44.8 (41.9-47.8)	76.3 (76.1-76.5)	76.8 (76.5-77.2)	87.1 (80.0-100)	0	4	1	=

Summary and conclusion

Based on the results of 47 field trials carried out in 2016 and 2017, the following can be concluded for the intended use of Boscalid 26.7% + Pyraclostrobin 6.7% WG applied at the dose rates of 1.5 kg/ha per application in the label's claimed crops:

Boscalid 26.7% + Pyraclostrobin 6.7% WG applied in sugarbeet, tomato, carrot and onion provided a moderate to excellent level control of target diseases with two or three applications at the recommended dose rate of 1.5 kg/ha.

Compared to the boscalid + pyraclostrobin and azoxystrobin+difenoconazole reference products tested, the efficacy obtained with Boscalid 26.7% + Pyraclostrobin 6.7% WG is comparable.

The trial results are considered valid for all intended Central zone ~~zone~~ countries.

Boscalid 26.7% + Pyraclostrobin 6.7% WG is suitable for the control on the key disease in sugarbeet, tomato, onion and carrot.

In cases of low number of trials, Poland can be able to take into account the results of the trials from Germany, Latvia or Czech Republic given comparable conditions because it is a neighbouring country.

This BAD clearly demonstrates that the efficacy and crop safety of Boscalid 26.7% + Pyraclostrobin 6.7% WG is equivalent to the standard boscalid + pyraclostrobin products to which the test product was compared. The applicant therefore wishes to cite the data on boscalid + pyraclostrobin containing products now out of protection in additional support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the zonal and national evaluators extrapolate from those data.

Comments of zRMS:	<p>All details about efficacy methodology used during efficacy trials are presented above by Applicant. The reports include a detailed data on soil and field conditions, agro-technological procedures, fore-crop as well as meteorological conditions and technical details of the spraying etc. Submitted efficacy trials are correctly performed according to appropriate EPPO standards. Studies were carried out by testing unit mandated to conduct research in the field of efficacy of plant protection products by the Chief Inspector of Plant Health and Seed Inspection and are officially GEP recognized.</p> <p>The applicant submitted 47 reports (in total) showing the results in research into product efficacy carried out in 2016, 2017 and 2019. So, the field trials were performed during different growing seasons, accordingly to EPPO PP 1/181(4).</p> <p>For sugar beet against CERCBE in total 19 trials were presented:</p> <ul style="list-style-type: none"> - Maritime – 7 trials (FR-5, DE-1, UK-1), eff. ME - Mediterranean – 3 trials (IT-1, ES-2), eff. ME - South-East – 2 trials (HU), eff. ME - North-East – 7 trials (PL), eff. ME <p>At least 6 trials are required for major pest and major crop. Applicant submitted enough trials for N-E and Maritime EPPO zone. For Poland we can also take into consideration results from neighbouring countries. In this way we have 8 valid trials: 1-DE, 7-PL. However, only extrapolation results from different EPPO zones can allow to register product in Mediterranean and South-East EPPO zone. So, concerned Member States will need to consider claims for these uses taking into account the limited amount of data and the current authorized uses for the reference product in their own Member State.</p> <p>For tomato against PHYTIN in total 6 trials were presented:</p> <ul style="list-style-type: none"> - Maritime – 1 trials (DE), eff. L - Mediterranean – 2 trials (IT), eff. ME - South-East – 3 trials (HU), eff. E - North-East – lack of trials <p>At least 2 trials are required for pest and 2-3 trials for minor crop. Applicant submitted enough trials for MED and S-E EPPO zone. For Poland we can take into consideration results from neighbouring countries. But, only one German trial is not sufficient. Applicant should submit at least 2-3 efficacy trials. Only extrapolation results from different EPPO zones can allow to register product in Maritime and North-East EPPO zone. So, concerned Member States will need to consider claims for these uses taking into account the limited amount of data and the current authorized uses for the reference product in their own Member State. For Poland, such extrapolation is not acceptable, so use against PHYTIN on tomato should be excluded from Polish label. Only according to Article 51 this use can be registered in Poland.</p> <p>For tomato against ALTESP in total 7 trials were presented:</p> <ul style="list-style-type: none"> - Maritime – lack of trials - Mediterranean – 5 trials (GR-1, IT-2, ES-2), eff. ME - South-East – lack of trials - North-East – 2 trials (PL), eff. ME <p>At least 2 trials are required for pest and 2-3 trials for minor crop. Applicant sub-</p>
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	<p>mitted enough trials for MED and N-E EPPO zone. Only extrapolation results from different EPPO zones can allow to register product in Maritime and South-East EPPO zone. So, concerned Member States will need to consider claims for these uses taking into account the limited amount of data and the current authorized uses for the reference product in their own Member State.</p> <p>For onion against PUCCAL in total 7 trials were presented:</p> <ul style="list-style-type: none"> - Mediterranean – 4 trials (GR-1, IT-2, ES-1), eff. ME - Maritime – 3 trials (FR-2, DE-1), eff. L - North-East – lack of trials - South-East – lack of trials <p>At least 2 trials are required for pest and 2-3 trials for minor crop. Applicant submitted enough trials for MED and MAR EPPO zone. For Poland we can take into consideration results from neighbouring countries. But, only one German trial is not sufficient. Applicant should submit at least 2-3 efficacy trials. Only extrapolation results from different EPPO zones can allow to register product in South-East and North-East EPPO zone. So, concerned Member States will need to consider claims for these uses taking into account the limited amount of data and the current authorized uses for the reference product in their own Member State. For Poland, such extrapolation is not acceptable, so use against PUCCAL on onion should be excluded from Polish label. Only, in line to Article 51 this use can be registered in Poland.</p> <p>For carrot against CERCCA in total 3 trials were presented:</p> <ul style="list-style-type: none"> - Mediterranean – lack of trials - North-East – 2 trials (LV), eff. ME - South-East – lack of trials - Maritime – 1 trial (DE), eff. L <p>At least 2-3 trials are required for minor crop. Applicant submitted enough trials for N-E EPPO zone. For Poland we can also take into consideration results from neighbouring countries. In this way we have 3 valid trials: 1-DE, 2-LV. However, only extrapolation results from different EPPO zones can allow to register product in Mediterranean, Maritime and South-East EPPO zone. So, concerned Member States will need to consider claims for these uses taking into account the limited amount of data and the current authorized uses for the reference product in their own Member State.</p> <p>For carrot against ALTESP in total 5 trials were presented:</p> <ul style="list-style-type: none"> - Mediterranean – lack of trials - North-East – 3 trials (LV-1, PL-2), eff. ME - South-East – 1 trial (HU), eff. E - Maritime – 1 trial (DE), eff. ME <p>At least 2-3 trials are required for minor crop. Applicant submitted enough trials for N-E EPPO zone. For Poland we can also take into consideration results from neighbouring countries. In this way we have 4 valid trials: 1-DE, 1-LV, 2-PL. However, only extrapolation results from different EPPO zones can allow to register product in Mediterranean, Maritime and South-East EPPO zone. So, concerned Member States will need to consider claims for these uses taking into account the limited amount of data and the current authorized uses for the reference product in their own Member State.</p> <p><u>Following BBCH were studied during trials:</u></p> <ul style="list-style-type: none"> - <i>sugar beet</i>: MAR: 34-49, N-E: 39-49; S-E: 41-49; MED: 31-40. In the opinion of Evalutaor, proposed window applicanton for sugar beet can be accepted (BBCH 31-39).
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	<p>- <i>tomato against PHYTIN</i>: MAR: 17-25; MED: 17-25; S-E: 63-72. In the opinion of Evaluator, proposed window application for tomato against PHYTIN can be accepted (BBCH: 20-87).</p> <p>- <i>tomato against ALTESP</i>: N-E: 73-84; MED: 21-87. In the opinion of Evaluator, proposed window application for tomato against ALTESP can be accepted (BBCH 20-87).</p> <p>- <i>carrot</i>: MAR: 41-45; N-E: 43-47; S-E: 41-44. In the opinion of Evaluator, proposed window application for carrot can be accepted (BBCH 41-49).</p> <p>- <i>onion</i>: MAR: 16-43; MED: 15-47. In the opinion of Evaluator, proposed window application for onion can be accepted (BBCH 41-49).</p> <p>On the basis on submitted documentation, max 2 application per season for sugar beet, tomato against PHYTIN, carrot and onion can be accepted, and for tomato against ALTESP – max 3 application per season can be accepted.</p> <p>The evaluation was carried out in accordance with the Uniform Principles. The presented data show that the efficacy rates of Casino Royal (SHA 7273 B) at 1,5 kg/ha are equivalent to the efficacy rates of the standard reference products.</p> <p>Due to the limited number of results for most uses, it is difficult to make a clear conclusion for the label, especially for pest which are considered to be major. Therefore the sufficiency of results should be considered on the national level based on importance of pests in their country, in the opinion of Evaluator.</p> <p>The applicant wishes to cite the original registrant's data on boscalid and pyraclostrobin out of protection in support of those recommendations on the draft label that are not adequately supported. Such extrapolations should be considered by individual member states on a national level based on current registration, data protection and experience with similar boscalid products. The spectrum of pests should be checked with label claims on these reference products. In Poland, on the basis on SIGNUM 33 WG, which was registered in Poland (R-33/2010, dated 19.04.2010), uses claimed in the GAP table (cabbage, tomato in greenhouses, strawberry, cherry, raspberry, blackcurrant) and Polish label project can be accepted. SIGNUM 33 WG contain the same amount of boscalid and pyraclostrobin as tested plant protection product – Casino Royal and have the same formulation (WG). Also, in efficacy trials this product was used in some efficacy trials. Also, during efficacy studies it was shown that both products have similar efficacy against annualizing diseases.</p> <p>Minor uses without any efficacy trials can be registered only in accordance to Article 51. So, following minor uses included in GAP table and label project can be accepted: beetroot, celery root, parsnip, parsley, radish, radish Horseradish, swedes/rutabagas, turnip, chicory roots, shallot, onion, aubergines/eggplants, ornamentals in field and greenhouses, redcurrant, white currant and salsifies.</p>
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3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

The following dossier section follows EPPO standard PP 1/213(4) *Resistance risk analysis* in particular point 6. *Registration requirements* and Appendix I of the standard.

Introduction

Resistance to crop protection chemicals is a natural biological phenomenon that occurs in insects, weeds and fungi. It usually becomes evident after the repeated use of a particular pesticide selects the naturally-

occurring resistant strains within the wild population and allows them to multiply over several seasons until they become dominant in the population and pose a control problem.

The fungicide-resistant population develops because the sensitive population is suppressed and the rare fungicide-resistant individual can multiply and occupy the biological niche previously filled by the sensitive population. An increase in the frequency of such resistant strains may result in loss of disease control. As a general principle, resistance develops at different rates depending on the pathogen type, nature of the epidemic (or disease severity) and use pattern of the fungicide.

Reports of the appearance of resistant strains in laboratory studies do not necessarily imply that any loss of control is expected in the field. Likewise, the appearance of less-sensitive strains in the field does not always result in failure of disease control. When the frequency of resistant individuals is low and/or the level of resistance is moderate, fungicide applications in most cases will provide satisfactory control.

To avoid the misinterpretation of potential and/or possible resistance cases, the Fungicide Resistance Action Committee (FRAC) states that the term resistance be limited to situations where the conditions in both (a) and (b) below are met:

- (a) the development of resistance leads to failure of disease control under practical field conditions following application of a fungicide correctly and according to the label and
- (b) a demonstration that a loss of control is due to the presence of pathogenic strains with reduced fungicide sensitivity.

Mode of action

Mode of Action of Boscalid

The active substance boscalid is a systemic compound. Depending on the type of formulation, it penetrates into the plant when applied to leaves (or roots), and it is then translocated acropetally. Boscalid belongs to the chemical class of pyridinecarboxamides in the group of complex II: succinate-dehydrogenase fungicides and is classified in Group 7 by FRAC (FRAC MOA Code: complex II : succinate-dehydrogenase, Group code 7).

Boscalid acts by blocking the enzyme succinate dehydrogenase, and by inhibiting the cytochrome II complex, prevents the development of the fungus by depriving the cells of their energy source and eliminates the formation of blocks for the synthesis of the essential components of the cells. Boscalid is developed in a preventive way preventing both germination of spores and germinative tube growth: the activity of pathogenic fungi is blocked from the early stages of infection.

Mode of Action of Pyraclostrobin

The active substance pyraclostrobin is a systemic compound. It is taken up rapidly by the plant and is largely retained by the waxes in the leaf cuticle. It demonstrates good traslaminar movement throught the leaf, resulting in disease control on both leaf surfaces. Pyraclostrobin belongs to the chemical class of methoxy-carbamates in the group of complex III: cytochrome bc1 (ubiquinol oxidase) at Qo site (cyt b gene) and is classified in the Group 11 by FRAC (FRAC MOA Code: complex III : cytochrome bc1 (ubiquinol oxidase) at Qo site (cyt b gene), Group code 11).

Pyraclostrobin acts by inhibition of plant pathogens by blocking the pathogens ability to produce energy. They do this by blocking the transfer of electrons at the Quinone "outside" site of the bc1 complex (complex III in the electron transport chain).

3.3.1 Mechanism of resistance

Mechanisms of Resistance, Boscalid

The FRAC SDHI Working Group was working in the resistance management recommendations for the SDHI fungicides and they have shown that target site mutations in *sdh* gene, e.g. H/Y (or H/L) at 257 *Ustilago maydis*, homolog to 267 in *Zymoseptoria tritici* and 272 in *Botrytis cinerea*.

SDHI fungicides were discovered more than 40 years ago. Due to the limited disease and application spectrum of the “first generation” carboxamides, resistance under commercial conditions remained limited to a few crop/pathosystems (primarily Basidiomycetes), e.g. *Puccinia horiana*, chrysanthemum rust, and *Ustilago nuda*, loose smut in barley.

In addition to these “first generation” molecules, SDHIs with increased spectrum and potency were launched starting in 2003 and new ones continue to be launched today. These modern generation SDHIs are rapidly achieving market share in many crops and new SDHIs are currently in development.

The target enzyme of SDH inhibitors is succinate dehydrogenase (SDH, so-called complex II in the mitochondrial respiration chain), which is a functional part of the tricarboxylic cycle and linked to the mitochondrial electron transport chain (Keon et al., 1991). SDH consists of four subunits (A, B, C and D) and the binding site of the SDHIs (the ubiquinone binding site) is formed by the subunits B, C and D. Target site mutations conferring reduced sensitivity can develop in all three subunits.

Mechanisms of Resistance, Pyraclostrobin

QoI fungicides or quinone outside inhibitors (also called strobilurins) have been widely used to control agriculturally important fungal pathogens since their introduction in 1996. The first QoI resistance in *Mycosphaerella graminicola* was detected retrospectively in UK in 2001 at a low frequency in QoI-treated plots.

The main mechanism conferring resistance to QoIs is target site modification, involving mutations in the cytochrome b gene CYTB, such as the substitution of glycine by alanine at position 143 (G143A) that occurs in several phytopathogenic fungi. The impact of other mechanisms, including alternative respiration and efflux transporters, on resistance seems to be limited. Interestingly, in some species QoI resistance is not supported by mutations in CYTB, while in others the structure of the gene is such that it is unlikely to undergo G143A mutations.

3.3.2 Evidence of resistance

Evidence of Resistance, Boscalid

Members of the Fungicide Resistance Action Committee (FRAC) have monitored the occurrence of resistance to multisite fungicides across Europe. According to the FRAC, some records of practical resistance to boscalid have been recorded in certain regions. In fungal diseases concern this registration, according to the monitoring program of FRAC (2016):

Tomato – Early blight, Alternaria leaf spot (*Alternaria solani*, *A. alternata*)

In *A. solani*, no resistance was detected in Poland and Italy in 2016. In *A. alternata*, few isolates showing reduced sensitivity were detected in Poland, Italy and Greece.

In 2015, no SDHI resistance was detected in *A. solani* in Poland, Bulgaria and Spain. In *A. alternata*, a single isolate from Italy showed reduced sensitivity. No SDHI resistance was reported from Spain and Bulgaria.

Stonefruit - Brown rot (*Monilinia* spp.)

In 2015, samples from Italy, France and Spain were studied (confirmation of species still open). Single isolates with reduced sensitivity were detected at 3 trial sites in France. Only sensitive phenotypes were reported from Italy and Spain.

Sensitivity of samples from Spain, France, Italy, Germany and Poland was analysed and showed full sensitivity in 2014. In 2015, samples originating from Belgium, France and Hungary were all sensitive, within the baseline.

Evidence of Resistance, Pyraclostrobin

Members of the Fungicide Resistance Action Committee (FRAC) have monitored the occurrence of resistance to QoI fungicides across Europe. According to the FRAC, a number of records of practical resistance to pyraclostrobin have been recorded in certain regions. Two years after their introduction to the

market, resistant populations of powdery mildew were observed in wheat crops in Germany and after resistant problems have been encountered in a range of target pathogens, for example *Mycosphaerella graminicola* (cause of leaf spot of wheat), *Plasmopara viticola* (downy mildew of grapes), *Venturia inaequalis* (cause of apple scab). In fungal diseases concern this registration, according to the monitoring program of FRAC (2017):

SugarBeet (*Cercospora beticola*)

Intensive monitoring was carried out across Europe in 2016. The levels of resistance found were: High levels; Austria, Belgium, France, Czech Republic, Italy, Slovakia, Sweden and Switzerland. In Germany, Poland and United Kingdom - Overall very heterogeneous across the country from zero to high levels. Monitoring is still ongoing.

