

FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: SHA 7273 A

Product name: CASINO ROYALE

Chemical active substances:

Boscalid, 267 g/kg

Pyraclostrobin, 67 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and Poland Conclusion

Supplements / clarifications after MS comments marked in yellow

Boscalid

Storage stability

Storage stability of Boscalid was demonstrated for a period of 16 months at -18 °C in commodities with high acid content (grape) and 24 months at -18 °C in commodities with high water content (cabbage, peach, pea), high oil content (rape seed), dry commodities (wheat grain) and cereal straw. Degradation of residues during storage of the trial samples is therefore not expected.

Storage stability of Boscalid and M510F01 in milk, muscle, fat, liver, kidney and egg for up to 5 months was demonstrated, when stored deep frozen. No additional studies are required.

Metabolism in plants and animals

Metabolism of boscalid was investigated for foliar treatment on fruits and fruiting vegetables (grapes), on pulses and oilseeds (beans) and on leafy vegetables (lettuce), using U-¹⁴C-diphenyl and 3-¹⁴C-pyridine labelled boscalid.

Plant residue definition for monitoring and risk assessment: boscalid

Animal residue definition for monitoring: Boscalid in muscle, fat milk and eggs; Sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates expressed as Boscalid in liver and kidney

Animal residue definition for risk assessment:

Boscalid in muscle, fat milk and eggs;

Sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates expressed as Boscalid in liver and kidney;

Sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates and the bound residues (measured as M510F52 or M510F53) expressed as Boscalid in Liver (ruminant and pig);

(EFSA 2014)

Magnitude of residues in plants

Sugar beet

Proposed GAP: BBCH 31-39, 2 application, interval 8-10 days, 0.4 kg a.s/ha, PHI – 14 days

Sufficient new trials on sugar beet are available to support the proposed uses (8 trials). The residue data are valid with regard to storage stability data. Trials GAP is consistent with the proposed (2 application 0.4 kg a.i./ha of boscalid, interval between application of 8 days, at BBCH 31-39, PHI = 14 days).

The determination of Boscalid residues has been performed by liquid chromatography, and consists in an separation on a reversed-phase column and detection by tandem mass spectrometry (MS/MS) by electrospray (ESI) operating with optimized conditions (LOQ = 0.01 mg/kg).

During the growing season of 2018, a total of 8 trials were conducted in sugarbeet in Northern Europe (Germany, Poland and United Kingdom).

Results: 3x< 0.01, 2 x 0.05, 0.07, 0.09, 0.14 mg/kg

The residues arising from the proposed uses will not exceed the MRLs established for sugar beet (0.4 mg/kg, (Reg. (EU) 2021/590).

Clarifications regarding the independence of the following trials:

Łukaszewski K., Report No. 18SGS17 (Ożarów Mazowiecki) and Rafal Figurski, 2019. Study No. PB-2018-10 (Ożarów Mazowiecki)

Trials can be considered as independent as:

-were done in two different places - the distance is about 20 km.

18SGS017 PL01 – post code 05-830

D-2018-10-F01 – post code 05-850

- different kind of soil

18SGS017 PL01 – silt loam (1.5% of organic matter)

D-2018-10-F01 – sandy loam (2.21 % of organic matter)

Tomato (field)

Proposed GAP: BBCH 20-87, 2 or 3 application, interval 8-10 days, 0.4 kg a.s/ha, PHI – 3 days

Sufficient new trials on tomato are available to support the proposed use No 2 (with max. 2 applications). The residue data are valid with regard to storage stability data. Trials GAP is consistent with the proposed (2 application 0.4 kg a.i./ha of boscalid, interval between application of 8 days, at BBCH 20-87, PHI = 3 days). There is no study available to cover use No 3 (max. 3 applications).

Results: 2x < 0.01, 0.05, 2x 0.08, 0.09, 0.25, 0.56 mg/kg

The determination of Boscalid residues has been performed by liquid chromatography, and consists in an separation on a reversed-phase column and detection by tandem mass spectrometry (MS/MS) by electrospray (ESI) operating with optimized conditions (LOQ = 0.01 mg/kg).

During the growing season of 2018, a total of 5 trials were conducted in tomato in Northern Europe (Poland, outdoor).

During the growing season of 2019, a total of 3 trials were conducted in tomato in Northern Europe (Hungary, outdoor).

The residues arising from the proposed uses will not exceed the MRLs established for tomato (3.0 mg/kg, (Reg. (EU) 2021/590).

Carrot

Proposed GAP: BBCH 41-49, 2 application, interval 8-10 days, 0.4 kg a.s/ha, PHI – 14 days

8 new trials were provided. Trials GAP: 2 application 0.4 kg a.i./ha of boscalid, interval between application of 14 days, at BBCH 48, PHI= 14 days

The residue data are valid with regard to storage stability data. Trials GAP is consistent with the proposed

Residues: 2x <0.01, 0.05, 0.05, 0.07, 0.10, 0.14, 0.23 mg/kg

The residues arising from the proposed uses will not exceed the MRLs established for carrot (2.0 mg/kg, (Reg. (EU) 2021/590).

Onion

Proposed GAP: BBCH 41-49, 2 application, interval 14 days, 0.4 kg a.s/ha, PHI – 14 days

8 new trials were provided. GAP: 2 application 0.4 kg a.i./ha of boscalid, interval between application of 14 days, at BBCH 43-49, PHI= 14 days

Three trials were conducted in Hungary in 2019 and five in Poland in 2018.

Results: 5x <0.01, 0.01, 2x 0.02 mg/kg

The residues arising from the proposed uses will not exceed the MRLs established for onion (5.0 mg/kg,

(Reg. (EU) 2021/590).

Unprotected data from Signum 33 WG

Cabbage

There is not enough data available to make an assessment.

Tomatoe in greenhouses

There is not enough data available to make an assessment.

Strawberry

There is not enough data available to make an assessment.

Cherry

Raspberry

There is not enough data available to make an assessment.

Blackcurrant

There is not enough data available to make an assessment.

Minor uses according to Article 51 (zonal uses)

Beetroot, Celery root, Parsnip, Parsley, Radish, Horseradish, Swedes/rutabagas, Turnip, Chicory roots

Beetroot

Proposed GAP: BBCH 15-49, 2 application, interval 10-14 days, 0.267 kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from carrot to whole subgroup (c) other root and tuber vegetables except sugar beets is possible.

Celery root

Proposed GAP: BBCH 15-49, 2 application, interval 10-14 days, 0.4 kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from carrot to whole subgroup (c) other root and tuber vegetables except sugar beets is possible.

Parship, Parsley

Proposed GAP: BBCH 15-49, 2 application, interval 21-28 days, 0.2 kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from carrot to whole subgroup (c) other root and tuber vegetables except sugar beets is possible.

Radish, Horseradish, turnip

Proposed GAP: BBCH 11-49 (radish, turnip), 15-49 (horse radish), 2 application, interval 14-21 days, 0.4 kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from carrot to whole subgroup (c) other root and tuber vegetables except sugar beets is possible.

Swedes/rutabagas

Proposed GAP: BBCH 15-49, 2 application, interval 10-14 days, 0.267 kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from carrot to whole subgroup (c) other root and tuber vegetables except sugar beets is possible.

Chicory roots

Proposed GAP: BBCH 13-47, 2 application, interval 14-21 days, 0.4 kg a.s/ha, PHI – 14 days
 According to the SANTE/2019/12752 extrapolation from carrot or sugar beet to chicory roots is possible.
 Salsifies (0213090)
 Proposed GAP: BBCH 41-49, 2 application, interval 8-10 days, 0.4 kg a.s/ha, PHI – 14 days
 According to the SANTE/2019/12752 extrapolation from carrot or sugar beet to chicory roots is possible.
Note:
 MRLs for whole subgroup (c) other root and tuber vegetables except sugar beets below.

(c) other root and tuber vegetables except sugar beets	Mg/kg
Beetroots	4
Carrots	2
Celeriacs/turnip rooted celeries	2
Horseradishes	2
Jerusalem artichokes	2
Parsnips	2
Parsley roots/Hamburg roots parsley	2
Radishes	2
Salsifies	2
Swedes/rutabagas	2
Turnips	2
Others (2)	2

An exceedance of the current MRLs is not expected.

Shallot, Onion “seven years old”

Proposed GAP: BBCH 13-48, 2 application, interval 14 (shallot), 21-28 (Onion “seven years old”) days, 0.267 (shallot), 0.4 (onion “seven years old) kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from onion is possible.

MRLs for onion, shallot and onion “seven years old”: 5 mg/kg. An exceedance of the current MRLs is not expected.

Aubergines/eggplants (field)

Proposed GAP: BBCH 20-87, 2 or 3 application, interval 7-10 days, 0.4 kg a.s/ha, PHI – 3 days

According to the SANTE/2019/12752 extrapolation from tomato is possible.

Only uses with two applications are acceptable.

MRLs for tomato and aubergines/eggplants: 3 mg/kg. An exceedance of the current MRLs is not expected.

According to the SANTE/2019/12752 extrapolation from field tomato to greenhouse Aubergines/eggplants is not possible.

Redcurrant, White currant

There is not enough data available to make an assessment.

Ornamentals in field and greenhouses

Uses are accepted

Magnitude of residues in livestock

There is no risk for animal MRL to be exceeded (Reg. (EU) 2021/590). Additional studies are not required.

Processing studies

Additional tests are not required.

Magnitude of residues in representative succeeding crops

Taking relatively low application rate of boscalid into account it can be concluded that specific plant-back restrictions related to the use of Boscalid 26.7% + Pyraclostrobin 6.7% WG are not required, provided that the product is used according to GAP. Exceedance of the MRLs set based on rotational crops residue studies is unlikely.

Consumer risk assessment

The proposed uses of Boscalid 26.7% + Pyraclostrobin 6.7% WG do not represent unacceptable chronic risks for the consumer.

Pyraclostrobin

Storage stability

Storage stability of pyraclostrobin and compound 500M07 under frozen conditions (below 10°C) was demonstrated for at least 18 months in high water, high acid, high oil, dry/high starch content and other commodities (Germany, 2001). No additional studies are required.

Metabolism in plants and animals

No new information has been submitted under the current application. Data included in EFSA Journal 2011;9(8):2344 are still applicable.

Plant residue definition for monitoring: Pyraclostrobin (Regulation n°2020/856)

Plant residue definition for risk assessment: Pyraclostrobin (EFSA 2011)

Animal residue definition for monitoring: Pyraclostrobin (Regulation n°2020/856)

Animal residue definition for risk assessment: sum of pyraclostrobin and its metabolites containing the 1-(4-chlorophenyl)-1H-pyrazole moiety or the 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazole moiety, expressed as pyraclostrobin (EFSA, 2011)

Conversion factor: 4 on ruminant liver and 1 on all other commodities (EFSA 2011)

Magnitude of residues in plants

Sugar beet

Proposed GAP: BBCH 31-39, 2 application, interval 8-10 days, 0.1 kg a.s/ha, PHI – 14 days

Sufficient new trials on sugar beet are available to support the proposed uses (8 trials). The residue data are valid with regard to storage stability data. Trials GAP is consistent with the proposed (2 application 0.1 kg a.i./ha of pyraclostrobin, interval between application of 8 days, at BBCH 31-39, PHI = 14 days).

The determination of pyraclostrobin residues has been performed by liquid chromatography, and consists in an separation on a reversed-phase column and detection by tandem mass spectrometry (MS/MS) by electrospray (ESI) operating with optimized conditions (LOQ = 0.01 mg/kg).

During the growing season of 2018, a total of 8 trials were conducted in sugarbeet in Northern Europe (Germany, Poland and United Kingdom).

Results: 3x<0.01, 3 x 0.02, 0.03, 0.04 mg/kg

The residues arising from the proposed uses will not exceed the MRLs established for sugar beet (0.2 mg/kg, (Reg. (EU) 2021/590).

Clarifications regarding the independence of the following trials:

Łukaszewski K., Report No. 18SGS17 (Ożarów Mazowiecki) and Rafal Figurski, 2019. Study No. PB-2018-10 (Ożarów Mazowiecki)

Trials can be considered as independent as:

-were done in two different places - the distance is about 20 km.

18SGS017 PL01 – post code 05-830

D-2018-10-F01 – post code 05-850

- different kind of soil

18SGS017 PL01 – silt loam (1.5% of organic matter)

D-2018-10-F01 – sandy loam (2.21 % of organic matter)

Tomato

Proposed GAP: BBCH 20-87, 2 or 3 application, interval 8-10 days, 0.1 kg a.s/ha, PHI – 3 days

Sufficient new trials on tomato are available to support the proposed use No 2 (with max. 2 applications). The residue data are valid with regard to storage stability data. Trials GAP is consistent with the proposed (2 application 0.1 kg a.i./ha of pyraclostrobin, interval between application of 8 days, at BBCH 20-87, PHI = 3 days). There is no study available to cover use No 3 (max. 3 applications).