Early blight (*Alternaria* spp.)

Monitoring was carried out in potatoes and tomatoes (*Alternaria solani* and *Alternaria alternata*) in Europe in 2016.

Alternaria solani- Tomato

Full sensitivity monitored in Poland.

Alternaria solani- Potato

Resistance to QoI is associated to the presence of the F129L mutation.

Less sensitive isolates were found at medium frequency in samples from Belgium, Denmark, Germany Netherlands and Sweden. Low frequencies of the F129L mutation were confirmed in Finland, Poland, Slovakia and United Kingdom.

All samples tested from Czech Republic, France, Greece, Hungary, Italy, Romania and Spain were sensitive.

As already observed with other pathogens, resistance factors are significantly lower in comparison with the G143A mutation and field performance of products used according to FRAC and Manufacturers' recommendations remains good.

Late blight (*Phytophthora infestans*) in potato/tomato

No resistance was detected in all isolates collected in 2016 from potato crops in Italy, Poland, Germany, Netherlands, Belgium, France, United Kingdom and Portugal.

Performance remains good.

Brown Rot in Stone Fruit (*Monilinia* spp.)

2016 monitoring is still ongoing.

Monitoring data for 2014 and 2015 showed all populations to be fully sensitive (France, Greece, Hungary, Italy, Poland and Spain).

These findings are most likely to be related to the reported presence of a lethal intron in several fungi making the G143A mutation unlikely to occur.

3.3.3 Cross-resistance

Boscalid

Work with isolates from both field and lab studies suggests that cross-resistance patterns between SDHIs for different target site mutations are complex. Different target site mutations confer varying degrees of insensitivity between the different SDHIs. This suggests the effect of these target site mutations on field performance of specific SDHIs may vary if they were to spread in field populations. The various degrees of reduced sensitivity to different target site mutations may be explained by structural differences between classes of SDHIs and how they interact with the target site of a specific pathogen (Scalliet et al. 2012). Additionally, the magnitude of the effect conferred by a specific target site mutation can vary from species to species. In other words, the reduction in sensitivity conferred by specific target site mutations may vary between pathogen species, SDHI used and geographic location of the isolates (Sierotzki and Scalliet 2013).

Pyraclostrobin

The QoI fungicides display a single-site mode of action. They exhibit protectant, systemic and eradicant action and have been widely and successfully used since they show very well activity against all major fungal genera. In general, where resistance has been observed, the resistant forms have shown cross-resistance to all the QoI fungicides.

3.3.4 Sensitivity data

Diseases vary in their sensitivity towards fungicides both between and within populations, and this natural variation should be understood before shifts in sensitivity can be assessed. SDH fungicides have been tested and used worldwide for +15 years (or more) and it is therefore difficult to find unexposed fungal populations. No true base line sensitivity data can therefore be established. FRAC has been monitoring the development in sensitivity in the most important diseases for a number of years, and Sharda will work closely together with FRAC to assist with this work.

3.3.5 Use pattern

Boscalid 26.7% + Pyraclostrobin 6.7% WG in the EU Central zone, the formulation is proposed for control of *Cercospora beticola*, *Phytophthora infestans*, *Alternaria* sp., *Alternaria dauci*, *Botrytis cinerea*, *Ramularia grevilleana*, *Spaerotheca macularis*, *Monilinia* sp., *Didymella applanata*, *Drepanopeziza ribis*, *Drepanopeziza rubric*, *Cronartium ribicola*, *Erysiphe betae*, *Erysiphe heracleidis*, *Sclerotinia sclerotiorum*, *Rhizoctonia solani*, *Peronospora* sp., *Puccinia allii*, *Thanatephorus cucumeris*, *Chicory Alternaria*, *Chicory Puccinia*, *Peronospora destructor*, *Stemphylium*, *Puccinia porri*, *Phytophthora porri*, *Leveillula taurica* in a range of crops. The fungicide is proposed applied up to three times during the season at the maximum recommended dose rates (0,75-2.0 kg/ha).

The application may be employed when the climatic conditions are favourable for infestation or when warnings have been released in the different regions. When applied as recommended, with 1.5 kg/ha, this will deliver 400 g Boscalid and 100 g Pyraclostrobin per hectare, per application.

3.3.6 Resistance risk assessment of unrestricted use pattern

The active substance

FRAC regards the resistance risk of the Group 7 (Boscalid) is medium to low.
FRAC regards the resistance risk of the Group 11 (Pyraclostrobin) is high.

The disease

The target diseases for the use of Boscalid 26.7% + Pyraclostrobin 6.7% WG has been shown to be able to develop resistance to a range of fungicide groups, hereunder also SDHI and QoI fungicides. The resistance risk associated with any individual disease is dependent on a number of factors related to the disease epidemiology, these include:

- Life cycle; the shorter the generation time, the more frequent the need for exposure to the fungicide and the faster the build-up of resistance.
- Abundance of sporulation; the more spores that are released in the crop the greater the availability of individual genomes for mutation and selection and the faster the spread of resistant strains.
- Isolation of pathogen populations; the more isolated the crop, through geography, or protected crops, the less chance of ingress of sensitive forms or loss of resistant forms.
- Occurrence of a sexual stage in the life cycle.

The intended disease target for Boscalid 26.7% + Pyraclostrobin 6.7% WG vary in terms of their intrinsic resistance risk. The resistance risk of target pathogens of Boscalid 50% WG is available at www.frac.info.

Agronomic practice

In terms of agronomic practice, the selection pressure on the intended disease target for Boscalid 26.7% + Pyraclostrobin 6.7% WG may be low to high in the label claimed crops (depending on whether a successful crop rotation system is applied or mono-cropping is carried out in the annual field crop).

The plant protection product

For optimum disease control, Boscalid 26.7% + Pyraclostrobin 6.7% WG is applied at the rates recommended on the proposed label. These have been shown to be the minimum effective dose for the major target pathogen (Section 6.1.2).

3.3.7 Test methods

There are several monitoring methods approved by FRAC (available on www.frac.info).

3.3.8 Acceptability of the resistance risk

In the absence of any potential resistance risk and in the absence of any other restrictions on the GAP (residues, toxicology etc.), the unrestricted use pattern for Boscalid 26.7% + Pyraclostrobin 6.7% WG would be season long usage with an unrestricted number of applications.

Overall it is clear that the unrestricted use of Boscalid 26.7% + Pyraclostrobin 6.7% WG presents an unacceptable resistance risk and therefore modifiers as part of a Management Strategy are proposed.

3.3.9 Resistance management strategy

As the unmodified use pattern is considered unacceptable, a number of modifiers are proposed which are entirely in accordance with the general recommendations made by FRAC.

- Use in alternation with fungicides with a different mode of action
- Use as recommended on the label. Do not use reduced doses.
- Application should be at an early stage of development (e.g. at the first signs of disease or as soon as disease symptoms appear) or as a protective application.
- Use other measures such as resistant varieties, good agronomic practice

3.3.10 Implementation of the Management Strategy

Information on the management of resistance and the specific Resistance Management Strategy for Boscalid 26.7% + Pyraclostrobin 6.7% WG is disseminated by a number of routes including, but not exclusively:

- Product label has a clear statement regarding resistance risk and the management strategy
- Pack inserts for general information or to address a particular issue in a specific geographical area where it to occur.
- Leaflets available at, and distributed by distributors/wholesalers/merchants
- Information released by national and local advisory services re. monitoring
- FRAC publications including the web site www.frac.info
- Training for distributors/wholesalers/merchants and farmer groups
- Links from company web sites to FRAC and local Fungicide Resistance working groups for information and advice

3.3.11 Monitoring, reporting and reaction to the change in performance

Monitoring of field performance

Where field performance is significantly less than expected (relative to field trial results presented in section 6.1.3) and where no other explanation can be found for the reduced performance e.g. application

errors, then samples may be taken for sensitivity testing. Where testing is carried out it will be conducted at laboratories experienced in carrying out such testing and using methods recommended by FRAC.

Analysis of performance-related complaints

Where no other reason for a failure in performance can be identified, samples may be taken for testing as described above

Where resistance can be confirmed as the cause for loss of field performance this will be reported to the authorities on an annual basis or as required.

Containment plan

The above recommendations will be adjusted as needed depending on the success of the proposed strategy. In the event that practical field resistance should occur on any significant scale, Sharda's plan for containing the further development or spread of resistance includes a number of possible actions on a temporary or permanent basis, including but not exclusively:

- Recommendations to use only fungicides from alternative mode of action groups for the remainder of the growing season
- Reduction in number of applications
- Recommendation to use only in a programme e.g. before or after an application of a fungicide from a different mode of action group.

Normally any action taken would be in consultation with the relevant authorities.

Comments of zRMS:	<p>Strategy against development of resistance is acceptable for Evaluator.</p> <p>The agronomic risk for active ingredients which include Casino Royal is estimated as medium to high:</p> <ul style="list-style-type: none"> - FRAC regards the resistance risk of the Group 7 (Boscalid) is medium to low. - FRAC regards the resistance risk of the Group 11 (Pyraclostrobin) is high. <p>The resistance management is coordinated by FRAC recommendations. Applying the anti-resistance use recommendations, development of resistance can be considerably decreased or avoided. The restriction should be put on the label.</p> <p><u>ZRMs accepted recommendations proposed by Applicant:</u></p> <ul style="list-style-type: none"> - Recommendations to use only fungicides from alternative mode of action groups for the remainder of the growing season - Reduction in number of applications - Recommendation to use only in a programme e.g. before or after an application of a fungicide from a different mode of action group. <p>Since the agronomic factors influencing the risk of resistance development tend to vary between the member states, the individual and detailed assessment of the resistance risk (Evaluation of the Agronomic risk of re-sistance, Management of resistance, Use pattern, Proposed Risk Modifiers) has to be finalised on national level.</p>
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3.4 Adverse effects on treated crops (KCP 6.4)

Information on trials submitted (3.4: Adverse effects on treated crops).

Table 3.4-1: Presentation of selectivity trials

Crop*	Country	Type of trial**	Number of trials				Years	GEP, non-GEP, official***	Comments (any other relevant information)
			EPPO zone						
			MAR	N-E	MED	S-E			
BEAVA	Spain	S + Y			1		2016	GEP	
	UK	S + Y	1				2016	GEP	
	Poland	S + Y + Q		4			2016, 2017	GEP	
	France	S + Y	3				2016	GEP	
	Total, Sugarbeet		4	4	1				
LYPES	Czech Republic	S + Q	1				2016	GEP	
	Germany	S + Y + Q	1				2016	GEP	
	Latvia	S		1			2016	GEP	
	Greece	S + Y			1		2016	GEP	
	Italy	S + Y + Q			1		2016	GEP	
	Spain	S + Y			1		2016	GEP	
	Total, Tomato		2	1	3				
ALLCE	Czech Republic	S + Y	2				2016	GEP	
	Germany	S	1				2016	GEP	
	Poland	S + Y + Q		1			2016	GEP	
	Italy	S + Y + Q			1		2016	GEP	
	Spain	S + Y			1		2016	GEP	
	Total, Onion		2	1	2				
DAUCS	Germany	S + Y	1				2016	GEP	
	UK	S + Y	1				2016	GEP	
	Poland	S + Y + Q		1			2016	GEP	
	Total, Carrot		2	1					

Table 3.4-2: Details on selectivity trial methodology

Guidelines	General guidelines	EPPO PP 1/152 (4), PP 1/181 (4), PP 1/135(3,4)
	Specific guidelines	EPPO PP 1/120(2) PP 1/214(3), PP 1/225/(2), PP 1 /239(2), PP 1/241(2), PP 1/271(2), PP 1/278(1), PP 1/226(2), PP 1/37(2), PP 1/1(4), PP 1/121(2)
Experimental design	Plot design	RCBD (4)
	Plot size	5 - 34 m ²
	Number of replications	4
Crop	Trials per crop	Sugarbeet (9), tomato (6), onion (6), and carrots (3)
	Varieties per crop	Sugarbeet: Salamanca, Jampol, Pikador, Hunor, Telimena, Sanlucar Tomato: Tolstoj, Elegance, Leader, Guarapo, Magnusa, Elpida. Onion: Wellina, Tamara, Hybelle, Hamasodachi 950, Bonus Carrot: Anina, Tamara, Elegance,
	Sowing period	Sugarbeet: November 2015 - April 2017 Tomato: October 2015 - June 2016 Onion: October 2015 - April 2015 Carrot: April - May 2016
	Application period	Sugarbeet: Apr - August 2016 Tomato: February - Novembre 2016 Onion: February - July 2016 Carrot: October - July 2016
	Crop stage (BBCH)* at application	Sugarbeet; BBCH 39-42 Tomato; BBCH 21-86 Onion BBCH 18-47 Carrot; BBCH 44 - 46
	Number of appl.	Sugarbeet: 2 Tomato: 3 Onion: 2 Carrot: 2
	Spray volumes	Sugarbeet: 200-1000 L/ha Tomato: 650-1000 L/ha Onion: 300-1000 L/ha Carrot: 200-300 L/ha
	Assessment types	- Visual estimation of crop injury and crop stand reduction (thinning) compared to 'untreated' ('untreated' = 0% crop injury; 100% crop injury = total crop destruction). Where appropriate this overall score was substituted or supplemented by assessments of individual symptoms. - Visual estimation of crop vigour (0-10 or 0-100 scale)
Assessment	Assessment dates	As a rule 3 to 5 crop injury ratings
Other relevant information	Soil type	Light to heavy soils
	Natural / artificial inoculation...	N Preferably disease-free conditions
	Field / Greenhouse...	Field

In the selectivity trials, the performance of Boscalid 26.7% + Pyraclostrobin 6.7% WG was measured against commercial standard formulation of Boscalid 26.7% WG + Pyraclostrobin 6.7%. The mixture Boscalid + Pyraclostrobin standard used was Signum, other standards of similar use were used as Amistar Top, Askon, Opera, Ortiva and Ortiva Top, Scorpion 325 SC and Optan 183 SE.

The reference products used in the trials are listed in Table 3.4-3.

Table 3.4-3: Presentation of test- and reference standards used in trials (selectivity trials, transformation trials...)

Trade name	Formulation	Composition	Rates [Kg-L/ha]	Indication	Country	N° of trials
Signum	WG	267 g/L Boscalid 67 g/L Pyraclostrobin	0.6 1 1.5 3	Sugarbeet, vegetables and stone fruits fungal diseases	IT LV FR	1 1 3
Amistar Top	SC	200 g/L Azoxystrobin 125 g /L Difenconazole	1 2	Sugarbeet, vegetables and stone fruits fungal diseases	UK	1
Askon	SC	200 g/L Azoxystrobin 125 g /L Difenconazole	1 2	Sugarbeet, vegetables and stone fruits fungal diseases	DE CZ	3 3
Opera	SE	133 g/L pyraclostrobin + 50 g/L epoxiconazole	1 2	Sugarbeet, vegetables and stone fruits fungal diseases	UK	1
Ortiva	SC	250 g/l Azoxystrobin	1 2	Sugarbeet, vegetables and stone fruits fungal diseases	ES	1
Ortiva Top	SC	200 g/L Azoxystrobin 125 g /L Difenconazole	1 2	Sugarbeet, vegetables and stone fruits fungal diseases	2	1 1 1
Scorpion 325 SC	SC	200 g/L Azoxystrobin 125 g /L Difenconazole	1 2	Sugarbeet, vegetables and stone fruits fungal diseases	PL	2
Optan 183 SE	SE	133 g/L pyraclostrobin + 50 g/L epoxiconazole	1 2	Sugarbeet, vegetables and stone fruits fungal diseases	PL	4

As Boscalid 26.7% + Pyraclostrobin 6.7% WG is a fungicide, no specific studies are required as long as in the efficacy trials no negative effects are observed. The crop safety of applying Boscalid 26.7% + Pyraclostrobin 6.7% WG at the recommended rates in sugarbeet, tomato, onion and carrot was evaluated in 88 efficacy trials (38 in the Maritime EPPO zone, 14 in the North-East EPPO zone, 20 in the South-East EPPO zone and 16 in the Mediterranean EPPO zone). In the efficacy trials, Boscalid 26.7% + Pyraclostrobin 6.7% WG EC was applied at 0.6 Kg/ha to 1.5 Kg/ha. Furthermore, to give additional evidence to the safe use of Boscalid 26.7% + Pyraclostrobin 6.7% WG in the GAP claimed crops, the results obtained in 23 selectivity trials (10 in the Maritime EPPO zone, 7 in the North-East EPPO zone and 6 in the Mediterranean EPPO zone) are reported. In the selectivity trials, Boscalid 26.7% + Pyraclostrobin 6.7% WG was applied at 1.5 Kg/ha to 3 Kg/ha. The results obtained in these trials, where reported, are presented in Appendix 7.

3.4.1.1 Sugarbeet

Crop phytotoxicity was evaluated in 21 efficacy trials and 9 crop safety trials where Boscalid 26.7% + Pyraclostrobin 6.7% WG was applied in two applications, when the crop was at growth stage BBCH 31-39 and 33-39 respectively, at the rate of 0.6-1.5 Kg/ha in sugarbeet. The 1.5 Kg/ha dose rate corresponds to 100% of the proposed dose rate. Crop phytotoxicity was assessed in the trials at various intervals from application and up to harvest.

Phytotoxicity in sugarbeet, Maritime EPPO zone

Ten efficacy trials and one crop safety trial were conducted in the Maritime EPPO zone to assess the crop safety of Boscalid 26.7% + Pyraclostrobin 6.7% WG when applied as recommended in sugarbeet. The trials were conducted on the commercially available varieties Salamanca, Cayman, Springbok, Lisanna, Hannibal, Rainette, Dragon, FD Schelem.

No adverse effects in regards to phytotoxicity and vigour were observed in any of the 10 efficacy trials or in the 4 selectivity trial conducted in the Maritime EPPO zone.

Phytotoxicity in sugarbeet, North-East EPPO zone

Seven efficacy and four selectivity trials were conducted in the North-East EPPO zone to assess the crop safety of Boscalid 26.7% + Pyraclostrobin 6.7% WG when applied as recommended in sugarbeet. The trials were conducted on the commercially available varieties Polanin, Telimena, Jampol, Lavenda, Schubert, Tapir, Jadeit and Contenta, Pikador, Hunor.

No adverse effects in regards to phytotoxicity and vigour were observed in any of the seven efficacy and four selectivity trials conducted in the North-East EPPO zone.

Phytotoxicity in sugarbeet, South-East EPPO zone

Two efficacy trials were conducted in the South-East EPPO zone to assess the crop safety of Boscalid 26.7% + Pyraclostrobin 6.7% WG when applied as recommended in sugarbeet. The trials were conducted on the commercially available varieties Harmonia and Legenda.

No adverse effects in regards to phytotoxicity and vigour were observed in any of one efficacy trial conducted in the South-East EPPO zone.

Phytotoxicity in sugarbeet, Mediterranean EPPO zone

Three efficacy trials and one crop safety were conducted in the Mediterranean EPPO zone to assess the crop safety of Boscalid 26.7% + Pyraclostrobin 6.7% WG when applied as recommended in sugarbeet. The trials were conducted on the commercially available varieties San Lucar, Altares and Bison.

No adverse effects in regards to phytotoxicity and vigour were observed in any of the three efficacy trials or in the one crop safety trial conducted in the Mediterranean EPPO zone.

3.4.1.2 Tomato

Crop phytotoxicity was evaluated in 32 efficacy and 6 selectivity trials where Boscalid 26.7% + Pyraclostrobin 6.7% WG was applied in two or three applications, when the crop was at growth stages ranging from BBCH 17 to BBCH 89, at the rates of 0.6-1-1.5 Kg/ha in tomato. The 1.5 kg/ha dose rate corresponds to 100% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals from application and up to harvest.

Phytotoxicity in tomato, Maritime EPPO zone

A total of fourteen efficacy trials and two selectivity trials were conducted in the Maritime EPPO zone to assess the crop safety of Boscalid 26.7% + Pyraclostrobin 6.7% WG when applied as recommended in tomato. The trials were conducted on commercially available varieties Magnusa, Tolstoj, Big Red, Hoffmanns Rendita and Miniboy.

No adverse effects in regards to phytotoxicity and vigour were observed in any of the four efficacy trials or the two selectivity trials conducted in the Maritime EPPO zone

Phytotoxicity in tomato, North-east EPPO zone

A total of two efficacy trials and one selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Boscalid 26.7% + Pyraclostrobin 6.7% WG when applied as recommended in tomato. The trials were conducted on commercially available varieties Magnusa, Tolstoj, Rallijs and Elegance.

No adverse effects in regards to phytotoxicity and vigour were observed in any of the four efficacy trials or the two selectivity trials conducted in the Maritime EPPO zone.

Phytotoxicity in tomato, Mediterranean EPPO zone

A total of nine efficacy trials and three selectivity trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Boscalid 26.7% + Pyraclostrobin 6.7% WG when applied as recommended in tomato. The trials were conducted on commercially available varieties. Elpida, Guarapo, Leader, Defender F1 Stratos F1, Fara, Sergio, Patriarca, Guarapo, Impact F1, Vulcan F1, H15.

No adverse effects in regards to phytotoxicity and vigour were observed in any of the nine efficacy trials or the three selectivity trials conducted in the Mediterranean EPPO zone.

Phytotoxicity in tomato, South-east EPPO zone

A total of 7 efficacy trials were conducted in the South-east EPPO zone to assess the crop safety of Boscalid 26.7% + Pyraclostrobin 6.7% WG when applied as recommended in tomato. The trials were conducted on commercially available varieties Sultan F1, Benito F1.

No adverse effects in regards to phytotoxicity and vigour were observed in any of the 7 efficacy trials conducted in the South-east EPPO zone.

3.4.1.3 Carrot (DAUCS)

Crop phytotoxicity was evaluated in 20 efficacy and 3 selectivity trials where Boscalid 26.7% + Pyraclostrobin 6.7% WG was applied in two applications, when the crop was at growth stages ranging from BBCH 41 to BBCH 46, at the rates of 0.6-1-1.5 Kg/ha in carrot. The 1.5 kg/ha dose rate corresponds to 100% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals from application and up to harvest.

Phytotoxicity in carrot, Maritime EPPO zone

A total of 8 efficacy and 2 selectivity trial were conducted in the Maritime EPPO zone to assess the crop safety of Boscalid 26.7% + Pyraclostrobin 6.7% WG when applied as recommended in carrot. The trials were conducted on commercially available varieties Nantes, Anina and Maestro, Sultan F1, Maestro F1, Rote Riesen 2, Carvora, Lange Rote Stumpfe, Calibra .

No adverse effects in regards to phytotoxicity and vigour were observed in 7 efficacy and 2 selectivity trials as well as no adverse effects were observed in any of the two selectivity trials conducted in the Maritime EPPO zone.

In the United Kingdom efficacy trial, conducted on the variety Nantes, minor reductions in general crop health (PHYGEN) were recorded at the last assessment after the second application in the plots treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG at 1 Kg/ha dose.

Table 3.4-4: Visual assessment of crop phytotoxicity in carrot treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG in one efficacy trial (maximum crop phytotoxicity observed).

					Max. phytotoxicity [%]					
Trial number	Crop	Variety	Ass. Date DAA/B	Untreated	Boscalid 26.7% WG + Pyraclostrobin 6.7%			Signum		Symptom
				-	0.6 Kg/ha	1 Kg/ha	1.5 Kg/ha	0.6 Kg/ha	1.5 Kg/ha	
SHA837-15-EFF004	DAUCS	Nantes	14(2)	0.0	0.0	0.5	0.0	0.0	0.0	PHYGEN (%)

Phytotoxicity in carrot, North-east EPPO zone

A total of four efficacy and one selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Boscalid 26.7% + Pyraclostrobin 6.7% WG when applied as recommended in carrot. The trials were conducted on commercially available varieties Volcano, Nates Forto, Elegance and Nerac.

No adverse effects in regards to phytotoxicity and vigour were observed in efficacy trials as well as no adverse effects were observed in any of the selectivity trials conducted in the North-East EPPO zone.

Phytotoxicity in carrot, South-east EPPO zone

A total of eight efficacy trials were conducted in the South-east EPPO zone to assess the crop safety of Boscalid 26.7% + Pyraclostrobin 6.7% WG when applied as recommended in carrot. The trials were conducted on commercially available varieties. Samson, Nipomo F1, Laguna F1.

No adverse effects in regards to phytotoxicity and vigour were observed in any of the eight efficacy trials conducted in the South-east EPPO zone.

3.4.1.4 Onion (ALLCE)

Crop phytotoxicity was evaluated in 15 efficacy and 5 selectivity trials where Boscalid 26.7% + Pyraclostrobin 6.7% WG was applied in two applications, when the crop was at growth stages ranging from BBCH 15 to BBCH 47, at the rates of 0.6-1-1.5 Kg/ha in onion. The 1.5 kg/ha dose rate corresponds to 100% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals from application and up to harvest.

Phytotoxicity in onion, Maritime EPPO zone

A total of five efficacy and two selectivity trials were conducted in the Maritime EPPO zone to assess the crop safety of Boscalid 26.7% + Pyraclostrobin 6.7% WG when applied as recommended in onion. The trials were conducted on commercially available varieties Cledor, Medusa, Tamara, Paradiso, Vares, Wellina.

No adverse effects in regards to phytotoxicity and vigour were observed in any of the three efficacy trials as well as no adverse effects were observed in any of the five efficacy and two selectivity trials conducted in the Maritime EPPO zone.

Phytotoxicity in onion, North-East EPPO zone

One efficacy trial and one selectivity trial was conducted in the North-East EPPO zone to assess the crop safety of Boscalid 26.7% + Pyraclostrobin 6.7% WG when applied as recommended in onion. The trials were conducted on commercially available variety Hybelle, Armstrong.

No adverse effects in regards to phytotoxicity and vigour were observed in One efficacy trial and one selectivity as well as no adverse effects were observed in any of the two efficacy trials conducted in the North-East EPPO zone.

Phytotoxicity in onion, South-East EPPO zone

A total of four efficacy trials was conducted in the South-East EPPO zone to assess the crop safety of Boscalid 26.7% + Pyraclostrobin 6.7% WG when applied as recommended in onion. The trials were conducted on commercially available variety Katinka F1, Bronson F1.

No adverse effects in regards to phytotoxicity and vigour were observed in efficacy trial as well as no adverse effects were observed in any of the four efficacy trial conducted in the South-East EPPO zone.

Phytotoxicity in onion, Mediterranean EPPO zone

A total of five efficacy and two selectivity trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Boscalid 26.7% + Pyraclostrobin 6.7% WG when applied as recommended in onion. The trials were conducted on commercially available varieties White Lisbon, Nevada, Dalila, Hamasodachi 950 and Bonus.

No adverse effects in regards to phytotoxicity and vigour were observed in any of the five efficacy trials as well as no adverse effects were observed in any of the two selectivity trials conducted in the Mediter-

ranean EPPO zone.

3.4.1.5 Overall conclusion

Boscalid 26.7% + Pyraclostrobin 6.7% WG applied at the recommended dose rate did not cause phytotoxicity in any of the trials conducted on sugarbeet, tomato, carrot and onion when applied as recommended. In the trials where Boscalid 26.7% + Pyraclostrobin 6.7% WG was applied at dose rates higher than the recommended, no detrimental effects were observed on selectivity, when assessed in the vast majority of the trials.

In cases of low number of trials, Poland can be able to take into account the results of the trials from Czech Republic, Latvia and Germany, given comparable conditions because it is a neighbouring country. For crops claimed on the label not sufficiently supported with trials, the applicant wishes to bridge to the trials conducted in sugarbeet, tomato, carrot and onion where selectivity data demonstrated the safe use following application of Boscalid 26.7% + Pyraclostrobin 6.7% WG as recommended. Therefore, for any label claims not adequately supported for one crop, Sharda requests that the zonal evaluators read across to the data on sugarbeet, tomato, carrot and onion.. This BAD also clearly demonstrates that the crop safety of Boscalid 26.7% + Pyraclostrobin 6.7% WG is equivalent to the standard Boscalid 26.7% + Pyraclostrobin 6.7% WG products (Signum) to which it was compared. The applicant therefore wishes to cite the original registrant's data on Boscalid 26.7% + Pyraclostrobin 6.7% WG now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Table 3.4-5: Phytotoxicity of product

Number of trials with...		Selectivity trials (23 trials)				Efficacy trials (88 trials)	
		Test product		Standard 1		Test product	Standard 1
		1.5 kg/ha	3 kg/ha	1.5 kg/ha	3 kg/ha	1.5 kg/ha	1N
Maximum of phytotoxicity recorded during the trials	0% to 5%	23	23	23	23	88	88
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	23	23	23	23	88	88
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0

Comments of zRMS:	<p>Applicant submitted in total 24 selectivity trials (N and 2N dose was studied):</p> <ul style="list-style-type: none"> - sugar beet (9 trials) MAR – 4 trials, N-E-4 trials, MED-1 trial No adverse effects in regards to phytotoxicity and vigour were observed in any of submitted trials. - tomato (6 trials) MAR – 2 trials, N-E – 1 trial, MED – 3 trials No adverse effects in regards to phytotoxicity and vigour were observed in any of submitted trials. - onion (6 trials) MAR – 3 trials, N-E -1 trial, MED – 2 trials No adverse effects in regards to phytotoxicity and vigour were observed in any of submitted trials.
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	<p>- carrot (3 trials) MAR – 2 trials, N-E – 1 trial No adverse effects in regards to phytotoxicity and vigour were observed in any of submitted trials.</p> <p>Both EU Directive 91/414 (EU, 1991) and EPPO PP 1/226 (3) – Number of efficacy trials requires testing phytotoxicity at normal (N) and double (2N) recommended dose. The reports submitted by Applicant take into account double dose combination of tested plant protection product in exception of S-E EPPO zone. However, EPPO 1/135 (3) – Phytotoxicity assessment states: ‘EPPO Standards on fungicides, insecticides and plant growth regulators, on the other hand, include only a relatively simple special section on phytotoxicity assessment, because, for these types of plant protection products, phytotoxic effects will be less frequent’. Selectivity trials were not required, which is in accordance with EPPO 1/135 (3). However, Applicant submitted in total 24 selectivity trials. Phytotoxicity was assessed also during efficacy trials. Detailed information’s are presented by Applicant. No phytotoxicity symptoms caused by a tested product at the proposed dose rate.</p>
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3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

To evaluate the effect of Boscalid 26.7% + Pyraclostrobin 6.7% WG on the yield, the results obtained in sixteen selectivity trials and eighteen efficacy trials conducted in 2016, 2017, 2019 have been included to support the registration of Boscalid 26.7% + Pyraclostrobin 6.7% WG in sugarbeet, tomato, onion and carrot. In support to the safe use of the tested product trials conducted on carrot are also presented.

Boscalid 26.7% + Pyraclostrobin 6.7% WG was applied between two and three times at growth stage relevant to the proposed GAP. All trials presented in this section of the Biological Assessment Dossier were located within the Maritime EPPO zone (9; i.e. the Czech Republic, United Kingdom, Germany), North-East EPPO Zone (15; i.e. Poland, Latvia) and the Mediterranean EPPO Zone (10; i.e. Spain, Greece and Italy) as defined by EPPO Standard PP1/241(1).

3.4.2.1 Materials and methods

Plot yields, as fresh weight plant material, were measured at harvest and converted to t/ha. The data of the treated plots are presented as relative values in relation to the fresh weight for the untreated plots. For further information on materials and methods please refer to section KCP 6.4.2.

3.4.2.2 Summary and evaluation of the field trials conducted in sugarbeet, tomato, carrot and onion, treated with two or three applications

Sugarbeet

A total of eight efficacy trials and six selectivity trials in sugarbeet were harvested. The trials were conducted in United Kingdom (1), Germany (2), Poland (10) and Spain (1) in 2016, 2017, 2019. In the efficacy trials, Boscalid 26.7% + Pyraclostrobin 6.7% WG was applied between one and two times application at 0.6, 1 and 1.5 kg/ha in the efficacy trials, and at 1.5 and 3 Kg/ha in the selectivity trials. The trials were sprayed at crop growth stages ranging between BBCH 31 and BBCH 42. The results obtained in the efficacy and selectivity trials when treated with the doses cited in the Maritime, North-East and Mediterranean EPPO Zone, respectively, are presented from Table 3.4-6 to Table 3.4-10.

Neither Boscalid 26.7% + Pyraclostrobin 6.7% WG nor the reference products (Signum, Optan 183 SE, Opera and Ortiva Top) significantly affected the yield when applied at the proposed dose rate (1.5 kg/ha) in any of the fourteen trials. Rather, overall Boscalid 26.7% + Pyraclostrobin 6.7% WG provided an increase in the yielded mass of the treated crop which is most likely as a consequence of the disease control in the efficacy trials. The results obtained in the trials supports the label claim that Boscalid 26.7% + Py-

raclostrobin 6.7% WG is safe to be applied at the recommended dose rate to sugarbeet at the recommended number of applications.

Tomato

A total of six efficacy trials and three selectivity trials in tomato were harvested. The trials were conducted in Latvia (2), Spain (3), Greece (2) and Italy (2) and in 2016. In the efficacy trials, Boscalid 26.7% + Pyraclostrobin 6.7% WG was applied at three times at 0.6, 1 and 1.5 kg/ha in the efficacy trials, and 1.5 and 3 Kg/ha in the selectivity trials. The trials were sprayed at crop growth stages ranging between BBCH 21 and BBCH 89.