Results: $3x < 0.01$, 0.01, 2×0.02 , 0.04, 0.07 mg/kg

The determination of pyraclostrobin residues has been performed by liquid chromatography, and consists in an separation on a reversed-phase column and detection by tandem mass spectrometry (MS/MS) by electrospray (ESI) operating with optimized conditions (LOQ = 0.01 mg/kg).

During the growing season of 2018, a total of 5 trials were conducted in tomato in Northern Europe (Poland).

During the growing season of 2019, a total of 3 trials were conducted in tomato in Northern Europe (Hungary).

The residues arising from the proposed uses will not exceed the MRLs established for tomato (0.3 mg/kg, (Reg. (EU) 2021/590).

Carrot

Proposed GAP: BBCH 41-49, 2 application, interval 8-10 days, 0.1 kg a.s/ha, PHI – 14 days

8 new trials were provided. Trials GAP: 2 application 0.1 kg a.i./ha of pyraclostrobin, interval between application of 14 days, at BBCH 48, PHI= 14 days

The residue data are valid with regard to storage stability data. Trials GAP is consistent with the proposed

Residues: $2x < 0.01$, 5×0.02 , 0.03 mg/kg

The residues arising from the proposed uses will not exceed the MRLs established for carrot (0.5 mg/kg, (Reg. (EU) 2021/590).

Onion

Proposed GAP: BBCH 41-49, 2 application, interval 14 days, 0.1 kg a.s/ha, PHI – 14 days

8 new trials were provided. GAP: 2 application 0.4 kg a.i./ha of pyraclostrobin, interval between application of 14 days, at BBCH 43-49, PHI= 14 days

Three trials were conducted in Hungary in 2019 and five in Poland in 2018.

Results: $8 \times < 0.01$ mg/kg

The residues arising from the proposed uses will not exceed the MRLs established for onion (1.5 mg/kg, (Reg. (EU) 2021/590).

Unprotected data from Signum 33 WG

Cabbage

There is not enough data available to make an assessment.

Tomatoe in greenhouses

There is not enough data available to make an assessment.

Strawberry

There is not enough data available to make an assessment.

Cherry

Raspberry

There is not enough data available to make an assessment.

Blackcurrant

There is not enough data available to make an assessment.

Minor uses according to Article 51 (zonal uses)

Beetroot, Celery root, Parsnip, Parsley, Radish, Horseradish, Swedes/rutabagas, Turnip, Chicory roots

Beetroot

Proposed GAP: BBCH 15-49, 2 application, interval 10-14 days, 0.0.067 kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from carrot to whole subgroup (c) other root and tuber vegetables except sugar beets is possible.

Celery root

Proposed GAP: BBCH 15-49, 2 application, interval 10-14 days, 0.1 kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from carrot to whole subgroup (c) other root and tuber vegetables except sugar beets is possible.

Parship, Parsley

Proposed GAP: BBCH 15-49, 2 application, interval 21-28 days, 0.05 kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from carrot to whole subgroup (c) other root and tuber vegetables except sugar beets is possible.

Radish, Horseradish, turnip

Proposed GAP: BBCH 11-49 (radish, turnip), 15-49 (horse radish), 2 application, interval 14-21 days, 0.1 kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from carrot to whole subgroup (c) other root and tuber vegetables except sugar beets is possible.

Swedes/rutabagas

Proposed GAP: BBCH 15-49, 2 application, interval 10-14 days, 0.067 kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from carrot to whole subgroup (c) other root and tuber vegetables except sugar beets is possible.

Chicory roots

Proposed GAP: BBCH 13-47, 2 application, interval 14-21 days, 0.1 kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from carrot or sugar beet to chicory roots is possible.

Salsifies (0213090)

Proposed GAP: BBCH 41-49, 2 application, interval 8-10 days, 0.1 kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from carrot or sugar beet to chicory roots is possible.

Note:

MRLs for whole subgroup (c) other root and tuber vegetables except sugar beets below.

(c) other root and tuber vegetables except sugar beets	Mg/kg
Beetroots	0.1
Carrots	0.5
Celeriacs/turnip rooted celeries	0.5
Horseradishes	0.3
Jerusalem artichokes	0.06
Parsnips	0.3
Parsley roots/Hamburg roots parsley	0.1
Radishes	0.5
Salsifies	0.1
Swedes/rutabagas	0.09
Turnips	0.09
Others (2)	0.02*

An exceedance of the current MRLs is not expected.

Shallot, Onion “seven years old”

Proposed GAP: BBCH 13-48, 2 application, interval 14 (shallot), 21-28 (Onion “seven years old”) days, 0.067 (shallot), 0.1 (onion “seven years old”) kg a.s/ha, PHI – 14 days

According to the SANTE/2019/12752 extrapolation from onion is possible.

MRLs for onion, shallot and onion “seven years old”: 0.3 mg/kg (shallots), 1.5 (Spring onions/green onions and Welsh onions). An exceedance of the current MRLs is not expected.

Aubergines/eggplants (field)

Proposed GAP: BBCH 20-87, 2 or 3 application, interval 7-10 days, 0.1 kg a.s/ha, PHI – 3 days

According to the SANTE/2019/12752 extrapolation from tomato is possible.

Only uses with two applications are acceptable.

MRLs for tomato and aubergines/eggplants: 0.3 mg/kg. An exceedance of the current MRLs is not expected.

According to the SANTE/2019/12752 extrapolation from field tomato to greenhouse Aubergines/eggplants is not possible.

Redcurrant, White currant

There is not enough data available to make an assessment.

Ornamentals in field and greenhouses

Uses are accepted

Magnitude of residues in livestock

There is no risk for animal MRL to be exceeded (Reg. (EU) 2021/590). Additional studies are not required.

Processing studies

Additional tests are not required.

Magnitude of residues in representative succeeding crops

Taking relatively low application rate into account it can be concluded that specific plant-back restrictions related to the use of Boscalid 26.7% + Pyraclostrobin 6.7% WG are not required, provided that the product is used according to GAP. Exceedance of the MRLs set based on rotational crops residue studies is unlikely.

Pyraclostrobin

The nature and magnitude of pyraclostrobin residues in rotational crops were assessed in the framework of the peer review. Active substance was applied at an application rate of 0.9 kg a.s./ha (Germany, 2002). It was concluded that significant residues are not expected in rotational crops for all plant back intervals (30, 120 and 365 DAT). Proposed application (total annual dose rates) on the accepted crops in the framework of this assessment range between 0.100 and 0.242 kg a.s./ha - largely below the 900 g/ha. It is expected that residues of pyraclostrobin resulting from soil uptake will not exceed 0.01 mg/kg provided that the active substance is applied according to the proposed GAPs.

In the EFSA Journal 2018;16(11):5472 and EFSA Journal 2019;17(10):5841 it was stated that previously derived conclusion (Germany, 2002) is still valid.

Additionally application rates on the intended uses are within rates assessed in the framework of review of the existing maximum residue levels (MRLs) for pyraclostrobin according to Article 12 of Regulation (EC) No 396/2005 (EFSA Journal 2011;9(8):2344).

Boscalid

Appropriate MRLs based on field rotational crop studies have been established for a large variety of crops. The maximum seasonal application rate for boscalid is 0.8 kg a.s./ha – lower than max. application rates supported in the framework of the MRL review.

Consumer risk assessment

The accepted uses of Boscalid 26.7% + Pyraclostrobin 6.7% WG do not represent unacceptable chronic risks for the consumer.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation Boscalid 26.7% + Pyraclostrobin 6.7% WG are presented in Table 7.1-1. They have been selected from the individual GAPs for the Central zone. A list of all intended uses within the zone is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs for Boscalid and for Pyraclostrobin, as laid down in Reg. (EU) 2020/856, and Reg. (EU) 2017/1016, respectively, is not expected.

The chronic and the short-term intakes of CASINO ROYALE residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, Poland agrees with the authorization of the intended accepted uses.

Data gaps

Data gaps should be listed in the summary to give an overview (especially for cMS).

Noticed data gaps are:

data gap 1

Residue trials according to uses No 3, No 6-11, 23, 25 and 29

Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8					9			10	11
GAP number (see part B.0)*	Crop and/ or situation **	Zone	Product code	F, Fn, Fpn G, Gn, Gpn or I***	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Conclusion
						Type	Conc. Of as	method kind	growth stage & season	number min max	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
1	Sugar beet	CEU	SHA 7273 A	F	<i>Cercospora beticola</i>	WG	267 g/kg +67 g/kg	Foliar Spray	BBCH 31-39	a) 2 b) 2	8-10	a) 0.067 boscalid + 0.0167 pyra-clostrobin b) 0.133 boscalid + 0.033 pyra-clostrobin	300-600	0.4 boscalid + 0.1 pyra-clostrobin	14	A
2	Tomato	CEU		F	<i>Phytophthora infestans</i> ,	WG	267 g/kg +67 g/kg	Foliar Spray	When first symptoms are visible BBCH 20-87	a) 2 b) 2	8-10	a) 0.067 boscalid + 0.0167 pyra-clostrobin b) 0.133 boscalid + 0.033 pyra-clostrobin	300-600	0.4 boscalid + 0.1 pyra-clostrobin	3	A
3	Tomato	CEU		F	<i>Alternaria sp.</i>	WG	267 g/kg +67 g/kg	Foliar Spray	When first symptoms are visible BBCH 20-87	a) 3 b) 3	8-10	a) 0.067 boscalid + 0.0167 pyra-clostrobin b) 0.133 boscalid + 0.033 pyra-clostrobin	300-600	0.4 boscalid + 0.1 pyra-clostrobin	3	N
4	Carrot	CEU		F	<i>Septoria apiicola</i> , <i>Cercospora sp.</i> , <i>Alternaria sp.</i>	WG	267 g/kg +67 g/kg	Foliar Spray	When first symptoms are visible BBCH 41-49	a) 2 b) 2	8-10	a) 0.067 boscalid + 0.0167 pyra-clostrobin b) 0.133 boscalid + 0.033 pyra-clostrobin	300-600	0.4 boscalid + 0.1 pyra-clostrobin	14	A

5	Onion	CEU		F	<i>Puccinia allii</i>	WG	267 g/kg +67 g/kg	Foliar Spray	When first symptoms are visible BBCH 41-49	a) 2 b) 2	14	a) 0.067 boscalid + 0.0167 pyraclostrobin b) 0.133 boscalid + 0.033 pyraclostrobin	300-600	0.4 boscalid + 0.1 pyraclostrobin	14	A
Unprotected use in SIGNUM																
6	Cabbage	PL	SHA 7273 A	F	<i>Alternaria, Botrytis cinerea</i>	WG	267 g/kg +67 g/kg	Spray	BBCH 41-49	a) 3 b) 3	7	a) 0.0334 boscalid + 0.008375 pyraclostrobin b) 0.0445 boscalid + 0.01117 pyraclostrobin	600-800	0.267 + 0.067	14	N
7	Tomatoe in green-houses	PL	SHA 7273 A	G	<i>Botrytis cinerea, Phytophthora infestans</i>	WG	267 g/kg +67 g/kg	Spray	BBCH 51-85	a) 2 b) 2	7	0.0534 boscalid + 0.0134 pyraclostrobin	1000	0.534 + 0.134	3	N
8	Strawberry	PL	SHA 7273 A	F	<i>Botrytis cinerea, Ramularia grevilleana, Spaerotheca macularis,</i>	WG	267 g/kg +67 g/kg	Spray	BBCH 60-81	a) 2 b) 2	5	a) 0.0687 boscalid + 0.0173 pyraclostrobin b) 0.0962 + 0.0242 pyraclostrobin	500-700	0.481 + 0.121	3	N
9	Cherry	PL	SHA 7273 A	F	<i>Monilinia sp.</i>	WG	267 g/kg +67 g/kg	Spray	BBCH 60-67	a) 2 b) 2	5	a) 0.0356 boscalid + 0.00893 pyraclostrobin b) 0.0534 boscalid + 0.0134 pyraclostrobin	500-750	0.267 + 0.067	7	N
10	Raspberry	PL	SHA 7273 A	F	<i>Botrytis cinerea, Didymella applanata</i>	WG	267 g/kg +67 g/kg	Spray	BBCH 51-90	a) 2 b) 2	7	a) 0.0687 boscalid + 0.01729 pyraclostrobin b) 0.0802 boscalid + 0.02017 pyraclostrobin	600-700	0.481 + 0.121	3	N
11	Blackcurrant	PL	SHA 7273 A	F	<i>Drepanopeziza ribis, Cronartium ribicola</i>	WG	267 g/kg +67 g/kg	Spray	BBCH 55-90	a) 2 b) 2	7-10	a) 0.0601 boscalid + 0.01513 pyraclostrobin b) 0.08017	600-800	0.481 + 0.121	3	N