Neither Boscalid 26.7% + Pyraclostrobin 6.7% WG, nor the reference products (Signum and Askon) significantly affected the yield when applied at the proposed dose rate (1.5 kg/ha) in any of the nine trials. Rather, overall Boscalid 26.7% + Pyraclostrobin 6.7% WG provided an increase in the yielded mass of the treated crop which is most likely as a consequence of the disease control in the efficacy trials. The results obtained in the trials supports the label claim that Boscalid 26.7% + Pyraclostrobin 6.7% WG is safe to be applied at the recommended dose rate to tomato at the recommended number of applications.

Carrot

In support of the safe use of the tested product, a total of three selectivity trials in carrot were harvested and results are presented. The trials were conducted in United Kingdom (1), Czech Republic (1), Poland (1) in 2016. In the selectivity trials, Boscalid 26.7% + Pyraclostrobin 6.7% WG was applied at two times at 1.5 and 3 Kg/ha. The trials were sprayed at crop growth stages ranging between BBCH 42 and BBCH 46.

Neither Boscalid 26.7% + Pyraclostrobin 6.7% WG nor the reference products (Amistar Top and Optan 183 SE) significantly affected the yield when applied at the proposed dose rate (1.5 kg/ha) in any of the three trials. Rather, overall Boscalid 26.7% + Pyraclostrobin 6.7% WG provided an increase in the yielded mass of the treated crop. The results obtained in the trials supports the label claim that Boscalid 26.7% + Pyraclostrobin 6.7% WG is safe to be applied at the recommended dose rate and at the recommended number of applications.

Onion

A total of four selectivity trials and four efficacy trials in onion were harvested. The trials were conducted in United Kingdom (1), Czech Republic (1), Germany (2), Poland (2), Spain (1) and Italy (1) in 2016. Boscalid 26.7% + Pyraclostrobin 6.7% WG was applied two times at 1.5 and 3 Kg/ha in the selectivity trials, and at 0.6 Kg/ha, 1 Kg/ha and 1.5 Kg/ha in the efficacy trial. The trials were sprayed at crop growth stages ranging between BBCH 18 and BBCH 47. The results obtained in the obtained in the efficacy and selectivity trials when with the doses cited in the Maritime EPPO Zone, North-East and Mediterranean EPPO zone respectively, are presented.

Neither Boscalid 26.7% + Pyraclostrobin 6.7% WG, nor the reference products (Ortiva Top and Ortiva) significantly affected the yield when applied at the proposed dose rate (1.5 kg/ha) in any of the eight trials. Rather, overall Boscalid 26.7% + Pyraclostrobin 6.7% WG provided an increase in the yielded mass of the treated crop which is most likely as a consequence of the disease control in the efficacy trials. The results obtained in the trials supports the label claim that Boscalid 26.7% + Pyraclostrobin 6.7% WG is safe to be applied at the recommended dose rate to onion at the recommended number of applications.

Table 3.4-6: Crop yield of Sugarbeet from efficacy trials treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). Maritime Zone

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 0.6 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 1 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha	Signum 1.5 Kg/ha	Signum 3 Kg/ha
								Mean	% relative	% relative	% relative	% relative	% relative
Sharda16-052	DEU	2016	Lisanna	39	83 (1)	Yield		48.8 a	123.4% a	133.2% a	104.5% a	114.1% a	119.3% a
Sharda16-053	DEU	2016	Hannibal	43	36 (2)	Yield		80.2 b	97.8% a	99% a	102.6% a	97.8% a	103.7% a
Mean								64.5	110.6%	116.1%	103.6%	105.95%	111.5%
Min								48.8	97.8%	99.0%	102.6%	97.8%	103.7%
Max								80.2	123.4%	133.2%	104.5%	114.1%	119.3%
No. of trials								2	2	2	2	2	2

Table 3.4-7: Crop yield of Sugarbeet from selectivity trial treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). Maritime Zone

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 3 Kg/ha	Opera 1 L/ha	Opera 2 L/ha
								Mean	% relative	% relative	% relative	% relative
SHA837-15-SEL001	UK	2016	Salamanca	41	70 (2)	Yield		65.0 a	97.1% a	88.3% a	111.1% a	115.6% a
Mean								65.0	97.1%	88.3%	111.1%	115.6%
Min								-	-	-	-	-
Max								-	-	-	-	-
No. of trials								1	1	1	1	1

Table 3.4 -8: Crop yield of Sugarbeet from efficacy trial treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). North-East EPPO Zone.

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 0.6 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 1 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha	Signum 0.6 Kg/ha	Signum 1.5 Kg/ha
								Mean	% relative	% relative	% relative	% relative	% relative
SF16BC301T	PL	2016	Polanin	39	39 (2)	Yield	Root	62.1 b	114.7% ab	114.8% ab	113.0% ab	113.0% ab	109.7% ab
354 01 F17 252	PL	2017	Lavenda	53(2)	53(2)	Yield	Root	78.3 b	99.7% a	99.7% a	99.7% a	99.7% a	99.9% a
354 02 F17 253	PL	2017	Schubert	53(2)	53(2)	Yield	Root	76.9 b	101% a	100.1% a	100% a	99.9% a	100% a
354 03 F17 254	PL	2017	Tapir	67(2)	67(2)	Yield	Root	69.2 b	110.1% abc	105.8% a	106.6% a	105.2% a	108.3% a
354 04 F17 255	PL	2017	Jadeit	78(2)	78(2)	Yield	Root	72.5 a	102.7% a	98.8% a	100.8% a	102.5% a	99.5% a
354 05 F17 256	PL	2017	Contenta	72(2)	72(2)	Yield	Root	85.8 b	104.9% a	104.8% a	103.7% a	103.8% a	104.9% a
Mean								74.1	105.5%	104%	103.9%	104.0%	103.7%
Min								62.1	99.7%	98.8%	99.7%	99.7%	99.5%
Max								85.8	114.7%	114.8%	113%	113%	109.7%
No. of trials								6	6	6	6	6	6

Table 3.4 -9: Crop yield of Sugarbeet from selectivity trials treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). North-East EPPO Zone.

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated		Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha		Bosc. 26.7% + Pyraclo. 6.7% WG 3 Kg/ha		Optan 183 SE 1 L/ha		Optan 183 SE 2 L/ha	
								Mean		% relative		% relative		% relative		% relative	
PL16009PL1	PL	2016	Jampol	42	67 (2)	YIELD	Root	90.4	a	98.3%	a	97.3%	a	99.0%	a	98.8%	a
FF16BC302T	PL	2016	Telimena	39	49 (2)	YIELD	Root	78.21	a	102.7%	a	101.3%	a	109.3%	a	104.2%	a
359_01_F17_267	PL	2017	Pikador	39	47	YIELD	Root	84.1	a	98.9%	a	99.4%	a	99.6%	a	101.1%	a
359_01_F17_267	PL	2017	Hunor	40	47	YIELD	Root	64.3	b	106.7%	a	106.7%	a	106.5%	a	106.5%	a
							Mean	79.3		101.7%		101.2%		103.6%		102.7%	
							Min	64.3		98.3%		97.3%		99.0%		98.8%	
							Max	90.4		106.7%		106.7%		109.3%		106.5%	
							No. of trials	4		4	4	4	4	4	4	4	4

Table 3.4-10: Crop yield of Sugarbeet from selectivity trial treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). Mediterranean Zone

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated		Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha		Bosc. 26.7% + Pyraclo. 6.7% WG 3 Kg/ha		Ortiva Top 1 L/ha		Ortiva Top 2 L/ha	
								Mean		% relative		% relative		% relative		% relative	
16/SHA/96	ES	2016	Sánlucar	40	77 (2)	Yield		159.6	a	103.5%	a	107.1%	a	109.4%	a	113.8%	a
							Mean	38.9		103.5%		107.1%	a	109.4%	a	113.8%	a
							Min	-		-		-		-		-	
							Max	-		-		-		-		-	
							No. of trials	2		1		1		1		1	

Table 3.4 -11: Crop yield of Tomato from efficacy trials treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). North-East EPPO Zone.

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated		Bosc. 26.7% + Pyraclo. 6.7% WG 0.6 Kg/ha		Bosc. 26.7% + Pyraclo. 6.7% WG 1 Kg/ha		Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha		Signum 1.5 Kg/ha		Signum 3 Kg/ha	
								Mean		% relative		% relative		% relative		% relative		% relative	
F-16-1-46-RR-2539	LVA	2016	Tolstoj	80 (3)	35 (2)	YIELD	Frut	288.0	a	96.6%	a	92.2%	a	95.6%	a	91.8%	a	99.1%	a
F-16-1-46-RR-2541	LVA	2016	Rallijs	85 (3)	7 (3)	YIELD	Fruit	115.3	a	102.4%	a	100.4%	a	105.2%	a	95.2%	a	187.5%	a
							Mean	201.6		99.5%		96.3%		100.4%		93.5%		143.3%	
							Min	115.3		96.6%		92.2%		95.6%		91.8%		99.1%	
							Max	288.0		102.4%		100.4%		105.2%		95.2%		187.5%	
							No. of trials	2		2		2		2		2		2	

Table 3.4-12: Crop yield of Tomato from efficacy trials treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). Mediterranean zone

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 0.6 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 1 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha	Signum 0.6 Kg/ha	Signum 1.5 Kg/ha
								Mean	% relative	% relative	% relative	% relative	% relative
16/SHA/100	ES	2016	Patriarca	87	7 (3)	YIELD		17.6 a	121.7% a	109.2% a	112.4% a	100.7% a	125.8% a
16/SHA/99	ES	2016	Guarapo	87	7 (3)	YIELD		18.0 a	119.7% a	92.4% a	103.5% a	117.5% a	107.8% a
PC 15 SHR 287	IT	2016	Vulcan	52	54 (3)	YIELD		102.0 b	120.0% a	121.0% a	122.1% a	120.0% a	122.2% a
TSTF2016033A	GR	2016	H15	76	36 (3)	YIELD		33.0 d	137.8% bc	167.1% ab	177.8% a	132.9% c	180.0% a
							Mean	42.7	124.8%	122.4%	129.0%	117.8%	134.0%
							Min	18.0	119.7%	92.4%	103.5%	100.7%	180.0%
							Max	102.0	137.8%	167.1%	177.8%	132.9%	107.8%
							No. of trials	4.0	4	4	4	4	4

Table 3.4-13: Crop yield of Tomato from selectivity trials treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). Mediterranean zone

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 3 Kg/ha	Askon 1 L/ha	Askon 0.6 L/ha
								Mean	% relative	% relative	% relative	% relative
TSTF2016032A	GR	2106	Elpida	89	28 (3)	YIELD		145.8	104.1% -	104.3% -	99.5% -	103.1% -
PC 15 SHR 288	IT	2016	Leader	52	53 (1)	YIELD		115.0	120.9% a	122.0% a	121.4% a	122.5% a
16/SHA/101	ES	2016	Guarapo	87	7 (3)	YIELD		10.3	102.3% a	109.5% a	101.9% a	105.8% a
							Mean	90.4	109.1%	111.9%	107.6%	110.5%
							Min	10.3	102.3%	104.3%	99.5%	103.1%
							Max	145.8	120.9%	121.9%	121.4%	122.5%
							No. of trials	3	3	3	3	3

Table 3.4-14: Crop yield of Carrot from selectivity trials treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). Maritime Zone

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 3 Kg/ha	Amistar Top 1.5 Kg/ha	Amistar Top 3 Kg/ha
								Mean	% relative	% relative	% relative	% relative
SHA837-16-SEL002	UK	2016	Nantes	42	37 (2)	Yield		4.95	101.8% a	103.8% a	111.9% a	102.4% a
SWEPL-CZE16-PYBO-DAUCS-TRU7	CZ	2016	Anina	46	83 (2)	Yield		112.08	97.5% -	102.2%	99.4%	99.1%
								Mean	58.515	99.7	103.0	105.7
								Min	4.95	97.5	102.2	99.4
								Max	112.08	101.8	103.8	111.9
								No. of trials	2	2	2	2

Table 3.4 -15: Crop yield of Carrot from selectivity trial treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). North-East EPPO Zone.

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 3 Kg/ha	Optan 183 SE 1 L/ha	Optan 183 SE 2 L/ha
								Mean	% relative	% relative	% relative	% relative
PL16007PL1	PL	2016	Elegance	45 (2)	58 (2)	YIELD	Root	68.1 a	115.9% a	125.1% a	112.3% a	101.3% a
								Mean	68.1	115.9%	125.1%	112.3%
								Min	-	-	-	-
								Max	-	-	-	-
								No. of trials	1	1	1	1

Table 3.4-16: Crop yield of Onion from efficacy trial treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). Maritime Zone

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 0.6 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 1 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha	Signum 0.6 Kg/ha	1.5 Kg/ha	Askon 1.0 L/ha
								Mean	% relative	% relative	% relative	% relative	% relative	
SHA837-15-EFF003	UK	2016	Corrando	45	320 (2)	Yield		12.73	104.7% a	112.6% a	100.5% a	96.6% a	63.2% a	-
CT19-4-9DE1	DE	2019	Paradiso	47/48	26	Yield		35.0	86.6% b	90.6% b	114.9% a		101.1% ab	97.5% ab
CT19-4-9DE2	DE	2019	Vares	43	24	Yield		48.1	107.4% c	110.0% c	116.2% b		119.5% b	123.5% a
								Mean	31.94	99.6%	104.4%	96.6%	94.6%	110.5%
								Min	12.73	86.6%	90.6%	-	63.2%	97.5%
								Max	48.1	107.4%	112.6%	-	119.5%	123.5%
								No. of trials	3	3	3	1	3	2

Table 3.4-17: Crop yield of Onion from selectivity trials treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). Maritime Zone

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 3 Kg/ha	Askon 1 L/ha	Askon 2 L/ha
								Mean	% relative	% relative	% relative	% relative
SWEPL-CZE16-PYBO-ALLXP-TRU6	CZ	2016	Wellina	43	80 (2)	Yield		65.15	99.6%	94.8% a	101.8% a	99.1% a
						Mean		38.94	100%	94.8%	101.8%	99.1%
						Min		-	-	-	-	-
						Max		-	-	-	-	-
						No. of trials		1	1	1	1	1

Table 3.4-18: Crop yield of Onion from efficacy trial, treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). North-East Zone.

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 0.6 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 1.0 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha	Signum 0,75 Kg/ha	Signum 1.0 Kg/ha
								Mean	% relative	% relative	% relative	% relative	% relative
356_01_F17_258	PL	2019	Armstrong	45	26/47	Yield		53.8 a	100.8% a	107.8% a	103.0% a	99.4% a	105.0% a
						Mean		53.8	100.8%	107.8%	103.0%	99.4%	105.0%
						Min		-	-	-	-	-	-
						Max		-	-	-	-	-	-
						No. of trials		1	1	1	1	1	1

Table 3.4 -19: Crop yield of Onion from selectivity trial treated with Pyraclostrobin 6.7 % + Boscalid 26.7 % WG as % of untreated (Untreated = 100%). North-East EPPO Zone.

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 3 Kg/ha	Signum 1.5 Kg/ha	Signum 3 Kg/ha
								Mean	% relative	% relative	% relative	% relative
PL16008PL1	PL	2016	Hybelle	43 (2)	42 (2)	YIELD	Root	18.2 b	98.9% a	94.0% a	85.2% a	103.8% a
						Mean		18.2	98.9%	94.0%	85.2%	103.8%
						Min		-	-	-	-	-
						Max		-	-	-	-	-
						No. of trials		1	1	1	1	1

**Table 3.4-20: Crop yield of Onion from selectivity trials treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%).
Mediterranean Zone**

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 3 Kg/ha	Signum 1.5 Kg/ha	Signum 3 Kg/ha	Ortiva 1 L/ha	Ortiva 2 L/ha
								Mean	% relative	% relative	% relative	% relative	% relative	% relative
PC 15 SHR 294	IT	2016	Bonus	18	62 (2)	YIELD		30 b	117.8% a	118.5% a	117.8% a	117.6% a		
16/SHA/106	ES	2016	Hamasodachi 950	45	127 (2)	YIELD		97.60 a	95.0% a	99.0% a			96.5% a	98.5% a
Mean								63.8	106.3%	108.7%	117.8%	117.6%	96.5%	98.5%
Min								30	95.0%	99.0%	-	-	-	-
Max								97.60	117.8%	118.5%	-	-	-	-
No. of trials								2	2	2	1	1	1	1

Comments of zRMS:	<p>To evaluate the effect of Casino Royal on the yield of sugar beet, tomato, onion and carrot, the results obtained in efficacy and selectivity trials conducted in 2016, 2017 and 2019. No negative impact or dose response was recorded during submitted trials.</p> <p>The applicant wishes to cite the original registrant's data on boscalid and pyraclostrobin now out of protection in support of those recommendations on the draft label that are not adequately supported. Such extrapolations should be considered by individual member states on a national level based on current registration, data protection and experience with similar boscalid and pyraclostrobin products. In Poland, uses included in GAP table from Signum 33 WG can be accepted.</p>
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3.4.2.3 Overall conclusion

Boscalid 26.7% + Pyraclostrobin 6.7% WG applied at the proposed dose rate, at a range of growth stages within the label recommended range, in sugarbeet, tomato, carrot and onion did not affect crop yield nor the quality of the crop yield significantly in any of the twenty two trials harvested. Furthermore, the data obtained in trials harvested demonstrate that Boscalid 26.7% + Pyraclostrobin 6.7% WG is as safe as the reference products used in the trials.