												boscalid + 0.02017 pyra- clostrobin				
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Minor uses according to Article 51 (zonal uses)																
12	Beetroot	PL	SHA 7273 A	F	<i>Erysiphe betae</i>	WG	267 g/kg +67 g/kg	Spray	BBCH 15-49	a) 2 b) 2	10-14	a) 0.0445 boscalid + 0.01117 pyraclostrobin b) 0.089 boscalid + 0.0223 pyraclostrobin	300-600	0.267 + 0.067	14	A
13	Celery root	PL	SHA 7273 A	F	<i>Sclerotinia sclerotiorum</i>	WG	267 g/kg +67 g/kg	Spray	BBCH 15-49	a) 2 b) 2	10-14	a) 0.067 boscalid + 0.0167 pyraclostrobin b) 0.133 boscalid + 0.033 pyraclostrobin	300-600	0.4 + 0.1	14	A
14	Parsnip, Parsley	PL	SHA 7273 A	F	<i>Alternaria sp. Alternata, Erysiphe heraclei</i>	WG	267 g/kg +67 g/kg	Spray	BBCH 15-49	a) 2 b) 2	21-28	a) 0.025 boscalid + 0.00625 pyraclostrobin b) 0.033 boscalid + 0.00833 pyraclostrobin	600-800	0.200 + 0.050	14	A
15	Radish	PL	SHA 7273 A	F	<i>Botrytis cinerea,</i>	WG	267 g/kg +67 g/kg	Spray	BBCH 11-49	a) 2 b) 2	14-21	a) 0.067 boscalid + 0.0167 pyraclostrobin b) 0.133 boscalid + 0.033 pyraclostrobin	300-600	0.4 + 0.1	14	A
16	Radish	PL	SHA 7273 A	F	<i>Rhizoctonia solani</i>	WG	267 g/kg +67 g/kg	Spray	BBCH 11-12	a) 1 b) 1	14-21	a) 0.067 boscalid + 0.0167 pyraclostrobin b) 0.133 boscalid + 0.033 pyraclostrobin	300-600	0.4+ 0.1	14	A
17	Horseradish	PL	SHA 7273 A	F	<i>Peronospora sp. Alternaria Erysiphe sp.</i>	WG	267 g/kg +67 g/kg		BBCH 15-49	a) 2 b) 2	14-21	a) 0.067 boscalid + 0.0167 pyraclostrobin b) 0.133 boscalid + 0.033 pyraclostrobin	300-600	0.4 + 0.1	14	A
18	Swedes/rutabagas	PL	SHA 7273 A	F	<i>Peronospora sp. Cercospora beticola</i>	WG	267 g/kg +67	Spray	BBCH 15-49	a) 2 b) 2	10-14	a) 0.0445 boscalid + 0.01117 pyraclostrobin	300-600	0.267 + 0.067	14	A

					<i>Erysiphe sp.</i>		g/kg					b) 0.089 boscalid + 0.0223 pyra- clostrobin				
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19	Turnip	PL	SHA 7273 A	F	<i>Botrytis cinerea</i> , <i>Thanatephorus cucumeris</i>	WG	267 g/kg +67 g/kg	Spray	BBCH 11-49	a) 2 b) 2	14-21	a) 0.067 boscalid + 0.0167 pyra- clostrobilin b) 0.133 boscalid + 0.033 pyra- clostrobilin	300-600	0.4 + 0.1	14	A
20	Chicory roots	PL	SHA 7273 A	F	<i>Chicory Alterna- ria</i> , <i>Chicory Puccinia</i>	WG	267 g/kg +67 g/kg	Spray	BBCH 13-47	a) 2 b) 2	14-21	a) 0.067 boscalid + 0.0167 pyra- clostrobilin b) 0.133 boscalid + 0.033 pyra- clostrobilin	300-600	0.4 + 0.1	14	A
21	Shallot	PL	SHA 7273 A	F	<i>Peronospora destructor</i> <i>Alternaria</i> , <i>Stemphylium</i>	WG	267 g/kg +67 g/kg	Spray	BBCH 13-48	a) 2 b) 2	14	a) 0.0445 bos- calid + 0.01117 pyraclostrobilin b) 0.089 boscalid + 0.0223 pyra- clostrobilin	300-600	0,267+ 0,067	14	A
22	Onion “seven years old”	PL	SHA 7273 A	F	<i>Puccinia porri</i> <i>Phytophthora porri</i> <i>Alternaria</i> ,	WG	267 g/kg +67 g/kg	Spray	BBCH 13-47	a) 2 b) 2	21-28	a) 0.067 boscalid + 0.0167 pyra- clostrobilin b) 0.133 boscalid + 0.033 pyra- clostrobilin	300-600	0.4 + 0.1	14	A
23	Aubergines/eggplants	PL	SHA 7273 A	G	<i>Botrytis cinerea</i> , <i>Sclerotinia scler- otiorum</i> <i>Leveillula taurica</i>	WG	267 g/kg +67 g/kg	Spray	BBCH 12-89	a) 2 b) 2	7-10	0.04 boscalid + 0.01 pyra- clostrobilin	1000	0.4 + 0.1	14	N
24	aubergines/eggplants	PL	SHA 7273 A	F	<i>Phytophthora infestans</i> ,	WG	267 g/kg +67 g/kg	Foliar Spray	When first symptoms are visible BBCH 20-87	a) 2 b) 2	8-10	a) 0.067 boscalid + 0.0167 pyra- clostrobilin b) 0.133 boscalid + 0.033 pyra- clostrobilin	300-600	0.4 boscalid + 0.1 pyra- clostrobilin	3	A
25	aubergines/eggplants	PL	SHA 7273 A	F	<i>Alternaria sp.</i>	WG	267 g/kg +67 g/kg	Foliar Spray	When first symptoms are visible BBCH 20-87	a) 3 b) 3	8-10	a) 0.067 boscalid + 0.0167 pyra- clostrobilin b) 0.133 boscalid + 0.033 pyra- clostrobilin	300-600	0.4 boscalid + 0.1 pyra- clostrobilin	3	N

26	Ornamentals in field and greenhouses	PL	SHA 7273 A	F/G	<i>Alternaria</i>	WG	267 g/kg +67 g/kg	Spray	BBCH 13-47	a) 2 b) 2	7-14	0.0267g boscalid+ 0.0067g pyraclostrobin	100	0.0267 boscalid+ 0.0067 pyraclostrobin	-	A
27	Ornamentals in field and greenhouses	PL	SHA 7273 A	F/G	<i>Erysiphales</i>	WG	267 g/kg +67 g/kg	Spray	BBCH 13-47	a) 2 b) 2	7-14	0.0481g boscalid+0.0121g pyraclostrobin	100	0.0481 boscalid+0.0121 pyraclostrobin	-	A
28	Ornamentals in field and greenhouses	PL	SHA 7273 A	F/G	<i>Botrytis cinerea</i> , <i>Sclerotinia sclerotiorum</i> <i>Thanatephorus cucumeris</i>	WG	267 g/kg +67 g/kg	Spray	BBCH 13-47	a) 2 b) 2	7-14	0.0401g boscalid+0.0101g pyraclostrobin	100	0.0401 boscalid+0.0101 pyraclostrobin	-	A
29	Redcurrant, White currant	PL	SHA 7273 A	F	<i>Drepanopeziza ribis</i> , <i>Drepanopeziza rubric</i> , <i>Botrytis cinerea</i> ,	WG	267 g/kg +67 g/kg	Spray	BBCH 55-90	a) 2 b) 2	7-10	a) 0.0008 boscalid + 0.01508 pyraclostrobin b) 0.0801 boscalid + 0.0201 pyraclostrobin	600-800	0.4806 boscalid + 0.1206 pyraclostrobin	3	N
30	Salsifies	PL	SHA 7273 A	F	<i>Botrytis cinerea</i> , <i>Sclerotinia sclerotiorum</i> <i>Rhizoctonia</i>	WG	267 g/kg +67 g/kg	Foliar Spray	When first symptoms are visible BBCH 41-49	a) 2 b) 2	8-10	a) 0.067 boscalid + 0.0167 pyraclostrobin b) 0.133 boscalid + 0.033 pyraclostrobin	300-600	0.4 boscalid + 0.1 pyraclostrobin	14	A

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

** Use also code numbers according to Annex I of Regulation (EU) No 396/2005

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

Explanation for Column 11 “Conclusion”

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

7.1.2 Summary of the evaluation

The preparation CASINO ROYALE is composed of Boscalid 26,7% and Pyraclostobin 6,7 % WG.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of Pyraclostobin and Boscalid

Reference value	Source	Year	Value	Study relied upon	Safety factor
Pyraclostrobin					
ADI	EC	2008	0.04 mg/kg bw per day	2 years rat oral feed	100
ArfD	EC	2008	Not necessary		
Boscalid					
ADI	EC	2008	0.04 mg/kg bw/d	Rat 2-yr oral feed	100
ArfD	EC	2008	Not allocated	-	-

7.1.2.1 Summary for Pyraclostobin

Table 7.1-3: Summary for Pyraclostobin

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Sugar beet	Yes	Yes	Yes	Yes	Yes	No	No
2-3	Tomato	Yes	Yes	Yes	Yes	Yes	No	No
4	Carrot	Yes	Yes	Yes	Yes	Yes	No	No
5	Onion	Yes	Yes	Yes	Yes	Yes	No	No
Unprotected use in SIGNUM								
6	Cabbage	Yes	Yes No	Yes No	Yes No	Yes No	No	No
7	Tomatoe in green-houses	Yes	Yes No	Yes No	Yes No	Yes No	No	No
8	Strawberry	Yes	Yes No	Yes No	Yes No	Yes No	No	No
9	Cherry	Yes	Yes No	Yes No	Yes No	Yes No	No	No
10	Raspberry	Yes	Yes No	Yes No	Yes No	Yes No	No	No
11	Blackcurrant	Yes	Yes No	Yes No	Yes No	Yes No	No	No

Use- No.*	Crop	Plant me- tabolism covered?	Sufficient residue trials?	PHI suffi- ciently sup- ported?	Sample storage covered by sta- bility data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for con- sumers identified?
Minor Crops								
12	Beetroot	Yes	Yes	Yes	Yes	Yes	No	No
13	Celery root	Yes	Yes	Yes	Yes	Yes	No	No
14	Parsnip, Parsley	Yes	Yes	Yes	Yes	Yes	No	No
15- 16	Radish	Yes	Yes	Yes	Yes	Yes	No	No
17	Horseradish	Yes	Yes	Yes	Yes	Yes	No	No
18	Swedes/rutabagas	Yes	Yes	Yes	Yes	Yes	No	No
19	Turnip	Yes	Yes	Yes	Yes	Yes	No	No
20	Chicory roots	Yes	Yes	Yes	Yes	Yes	No	No
21	Shallot	Yes	Yes	Yes	Yes	Yes	No	No
22	Onion “seven years old”	Yes	Yes	Yes	Yes	Yes	No	No
23- 24- 25	aubergines/eggplants	Yes	Yes	Yes	Yes	Yes	No	No
26- 28	Ornamentals in field and greenhouses	Yes	Yes	Yes	Yes	Yes	No	No
29	Redcurrant, White currant	Yes	Yes No	Yes No	Yes	Yes No	No	No
30	Salsifies	Yes	Yes	Yes	Yes	Yes	No	No

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

To cover uses on cabbage, tomatoes in greenhouses, strawberries, cherries, raspberries and black currant, applicant refers to unprotected data on the reference product SIGNUM (Registration No. R – 33/2010, 19/04/2010).

7.1.2.2 Summary for Boscalid

Table 7.1-4: Summary for Boscalid

Use- No.*	Crop	Plant me- tabolism covered?	Sufficient residue trials?	PHI suffi- ciently sup- ported?	Sample storage covered by sta- bility data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for con- sumers identified?
1	Sugar beet	Yes	Yes	Yes	Yes	Yes	No	No
2-3	Tomato	Yes	Yes	Yes	Yes	Yes	No	No
4	Carrot	Yes	Yes	Yes	Yes	Yes	No	No
5	Onion	Yes	Yes	Yes	Yes	Yes	No	No

Use- No.*	Crop	Plant me- tabolism covered?	Sufficient residue trials?	PHI suffi- ciently sup- ported?	Sample storage covered by sta- bility data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for con- sumers identified?
Unprotected use in SIGNUM								
6	Cabbage	Yes	Yes No	Yes No	Yes No	Yes No	No	No
7	Tomatoe in green- houses	Yes	Yes No	Yes No	Yes No	Yes No	No	No
8	Strawberry	Yes	Yes No	Yes No	Yes No	Yes No	No	No
9	Cherry	Yes	Yes No	Yes No	Yes No	Yes No	No	No
10	Raspberry	Yes	Yes No	Yes No	Yes No	Yes No	No	No
11	Blackcurrant	Yes	Yes No	Yes No	Yes No	Yes No	No	No
Minor Crops								
12	Beetroot	Yes	Yes	Yes	Yes	Yes	No	No
13	Celery root	Yes	Yes	Yes	Yes	Yes	No	No
14	Parsnip, Parsley	Yes	Yes	Yes	Yes	Yes	No	No
15- 16	Radish	Yes	Yes	Yes	Yes	Yes	No	No
17	Horseradish	Yes	Yes	Yes	Yes	Yes	No	No
18	Swedes/rutabagas	Yes	Yes	Yes	Yes	Yes	No	No
19	Turnip	Yes	Yes	Yes	Yes	Yes	No	No
20	Chicory roots	Yes	Yes	Yes	Yes	Yes	No	No
21	Shallot	Yes	Yes	Yes	Yes	Yes	No	No
22	Onion “seven years old”	Yes	Yes	Yes	Yes	Yes	No	No
23 24 25	aubergines/eggplants	Yes	Yes	Yes	Yes	Yes	No	No
26- 28	Ornamentals in field and greenhouses	Yes	Yes	Yes	Yes	Yes	No	No
29	Redcurrant, White currant	Yes	Yes No	Yes No	Yes	Yes No	No	No
30	Salsifies	Yes	Yes	Yes	Yes	Yes	No	No

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

To cover uses on cabbage, tomatoes in greenhouses, strawberries, cherries, raspberries and black currant, applicant refers to unprotected data on the reference product SIGNUM (Registration No. R – 33/2010, 19/04/2010).

7.1.2.3 Summary for Boscalid 26.7% + Pyraclostrobin 6.7% WG

Table 7.1-5: Information on Boscalid 26.7% + Pyraclostrobin 6.7% WG (KCA 6.8)

Crop	PHI for Boscalid 26.7% + Pyraclostrobin 6.7% WG proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for Boscalid 26.7% + Pyraclostrobin 6.7% WG proposed by zRMS	zRMS Comments (if different PHI proposed)
		Pyraclostrobin	Boscalid		
Sugar beet	NR	NR	NR	NR	
Tomato	NR	NR	NR	NR	
Carrot	NR	NR	NR	NR	
Onion	NR	NR	NR	NR	

NR: not relevant

* Purpose of withholding period to be specified

** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Table 7.1-6: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops			Overall waiting period proposed by zRMS for Boscalid 26.7% + Pyraclostrobin 6.7% WG
Crop group	Led by Pyraclostrobin	Led by Boscalid	
Leafy vegetables	NR	NR	
Root vegetables	NR	NR	
Fruiting vegetables	NR	NR	
Bulb vegetables	NR	NR	

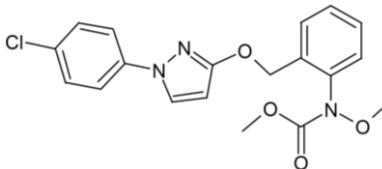
NR: not relevant

Assessment

7.2 Pyraclostrobin

General data on Pyraclostrobin are summarized in the table below (last updated 2017/01/24)

Table 7.2-1: General information on Pyraclostrobin

Active substance (ISO Common Name)	Pyraclostrobin
IUPAC	methyl N-(2-{[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxymethyl}phenyl) N-methoxy carbamate
Chemical structure	
Molecular formula	C ₁₉ H ₁₈ ClN ₃ O ₄
Molar mass	387.82 g/mol
Chemical group	Strobin
Mode of action (if available)	Inhibition of cell respiration (mitochondria).
Systemic	Yes
Company	BASF AG.
Rapporteur Member State (RMS)	Germany
Approval status	Approved Date of (01/06/2004) and reference to decision (COMMISSION DIRECTIVE 2004/30/EC – REGULATION (EU) No 2018/84) http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004L0030&from=EN http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0084&from=EN
Restriction	Only uses as fungicides may be authorised
Review Report	SANCO/1420/2001-Final. 8 September 2004
Current MRL regulation	Regulation (EU) 2020/856
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Pending
EFSA Journal : conclusion on article 12	No
Current MRL applications on intended uses	EFSA-Q-2008-620 (Germany) Status: Reasoned opinion available (EFSA Journal 2011;9(8):2344)

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.2-2: Summary of stability data achieved at $\leq -18^{\circ}\text{C}$ (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Tomato Sugar beet tops and roots	High water content	18 months	Abdel Baky, 2000 Report No. 2000-2043 DAR, 2001 EFSA, 2011
Peanut oil and nutmeat	High oil content	18 months	
Grape juice	High acid content	18 months	
Wheat grain and straw	Dry commodities / High starch content	18 months	
Animal Products			
Ruminant	Liver	8 months	Tilting, 2000 Report No. RIP2000-2042 DAR, 2001 EFSA, 2011
Ruminant	Milk	8 months	
Ruminant	Muscle	8 months	

Conclusion on stability of residues during storage

Conclusions drawn from EFSA Journal 2011;9(8):2344 are reported below:

The demonstrated storage stability of Pyraclostrobin in treated crops was evaluated under the peer review of Directive 91/414/EEC (Germany, 2001). Studies demonstrated storage stability of Pyraclostrobin in high oil content, high water content, acidic and dry commodities for up to 18 months when stored deep frozen. The storage conditions for most of the residues trials were not reported but considering that storage stability of Pyraclostrobin was demonstrated for a long period of time, degradation of residues during the storage of the residues trials samples is not expected. The storage stability of Pyraclostrobin in animal products was evaluated under the peer review of Directive 91/414/EEC (Germany, 2001). Studies demonstrated storage stability of Pyraclostrobin in milk and animal tissues for up to 8 months when stored deep frozen. No storage stability study was performed on poultry eggs.

On the basis of the available data, storage stability of residues was sufficiently investigated for the intended uses claimed in this dossier.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

No data was submitted and required at EU level during the EU Review of Pyraclostrobin.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Grape	[tolyl-U- ¹⁴ C]-pyraclostrobin and [chlorophenyl-U- ¹⁴ C]-pyraclostrobin	foliar treatment, F	0.48, 0.24, 0.18, 0.13, 0.24, 0.24	6	40	Applications: BBCH 53-55 (1 st appli.); BBCH 81 (last application)	Hamm, 1998 Report No. RIP 2000-1050 and RIP 2000-1275 DAR, 2001 EFSA, 2011
Root and tuber vegetables	Potatoes		foliar treatment, F	0.30, 0.30; 0.30; 0.40; 0.30; 0.30	6	7 days after the 3 rd application and 7 days after last application (maturity)	Applications: BBCH 31 (1 st appli.) then application every 9 days	Bross, Mackenroth, 1999 Report No. RIP 2000-1051 and RIP 2000-1041 DAR, 2001 EFSA, 2011
Cereals	Wheat		foliar treatment, F	0.30	2	0, 31, 41	Applications: BBCH 32 (1 st appli.); BBCH 61 (2 nd appli.)	Reinhard, 1999 Report No. RIP 2000-1009 DAR, 2001 EFSA, 2011

Summary of plant metabolism studies reported in the EU

Conclusions drawn from EFSA Journal 2011;9(8):2344 are reported below:

Metabolism of Pyraclostrobin was investigated for foliar applications on cereals (wheat), on fruits and fruiting vegetables (grapes) and on root and tuber vegetables (potatoes) using [tolyl-¹⁴C]-pyraclostrobin and [chlorophenyl-¹⁴C]-pyraclostrobin (Germany, 2001).

The relevant residue in grapes consisted of parent pyraclostrobin (55.7 – 66 % TRR) and its desmethoxy metabolite 500M0715 (11.2 – 15.3 % TRR). In potatoes the highest TRR was identified in green matter (41.2 – 57.9 mg/kg) in both studies. Parent pyraclostrobin was the main component of the TRR in green matter and potato tubers in studies with [chlorophenyl-¹⁴C]-pyraclostrobin, amounting for 55 % and 29.4 % of the TRR, respectively. In the green matter desmethoxy metabolite 500M07 was identified in

levels > 20 % of the TRR in both studies. In the tolyl study the major component of the TRR in potato tubers was identified as natural amino acid L-tryptophan (29.2 % TRR). In cereals, the lowest TRR was found in grains, varying between 0.098 mg/kg in the chlorophenyl labelled and 0.441 mg/kg in the tolyl labelled matrix. The highest TRR was identified in wheat straw, amounting for up to 37.76 mg/kg (chlorophenyl study) and 40.46 mg/kg (tolyl study). The major component of the TRR in straw and grain in the chlorophenyl study was parent pyraclostrobin and its desmethoxy metabolite (500M07). In the tolyl study the major component of the TRR in grain was L-tryptophan (23 % TRR), any other components being below 10 % of the TRR. L-tryptophan is an essential natural amino acid therefore it is of no toxicological relevance (EFSA, 2010).

Conclusion on metabolism in primary crops

Conclusions drawn from EFSA Journal 2011;9(8):2344 are reported below:

Generally it was concluded in the peer review (EC, 2002) that the metabolic pathway is similar in all crop groups investigated. Results from the supervised residue trials indicated that desmethoxy metabolite 500M07 occurs in crops in small amounts compared to parent Pyraclostrobin; therefore in the peer review it was concluded that a general residue definition for risk assessment and enforcement should be set as parent Pyraclostrobin only.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-4: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Lettuce	[tolyl-U- ¹⁴ C]-pyraclostrobin and	F	0.90	30, 120, 365	At maturity	-	Veit, 2000 Report No. RIP2000-1085 DAR, 2001 EFSA, 2011
Root and tuber vegetables	Radish	[chlorophenyl-U- ¹⁴ C]-pyraclostrobin	F	0.90	30, 120, 365	At maturity	-	
Cereals	Wheat		F	0.90	30, 120, 365	At maturity	-	

* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Summary of plant metabolism studies reported in the EU

Conclusions drawn from EFSA Journal 2011;9(8):2344 are reported below:

In the peer review the metabolism of pyraclostrobin in rotational crops was studied in lettuce, radish and wheat with [tolyl-U-¹⁴C]-pyraclostrobin and [chlorophenyl-U-¹⁴C]-pyraclostrobin (Germany, 2001). The radiolabelled active substance was applied on a bare soil once at an application rate of 0.9 kg a.s./ha and respective crops were sown or planted at 30, 120 and 365 DAT.

Conclusion on metabolism in rotational crops

Conclusions drawn from EFSA Journal 2011;9(8):2344 are reported below:

The peer review concluded that the metabolic pathway of pyraclostrobin in rotational crops is similar to

that in primary crops and no formation of new metabolites was observed. There is no accumulation of pyraclostrobin or its degradation products (including 500M07) in the parts of plants used for human or animal consumption. The relevant residue in rotational crops therefore should be defined as parent pyraclostrobin.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-5: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)* Chlorophenyl label	Identified compound(s) (%)* Tolyl label	Reference
EU data			
Pasteurisation (20 minutes, 90°C, pH 4)	Parent (98.1%)	Parent (103.9%)	Scharf, 1998 Report No. RIP 2000-1078 DAR, 2001 EFSA, 2011
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Parent (110.9%)	Parent (98.1%)	
Sterilisation (20 minutes, 120°C, pH 6)	Parent (97.4%)	Parent (96.1%)	

* Total applied radioactivity after test

Conclusion on nature of residues in processed commodities

Conclusions drawn from EFSA Journal 2011;9(8):2344 are reported below:

The effect of processing on the nature of Pyraclostrobin residues was investigated in the framework of the peer review. A study was conducted simulating representative hydrolytic conditions for pasteurisation (20 minutes at 90 C, pH 4), boiling/brewing/baking (60 minutes at 100 C pH 5) and sterilisation (20 minutes at 120 C, pH 6). This study demonstrates that food processes such as brewing, cooking, sterilisation or pasteurisation, will not impact on the nature of Pyraclostrobin residues. The relevant residue for enforcement and risk assessment in processed commodities is therefore expected to be the same as for primary crops (Germany, 2001).