In cases of low number of trials, Poland can be able to take into account the results of the trials from Czech Republic, Germany, Latvia given comparable conditions because it is a neighbouring country. For recommendations on the label not sufficiently supported with trials harvested, the applicant wishes to bridge to the trials conducted in sugarbeet, tomato, carrot and onion where harvest data demonstrated the safe use following application of Boscalid 26.7% + Pyraclostrobin 6.7% WG as recommended. Furthermore, the data presented in this BAD also clearly demonstrates that the efficacy and crop safety of Boscalid 26.7% + Pyraclostrobin 6.7% WG is equivalent to the standard Boscalid 26.7% + Pyraclostrobin 6.7% WG products to which it was compared. The applicant therefore wishes to cite the original registrant's data on Boscalid 26.7% + Pyraclostrobin 6.7% WG now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

Twenty two efficacy and selectivity trials treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG were harvested and yields and/or quality of yield recorded. In a number of these, assessments on the potential impact of treatment on a range of quality parameters including sugar content, Na, K and AMN content, weight increase, fresh weight, marketable and unmarketable fruits were conducted.

Sugarbeet

In three selectivity trial and eleven efficacy trials conducted in sugarbeet quality parameters were evaluated: Sugar content, Na, Ka and AMN content: The results obtained are presented in Table 3.4-21 to Table 3.4-28. The data were obtained from the Maritime and North-East EPPO zone.

In the trial where the quality parameters were evaluated, Boscalid 26.7% + Pyraclostrobin 6.7% WG had no detrimental effect on the quality parameters assessed on the harvested sugarbeet crop. When comparing the results obtained with Boscalid 26.7% + Pyraclostrobin 6.7% WG against the results obtained with the Boscalid 26.7% + Pyraclostrobin 6.7% WG reference product (Signum and Optan 183 SE) at the applied dose rates, both products performed statistically similar.

Tomato

In total of three selectivity trials and two efficacy trials conducted in tomato quality parameters were evaluated: Sugar content, weight increase, fresh weight, marketable and unmarketable fruits. The results obtained are presented from Table 3.4-29 to **Błąd! Nie można odnaleźć źródła odwołania.**³³. The data were obtained from the Maritime, North-East and Mediterranean EPPO zone.

In the trials where the quality parameters were evaluated, Boscalid 26.7% + Pyraclostrobin 6.7% WG had no detrimental effect on the quality parameters assessed on the harvested tomato crop. When comparing the results obtained with Boscalid 26.7% + Pyraclostrobin 6.7% WG against the results obtained with the Boscalid 26.7% + Pyraclostrobin 6.7% WG reference and national standard products (Signum, Ortiva Top and Askon) at the applied dose rates, all products performed statistically similar.

Carrot

In one selectivity trial conducted in carrot quality parameters were evaluated. The results obtained are presented in Table 3.4-34. The data were obtained from the North-East EPPO zone.

In the trial where the quality parameters were evaluated, Boscalid 26.7% + Pyraclostrobin 6.7% WG had no detrimental effect on the quality parameters assessed on the harvested sugarbeet crop. When comparing the results obtained with Boscalid 26.7% + Pyraclostrobin 6.7% WG against the results obtained with the Boscalid 26.7% + Pyraclostrobin 6.7% WG reference product (Scorpion) at the applied dose rates, both products performed statistically similar..

Onion

In one selectivity trial and one efficacy trials conducted in onion quality parameter were evaluated: Weight increase. The results obtained are presented in the Table 3.4-35 to Table 6.1.4-36. The data were obtained from the Mediterranean and North-East EPPO Zone.

In the trial where the quality parameter was evaluated, Boscalid 26.7% + Pyraclostrobin 6.7% WG had no detrimental effect on the quality parameter assessed on the harvested onion. When comparing the results obtained with Boscalid 26.7% + Pyraclostrobin 6.7% WG against the results obtained with the Boscalid 26.7% + Pyraclostrobin 6.7% WG reference product (Signum and Escorpion) at the applied dose rates. both products performed statistically similar.

Table 3.4-21: Yield quality parameters from efficacy trial of Sugarbeet, treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). Maritime Zone

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 0.6 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 1 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha	Signum 1.5 Kg/ha	Signum 3 Kg/ha
								Mean	% relative	% relative	% relative	% relative	% relative
Sharda16-052	DEU	2016	Lisanna	39	83 (1)	SUG-CON		20.29 a	99% a	101.3% a	98.8% a	96.1% a	100.5% a
Sharda16-052	DEU	2016	Lisanna	39	83 (1)	NA-CON		0.66 a	148.5% a	131.8% a	106.1% a	97% a	116.7% a
Sharda16-052	DEU	2016	Lisanna	39	83 (1)	KA-CON		3.47 a	110.4% a	107.2% a	111.2% a	98.3% a	98.8 a
Sharda16-052	DEU	2016	Lisanna	39	83 (1)	AMN-CON		2.53 a	120.9% a	111.5% a	100% a	98.4% a	107.1% a

Table 3.4-22: Yield quality parameters from efficacy trial of Sugarbeet, treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). North-East Zone.

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 0.6 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 1 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha	Signum 0,6 Kg/ha	Signum 1.5 Kg/ha
								Mean	% relative	% relative	% relative	% relative	% relative
SF16BC301T	PL	2016	Polanin	39 (2)	39 (2)	Biological Sugar yield	Root	10.7 b	119.6% a	118.7% a	121.5% a	117.8% a	115.0% a
							Mean	10.7	119.6%	118.7%	121.5%	117.8%	115.0%
							Min	-	-	-	-	-	-
							Max	-	-	-	-	-	-
							No. of trials	1	1	1	1	1	1

Table 3.4-23: Yield quality parameters from efficacy trial of Sugarbeet, treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). North-East Zone.

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 0.6 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 1 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha	Signum 0,6 Kg/ha	Signum 1.5 Kg/ha
								Mean	% relative	% relative	% relative	% relative	% relative
SF16BC301T	PL	2016	Polanin	39 (2)	39 (2)	Technological sugar yield	Root	9.6 b	119.8% a	118.8% a	121.9% a	116.7% a	115.6% a
							Mean	9.6	119.8%	118.8%	121.9%	116.7%	115.6%
							Min	-	-	-	-	-	-
							Max	-	-	-	-	-	-
							No. of trials	1	1	1	1	1	1

Table 3.4-24: Yield quality parameters from efficacy trial of Sugarbeet, treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). North-East Zone.

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 0.6 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 1 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha	Signum 0,6 Kg/ha	Signum 1.5 Kg/ha
								Mean	% relative	% relative	% relative	% relative	% relative
SF16BC301T	PL	2016	Polanin	39 (2)	39 (2)	SUGCON	Root	17.3	104.2% f	102.9% a	107.0% a	103.5% h	104.2% e
354 01 F17 252	PL	2017	Lavenda	53(2)	53(2)	SUGCON	Root	16.8	99.6% a	99.4% a	99.9% a	99.7% a	99.4% a
354 02 F17 253	PL	2017	Schubert	53(2)	53(2)	SUGCON	Root	16.7	99.9% a	99.9% a	99.9% a	100.1% a	99.9% a
354 03 F17 254	PL	2017	Tapir	67(2)	67(2)	SUGCON	Root	14.9	107% a	107.4% a	111.2% a	103.3% a	110.3% a
354 04 F17 255	PL	2017	Jadeit	78(2)	78(2)	SUGCON	Root	16.7	100.1% a	98.5% a	100.2% a	101.0% a	99.9% a
354 05 F17 256	PL	2017	Contenta	72(2)	72(2)	SUGCON	Root	13.5	104.3% a	104.2% a	103.9% a	104.2% a	103.7% a
							Mean	15.9	102.5%	102.0%	103.7%	101.9%	102.9%
SF16BC301T	PL	2016	Polanin	39 (2)	39 (2)	K-CON		31.5	101.9% q	98.7% j	114.6% b	117.8% a	101.0% h
354 01 F17 252	PL	2017	Lavenda	53(2)	53(2)	K-CON		26.0	99.8% a	102.1% a	100.9% a	99.5% a	98.8% a
354 02 F17 253	PL	2017	Schubert	53(2)	53(2)	K-CON		26.4	98% a	100.3% a	100.1% a	99.3% a	98.7% a
354 03 F17 254	PL	2017	Tapir	67(2)	67(2)	K-CON		25.4	103.6% a	104.4% a	103.9% a	102.3% a	101.3% a
354 04 F17 255	PL	2017	Jadeit	78(2)	78(2)	K-CON		25.4	96.4% a	99.3% a	97.8% a	99.8% a	98.3% a
354 05 F17 256	PL	2017	Contenta	72(2)	72(2)	K-CON		25.4	97.8% a	100.8% a	99.1% a	99.1% a	98.5% a
							Mean	26.7	99.6%	100.9%	102.7%	102.9%	99.4%
SF16BC301T	PL	2016	Polanin	39 (2)	39 (2)	Na-CON		3	76.7% d	100.0% a	76.7% d	80.0% c	90.0% b

354 01 F17 252	PL	2017	Lavenda	53(2)	53(2)	Na-CON	1.9	102.5%	a	100%	a	97.4%	a	100%	a	105.1%	a
354 02 F17 253	PL	2017	Schubert	53(2)	53(2)	Na-CON	1.9	97.4%	a	106.7%	a	101%	a	101.0%	a	102.6%	a
354 03 F17 254	PL	2017	Tapir	67(2)	67(2)	Na-CON	1.9	94.7%	a	96.3%	a	109.4%	a	109.4%	a	110.5%	a
354 04 F17 255	PL	2017	Jadeit	78(2)	78(2)	Na-CON	1.7	93.1%	a	102.8%	a	97.1%	a	88.5%	a	94.3%	a
354 05 F17 256	PL	2017	Contenta	72(2)	72(2)	Na-CON	1.8	95.5%	a	103.9%	a	94.4%	a	88.7%	a	95.5%	a
Mean							2.0	93.3%		101.6%		96%		94.6%		99.6%	
SF16BC301T	PL	2016	Polanin	39 (2)	39 (2)	N-CON	16.3	89.6%	c	87.1%	d	77.9%	h	106.7%	a	73.6%	j
354 01 F17 252	PL	2017	Lavenda	53(2)	53(2)	N-CON	15.8	100.6%	a	100.9%	a	100.8%	a	97.7%	a	99.7%	a
354 02 F17 253	PL	2017	Schubert	53(2)	53(2)	N-CON	15.6	100.3%	a	99.2%	a	99.2%	a	101.6%	a	103.5%	a
354 03 F17 254	PL	2017	Tapir	67(2)	67(2)	N-CON	15.7	99.4%	a	102.2%	a	101.8%	a	99.9%	a	99.4%	a
354 04 F17 255	PL	2017	Jadeit	78(2)	78(2)	N-CON	16.0	97.8%	a	98.9%	a	100%	a	95.6%	a	95%	a
354 05 F17 256	PL	2017	Contenta	72(2)	72(2)	N-CON	15.9	97.5%	a	100.2%	a	99.9%	a	98.4%	a	96.2%	a
Mean							15.9	97.5%		98%		96.6%		99.9%		98.7%	

Table 3.4-25: Yield quality parameters from selectivity trial of Sugarbeet, treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). North-East Zone.

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha		Bosc. 26.7% + Pyraclo. 6.7% WG 3 Kg/ha		Optan 183 SE 1 l/ha	Optan 183 SE 2 l/ha
								Mean	% relative		% relative		% relative	% relative
PL16009PL1	PL	2016	Jampal	42 (2)	67 (2)	SUGCON	Root	18.2	100.0%	a	102.2%	a	98.9% a	99.5% a
359_01_F17_267	PL	2017	Pikador	39 (2)	47 (2)	SUGCON	Root	2.9	100.0%	a	117.3%	a	106.9% a	110.3% a
359_01_F17_267	PL	2017	Hunor	40 (2)	47 (2)	SUGCON	Root	16.4	104.3%	a	104.3%	a	104.3% a	103.7% a
Mean								12.5	101.4%		107.9%		103.4%	104.5%
359_01_F17_267	PL	2017	Pikador	39 (2)	47 (2)	NITCON	Root	13.5	100.0%	a	97.7%	a	103.1% a	103.8% a
359_01_F17_267	PL	2017	Hunor	40 (2)	47 (2)	NITCON	Root	17.3	100.0%	a	100.0%	a	100.6% a	100.0% a
Mean								15.4	100.0%		98.9%		101.9%	101.9%
359_01_F17_267	PL	2017	Pikador	39 (2)	47 (2)	SODCON	Root	2.9	100.0%	a	117.2%	a	106.9% a	110.3% a
359_01_F17_267	PL	2017	Hunor	40 (2)	47 (2)	SODCON	Root	3.1	90.3%	a	106.5%	a	93.5% a	103.2% a
Mean								3.0	95.2%		111.9%		100.2%	106.8%
359_01_F17_267	PL	2017	Pikador	39 (2)	47 (2)	POTCON	Root	33.1	105.1%	a	101.8%	a	97.9% a	104.5% a
359_01_F17_267	PL	2017	Hunor	40 (2)	47 (2)	POTCON	Root	33.5	97.6%	a	105.1%	a	101.2% a	96.7% a
Mean								33.3	101.4%		103.5%		99.6%	100.6%

Table 3.4-26: Yield quality parameters from selectivity trial of Sugarbeet, treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). North-East Zone.

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha		Bosc. 26.7% + Pyraclo. 6.7% WG 3 Kg/ha		Optan 183 SE 1 l/ha	Optan 183 SE 2 l/ha
								Mean	% relative		% relative		% relative	% relative
PL16009PL1	PL	2016	Jampal	42 (2)	67 (2)	SUGCON	Root	18.2	100.0%	a	102.2%	a	98.9% a	99.5% a
Mean								18.2	100.0%		102.2%		98.9%	99.5%
Min								-	-		-		-	-
Max								-	-		-		-	-
No. of trials								1	1		1		1	1

Table 3.4-27: Yield quality parameters from selectivity trial of Sugarbeet, treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). North-East Zone.

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha		Bosc. 26.7% + Pyraclo. 6.7% WG 3 Kg/ha		Optan 183 SE 1 l/ha	Optan 183 SE 2 l/ha
								Mean	% relative		% relative		% relative	% relative
PL16009PL1	PL	2016	Jampal	42 (2)	67 (2)	Biological sugar yield	Root	13.23 c	104.2%	bc	101.6%	c	114.7% a	111.0% ab
Mean								18.2	104.2%		101.6%		114.7%	111.0%
Min								-	-		-		-	-
Max								-	-		-		-	-
No. of trials								1	1		1		1	1

Table 3.4-28: Yield quality parameters from selectivity trial of Sugarbeet, treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). North-East Zone.

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 3 Kg/ha	Optan 183 SE 1 l/ha	Optan 183 SE 2 l/ha
								Mean	% relative	% relative	% relative	% relative
PL16009PL1	PL	2016	Jampal	42 (2)	67 (2)	Technological sugar yield	Root	11.2 c	105.6% c	102.7% c	117.1% a	114.2% ab
							Mean	11.2	105.6%	102.7%	117.1%	114.2%
							Min	-	-	-	-	-
							Max	-	-	-	-	-
							No. of trials	1	1	1	1	1

Table 3.4-29: Yield quality parameters from selectivity trial of Tomato, treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). Maritime Zone

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 3 Kg/ha	Ortiva Top 1 L/ha	Ortiva Top 2 L/ha
								Mean	% relative	% relative	% relative	% relative
SWEPL-CZE16-PYBO-LYPES-NECH4	CZ	2016	Tolstoj		48 (3)	FRUMAR		34.62	100.3%	90.6%	103.4%	92.7%
SWEPL-CZE16-PYBO-LYPES-NECH4	CZ	2016	Tolstoj		48 (3)	FRUUNM		0.72	261.1%	111.1%	131.9%	83.3%

Table 3.4-30: Yield quality parameters from efficacy trial of Tomato, treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). Maritime Zone

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 0.6 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 1 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha	Signum 0.6 Kg/ha	Signum 1.5 Kg/ha
								Mean	% relative	% relative	% relative	% relative	% relative
Sharda16-054	DEU	2016	Hoffmans Rendita	81	8 (2)	WEIFRE		7.6	104% a	74.6% a	92.3% a	98.1% a	103.5% a

Table 3.4-31: Yield quality parameters from selectivity trial of Tomato, treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). Maritime Zone

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 3 Kg/ha	Askon 1 L/ha	Askon 0.6 L/ha
								Mean	% relative	% relative	% relative	% relative
Sharda16-057	DEU	2016	Magnusa	75	12 (2)	WEIFRE		13	100.2% a	104.2% a	87.6% a	96.3% a

Table 3.4-32: Yield quality parameters from selectivity trial of Tomato, treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). Mediterranean Zone

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 3 Kg/ha	Ortiva Top 1 L/ha	Ortiva Top 2 L/ha
								Mean	% relative	% relative	% relative	% relative
PC 15 SHR 288	IT	2016	Leader	52	53 (1)	WEIINC		100 b	120.9% a	122.05% a	121.5% a	122.6% a

Table 3.4-33: Yield quality parameters from selectivity trial of Tomato, treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). Maritime Zone

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 3 Kg/ha	Askon 1 L/ha	Askon 0.6 L/ha
								Mean	% relative	% relative	% relative	% relative
Sharda16-054	DEU	2016	Hoffmans Rendita	81	8 (2)	SUGCON		6.3	103.2% a	101.6% a	106.3% a	103.2% a

Table 3.4 -34: Yield quality parameters form selectivity trial of Carrot treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). North-East Zone.