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.2-6: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Root and tuber vegetables (Potatoes) Fruits (grapes) Cereals (Wheat)
Rotational crops covered	Root and tuber vegetables (Radish) Leafy vegetables (Lettuce) Cereals (Wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	a.s. is stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to	Yes

pattern in raw commodities?	
Plant residue definition for monitoring	Pyraclostrobin (Regulation n°2020/856)
Plant residue definition for risk assessment	Pyraclostrobin (EFSA 2011)
Conversion factor from enforcement to RA	None (Germany, 2001; EFSA, 2011)

7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

Table 7.2-7: Summary of animal metabolism studies

Group	Species	Label posi- tion	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of samp- ling	
EU data								
Lactating ruminants	Goat	¹⁴ C- chlorophenyl	2 (12 mg/kg DM feed)	0.9 – 1.0	5	Milk	Twice daily	Leibold, et. Al., 1998 Report No. RIP 2000-1018 DAR, 2001 EFSA, 2011
			1 (50 mg/kg DM feed)	2.72		Urine and faeces	Daily	
						Tissues	At sacrifice	
		¹⁴ C-tolyl	2 (12 mg/kg DM feed)	0.65-0.75	5	Milk	Twice daily	
			1 (50 mg/kg DM feed)	1.37		Urine and faeces	Daily	
						Tissues	At sacrifice	
Laying poultry	Hens	¹⁴ C- chlorophenyl	11 (12 mg/kg DM feed)	0.70	7	Eggs	Twice daily	Leibold, et. Al., 1998 Report No. RIP 2000-1021 DAR, 2001 EFSA, 2011
						Excreta	Daily	
						Tissues	At sacrifice	
		¹⁴ C-tolyl	11 (13 mg/kg DM feed)	0.88	7	Eggs	Twice daily	
						Excreta	Daily	
						Tissues	At sacrifice	

Summary of plant metabolism studies reported in the EU

Conclusions drawn from EFSA Journal 2011;9(8):2344 are reported below:

The nature of Pyraclostrobin residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (Germany, 2001). Reported metabolism studies include 4 studies, two in lactat-

ing goats and two in laying hens using ¹⁴C-chlorophenyl labelled Pyraclostrobin and ¹⁴C-tolyl labelled Pyraclostrobin.

Studies of the metabolism of Pyraclostrobin in goats showed that residues in products of animal origin derive from the parent compound as well as from its desmethoxy metabolite (500M07). After five consecutive daily oral administrations of ¹⁴C-pyraclostrobin at a nominal dosage of 12 or 50 mg/kg DM feed, there was rapid absorption from the gastrointestinal tract. Radioactivity was excreted mainly via the faeces. The radiolabel in milk accounted for only 0.1–0.5% of the total applied radioactivity. There was no indication of accumulation of ¹⁴C-pyraclostrobin in tissues. The parent compound was found in fat, muscle and, at lower amounts, in liver. Metabolites are formed in liver and kidney by hydroxylation of the chlorophenyl and tolyl rings and by cleavage of the molecule. Little extraction was seen in liver. Pyraclostrobin was present in all tissues and in milk and was the main residue component in muscle and in fat (log Pow = 3.9) (FAO, 2004).

Tissues and eggs from hens that received an exaggerated dose of 0.70 or 0.88 mg/kg bw/d on seven consecutive days contained low residue levels consisting of three main metabolites. The parent compound was found in fat and eggs but not in liver. The main metabolite in liver was the glucuronic acid conjugate, which was bound to the tolyl ring of the demethoxylated parent structure. The desmethoxy metabolite (500M07) was also present in fat and eggs. The main metabolite in fat and eggs was 500M07, and that in liver was the glucuronic acid conjugate (FAO, 2004).

Conclusion on metabolism in livestock

Conclusions drawn from EFSA Journal 2011;9(8):2344 are reported below:

The metabolic patterns identified for goats and hens were consistent with the rat metabolism and a specific metabolism study in pigs is not considered necessary. Pyraclostrobin was identified as the major indicator compound in commodities of animal origin except in ruminant liver and milk fat. Based on these findings the JMPR defined the parent compound as the only relevant residue for enforcement and risk assessment but EFSA is of the opinion that consideration should be given to the presence of the desmethoxy metabolite (500M07). An ideal residue definition for ruminant products would therefore include parent and at least metabolite 500M07 (and possibly also metabolite 500M0416); however the difficulty is that a method of analysis specific to individual metabolites is not available (EC, 2002). Moreover, based on the available livestock feeding study in cows it is expected that relevant metabolites will only be present in ruminant liver and that residues will decline quickly after the end of dosing. Hence the relevant residue for enforcement is defined as the parent compound Pyraclostrobin in commodities of animal origin. The relevant residue for risk assessment is defined as the sum of Pyraclostrobin and its metabolites containing the 1-(4-chlorophenyl)-1H-pyrazole moiety or the 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazole moiety, expressed as Pyraclostrobin. EFSA proposes to set different levels of conversion factor from enforcement to risk assessment. Conversion factors will be set at 4 for ruminant liver and at 1 for all other commodities. In the framework of the peer review, the proposed residue definition was considered to be fat soluble based on the fact that the log Po/w of Pyraclostrobin is higher than 3 (DAR, 2001).

7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.2-8: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	About 3 days in milk
	Not reached after 6 days of dosing in eggs
Animal residue definition for monitoring	Pyraclostrobin (Regulation n°2020/856)

Animal residue definition for risk assessment	sum of pyraclostrobin and its metabolites containing the 1-(4-chlorophenyl)-1H-pyrazole moiety or the 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazole moiety, expressed as pyraclostrobin (EFSA, 2011)
Conversion factor	4 on ruminant liver and 1 on all other commodities (EFSA 2011)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes

7.2.3 Magnitude of residues in plants (KCA 6.3)

7.2.3.1 Summary of European data and new data supporting the intended uses

Table 7.2-9: Summary of new data supporting the intended uses of SHA 7273 A and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Sugarbeet → extrapolated to Beetroot, celery root, horseradish, Swedes, rutabagas, turnip, chicory roots	New trials	N-EU	GAP: 2 application of 0.1 Kg a.i./ha of pyraclostrobin, interval between application of 8 days, at BBCH 31-39, PHI= 14 days. Pyraclostrobin: 3x<LOD (0,002mg/kg), 2x0.017, 0.02, 0.03, 0.037 3x<0.01 3x0.02, 0.03, 0.04	N/A				
	Overall supporting data for cGAP	N-EU	Pyraclostrobin: 3x<LOD (0,002mg/kg), 2x0.017, 0.02, 0.03, 0.037 3x<0.01, 3x0.02, 0.03, 0.04	0.02	0.037	0.068 0.063	0.2	Yes
Tomato → extrapolated to aubergines/egg plants	New trials	N-EU	GAP: 2 application of 0.1 Kg a.i./ha of pyraclostrobin, interval between application of 8 days, at BBCH 20-87, PHI= 3 days (outdoor) Pyraclostrobin: 2x<LOD (0.002 mg/kg), 0.006 (<LOQ), 0.011, 0.016, 0.017, 0.04, 0.065 3x<0.01, 0.01, 2 x 0.02, 0.04, 0.07	N/A				

	Overall supporting data for cGAP	N-EU	<p>Pyraclostrobin: 2x<LOD (0.002 mg/kg), 0.006 (<LOQ), 0.011, 0.016, 0.017, 0.04, 0.065</p> <p>3x<0.01, 0.01, 2 x 0.02, 0.04, 0.07</p>	0.0135	0.065	0.108 0.109	0.3 0.3 mg/kg (shallots), 1.5 (Spring onions/green onions and Welsh onions)	Yes
Onion → extrapolated to Onion “seven years old”, Shallot	New trials	N-EU	<p>GAP: 2 application of 0.1 Kg a.i./ha of pyraclostrobin, interval between application of 8 days, at BBCH 43-49, PHI= 14 days</p> <p>Pyraclostrobin: 8x<LOD (0.002 mg/kg)</p> <p>8 x < 0.01 mg/kg</p>	N/A				
	Overall supporting data for cGAP	N-EU	<p>Pyraclostrobin: 8x<LOD (0.002 mg/kg)</p> <p>8 x < 0.01 mg/kg</p>	0.01	0.01	0.01	1.5	Yes
Carrot → extrapolated to radish, beetroot, celery root, horseradish, swedes, rutabagas, turnip, chicory roots, parsnip, parsley, salsifies	New trials	N-EU	<p>GAP: 2 application of 0.1 Kg a.i./ha of pyraclostrobin, interval between application of 14 days, at BBCH 48, PHI= 14 days</p> <p>Pyraclostrobin: 2x<LOD (0.002), 0.015, 0.016, 0.021, 0.023, 0.024, 0.026</p> <p>2x<0.01, 5 x 0.02, 0.03</p>	N/A				
	Overall supporting data for cGAP	N-EU	<p>Pyraclostrobin: 2x<LOD (0.002), 0.015, 0.016, 0.021, 0.023, 0.024, 0.026</p> <p>2x<0.01, 5 x 0.02, 0.03</p>	0.0185	0.026	0.054 0.047	0.5	Yes

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on sugar beet, tomato, carrot and onion are considered acceptable, for outdoor uses.

According to appendix D of EU guidelines, extrapolation to Beetroot, celery root, horseradish, Swedes, rutabagas, turnip, chicory roots is possible with 8 N-EU trials on Sugar beet, which is the case here.

According to appendix D of EU guidelines, extrapolation to aubergines/egg plants is possible with 8 N-EU trials on Tomato, which is the case here.

According to appendix D of EU guidelines, extrapolation to Onion “seven years old”, Shallot is possible with 8 N-EU trials on Onion, which is the case here.

According to appendix D of EU guidelines, extrapolation to radish, beetroot, celery root, horseradish, swedes, rutabagas, turnip, chicory roots, parsnip, parsley, salsifies is possible with 8 N-EU trials on Carrot, which is the case here.

To cover uses on cabbage, tomatoes in greenhouses, strawberries, cherries, raspberries and black currant, applicant refers to unprotected data on the reference product SIGNUM (Registration No. R – 33/2010, 19/04/2010).

According to appendix D of EU guidelines, extrapolation to red and white currant is possible with N-EU residue trials from reference product SIGNUM (Registration No. R – 33/2010, 19/04/2010).

The data submitted show that no exceedance of the MRL will occur.

The uses are considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Table 7.2-10: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Barley straw	3.38	Median residue	6.92	Highest residue
Sugar beet tops	0.07	Median residue	0.18	Highest residue
Cabbage heads	0.02	Median (0.1) x 5	0.09	Median (0.1) x 5
Oat straw	3.38	Median residue	0.07	Median residue
Wheat straw	1.85	Median residue	5.68	Median residue
Potato culls	0.02	Median residue	0.02	Median residue

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Barley grain	0.07	Median residue (0.07) x PF (3.3)	0.07	Median residue (0.07) x PF (3.3)
Corn, field grain	0.02	Median residue (0.02) x PF (1)	0.02	Median residue (0.02) x PF (1)
Corn, pop grain	0.02	Median residue (0.02) x PF (1)	0.02	Median residue (0.02) x PF (1)
Oat grain	0.07	Median residue (0.02) x PF (1)	0.07	Median residue (0.02) x PF (1)
Pea seed	0.04	Median residue (0.02) x PF (1)	0.04	Median residue (0.02) x PF (1)
Rye grain	0.02	Median residue (0.02) x PF (3.3)	0.02	Median residue (0.02) x PF (3.3)
Soybean seed	0.02	Median residue (0.02) x PF (1.8)	0.02	Median residue (0.02) x PF (1.8)
Wheat grain	0.02	Median residue (0.02) x PF (7)	0.02	Median residue (0.02) x PF (7)
Apple pomace wet	0.50	Median residue (0.1) x PF (3.3)	0.50	Median residue (0.1) x PF (3.3)
Citrus dried pulp	1.96	Median residue (0.196) x PF (10)	1.96	Median residue (0.196) x PF (10)
Corn, field milled by-pdts	0.02	Median residue	0.02	Median residue
Corn, field hominy meal	0.12	Median residue (0.02) x PF (6)	0.12	Median residue (0.02) x PF (6)
Corn, field gluten feed	0.05	Median residue (0.02) x PF (2.5)	0.05	Median residue (0.02) x PF (2.5)
Corn, field gluten, meal	0.02	Median residue	0.02	Median (0.04) x PF (3)
Distiller's grain dried	0.07	Median residue (0.02) x PF (3.3)	0.07	Median residue (0.02) x PF (3.3)
Peanut meal	0.04	Median residue (0.02) x PF (2)	0.04	Median residue (0.02) x PF (2)
Potato process waste	0.40	Median residue (0.02) x PF (20)	0.40	Median residue (0.02) x PF (20)
Potato dried pulp	0.76	Median residue (0.02) x PF (38)	0.76	Median residue (0.02) x PF (38)
Soybean meal	0.03	Median residue (0.02) x PF (1.3)	0.03	Median residue (0.02) x PF (1.3)
Soybean hulls	0.26	Median residue (0.02) x PF (13)	0.26	Median residue (0.02) x PF (13)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sunflower meal	0.08	Median residue (0.04) x PF (2)	0.08	Median residue (0.04) x PF (2)
Wheat gluten meal	0.04	Median residue (0.02) x PF (1.8)	0.04	Median residue (0.02) x PF (1.8)
Wheat milled by-pdts	0.14	Median residue (0.02) x PF (7)	0.14	Median residue (0.02) x PF (7)

Table 7.2-11: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Cattle (all diets)	0.084	0.129	Barley straw	3.69	Yes
Cattle (dairy only)	0.084	0.129	Barley straw	3.36	Yes
Sheep (all diets)	0.126	0.227	Barley straw	6.00	Yes
Sheep (ewe only)	0.120	0.200	Barley straw	6.00	Yes
Swine (all diets)	0.017	0.018	Potato, process waste	0.80	Yes
Poultry (all diets)	0.027	0.057	Wheat straw	0.83	Yes
Poultry (layer only)	0.027	0.057	Wheat straw	0.83	Yes

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

No new data were submitted in the framework of this application.

Table 7.2-12: Overview of the values derived from livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) ^(b)	Highest residue (mg/kg) ^I	Calculated MRL (mg/kg)	CF for RA ^(d)
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enforce-ment		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (DAR, 2001; EFSA, 2011)												
Residue definition for enforcement: pyraclostrobin and risk assessment: sum of pyraclostrobin and its metabolites containing the 1-(4-chlorophenyl)-1H-pyrazole moiety or the 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazole moiety, expressed as pyraclostrobin												
Pig meat	0.017	0.018	0.22	3	< 0.05	n.p.	< 0.05	n.p.	0.05	0.05	0.05*(^F)	1.00
			0.67	3	< 0.05	n.p.	< 0.05	n.p.				
			2.40	3	< 0.05	n.p.	< 0.05	n.p.				
Pig fat			0.22	3	< 0.05	n.p.	< 0.05	n.p.	0.05	0.05	0.05*	1.00
			0.67	3	< 0.05	n.p.	< 0.05	n.p.				
			2.40	3	< 0.05	n.p.	< 0.05	n.p.				
Pig kidney			0.22	3	< 0.05	n.p.	< 0.05	n.p.	0.05	0.05	0.05*	1.00
			0.67	3	< 0.05	n.p.	< 0.05	n.p.				
			2.40	3	< 0.05	n.p.	< 0.05	n.p.				
Pig liver			0.22	3	< 0.05	n.r.	0.20	n.r.	0.05	0.05	0.05*	4.00
			0.67	3	< 0.05	n.r.	0.52	n.r.				
			2.40	3	< 0.05	n.r.	2.48	n.r.				
Ruminant meat	0.084	0.129	0.22	3	< 0.05	n.p.	< 0.05	n.p.	0.05	0.05	0.05*(^F)	1.00
			0.67	3	< 0.05	n.p.	< 0.05	n.p.				
			2.40	3	< 0.05	n.p.	< 0.05	n.p.				

Ruminant fat			0.22	3	< 0.05	n.p.	< 0.05	n.p.	0.05	0.05	0.05*	1.00
			0.67	3	< 0.05	n.p.	< 0.05	n.p.				
			2.40	3	< 0.05	n.p.	< 0.05	n.p.				
Ruminant kidney			0.22	3	< 0.05	n.p.	< 0.05	n.p.	0.05	0.05	0.05*	1.00
			0.67	3	< 0.05	n.p.	< 0.05	n.p.				
			2.40	3	< 0.05	n.p.	< 0.05	n.p.				
Ruminant liver			0.22	3	< 0.05	n.r.	0.20	n.r.	0.05	0.05	0.05*	4.00
			0.67	3	< 0.05	n.r.	0.52	n.r.				
			2.40	3	< 0.05	n.r.	2.48	n.r.				
Milk	0.084	0.0129	0.22	12	< 0.01	N/A	< 0.02	N/A	0.01	0.01	0.01	1.00
			0.67	12	< 0.01	N/A	< 0.02	N/A				
			2.40	70	< 0.01	N/A	< 0.07	N/A				

N/A: Not applicable – only the mean values are considered for calculating MRLs in milk.

n.r.: Not reported but not considered relevant in this case because residues according to the enforcement residues definition are always below the LOQ

(*): Indicates that the MRL is set at the limit of analytical quantification.

(F): MRL is expressed as mg/kg of fat contained in the whole product.

(b): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).

I: Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).

(d): The median conversion factor for enforcement to risk assessment.

I: Mean residue level from day X until day XX (X cows, Y sampling days).

Conclusion on feeding studies

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded. Moreover, no livestock feeding study is available for poultry but the metabolism study in laying hens was performed at dose levels of approximately 0.7 and 0.88 mg/kg bw/d, which represents 100 times the calculated dietary intake. When extrapolating residue levels obtained in the metabolism study to the calculated intake, no residues above LOQ are expected in any poultry tissues or eggs. Then no feeding study is necessary and MRLs in eggs and poultry tissues are proposed at the level of the LOQ (DAR, 2001).

7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

7.2.5.1 Available data for all crops under consideration

No new data were submitted in the framework of this application.

Table 7.2-13: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Processing factors recommended for enforcement and risk assessment (sufficiently supported by data)					
Citrus fruits, peeled	6	0.14	1.00		EFSA, 2011
Cherries, canned	4	1.00	1.00	-	EFSA, 2011
Cherries, juice	4	0.17	1.00	-	EFSA, 2011
Plums, dried (prunes)	4	4.7	1.00		EFSA, 2011
Plums, jam	4	1.74	1.00		EFSA, 2011
Wine grapes, juice	4	0.03	1.00		Germany, 2001 EFSA, 2011
Wine grapes, wet pomace	4	3.75	1.00		DAR, 2001 EFSA, 2011
Wine grapes, must	4	0.03	1.00		DAR, 2001 EFSA, 2011
Wine grapes, white wine	4	0.03	1.00		DAR, 2001 EFSA, 2011
Melons, peeled Pumpkins, peeled Watermelons, peeled	7	0.50	1.00		EFSA, 2011
Barley, brewing malt	4	1.20	1.00		DAR, 2001 EFSA, 2011
Barley, beer	4	0.70	1.00		DAR, 2001 EFSA, 2011
Indicative processing factors (limited data sets)					
Table grapes, dried (rai-	2	2.70	1.00	-	DAR, 2001 EFSA, 2011

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
sins)					
Barley, pot/pearl	1	0.70	1.00		DAR, 2001 EFSA, 2011
Wheat and rye, white flour	1	0.06	1.00		DAR, 2001 EFSA, 2011

* The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

** The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

7.2.5.2 Conclusion on processing studies

Conclusions drawn from EFSA Journal 2011;9(8):2344 are reported below:

Studies investigating the magnitude of residues in processed commodities of table and wine grapes, barley and wheat were also reported in the framework of the peer review (DAR, 2001). After Pyraclostrobin was included in Annex I to Directive 91/414/EEC, studies investigating the magnitude of residues in processed commodities of cherries, plums, peeled melons and peeled citrus fruits were evaluated by EFSA, EMSs or JMPR. An overview of all available processing studies is available in Table 3-3. Robust processing factors could only be derived for peeled citrus fruits, canned cherries, cherry juice, prunes, jam of plums, peeled melons, grape juice, grape pomace (wet), must, white wine and beer. The processing factors reported for the other processed commodities should be considered as indicative as a minimum of 3 processing studies is normally required. Further processing studies are not required as they are not expected to affect the outcome of the risk assessment. However, if there would be the intention to derive more robust processing factors, in particular for enforcement purposes, additional processing studies would be required.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see 7.2.2.2), no study dealing with magnitude of residues in succeeding crops is needed.

Conclusions drawn from EFSA Journal 2011;9(8):2344 are reported below:

According to the studies reported in section 3.1.2.2. (nature of residues), the total radioactive residues in the edible parts of succeeding crops were very low for all plant back intervals: radish roots, lettuce ≤ 0.04 mg/kg and wheat grain ≤ 0.089 mg/kg. No accumulation of Pyraclostrobin or its residues was observed in rotational crops.

Application rates supported in the framework of this review range between 0.05 and 0.67 kg a.s./ha. Considering the overdosing factor of the above study and the fact that Pyraclostrobin was applied to a bare soil (interception of Pyraclostrobin by the plants is expected in practice), it is expected that residues of Pyraclostrobin resulting from soil uptake will not exceed 0.01 mg/kg. Specific plant-back restrictions related to the use of Pyraclostrobin are therefore not required, provided that Pyraclostrobin is applied in compliance with the GAPs evaluated in the framework of this review.

7.2.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might

arise from the use of Boscalid 26.7% + Pyraclostrobin 6.7% WG. Therefore, other special studies are not needed.

7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-14: Input values for the consumer risk assessment

Commodity	Acute risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition: Pyraclostrobin (EFSA,2011)		
Raspberries	0.87/1.30	STMR / Highest residue (EFSA, 2011)
Currants (Black, red, white)	0.94/2.10	STMR / Highest residue (EFSA, 2011)
Cherry	0.49/1.60	STMR / Highest residue (EFSA, 2011)
Carrots	0.04/0.06	STMR / Highest residue (EFSA, 2011)
Onions	0.02/0.21	STMR / Highest residue (EFSA, 2011)
Other plant and animal commodities	Reg. (EU) 2020/1633	STMR / Highest residue (EFSA, 2011)

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-15: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo 3.1	86 % (based on NL Toddler)
IEDI (% ADI) according to EFSA PRIMo 3.1	Not relevant
IESTI (% ArfD) according to EFSA PRIMo*	Unprocessed commodities: Results for children Cherries (sweet): 122% Onions: 114% Carrots: 106% Raspberries: 92% Celeriacs: 92% Strawberries: 82% Currants: 79% Head cabbages: 59% Tomatoes: 58% Radishes: 41% Parsnips: 36% Aubergines/egg plants: 25% Beetroots: 19% Swedes: 16% Turnips: 11%

	<p>Results for adults Cherries (sweet): 100% Onions: 74% Currants: 66% Head cabbages: 56% Raspberries: 54% Strawberries: 47% Carrots: 33% Aubergines/egg plants: 27% Celeriacs: 20% Radishes: 17% Tomatoes: 16% Parsnips: 14% Swedes: 10% Beetroots: 8% Horseradishes: 7%</p> <p>Processed commodities: Results for children Currants/juice: 266% Raspberries/juice: 117% Sugar beets (root/sugar): 73% Carrots/juice: 60% Parsnips/boiled: 51% Celeriacs/juice: 24% Tomatoes/juice: 19% Shallots/boiled: 16% Turnips/boiled: 15% Beetroots/boiled: 15% Tomatoes.sauce.puree: 10% Salsifies/boiled: 9% Head Cabbages/canned: 8% Jerusalem artichokes/boiled: 5% Chicory roots/processed: 0.2%</p> <p>Results for adults Currants/juice: 128% Onions/boiled: 47% Celeriacs/boiled: 30% Sugar beets (root)/sugar: 29% Parsnips/boiled: 21% Carrots/canned: 14% Beetroots/boiled: 13% Head cabbages/canned: 13% Tomatoes/sauce/puree: 8% Shallots/boiled: 6% Turnips/boiled: 6% Salsifies/boiled: 3% Jerusalem artichokes/boiled: 2% Chicory roots/processed: 0.08%</p> <p>Results considering STMR/HR Unprocessed commodities: Results for children Celeriacs: 92% Strawberries: 82% Cherries (sweet): 65% Head Cabbages: 59% Tomatoes: 58% Currants: 55%</p>
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	<p>Radishes: 41%</p> <p>Raspberries: 40%</p> <p>Parsnips: 36%</p> <p>Aubergines/egg plants: 25%</p> <p>Beetroots: 19%</p> <p>Onions: 16%</p> <p>Swedes: 16%</p> <p>Carrots: 13%</p> <p>Turnips: 11%</p> <p>Results for adults:</p> <p>Head cabbages: 56%</p> <p>Cherries (sweet): 53%</p> <p>Strawberries: 47%</p> <p>Currants: 46%</p> <p>Aubergines/egg plants: 27%</p> <p>Raspberries: 23%</p> <p>Celeriacs: 20%</p> <p>Radishes: 17%</p> <p>Tomatoes: 16%</p> <p>Parsnips: 14%</p> <p>Onions: 10%</p> <p>Swedes: 10%</p> <p>Beetroots: 8%</p> <p>Horseradishes: 7%</p> <p>Carrots: 4%</p> <p>Processed commodities:</p> <p>Results for children</p> <p>Currants/juice: 90%</p> <p>Sugar beets (root)/sugar: 73%</p> <p>Parsnips/boiled: 51%</p> <p>Raspberries/juice: 34%</p> <p>Celeriacs/juice: 24%</p> <p>Tomatoes/juice: 19%</p> <p>Shallots/boiled: 16%</p> <p>Turnips/boiled: 15%</p> <p>Beetroots/boiled: 15%</p> <p>Tomatoes/sauce/puree: 10%</p> <p>Salsifies/boiled: 9%</p> <p>Head cabbages/canned: 8%</p> <p>Jerusalem artichokes/boiled: 5%</p> <p>Carrots/juice: 5%</p> <p>Chicory roots/processed: 0.2%</p> <p>Results for adults:</p> <p>Currants/juice: 40%</p> <p>Celeriacs/boiled: 30%</p> <p>Sugar beets (root)/sugar: 29%</p> <p>Parsnips/boiled: 21%</p> <p>Beetroots/boiled: 13%</p> <p>Head cabbages/canned: 13%</p> <p>Tomatoes/sauce/puree: 8%</p> <p>Onions/boiled: 7%</p> <p>Shallots/boiled: 6%</p> <p>Turnips/boiled: 6%</p> <p>Salsifies/boiled: 3%</p> <p>Jerusalem artichokes/boiled: 2%</p> <p>Carrots/canned: 1%</p> <p>Chicory roots/prcessed: 0.08%</p>
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NTMDI (% ADI) **	-
NEDI (% ADI) **	-
NESTI (% ArfD) **	-


* include raw and processed commodities if both values are required for PRIMo

** if national model is available

The ~~proposed~~ accepted uses of Pyraclostrobin in the formulation Boscalid 26.7% + Pyraclostrobin 6.7% WG do not represent unacceptable acute and chronic risks for the consumer.