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 3 Kg/ha	ESCORPION SE 1 l/ha	ESCORPION SE 2 l/ha
								Mean	% relative	% relative	% relative	% relative
PL16007PL1	PL	2016	Elegance	45 (2)	58 (2)	> 4.5 cm		5.8	139.7% a	143.1% a	129.3% a	106.9% a
PL16007PL1	PL	2016	Elegance	45 (2)	58 (2)	3-4.5 cm		37.0	118.6% a	126.5% a	115.7% a	104.6% a
PL16007PL1	PL	2016	Elegance	45 (2)	58 (2)	< 3 cm		7.2	83.3% a	104.2% a	81.9% a	81.9% a

Table 3.4-35: Yield quality parameters from selectivity trial of Onion, treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). Mediterranean Zone

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 3 Kg/ha	Signum 1.5 Kg/ha	Signum 3 Kg/ha
								Mean	% relative	% relative	% relative	% relative
PC 15 SHR 294	IT	2016	Bonus	18	62 (2)	WEIINC		100.0 b	118.1% a	118.9% a	118.1% a	119.1% a

Table 3.4-36: Yield quality parameters from efficacy trial of onion treated with Boscalid 26.7% + Pyraclostrobin 6.7% WG as % of untreated (Untreated = 100%). North-East Zone.

Trial ID	Country	Year	Variety	GS at appl.	Assessm. Days after last appl.	Assess. Type	Part assess.	Untreated	Bosc. 26.7% + Pyraclo. 6.7% WG 1.5 Kg/ha	Bosc. 26.7% + Pyraclo. 6.7% WG 3 Kg/ha	Signum 0,6 Kg/ha	Signum 1.5 Kg/ha
								Mean	% relative	% relative	% relative	% relative
PL16008PL1	PL	2016	Hybelle	43 (2)	42 (2)	COLOR		5 a	100.0% a	100.0% a	100.0% a	100.0% a
PL16008PL1	PL	2016	Hybelle	43 (2)	42 (2)	<6 cm		25.2 a	101.2% a	97.6% a	84.1% a	115.9% a
PL16008PL1	PL	2016	Hybelle	43 (2)	42 (2)	4-6 cm		17.0 a	98.2% a	89.4% a	86.5% a	88.8% a
PL16008PL1	PL	2016	Hybelle	43 (2)	42 (2)	< 6cm		1.5 a	60.0% a	66.7% a	80.0% a	60.0% a

Comments of zRMS:	<p>No negative effect on quality and quantity of yield during trials was observed. Results were compared to standard reference product</p> <p>The applicant refers to comparability with reference boscalid and pyraclostrobin product and wishes to cite the original registrant's data on boscalid now out of protection in support of those recommendations on the draft label that are not adequately supported. Such extrapolations should be considered by individual member states on a national level based on current registration, data protection and experience with similar boscalid and pyraclostrobin products. In Poland, uses included in GAP table from Signum 33 WG (unprotected data) can be accepted.</p>
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3.4.4 Effects on transformation processes (KCP 6.4.4)

There are no indications that the use of Boscalid 26.7% + Pyraclostrobin 6.7% WG will have influence on possible transformation processes. It is therefore expected that Boscalid 26.7% + Pyraclostrobin 6.7% WG, when applied in accordance with good agricultural practices will not cause any unacceptable adverse effects on transformation processes. Fungicides are usually only considered in regards to their potential effect on transformation processes if applied close to harvest (EPPO standard PP 1/243(1) Effects of plant protection products on transformation processes). Boscalid 26.7% + Pyraclostrobin 6.7% WG is not applied close to harvest.

Comments of zRMS:	Evaluator agrees with Applicant. Argumentation on impact on “transformation procedure” is deemed sufficient. Data should be submitted according to the requirements of the EPPO Standard PP 1/243(2). No studies were submitted by the applicant. Due to this fact the restriction may be considered to be put on the label. e.g. Effects on transformation processes should be consulted with the authorization holder. However, in the opinion of Evaluator on the basis on information's that no cases of negative influences on parameters influencing the processing procedure were reported. So, lack of special studies is accepted.
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3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

Boscalid 26.7% + Pyraclostrobin 6.7% WG is composed of boscalid and pyraclostrobin, which has been widely used for several years on a range of crops, without identifying any issues in regards to ability of grains of treated plants to germinate.

Thus, negative effects of boscalid and pyraclostrobin on parts of plant used for propagating purposes can be excluded. Furthermore, phytotoxicity assessments in the performed trials demonstrated the complete crop safety of the product and the absence of any negative effect on the plants or plant products.

The product complies with the Uniform Principles.

Comments of zRMS:	ZRM's agrees with Applicant's argumentation.
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3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

Boscalid

Results according to Additional Report to DAR of Boscalid, point B.7.9., Published on November 08, 2002, shows the results of the report made by Hamm RT, Veit P. 2001 in Germany for Boscalid residues levels in succeeding crops .

Material and methods

The test compound was applied, as an acetonic solution to the surface of a bare, loamy sand soil at an application rate equivalent to 2100 g as/ha. After application, the soil was aged for 30 days (simulating an emergency plant back; 30 DAT), 120 days, 270 days and 365 days. After 30 days, ploughing was simulated by mixing the treated and untreated soil layers (about 20 cm). Afterwards, the crops: radish, lettuce and wheat were sowed or planted and grown either in growth chambers, where natural climatic conditions were simulated, or in a vegetation hall or in a green house.

After each harvest, the top layer of 20 cm was dugged up again and the next plants were sowed or planted correspondent to the ageing periods. The roots of wheat and lettuce remained in the soil after harvest.

Food and feed items of mature crops were harvested, processed and analysed by combustion and subsequent radioactivity measurement for the determination of the total radioactive residues in the raw agricultural commodities (RAC's). In addition soil samples were taken after application, ploughing and after each harvest of mature crops.

The total radioactive residues (TRR) of each sample were determined by combustion analysis. All samples were extracted with methanol and in some cases an additional aqueous ammonia extraction was added. The remaining post extraction solids from the wheat matrices: forage, straw and grain and in addition from radish leaf and root (diphenyl label, 120 DAT) were treated with sodium hydroxide or DMSO to release part of the remaining radioactivity. Methanol extracts of all samples under investigation were analysed by HPLC.

Soil

The total radioactive residues in soil (see Table 3.5-1) after ageing and ploughing decreased at longer ageing intervals. After the 1st ageing period (30 DAT), the TRR level in the diphenyl treated soil was higher than in the pyridine treated soil (1.112 to 0.716 mg/kg) but the levels were close after an ageing interval of 365 days (0.429 to 0.356 mg/kg).

The TRR levels in soils after harvest varied within the crops and the plant back intervals. A tendency could not be detected. Soils after harvest were extracted with methanol and analysed by HPLC. Only parent was detected.

Table 3.5-1: Total radioactive residues in soil samples after treatment with ¹⁴C-boscalid (pyridine and diphenyl label)

Soil Samples	Pyridine label TRR [mg/kg]	Diphenyl label TRR [mg/kg]
After application		
Plant back intervals (after soil ageing, ploughing)		
30 DAT	0.716	1.112
120 DAT	0.648	0.813
270 DAT	0.647	n.d.
365 DAT	0.356	0.429
After harvest of ripe crops		
Plant back interval: 30 DAT		
Radish	n.d.	0.731
Lettuce	0.545	0.747
Wheat	0.379	0.393
Plant back interval: 120 DAT		
Radish	0.548	0.585
Lettuce	0.484	0.409
Wheat	0.386	0.506
Plant back interval: 270 DAT		
Radish	0.377	0.521
Lettuce	0.321	0.436
Wheat	0.537	0.551
Plant back interval: 365 DAT		
Radish	n.d.	0.460
Lettuce	n.d.	0.434
Wheat	0.125	0.343

n.d. = not determined

Metabolism

The methanol extractable ^{14}C -residues were characterised by different HPLC methods. In all extracts, the most prominent peak was ^{14}C -boscalid.

In *lettuce*, the ^{14}C -boscalid concentration ranged from 0.014 – 0.072 mg/kg/ 55.6 – 94.1 % TRR for the both labels. One higher value was detected after 120 days of soil ageing for the pyridine label at 0.146 mg/kg. One polar peak at low concentrations was detected in both labels.

In *radish root*, the concentration of ^{14}C -boscalid varied between 0.009 - 0.091 mg/kg (52.6 – 92.8 % TRR) for both labels. In addition, the metabolite M510F61, a sugar conjugate of the parent compound, was detected in a concentration of ≤ 0.006 mg/kg (diphenyl label) after a soil ageing period of 120 and 365 days and a polar peak was detected.

In *radish leaves* the concentration of ^{14}C -boscalid varied between 0.088 to 0.304 mg/kg for both labels. The metabolite M510F61 was found in most of the radish leave samples (0.004 – 0.032 mg/kg; with the highest values for the diphenyl label). Additionally, in the sample at 120 DAT of the diphenyl label a polar peak in a concentration of 0.039 mg/kg / 13.2% TRR was found.

In *wheat straw*, the concentration of ^{14}C -boscalid varied between 0.808 to 3.156 mg/kg (50.0 – 87.5 % TRR) for the pyridine label and between 1.088 – 7.991 mg/kg (70.8 – 84.6 % TRR) for the diphenyl label. In addition, the metabolite M510F61 was detected in a concentration of ≤ 0.117 mg/kg for the pyridine label and with a concentration of 0.025 – 0.423 mg/kg for the diphenyl label. At plant back intervals of 270 DAT and 365 DAT two peaks were detected in concentrations of ≤ 0.032 mg/kg / 2.0 % TRR (pyridine label) and 0.140 – 0.174 mg/kg / 5.4 – 10.0 % TRR (diphenyl label).

In *wheat grain*, the concentration of ^{14}C -boscalid ranged from 0.005 to 0.015 mg/kg for the pyridine label and from 0.008 – 0.028 mg/kg for the diphenyl label. The metabolite M510F61 was not detected in grain. A polar peak amounted to ≤ 0.010 mg/kg ($\leq 3.8\%$ TRR) for both labels.

Table B.3.5-1: Investigation of the nature of the residues in rotational crops after treatment with pyridine labelled ¹⁴C-boscalid

Crop parts	TRR	ERR	RRR	Boscalid	M510F61	Unidentified Metabolites	
	mg/kg	mg/kg (% TRR)	mg/kg (% TRR)	mg/kg (% TRR)	mg/kg (% TRR)	mg/kg	% TRR
Plant back interval: 30 DAT							
lettuce leaf	0.035	0.028 (81.2)	0.007 (18.8)	0.020 (58.5)	-	1 peak	0.008 22.7%
radish leaf	0.343	0.317 (92.2)	0.027 (7.8)	0.301 (87.6)	0.016 (4.6)	-	
radish root	0.048	0.039 (80.7)	0.009 (19.3)	0.030 (62.7)	-	1 peak:	0.009 18.0%
wheat forage	0.690	0.643 (93.2)	0.047 (6.8)	0.619 (89.8)	0.024 (3.4)	-	
wheat straw	3.609	3.258 (90.3)	0.351 (9.7)	3.156 (87.5)	0.102 (2.8)	-	
wheat grain	0.147	0.017 (11.7)	0.130 (88.3)	0.009 (6.1)	-	2 peaks:	0.006 3.8% 0.003 1.8%
Plant back interval: 120 DAT							
lettuce leaf	0.161	0.146 (90.8)	0.015 (9.2)	0.146 (90.8)	-	-	
radish leaf	0.211	0.187 (88.8)	0.024 (11.2)	0.172 (81.8)	0.015 (7.0)	-	
radish root	0.038	0.031 (81.6)	0.007 (18.4)	0.023 (60.1)	-	1 peak:	0.008 21.5%
wheat forage	0.433	0.379 (87.5)	0.054 (12.5)	0.379 (87.5)	-	-	
wheat straw	4.008	2.715 (67.7)	1.293 (32.3)	2.598 (64.8)	0.117 (2.9)	-	
wheat grain	0.285	0.025 (8.9)	0.260 (91.1)	0.015 (5.3)	-	1 peak:	0.010 3.6%
Plant back interval: 270 DAT							
lettuce leaf	0.031	0.023 (74.5)	0.008 (25.5)	0.020 (65.1)	-	1 peak:	0.003 9.4%
radish leaf	0.125	0.108 (86.1)	0.017 (13.9)	0.104 (82.5)	0.004 (3.6)	-	
radish root	0.017	0.013 (77.1)	0.004 (22.9)	0.009 (52.6)	-	1 peak:	0.004 24.5%
wheat forage	0.230	0.224 (97.3)	0.006 (2.7)	0.214 (92.8)	0.005 (2.3)	1 peak	0.005 2.2%
wheat straw	1.614	0.911 (56.4)	0.703 (43.6)	0.808 (50.0)	0.071 (4.4)	1 peak:	0.032 2.0%
wheat grain	0.271	0.011 (4.0)	0.260 (96.0)	0.005 (1.9)	-	1 peak:	0.006 2.1%
Plant back interval: 365 DAT							
lettuce leaf	0.022	0.017 (76.1)	0.005 (23.9)	0.014 (61.6)	-	1 peak:	0.003 14.5%
radish leaf	0.113	0.103 (91.1)	0.010 (8.9)	0.088 (78.2)	0.013 (11.2)	1 peak:	0.002 1.7%

Crop parts	TRR	ERR	RRR	Boscalid	M510F61	Unidentified Metabolites
	mg/kg	mg/kg (% TRR)	mg/kg (% TRR)	mg/kg (% TRR)	mg/kg (% TRR)	mg/kg % TRR
radish root	0.066	0.060 (91.0)	0.006 (9.0)	0.060 (91.0)	-	-
wheat forage	0.255	0.213 (83.5)	0.042 (16.5)	0.191 (74.7)	0.008 (2.9)	2 peaks: 0.005 1.8% 0.010 4.0%
wheat straw	1.925	1.488 (77.3)	0.437 (22.7)	1.488 (77.3)	-	-
wheat grain	0.148	0.010 (6.8)	0.138 (93.2)	0.006 (4.2)	-	1 peak: 0.004 2.6%

Table B.3.5-2: Investigation of the nature of the residues in rotational crops after treatment with diphenyl labelled ¹⁴C-boscalid

Crop parts	TRR	ERR	RRR	Boscalid	M510F61	Unidentified Metabolites
	mg/kg	mg/kg (% TRR)	mg/kg (% TRR)	mg/kg (% TRR)	mg/kg (% TRR)	mg/kg % TRR
Plant back interval: 30 DAT						
lettuce leaf	0.050	0.047 (93.8)	0.003 (6.2)	0.047 (93.8)	-	-
radish leaf	0.337	0.324 (96.1)	0.013 (3.9)	0.304 (90.2)	0.020 (5.9)	-
radish root	0.072	0.067 (93.1)	0.005 (6.9)	0.064 (89.6)	-	1 peak: 0.003 3.5%
wheat forage	1.575	1.504 (95.5)	0.071 (4.5)	1.472 (93.5)	0.032 (2.0)	-
wheat straw	9.826	8.414 (85.6)	1.412 (14.4)	7.991 (81.3)	0.423 (4.3)	-
wheat grain	0.166	0.031 (18.4)	0.135 (81.6)	0.028 (16.8)	-	1 peak: 0.003 1.6%
Plant back interval: 120 DAT						
lettuce leaf	0.084	0.075 (89.2)	0.009 (10.8)	0.072 (85.2)	-	1 peak: 0.003 4.0%
radish leaf	0.294	0.248 (84.4)	0.046 (15.6)	0.209 (71.2)	-	1 peak: 0.039 13.2%
radish root	0.052	0.041 (78.7)	0.011 (21.3)	0.035 (67.8)	0.006 (10.9)	-
wheat forage	0.980	0.867 (88.5)	0.113 (11.5)	0.846 (86.4)	0.021 (2.1)	-
wheat straw	3.912	3.498 (89.4)	0.414 (10.6)	3.311 (84.6)	0.187 (4.8)	-
wheat grain	0.243	0.030 (12.3)	0.213 (87.8)	0.023 (9.6)	-	1 peak: 0.007 2.7%
Plant back interval: 270 DAT						
lettuce leaf	0.067	0.063 (94.1)	0.004 (5.9)	0.063 (94.1)	-	-
radish leaf	0.150	0.141 (94.3)	0.009 (5.7)	0.109 (73.1)	0.032 (21.2)	-
radish root	0.098	0.091	0.007	0.091	-	-

Crop parts	TRR	ERR	RRR	Boscalid	M510F61	Unidentified Metabolites		
	mg/kg	mg/kg (% TRR)	mg/kg (% TRR)	mg/kg (% TRR)	mg/kg (% TRR)	mg/kg % TRR		
		(92.8)	(7.2)	(92.8)				
wheat forage	0.562	0.496 (88.3)	0.066 (11.7)	0.352 (62.8)	0.102 (18.1)	2 peaks:	0.024 0.018	4.2% 3.3%
wheat straw	3.226	2.487 (77.1)	0.739 (22.9)	2.283 (70.8)	0.030 (0.9)	1 peak:	0.174	5.4%
wheat grain	0.023	0.008 (35.4)	0.015 (64.6)	0.008 (35.4)	-	-		
Plant back interval: 365 DAT								
lettuce leaf	0.028	0.018 (62.8)	0.010 (37.2)	0.016 (55.6)	-	1 peak:	0.002	7.2%
radish leaf	0.207	0.197 (95.2)	0.018 (4.8)	0.144 (69.4)	0.032 (15.5)	2 peaks:	0.018 0.004	8.5% 1.7%
radish root	0.030	0.027 (89.9)	0.003 (10.1)	0.024 (78.4)	0.001 (4.0)	1 peak:	0.002	7.5%
wheat forage	0.265	0.247 (93.1)	0.018 (6.9)	0.199 (75.0)	0.026 (9.8)	1 peak:	0.002	8.3%
wheat straw	1.404	1.253 (89.3)	0.151 (10.7)	1.088 (77.6)	0.025 (1.8)	1 peak:	0.140	10.0%
wheat grain	0.048	0.012 (25.1)	0.036 (74.9)	0.011 (23.6)	-	1 peak:	0.001	1.5%

Conclusion

This study was conducted with an application rate of 2.1 kg as/ha to bare soil. The application rate according to GAP is 2 x 500 g as/ha for beans and peas.