Evaluator's comment

TMDI (% ADI) according to EFSA PRIMo 3.1 (input values: plant and animal commodities - Reg. (EU) 2020/1633

 <p>European Food Safety Authority</p> <p>EFSA PRIMO revision 3.1; 2019/03/19</p>		Pyraclostrobin		Input values							
		LOQs (mg/kg) range from: to:		Details - chronic risk assessment							
		Toxicological reference values		Supplementary results - chronic risk assessment							
		ADI (mg/kg bw/day): 0,03	ARID (mg/kg bw): 0,03	Details - acute risk assessment/children							
Source of ADI:		Source of ARID:		Details - acute risk assessment/adults							
Year of evaluation:		Year of evaluation:									
Comments:											
Normal mode											
Chronic risk assessment: JMPR methodology (IED/TMDI)											
		No of diets exceeding the ADI : ---									
TMDI/NED/IED calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
	83%	DE child	24,76	27%	Oranges	21%	Apples	4%	Cherries (sweet)		
	83%	NL toddler	24,76	18%	Apples	15%	Oranges	7%	Pears		
	55%	NL child	16,58	10%	Apples	9%	Oranges	6%	Sugar beet roots		
	50%	FR child 3 15 yr	15,11	23%	Oranges	4%	Other lettuce and other salad plants	3%	Wheat		
	44%	GEMS/Food G06	13,25	7%	Oranges	5%	Wheat	4%	Onions		
	41%	GEMS/Food G10	12,24	8%	Oranges	3%	Onions	3%	Wheat		
	40%	IE adult	12,00	7%	Oranges	5%	Grapefruits	3%	Mandarins		
	39%	GEMS/Food G11	11,66	5%	Oranges	3%	Lamb's lettuce/corn salads	3%	Barley		
	39%	GEMS/Food G07	11,62	9%	Oranges	3%	Wheat	2%	Barley		
	38%	DE women 14-50 yr	11,36	13%	Oranges	4%	Apples	3%	Sugar beet roots		
	38%	FR toddler 2 3 yr	11,35	10%	Oranges	5%	Apples	5%	Mandarins		
	37%	GEMS/Food G08	11,07	3%	Oranges	3%	Barley	3%	Wheat		
	35%	DE general	10,51	10%	Oranges	4%	Apples	3%	Sugar beet roots		
	34%	UK toddler	10,31	13%	Oranges	3%	Apples	3%	Wheat		
	34%	GEMS/Food G15	10,23	4%	Oranges	3%	Wheat	3%	Barley		
	33%	ES child	10,02	14%	Oranges	3%	Wheat	3%	Lettuces		
	31%	SE general	9,36	5%	Oranges	3%	Mandarins	3%	Lettuces		
	27%	DK child	8,23	4%	Apples	4%	Rye	3%	Wheat		
	27%	UK infant	8,05	9%	Oranges	3%	Apples	2%	Carrots		
	26%	RO general	7,94	4%	Onions	3%	Wheat	2%	Apples		
	26%	ES adult	7,83	9%	Oranges	4%	Lettuces	2%	Barley		
	26%	NL general	7,75	7%	Oranges	2%	Apples	2%	Sugar beet roots		
	25%	IT toddler	7,53	4%	Wheat	4%	Other lettuce and other salad plants	3%	Oranges		
	24%	IT adult	7,18	5%	Other lettuce and other salad plants	3%	Wheat	3%	Lettuces		
	23%	FI 3 yr	6,89	3%	Mandarins	2%	Onions	2%	Oat		
	23%	FR adult	6,82	5%	Other lettuce and other salad plants	4%	Oranges	2%	Wine grapes		
21%	PT general	6,32	4%	Oranges	3%	Wheat	2%	Onions			
18%	FI adult	5,34	6%	Coffee beans	3%	Oranges	1,0%	Apples			
18%	UK vegetarian	5,30	6%	Oranges	1%	Wheat	1%	Onions			
18%	FI 6 yr	5,28	2%	Mandarins	1%	Onions	1%	Strawberries			
17%	FR infant	5,11	3%	Apples	2%	Carrots	2%	Oranges			
13%	UK adult	3,92	4%	Oranges	1%	Wheat	0,8%	Lettuces			
12%	PL general	3,62	3%	Apples	2%	Onions	0,9%	Cherries (sweet)			
11%	DK adult	3,44	2%	Apples	1,0%	Oranges	0,8%	Carrots			
10%	LT adult	3,10	3%	Apples	0,7%	Rye	0,7%	Wheat			
4%	IE child	1,26	0,8%	Wheat	0,6%	Oranges	0,5%	Apples			
Conclusion: The estimated long-term dietary intake (TMDI/NED/IED) was below the ADI. The long-term intake of residues of Pyraclostrobin is unlikely to present a public health concern.											

IESTI (% ARfD) according to EFSA PRIMo 3.1 (input: EFSA Journal 2019;17(10):5841)

Acute risk assessment /children					Acute risk assessment /adults / general population				
Details - acute risk assessment /children					Details - acute risk assessment/adults				
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.									
Show results for all crops									
Unprocessed commodities	Results for children				Results for adults				
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):				2
	IESTI				IESTI				
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	
	575%	Oranges	0 / 1,3	172	133%	Oranges	0 / 1,3	40	
	340%	Grapefruits	0 / 1,3	102	100%	Wine grapes	0 / 1,27	30	
	237%	Mandarins	0 / 1,2	71	77%	Grapefruits	0 / 1,3	23	
	149%	Lemons	0 / 1,3	45	74%	Red mustards	0 / 4,16	22	
	147%	Melons	0 / 0,29	44	72%	Mandarins	0 / 1,2	22	
	134%	Pears	0 / 0,29	40	64%	Blueberries	0 / 2,1	19	
118%	Watermelons	0 / 0,29	35	62%	Globe artichokes	0 / 1,44	19		
109%	Table grapes	0 / 0,45	33	53%	Cherries (sweet)	0 / 1,6	16		
104%	Apples	0 / 0,29	31	51%	Chinese cabbages/pe-tsai	0 / 0,61	15		
103%	Lettuces	0 / 0,81	31	51%	Chards/beet leaves	0 / 0,81	15		
90%	Cucumbers	0 / 0,41	27	51%	Table grapes	0 / 0,45	15		
89%	Kales	0 / 0,61	27	46%	Currants (red, black and	0 / 2,1	14		
87%	Limes	0 / 1,3	26	39%	Watermelons	0 / 0,29	12		
84%	Globe artichokes	0 / 1,44	25	39%	Kales	0 / 0,61	12		
76%	Celeries	0 / 0,61	23	39%	Lemons	0 / 1,3	12		
Expand/collapse list									
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)				11					

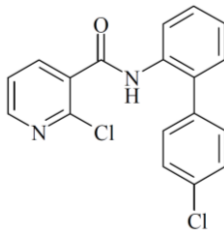
Processed commodities	Results for children				Results for adults				
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):				---
	IESTI				IESTI				
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	
	105%	Oranges / juice	0 / 0,6	32	69%	Celeries / boiled	0 / 0,61	21	
	92%	Florence fennels / boiled	0 / 0,61	28	53%	Pumpkins / boiled	0 / 0,29	16	
	90%	Currants (red, black and w	0 / 0,94	27	40%	Wine grapes / wine	0 / 1,27	12	
	86%	Pumpkins / boiled	0 / 0,29	26	40%	Currants (red, black and	0 / 0,94	12	
	84%	Chards/beet leaves / boiled	0 / 0,81	25	39%	Florence fennels / boiled	0 / 0,61	12	
	70%	Wine grapes / juice	0 / 0,48	21	34%	Chards/beet leaves /	0 / 0,81	10	
62%	Escaroles/broad-leaved ar	0 / 0,28	19	33%	Wine grapes / juice	0 / 0,48	10,0		
56%	Kales / boiled	0 / 0,61	17	30%	Oranges / juice	0 / 0,6	9,1		
55%	Leeks / boiled	0 / 0,29	17	29%	Elderberries / juice	0 / 0,94	8,6		
50%	Elderberries / juice	0 / 0,94	15	26%	Cauliflowers / boiled	0 / 0,19	7,9		
50%	Broccoli / boiled	0 / 0,19	15	21%	Courgettes / boiled	0 / 0,27	6,2		
44%	Cauliflowers / boiled	0 / 0,19	13	20%	Grapefruits / juice	0 / 0,54	5,9		
34%	Raspberries / juice	0 / 0,87	10	19%	Escaroles/broad-leaved	0 / 0,28	5,7		
32%	Courgettes / boiled	0 / 0,27	9,6	17%	Leeks / boiled	0 / 0,29	5,1		
30%	Parsnips / boiled	0 / 0,18	9,1	16%	Apples / juice	0 / 0,14	4,7		
Expand/collapse list									

Conclusion: there is not risk for consumers after accepted uses of Pyraclostrobin in the formulation Boscalid 26.7% + Pyraclostrobin 6.7% WG.

7.3 Boscalid

General data on Boscalid are summarized in the table below (last updated 2017/01/24)

Table 7.3-1: General information on Boscalid

Active substance (ISO Common Name)	Boscalid
IUPAC	2-Chloro-N-(4'-chlorobiphenyl-2-yl)nicotinamide
Chemical structure	
Molecular formula	C ₁₈ H ₁₂ Cl ₂ N ₂ O
Molar mass	343.21 g/mol
Chemical group	Pyridine-carboxamides
Mode of action (if available)	Succinate dehydrogenase inhibitors
Systemic	Yes
Company	BASF AG.
Rapporteur Member State (RMS)	Slovakia (original RMS was Germany)
Approval status	Approved Date of (01/08/2008) and reference to decision (COMMISSION DIRECTIVE 2008/44/EC – REGULATION (EU) No 540/2011) http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008L0044&from=EN http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0540&from=EN
Restriction	Only uses as fungicide may be authorised
Review Report	SANCO/3919 /2007-rev. 5 21 January 2008
Current MRL regulation	Reg. (EU) 2016/156 Reg. (EU) 2021/590
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Pending
EFSA Journal : conclusion on article 12	Yes
Current MRL applications on intended uses	EFSA-Q-2008-500 (Germany) Status: Reasoned opinion available (EFSA Journal 2014;12(7):3799)

* Notifier in the EU process to whom the a.s. belong(s)

** If yes: EFSA, YYYY – see list of references

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.3-2: Summary of stability data achieved at $\leq -18^{\circ}\text{C}$ (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Cabbage, peach and pea	High water content	24 months	H. Funk, Ch. Mackeroth, 2001 Report No. 2001/10115028 DAR, 2002 EFSA, 2014
Grape	High acid content	16 months	
Rape seed	High oil content	24 months	
Wheat grain, plant and straw Sugar beet roots	Dry commodities / high starch content	24 months	
Animal Products			
Ruminant	Liver	5 months	F. Grosshans, 2001 Report No. 2000/1017229 DAR, 2002 EFSA, 2014
Ruminant	Milk	5 months	
Ruminant	Muscle	5 months	
Ruminant	Fat	5 months	
Ruminant	Kidney	5 months	
Poultry	Egg	5 months	

Conclusion on stability of residues during storage

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

Storage stability of Boscalid was demonstrated for a period of 16 months at -18°C in commodities with high acid content (grape) and 24 months at -18°C in commodities with high water content (cabbage, peach, pea), high oil content (rape seed), dry commodities (wheat grain) and cereal straw. Degradation of residues during storage of the trial samples is therefore not expected. Storage stability of Boscalid and M510F01 in milk, muscle, fat, liver, kidney and egg for up to 5 months was demonstrated, when stored deep frozen.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

No data was submitted and required at EU level during the EU Review of Boscalid.