With the exception of wheat grain the major part of the residues in all other matrices was identified as parent. The concentrations of boscalid were relatively low in lettuce leaf (0.014 – 0.072 mg/kg, one sample = 0.146 mg/kg) and radish root (0.009 – 0.09 mg/kg). Higher residues were found in radish leaves (0.09 – 0.30 mg/kg) and wheat forage (0.19 – 1.47 mg/kg) and very high residues in wheat straw (0.81 – 7.99 mg/kg).

In wheat grain, the concentration of parent was low (≤ 0.028 mg/kg). The greater portion of the TRR were non extractable residues and part of these radioactive residues, especially for the pyridine label, could be detected in the starch fraction (36.2 – 48.4 % TRR for pyridine label, 0.6 – 4.3 % TRR for diphenyl label). Ammonia solubility of the residual residues in wheat grain was in the range of 12.9 – 22.9 % TRR.

Besides parent one metabolite (M510F61) could be identified in low concentrations in radish leaves/roots and in wheat straw/forage. This metabolite was a sugar conjugate of the parent compound.

Although only some of the lettuce leaf and radish root samples exceed the LOQ of the enforcement method (0.05 mg/kg) which could be assigned to an exaggerated application rate, significantly higher levels were found in radish leaves and wheat forage and very high levels in straw even after plant back intervals of 270 and 365 days. This indicates that residues of boscalid could occur above the LOQ of 0.05 mg/kg in edible parts of other crops than investigated.

Field test

It was found in the confined rotational crop study of the DAR of boscalid that wheat grain contained total residues above the limit of quantitation of the residue methods. However, the part of the parent compound was clearly below the LOQ (0.028 mg/kg). Since for this crop no data from residue trials were available (because of the intended use pattern of boscalid), wheat samples were analysed grown as succeeding crop after boscalid application in order to confirm these data under normal practical conditions.

This Report was carried out by Funk H., Mackenroth C. 2001 and called Determination of the residues of BAS 510 F in wheat obtained from the trial year 2000.

Material and methods

In 1998 and 1999 respectively, two trials were performed applying boscalid to either vegetables (accumulation study) or winter rape (field residue study see point B.7.6 of DAR, RIP 2001-339) in order to investigate the residue situation. In both cases, wheat was planted on those plots in the succeeding season. Wheat samples were taken in normal practical conditions.

In the accumulation study (BOD 2001-296, see point B.8 of DAR), boscalid was applied in 1998 onto lettuce (2 x 300 g as/ha) and green beans (3 x 500 g as/ha) and in 1999 onto carrots (3 x 300 g as/ha) and cauliflower (2 x 400 g as/ha). The total amounts of boscalid applied were 2.1 kg in 1998 and 1.7 kg in 1999. In 2000 spring wheat was grown on the plots and no product containing boscalid was applied to the plots. Growth of vegetables in 2 succeeding years followed by cultivation of cereals during the third year. It represents a reasonable worst case for the application of boscalid in a crop rotation.

In the residue trial, BAS 510 01 F was applied once onto winter rape at an application rate of about 0.5 kg/ha (1 x 250 g as/ha). In 2000 wheat was grown on the plots and no product containing boscalid was applied to the plots. Sampling of wheat was not performed under GLP.

For the analysis grain and straw were sampled at a growth stage of about 92 (BBCH code). In one trial also plant without root was taken at an earlier stage. The samples were analysed with BASF method no. 445/0. The method quantifies the relevant residue of boscalid with a limit of quantitation of 0.05 mg/kg in all sample materials. The results of procedural recovery experiments obtained with each analytical series were about 90% at fortification levels of 0.05 mg/kg and 5.0 mg/kg.

Findings

Planting wheat as a succeeding crop, no residues of boscalid above the limit of quantification were found in the food item wheat grain under practical conditions.

For wheat succeeding treated vegetables, residues of boscalid were found in plant without root (0.10 mg/kg) and wheat straw (0.75 mg/kg). The concentrations of boscalid in soil before sowing as well as for forage and straw were at about half of those found in the rotational crop study for a plant back interval of 365 days. A comparison of the results is shown in Table 3.5-2.

No residues were found in straw (< 0.05 mg/kg) succeeding treated rape. The results of the field test are summarised in Table 3.5-3.

Table 3.5-2: Comparison of residues of boscalid found in the rotational crop study and the field test

	Soil before sowing mg/kg	Wheat plant mg/kg	Straw mg/kg
Rotational crop study			
Pyridine label (365 DAT)	0.356	0.19	1.49
Diphenyl label (365 DAT)	0.429	0.20	1.09
Field test	0.24*	0.10	0.75

* average of three plots and of layers from 0 to 25 cm after ploughing

Table 3.5-3: Summary of the residue of boscalid in wheat grown as succeeding crop after boscalid application

Crops planted in preceding years	Total application rate (g as /ha)	Succeeding crop	Portion analysed	Boscalid (mg/kg)
Lettuce, green beans	2100	Spring wheat	plant without root	0.10
Carrots, cauliflower	1700		straw	0.75
			grain	< 0.05
Rape	250	Winter wheat*	straw	< 0.05
			grain	< 0.05

* sampling not performed under GLP

Conclusion

Residues were found in wheat forage and wheat straw after two years treatment of vegetables. Although the applied amounts of boscalid were higher than would be according to GAP and future intended uses, it can be seen from the accumulation study that under practical conditions concentrations of boscalid remain in the soil which lead to residues in green plant parts and straw (for details see B.8.1 of the DAR of boscalid).

Pyraclostrobin

Test system

The residue levels and the nature of the residues in three different succeeding crops were investigated following application of ¹⁴C-pyraclostrobin (BAS 500 F) (tolyl and chlorophenyl label). The test compound was applied, as an acetonic solution, to the surface of a bare, loamy sand soil at an application rate equivalent to 900 g as/ha. In addition, the study was also performed with an application rate of 1500 g as/ha to cover to the maximum recommended use rate in the US. In the following only the distribution of the radioactive residues from the use rate relevant for Europe (900 g as/ha) are discussed in detail.

After application, the soil was aged for 30 days (simulating an emergency plant back; 30 DAT), 120 days (simulating a fall plant back; 120 DAT) and 365 days (365 DAT) under natural climatic conditions. After those time intervals, ploughing was simulated by mixing the top layer of 20 cm soil. Afterwards, the following crops were sowed or planted:

- **radish**
- **lettuce**
- **wheat**

Food and feed items of mature crops were harvested, processed and analyzed by combustion and subsequent radioactivity measurement for the determination of the total radioactive residues (TRR) in the raw agricultural commodities (RAC's). In addition, soil samples were taken after application, ploughing and after harvest of mature crops.

The soil characteristic is summarised in Table 3.5-4.

Table 3.5-4: Soil used to investigate radioactive residues in succeeding crops

Origin of soil	Landwirtschaftliche Versuchsstation, Li 35 b
Soil type	Loamy sand (German scheme)
% Organic matter	0.8 %
Textural analysis: Sand	
Silt	89 %
Clay	6 %
	5 %
Cation exchange capacity mVal/100 g	5.3
Soil pH	6.4

The total radioactive residues (TRR) of each sample were determined by combustion analysis. All samples were extracted with methanol and, in some cases, an additional water extraction and/ or a subsequent aqueous ammonia extraction were added. The remaining residual radioactive residues were treated with DMSO, sodium hydroxide and/ or different enzymes to release part of the remaining radioactivity. All methanol extracts yielding residues

>0.009 mg/kg and, in addition, the methanol extract of wheat grain with a lower concentration were analysed by high pressure liquid chromatography.

Findings

The distribution of the total radioactive residues (TRR), the extractable radioactive residues (ERR) and the residual radioactive residues (RRR) in the individual samples are summarised in Table B.7.9-2 and Table B.7.9-3. A comparison to the results of the higher application rate relevant for the US (1500 g as/ha) showed that for most of the plant matrices, no major differences in the residue levels could be detected.

The low residue levels in the crops indicated that only a small portion of the available radioactive residues in the soil were translocated from the soil, through the roots and into the plant.

Table 3.5-5: Quantitative distribution of radioactive residues in rotational crops after treatment with 14C-pyraclostrobin (BAS 500 F) (tolyl and chlorophenyl label)

Crop parts	TRR	MeOH		ERR (MeOH + H ₂ O + NH ₃)		RRR	
Days after sowing / planting DAP	mg/kg	mg/kg	% TRR	mg/kg	% TRR	mg/kg	% TRR
Plant back interval: 30 DAT							
Tolyl label							
Radish Plant 48	0.025	0.010	39.5	0.010	39.5	0.013	52.5
Radish Roots 48	0.025	0.012	45.9	0.012	45.9	0.011	44.7
Lettuce Head 61	0.013	0.005	42.1	0.005	42.1	0.007	55.3
Wheat Straw 167	0.114	0.019	16.6	0.030	26.0	0.072	63.2
Wheat Grain 167	0.082	0.005	6.5	0.020	24.0	0.060	73.7
Chlorophenyl label							
Radish Plant 47	0.028	0.011	38.8	0.014	49.2	0.007	26.8
Radish Roots 47	0.040	0.018	44.3	0.020	48.8	0.017	43.5
Lettuce Head 60	0.011	0.005	42.3	0.005	45.8	0.004	40.6
Wheat Straw 166	0.112	0.024	21.4	0.030	26.8	0.071	63.2
Wheat Grain 166	0.078	0.003	4.5	0.006	9.0	0.065	84.2
Plant back interval: 120 DAT							
Tolyl label							
Radish Plant 65	0.009	0.003	35.2	0.003	35.2	0.006	67.9
Radish Roots 65	0.008	n. d.	n. d.	n. d.	n. d.	n. d.	n. d.
Lettuce Head 76	0.011	0.004	37.1	0.004	37.1	0.007	62.1
Wheat Straw 157	0.081	0.009	11.6	0.014	17.4	0.055	68.2
Wheat Grain 157	0.089	0.006	6.3	0.020	22.1	0.064	71.6
Chlorophenyl label							
Radish Plant 64	0.011	0.004	32.1	0.005	37.5	0.004	38.8
Radish Roots 64	0.006	0.003	43.1	0.003	47.4	0.002	36.2
Lettuce Head 75	0.009	0.003	34.8	0.004	43.6	0.004	45.0
Wheat Straw 156	0.079	0.012	15.0	0.015	18.9	0.063	79.9
Wheat Grain 156	0.079	0.005	6.6	0.009	11.7	0.058	72.9

TRR = total radioactive residues

ERR = extractable radioactive

residues RRR = residual radio-
active residues

n. d. = not determined

After a plant back interval of 30 days, the highest total radioactive residues were found in wheat straw (0.114/ 0.112 mg/kg tolyl-/ chlorophenyl-label). In wheat grain, the residue levels were lower with a concentration of 0.082/ 0.078 mg/kg tolyl-/ chlorophenyl-label. The lowest residue levels were detected in lettuce head (0.013/ 0.011 mg/kg tolyl-/ chlorophenyl-label). The residue level in radish roots reached a concentration of 0.025/ 0.040 mg/kg tolyl-/ chlorophenyl-label.

After longer plant back intervals, the residue levels in radish roots decreased to 0.008/ 0.006 mg/kg tolyl-/ chlorophenyl-label for a plant back interval of 120 days and to 0.014/ 0.004 mg/kg tolyl-/ chlorophenyl-label for a plant back interval of 365 days. In lettuce head, the residue levels did not change significantly after longer plant back intervals. The residue levels in wheat grain after a plant back interval of 120 days were similar to those after a plant back interval of 30 days. In this matrix, the residue levels decreased significantly after a plant back interval of 365 days to 0.013/ 0.010 mg/kg tolyl-/ chlorophenyl-label. The residue levels in wheat straw declined continuously with subsequent plant back periods (120

DAT: 0.081/ 0.079 mg/kg tolyl-/ chlorophenyl-label; 365 DAT: 0.067/ 0.069 mg/kg tolyl-/ chlorophenyl-label).

A MeOH extraction could only release <45.9 % of the total radioactive residues (TRR), for all matrices. In the dry plant matrices, such as wheat straw and grain, the extractability with MeOH was even lower (<30.8 % TRR for wheat straw and <6.6 % TRR for wheat grain).

Extra extraction steps with water and/ or an aqueous ammonia solution released only a very low amount of additional radioactive residues.

The low extractability levels indicated that a portion of the radioactivity remained in the residual radioactive residues (RRR) of the samples under investigation. Because of the overall low residue levels in radish and lettuce samples, the concentration of the radioactivity in the residual residues were <0.017 mg/kg. The residue levels in the non-extractable residues of wheat straw and wheat grain were higher. For wheat straw, the concentration levels in those residues ranged from 0.046 mg/kg - 0.072 mg/kg (>63.2 % TRR). For wheat grain, the concentration levels ranged from 0.007 mg/kg - 0.065 mg/kg (>53.7 % TRR); with the lowest concentration after a plant back interval of 365 days.

Residual radioactive residues from radish plant, radish roots and lettuce head were treated with a macer-ozyme (enzyme mix: cellulase, pectinase and hemicellulase) incubation to release additional radioactive residues. An additional 8.4 - 13.6 % of the remaining radioactivity in the residues of radish roots could be released with this method. These results indicate that a portion of the radioactive residues were connected with natural products, such as cellulose or hemicellulose.

The major part of the radioactivity in the residual residues of wheat straw could be released with extrac-tion and precipitation methods for cellulose and lignin. After plant back intervals of 30 and 120 days, the concentration of radioactive residues in the cellulose fraction ranged from 0.018 mg/kg to 0.020 mg/kg (>17.0 % TRR) and after 365 days this concentration decreased to 0.014/ 0.008 mg/kg (21.2/ 11.6 % TRR) tolyl-/chlorophenyl-label .

Another portion of the radioactivity in the residual residues was found in the lignin fractions (lignin solid: <0.001 - 0.021 mg/kg; lignin liquid: 0.004 - 0.033 mg/kg).

For the residual radioactive residues of wheat grain, additional extractions, precipitation and enzyme in-cubation steps were added to determine the concentration of radioactive residues in the starch fraction. The radioactive residues in the starch fractions accounted for 0.001 to

0.036 mg/kg for all wheat grain samples. The lowest concentrations were observed after a plant back in-terval of 365 days. In addition, low concentrations of radioactive residues were detected in the cellulose fraction, in the lignin solid and lignin liquid fractions.

Table 3.5-6: Total radioactive residues in soil samples after treatment with 14C-pyraclostrobin (BAS 500 F) (tolyl and chlorophenyl label)

Soil samples	Tolyl label TRR [mg/kg]	Chlorophenyl label TRR [mg/kg]
After application 0 DAT	8.621	9.681
Plant back intervals (after soil aging and ploughing)		
30 DAT	0.315	0.373
120 DAT	0.339	0.351
365 DAT	0.304	0.309
After harvest of mature crops		
Plant back interval: 30 DAT		
Radish	0.273	0.356
Lettuce	0.338	0.371
Wheat	0.347	0.367
Plant back interval: 120 DAT		
Radish Lettuce	0.300	0.320
Wheat	0.289	0.310
	0.260	0.305

Soil samples	Tolyl label TRR [mg/kg]	Chlorophenyl label TRR [mg/kg]
Plant back interval: 365 DAT		
Radish	0.287	0.273
Lettuce	0.191	0.284
Wheat	0.242	0.242

Soil samples analysed after three time periods of soil aging did not show a major decrease of the residue levels after longer time intervals. After harvest of the mature crops, only a slightly decrease in the residue level of the remaining soil could be detected.

Table 3.5-7: Investigation of the nature of the residues in rotational crops after treatment with 14C-pyraclostrobin (BAS 500 F) (tolyl and chlorophenyl label)

Crop parts DAP	TRR [mg/kg]	RRR [mg/kg] [% TRR]	MeOH [mg/kg] [% TRR]	Parent + Desmethoxy [mg/kg] (% TRR)	Metabolites [combined in regions defined by retention times) [mg/kg] / [% TRR]
Tolyl label					
Plant back interval: 30 DAT					
Radish Plant 48	0.025	0.013 (52.5 %)	0.010 (39.5 %)	0.0011 (4.4 %)	polar region: 0.0021 / 8.1 % medium polar region a: 0.0051 / 20.4 % (3 peaks)
Radish Roots 48	0.025	0.011 (44.7 %)	0.012 (45.9 %)	0.0024 (9.0 %)	polar region: 0.0078 / 29.9 % medium polar region a: 0.0004 / 1.7 %
				(0.8 %)	medium polar region b: 0.0012 / 4.6 % (2 peaks)
Wheat Straw 167	0.114	0.072	0.019	0.0120	polar region: 0.0070 / 6.1 %

Crop parts DAP	TRR [mg/kg]	RRR [mg/kg] [% TRR]	MeOH [mg/kg] [% TRR]	Parent + Desmethoxy [mg/kg] (% TRR)	Metabolites [combined in regions defined by retention times) [mg/kg] / [% TRR]
Tolyl label					
		(63.2 %)	(16.6 %)	(10.5 %)	(2 peaks)
Plant back interval: 365 DAT					
Wheat Straw 153	0.067	0.046 (68.8 %)	0.009 (12.9 %)	0.0010 (1.4 %)	polar region: 0.0022 / 3.2 % medium polar region c: 0.0058 / 8.3 % (2 peaks)

polar region: retention time from ≥ 7.40 - ≤ 10.11 min medium polar region a: retention time from ≥ 22.25 - ≤ 27.30 min medium polar region b: retention time from ≥ 35.60 - ≤ 37.53 min medium polar region c: retention time from ≥ 45.36 - ≤ 46.88 min

Crop parts DAP	TRR [mg/kg]	RRR [mg/kg] [% TRR]	MeOH [mg/kg] [% TRR]	Parent + Desmethoxy [mg/kg] (% TRR)	Metabolites (com- bined in regions defined by retention times) [mg/kg] / [% TRR]
Chlorophenyl label					
Plant back interval: 30 DAT					
Radish Plant 47	0.028	0.007 (26.8 %)	0.011 (38.8 %)	0.0103 (36.4 %)	polar region: 0.0001 / 0.3 % medium polar region b: 0.0006 / 2.2 % (2 peaks)
Radish Roots 47	0.040	0.017 (43.5 %)	0.018 (44.3 %)	0.0106 (26.0 %)	polar region: 0.0046 / 11.3 % medium polar region b: 0.0026 / 6.3 % (2 peaks) nonpolar region: 0.0003 / 0.6 % (2 peaks)
Wheat Straw 166	0.112	0.071 (63.2 %)	0.024 (21.4 %)	0.0147 (13.1 %)	polar region: 0.0032 / 2.9 % (2 peaks) medium polar region a: 0.0037 / 3.3 % medium polar region b: 0.0012 / 1.1 % (2 peaks) medium polar region c: 0.0012 / 1.1 % (3 peaks)

Crop parts DAP	TRR [mg/kg]	RRR [mg/kg] [% TRR]	MeOH [mg/kg] [% TRR]	Parent + Desmethoxy [mg/kg] (% TRR)	Metabolites (com- bined in regions defined by retention times) [mg/kg] / [% TRR]
Chlorophenyl label					
Plant back interval: 120 DAT					
Wheat Straw 156	0.079	0.063 (79.9 %)	0.012 (15.0 %)	0.0011 (1.4 %)	polar region: 0.0027 / 3.4 % medium polar region a: 0.0042 / 5.1 % (4 peaks) medium polar region b: 0.0016 / 2.0 % medium polar region c: 0.0025 / 3.1 %
Wheat Grain 156	0.079	0.058 (72.9 %)	0.005 (6.6 %)	n. d.	polar region: 0.0050 / 6.6 %
Plant back interval: 365 DAT					
Wheat Straw 152	0.069	0.046 (67.0 %)	0.021 (30.8 %)	0.0023 (3.3 %)	polar region: 0.0019 / 2.7 % (3 peaks) medium polar region a: 0.0020 / 2.9 % medium polar region c: 0.0149 / 21.8 % (3 peaks)

polar region: retention time from ≥ 8.13 - ≤ 12.78 min medium polar region a: retention time from ≥ 26.32 - ≤ 29.55 min medium polar region b: retention time from ≥ 33.27 - ≤ 37.41 min medium polar region c: retention time from ≥ 43.64 - ≤ 47.20 min nonpolar region: retention time from ≥ 51.70 - ≤ 64.40 min

The MeOH extractable radioactive residues were characterised by different HPLC methods and in some cases by TLC, provided that the concentration levels were high enough for detection.

Because of the overall low radioactive residues, only the parent compound (^{14}C -pyraclostrobin (BAS 500 F)) and the desmethoxy metabolite (500M07) were identified by co-chromatography. All the other degradation products were combined in regions defined by retention times and polarity, where each region consisted of one or more peaks (the concentration of individual peaks was very low). For all samples under investigation, a total of 5 different regions could be defined (polar region, medium polar regions a-c and a nonpolar region). Nonpolar metabolites known from soil degradation studies were not observed in the different plant matrices from any of the 3 different plant back intervals. Those metabolites were apparently not translocated from the soil, through the roots to the other parts of the plant.

After a plant back interval of 30 days, a major part of the radioactivity in the extracts of radish roots was detected in the polar region. Parent was found in a concentration range of 0.0024/ 0.0106 mg/kg (tolyl-/chlorophenyl-label). Minor portions of the radioactive residues were found in the polar and in the medium polar regions a and b.

In the extracts of wheat straw after a plant back interval of 30 days, parent was detected at a concentration of 0.0120/ 0.0147 mg/kg (10.5/ 13.1 % TRR) for the tolal- and chlorophenyl- label. In addition, the polar region and, in case of the chlorophenyl-label, the medium polar regions a and b could be observed.

After a plant back interval of 120 days, the concentration of parent was lower in the extract of wheat straw (chlorophenyl-label: 0.0011 mg/kg or 1.4 % TRR). In addition, the polar region and the medium polar regions a and b could be observed. After a plant back interval of 365 days, the concentration of parent in the extract of wheat straw ranged from 0.0010 to 0.0023 mg/kg (1.4/ 3.3 % TRR; tolyl-/ chloro-

phenyl-label). In addition, the polar region and the medium polar regions a and c could be observed. The medium polar region c was only found in the wheat samples.

In the case where the MeOH extracts of wheat grain was analyzed, the parent compound could not be detected and the radioactivity was observed in the very polar region. This region included more than one peak.

Metabolic pathway:

For succeeding crops, the proposed metabolic pathway involves demethoxylation, a further degradation to various medium polar and polar metabolites and afterwards, most likely, conjugation reactions and final incorporation and/ or association into natural products, such as starch, cellulose and/ or lignins.

There are no new metabolites in significant amounts identified which are not already known from the metabolism in plants.

Conclusion:

The total radioactive residues in the edible parts of succeeding crops destined for human consumption are very low (radish roots, lettuce: < 0.040 mg/kg; wheat grain: < 0.089 mg/kg) after all 3 plant back intervals.

There is no accumulation of pyraclostrobin (BAS 500 F) or its degradation products in the parts of plants used for human food or animal feed consumption.

In the case of root vegetables (radish), leafy vegetables (lettuce), the concentration of parent was < 0.0106 mg/kg. For wheat straw, the concentration of parent was < 0.0147 mg/kg and in wheat grain parent was not detectable.

The levels of individual metabolites present were below 0.01 mg/kg.

Due to the low concentration of pyraclostrobin (BAS 500 F) and its degradation products in succeeding crops, no field trials are required.

Comments of zRMS:	<p>There are no restrictions on following crops in a normal rotation on the label of standard product in PL. Standard boscalid and pyraclostrobin products are many years on the market. Therefore any data out of protection and experience with these products and warnings/recommendations on the labels should be implemented.</p> <p>The zRMS concluded that all presented findings including recommendations for label text are more or less only general and more detailed evaluations are necessary in cMS considering the specific environment conditions agronomic practice and also national requirements.</p>
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3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

EPPO guidelines PP1/256 is intended to examine whether the active substance of a plant protection product can cause negative effects on crop which would be in contact with that product. Based on the actual drift value calculated with the Ganzelmeier model. and on the bio assay results from the Vegetative vigour test and from the seedling emergence study TER values are obtained.

- If the active substance has no activity against plants at the highest doses tested in the bio-assays. then field trials are unnecessary.
- If the TER values are > 1. then no further testing is necessary.
- If the TER values are ≤ 1. damage to the relevant succeeding crop is possible and further field testing is necessary as described in the EPPO guideline.

Table 3.5-8: PEC-values (mg/ha) (drift) in boscalid – field crops

Distance to adjacent crop (m)	% drift	MAF	Drift test product (mg a.s./ha)
1	2.38	1.7	16184

Table 3.5-9: PEC-values (mg/ha) (drift) in boscalid – fruiting vegetable crops

Distance to adjacent crop (m)	% drift	MAF	Drift test product (mg a.s./ha)
3	6.9	2.3	6348

Table 3.5-10: PEC-values (mg/ha) (drift) in boscalid – orchard crops

Distance to adjacent crop (m)	% drift	MAF	Drift test product (mg a.s./ha)
3	23.96	2.3	110216

Table 3.5-11: PEC-values (mg/ha) (drift) in pyraclostrobin– field crops

Distance to adjacent crop (m)	% drift	MAF	Drift test product (mg/ha)
1	2.38	1.7	4046

Table 3.5-12: PEC-values (mg/ha) (drift) in pyraclostrobin– fruiting vegetable crops

Distance to adjacent crop (m)	% drift	MAF	Drift test product (mg/ha)
3	6.9	2.3	15870

Table 3.5-13: PEC-values (mg/ha) (drift) in pyraclostrobin– orchard crops

Distance to adjacent crop (m)	% drift	MAF	Drift test product (mg/ha)
3	23.96	2.3	27554

Greenhouse studies on vegetative vigour were conducted with the representative formulation BAS 510 01 F, were submitted in DAR. These studies were applied in 3 mono and 3 dicotyledonous species. Applications were made post-emergence. The results obtained will be used to assess the TER and compare it to the trigger value of 1. The values of $ER_{50} > 3600$ g a.s./ha from the 14d post-emergence study are chosen for this risk assessment.

Table 3.5-14: ED50-values (mg a.s./ha) of different test plants for boscalid

Test plant		EPPO Code	ER ₅₀ Boscalid (mg a.s./ha)
Common name	Scientific name (lat.)		
Carrot	<i>Daucus carota</i>	DAUCA	>3600000
Cabbage	<i>Brassica oleracea</i>	BRSOX	>3600000
Pea	<i>Pisum sativum</i>	PIBSX	>3600000
Corn	<i>Zea Mays</i>	ZEAMX	>3600000
Oats	<i>Avena sativa</i>	AVESA	>3600000
Onion	<i>Allium cepa</i>	ALLCE	>3600000

Greenhouse studies on vegetative vigour were conducted with the representative formulation BAS 500 00 F, were submitted in DAR. These studies were applied in 3 mono and 3 dicotyledonous species. Applications were made post-emergence. The results obtained will be used to assess the TER and compare it to the trigger value of 1. The values of ER₅₀ >4800 g a.s./ha from the 14d post-emergence study are chosen for this risk assessment.

Table 3.5-15: ED50-values (mg a.s./ha) of different test plants for pyraclostrobin

Test plant		EPPO Code	ER ₅₀ Boscalid (mg a.s./ha)
Common name	Scientific name (lat.)		
Carrot	<i>Daucus carota</i>	DAUCA	>4800000
Oilseed rape	<i>Brassica napus</i>	BRNN	>4800000
Pea	<i>Pisum sativum</i>	PIBSX	>4800000
Corn	<i>Zea Mays</i>	ZEAMX	>4800000
Oats	<i>Avena sativa</i>	AVESA	>4800000
Onion	<i>Allium cepa</i>	ALLCE	>4800000

These values were used to assess the TER and to compare it to the trigger value of 1.

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SAN-CO/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.

Table 3.5-16: Assessment of the risk for non-target plants due to the use of boscalid in fruiting vegetables

Intended use		Fruting vegetables		
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 ≥ 1
<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

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 3.5-17: Assessment of the risk for non-target plants due to the use of pyraclostrobin 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 ≥ 1
<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

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 and onion.

Table 3.5-18: Assessment of the risk for non-target plants due to the use of boscalid in field crops

Intended use		Field crops		
Active substance/product		Boscalid		
Application rate (g/ha)		3 × 400		
MAF		1.7		
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 1
<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	>222.44

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 3.5-19: Assessment of the risk for non-target plants due to the use of pyraclostrobin in field crops

Intended use		Field crops		
Active substance/product		Pyraclostrobin		
Application rate (g/ha)		3 × 100		
MAF		1.7		
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 1
<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	>118.64

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 stone fruits.

Table 3.5-20: Assessment of the risk for non-target plants due to the use of boscalid in orchards

Intended use	Orchards			
Active substance/product	Boscalid			
Application rate (g/ha)	3 × 200			
MAF	2.3			
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 1
<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	0.2396	110.22	>32.66

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 3.5-21: Assessment of the risk for non-target plants due to the use of pyraclostrobin in orchards

Intended use	Orchards			
Active substance/product	Pyraclostrobin			
Application rate (g/ha)	3 × 50			
MAF	2.3			
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 1
<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	0.2396	27.55	>17.42

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The calculated TER values are higher than trigger of 1 for all crop groups. Therefore, no risk mitigation measures are required.

Comments of zRMS:	The risk for terrestrial non-target plants is acceptable by ZRMs. No risk for terrestrial non-target plants is likely to occur. However, ZRMs concluded that all presented findings including recommendations for label text are more or less only general and more detailed evaluations are necessary in cMS considering the specific environment conditions agronomic practice and also national requirements.
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3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

From the experimentation carried out with Boscalid 26.7% + Pyraclostrobin 6.7% WG 2016, no problems regarding adverse effects on beneficial organisms were reported.

Special tests to investigate this purpose are not required.

For more information, see the results of the standard ecotoxicological tests being presented in dRR Part B section 6.

The product complies with the Uniform Principles.

Compatibility with current management practices including IPM

This is not an EC data requirement/ not required by Directive 91/414/EEC.

Comments of zRMS:	For detailed consideration of risks to beneficial organisms please see the ecotoxicology section B section 6.
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3.6 Other/special studies

No other studies were conducted.

3.7 List of test facilities including the corresponding certificates

The following table gives information about the testing facilities where trials mentioned in this document were conducted. All facilities are certified and the trials were conducted according to GEP guidelines.

Table 3.7-1: List of test facilities

Testing facility	Zone	Country	Year 2016	Year 2017	Year 2019
BIOFARM S.R.L. CENTRO DI SAGGIO	MED	IT	9		
BIOTEK AGRICULTURE HUNGARY KFT.	SE	HU	1		
DAYE DESARROLLO AGRÍCOLA S. COOP.	MED	ES	10		
EUROFINS AGROSCIENCE SERVICES	MED	FR	4		
EUROFINS AGROSCIENCE SERVICES	MAR	FR	1		
GOVERNMENT OFFICE OF KOMAROM ESTERGOM COUNTY	SE	HU	2		
HET TERICH FIELDWORK GBR	MAR	DE	9		
NOVACERT LTD	MED	GR	3		
SGS	MAR	UK	7		
ZKUŠEBNÍ STANICE TRUTNOV S.R.O.,	MAR	CZ	3		
ANADIAG POLSKA	NE	PL	4		
Institute of Plant Protection.	NE	PL	2		
Latvian Plant Protection Research Centre Ltd.	NE	LV	6		
Fertico	NE	PL		9	
Fructika KFT.	SE	HU			18
Plant-Art Research KFT.	SE	HU			1
AGRODONT EXPERIMENT KFT.	SE	HU			1
CropTrials GmbH	MAR	DE			11
BioChem agrar GmbH	MAR	DE			2
Agrostation	MED	FR			8

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
CP 6.0-001	Anonymous	2020	Biological Assessment Dossier: Boscalid 26.7% + Pyraclostrobin 6.7% WG – EU Central zone Sharda Cropchem España -, - Unpublished	N	Sharda Cropchem Limited