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Grape	U- ¹⁴ C-diphenyl and 3- ¹⁴ C-pyridine	foliar treatment, F	0.8	3	45	-	U. Rabe, H. Schlueter, 2001 Report No. 2000/1014860 DAR, 2002 EFSA, 2014
Leafy vegetables	Lettuce		foliar treatment, G	0.7	3	18	-	R. T. Hamm, 1999 Report No. 1999/11240 DAR, 2002 EFSA, 2014
Pulses and oilseeds	Bean		foliar treatment, G	0.5	3	0 ^(a) , 14 ^(b) , 53 ^(c)	-	P. Veit, 2001 Report No. 2000/1014861 DAR, 2002 EFSA, 2014

(a) whole plant

(b) forage, green beans, pods and seeds

I bean straw, bean dry pods and dry seeds

Summary of plant metabolism studies reported in the EU

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

Metabolism of Boscalid was investigated for foliar treatment on fruits and fruiting vegetables (grapes), on pulses and oilseeds (beans) and on leafy vegetables (lettuce), using U-14C-diphenyl and 3-14C-pyridine labelled Boscalid (DAR, 2002).

In grapes, the highest TRR was identified in leaves and stalks (63.4 and 19.6 mg eq/kg respectively), whereas only 2 mg eq/kg was found in grapes (fruits). Unchanged parent Boscalid was the main component of the TRR in all plant parts, ranging from 92.7 % in grape fruits to 96.4 % in stalks. In lettuce, Boscalid was almost not metabolised. The residues in beans (edible part) were much lower compared to the rest of the plant. When separating greens beans into pods and seeds, the major part of radioactivity was found in pods (0.9 mg eq/kg) rather than in seeds (0.2 mg eq/kg). Residue levels were also higher in dry pods (6.1 mg eq/kg) than in dry seeds (0.2 mg eq/kg). Parent Boscalid was identified as the major compound of the TRR in bean leaves and forage (>98 %), in green beans and green pods (97 %), in bean straw (≥94 %), in dry pods (80-95 %) and in dry seeds (72 %). The cleavage products chlorophenylaminobenzene and 2-chloronicotinic acid were also identified in green beans and seeds but only in low con-

centrations (< 0.01 mg eq/kg). The metabolism studies showed that the metabolic pathway is similar in all crops.

Conclusion on metabolism in primary crops

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

Consequently, the residue for enforcement and risk assessment in all plant commodities is defined as boscalid only. Validated analytical methods for enforcement of the proposed residue definition are available, except for hops, spices and herbal infusions. The conclusions reached by EFSA reflect the views of the RMS and are also in line with those of the JMPR (FAO, 2006).

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-4: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Re- marks	
EU data								
Leafy vegetables	Lettuce	U- ¹⁴ C-diphenyl and 3- ¹⁴ C-pyridine	Bare soil, G	2.1	30, 120, 270, 365	Mature crops	-	P. Veit, R. T. Hamm, 2001 Report No. 2000/1014862 DAR, 2002 EFSA, 2014
Root and tuber vegetables	Radish						-	
Cereals	Wheat						-	

* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Summary of plant metabolism studies reported in the EU

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

The metabolism of Boscalid in rotational crops – lettuce, radish, wheat – has been evaluated (DAR, 2002). One confined rotational crop study investigating the nature of residues following different plant-back intervals is available.

The highest TRR values were observed in radish leaves (0.34 mg eq/kg; 30 DAT, pyridine study) and in wheat straw (9.83 mg eq/kg, 30 DAT, diphenyl study and 4.01 mg eq/kg, 120 DAT, pyridine study). The highest TRR in lettuce amounted to 0.16 mg eq/kg (120 DAT, pyridine study), in radish root to 0.098 mg eq/kg (270 DAT, diphenyl study) and 0.066 mg eq/kg (365 DAT, pyridine study) and in wheat grain to 0.285 mg eq/kg (120 DAT, pyridine study) and 0.243 mg eq/kg (120 DAT, diphenyl study).

Except in wheat grain, parent boscalid was the major component of the TRR in all crops. Levels of the parent compound ranged from 50 % TRR in wheat straw (270 DAT, pyridine label) to 93 % TRR in wheat forage (270 DAT, pyridine label), and in lettuce leaves from 55.6 % TRR (270 DAT, diphenyl label) to 94.1 % TRR (365 DAT, diphenyl label). In wheat grain, the concentration of parent was low (between 1.9 % TRR at 270 DAT with the pyridine label and 16.8 % TRR at 30 DAT with the diphenyl label). Most of the radioactive residues in grain were not extractable (65 to 96 % TRR) and were detected in the starch fraction (36.2 to 48.4 % TRR, 0.06-0.12 mg eq/kg, pyridine label). The metabolite M510F61 (sugar conjugate of hydroxylated boscalid) was the only metabolite identified at levels exceeding 10 % TRR, in wheat forage (18.1 % TRR, diphenyl label, 270 DAT) and in radish leaves (21.2 % TRR for diphenyl label, 270 DAT and 11.2-15.5 % TRR, 365 DAT).

Conclusion on metabolism in rotational crops

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

The proposed metabolic pathway in succeeding crops involves hydroxylation and conjugation reactions. A part of the residue was also incorporated into and/or associated with natural products, such as starch, cellulose and lignin. The parent compound is therefore the main substance of concern in rotational crops and no metabolites of concern were identified in soil. Consequently, metabolic patterns in primary and rotational crops are found to be similar and a specific residue definition for rotational crops is not deemed necessary.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-5: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)* Diphenyl-label	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	Parent (99.3%)	J. Scharf, 1998 Report No. 1998/10878 DAR, 2002 EFSA, 2014
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Parent (100.2%)	
Sterilisation (20 minutes, 120°C, pH 6)	Parent (91.1%)	

* Total applied radioactivity after test

Conclusion on nature of residues in processed commodities

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

The effect of processing on the nature of Boscalid was investigated in the framework of the peer review. Studies were conducted simulating representative hydrolytic conditions for pasteurisation (20 minutes at 90°C, pH 4), boiling/brewing/baking (60 minutes at 100°C, pH 5) and sterilisation (20 minutes at 120°C, pH 6). From these studies, it was concluded that these processing conditions are not expected to have a significant impact on the composition of residues in matrices of plant origin (DAR, 2002). The relevant residue for enforcement and risk assessment in processed commodities is therefore expected to be the same as for primary crops.

7.3.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.3-6: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Fruits and fruiting vegetables (grapes) Leafy vegetables (lettuce) Pulses and oilseeds (bean)
Rotational crops covered	Root and tuber vegetables (Radish) Leafy vegetables (Lettuce) Cereals (Wheat)
Metabolism in rotational crops similar to metabolism	Yes

in primary crops?	
Processed commodities	a.s. is stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Boscalid (Regulation n°2016/156)
Plant residue definition for risk assessment	Boscalid (EFSA 2014)
Conversion factor from enforcement to RA	None (DAR, 2002; EFSA, 2014)

7.3.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

Table 7.3-7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	U- ¹⁴ C-diphenyl	2	1.46 – 1.73	5	Milk	Twice daily	E. Fabian, F. Grosshans, 2000 Report No. 2000/1017221 DAR, 2002 EFSA, 2014
						Urine and faeces	Daily	
						Tissues	After sacrifice	
Laying poultry	Hens	U- ¹⁴ C-diphenyl	10	0.80 – 1.14	10	Eggs	Daily	D.A. Nietzsche, W. Lam, 2000 Report No. 2000/5154 DAR, 2002 EFSA, 2014
						Excreta	Daily	
						Tissues	After sacrifice	

Summary of plant metabolism studies reported in the EU

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

The nature of Boscalid residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (DAR, 2002). Reported metabolism studies include one study in lactating goats and one study in laying hens, both using [U-¹⁴C-diphenyl] labelled Boscalid.

Lactating goats were dosed with 1.46 – 1.73 mg/kg bw per day of Boscalid. These dose levels represent at least 0.7 (including uptake of residues from previously treated soil) and 1 (resulting from the primary crop use only) time the maximum dietary burden of meat ruminant.

Boscalid is extensively excreted (89-93 % AR), with a relatively low transfer of residues to tissues (0.4-0.6 % AR in liver, 0.01-0.02 % AR for muscle, fat and kidney) and milk (0.06-0.15 % AR). The highest TRR was found in liver (2.59 mg eq/kg). Other TRR values were 0.27 mg eq/kg in kidney, 0.04 mg eq/kg in milk, 0.036 mg eq/kg in fat and 0.012 mg eq/kg in muscle.

Boscalid was the most abundant compound in fat (0.012 mg eq/kg; 34.6 % TRR) and represented a major part of the residue in muscle (0.002 mg eq/kg; 20.4 % TRR). It was also detected in liver (0.129 mg eq/kg;

5 % TRR), milk (0.001 mg eq/kg; 3.2 % TRR) and kidney (0.007 mg eq/kg; 2.5 % TRR). The metabolite M510F01 was the most abundant compound in muscle (0.003 mg eq/kg; 20.6 % TRR) and represented a major part of the residue in fat (0.009 mg eq/kg; 26.3 % TRR). It was also detected in liver (0.074 mg eq/kg; 2.9 % TRR), milk (0.006 mg eq/kg; 14.9 % TRR) and kidney (0.023 mg eq/kg; 8.6 % TRR). M510F02, the glucuronide conjugate of M510F01, is the most abundant compound in kidney (0.136 mg eq/kg; 50.3 % TRR) and was also detected in muscle (0.001 mg eq/kg; 11.9 % TRR) and milk (0.002 mg eq/kg; 6.4 % TRR).

Non-extractable residues accounted for 85 % TRR (2.2 mg eq/kg) in liver. Further extraction was conducted with either a mixture of acetic acid and acetone or with formic acid. Extraction released either M510F53 (43.6 % TRR; 1.13 mg eq/kg) or M510F52 (35.4 % TRR; 0.92 mg eq/kg), respectively for each solvent. Other compounds were detected but these compounds were demonstrated to be formed from extractable residues only (DAR, 2002). Therefore, only M510F53 and M510F52 are deemed to be representative of the bound residues in liver. It demonstrated that those residues mainly included components containing the unchanged diphenyl moiety, but also that a cleavage on the amine bound of Boscalid cannot be excluded. Consequently, as it is likely that bound residues are released during cooking of liver and that compounds comprising the pyridine moiety will have a different behaviour than the ones containing the diphenyl moiety, further investigation on the fate of the pyridine moiety in ruminant liver is still required.

Laying hens were dosed with 0.80 – 1.14 mg/kg bw per day of Boscalid. These dose levels represent at least 3.5 (including uptake of residues from previously treated soil) and 4.4 (resulting from the primary crop use only) times the maximum dietary burden of poultry.

Boscalid is extensively excreted (97.7 % AR), with a relatively low transfer of residues to tissues (0.04 % AR in liver, 0.003-0.004 % AR for muscle and fat) and eggs (0.12 % AR). The highest TRR was found in liver (0.17 mg eq/kg). Other TRR values were 0.058 mg eq/kg in eggs (with a maximum of 0.08 mg eq/kg), 0.025 mg eq/kg in fat and 0.003 mg eq/kg in muscle. A plateau is reached in eggs at day 6 (0.07 mg eq/kg).

Boscalid is the main compound in fat (0.023 mg eq/kg; 93.3 % TRR) and eggs (0.02 mg eq/kg; 35.5 % TRR). M510F01 was detected in eggs (0.015 mg eq/kg; 26.9 % TRR) and liver (0.009 mg eq/kg; 5.6 % TRR) and its conjugate M510F02 was detected in muscle (0.001 mg eq/kg; 11.9 % TRR) and eggs (0.01 mg eq/kg, 17.3 % TRR). Liver was only analysed using the microwave extraction used in the metabolism study on goats (only with formic acid). The results are similar to those observed in goats, M510F52 being the main compound (0.071 mg eq/kg; 42 % TRR). Therefore, further investigation on the fate of the pyridine moiety in poultry liver is also required.

The metabolism studies on both ruminant and poultry show that parent compound, its hydroxy metabolite M510F01 and its conjugate are the main components of the residue in animal tissues and products, except in liver where the bound residues (measured as M510F53 and M510F52) were found to be the main components of the residue but the actual identity of those bound residues was not elucidated. The general metabolic pathways in rodents and ruminants were found to be comparable; the findings in ruminants can therefore be extrapolated to pigs.

Conclusion on metabolism in livestock

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

During the Member States' consultation, it was agreed that conjugates of M510F01 are difficult to analyse routinely and that, based on the findings from metabolism study, Boscalid and M510F01 (free form) are deemed to be sufficient markers in liver and kidney. Nevertheless, as the available livestock feeding studies do not provide separate results for M510F01 and its conjugates, it is not possible to exclude conjugates of M510F01 from the enforcement residue definition in liver and kidney without additional data. Therefore, the relevant residue for enforcement is defined as Boscalid in muscle, fat, milk and eggs and as the sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates expressed as Boscalid in liver and kidney.

For risk assessment in liver, bound residues (measured as M510F53 and M510F52, but expressed as Boscalid) should also be included, but data is sufficient to derive a conversion factor for ruminant and pig livers only and supplementary data on the nature and magnitude of the bound residues in poultry liver

are required. Since log Po/w of Boscalid is close to 3 (DAR, 2002) and residues in fat were found to be higher than in muscle, EFSA concludes that the residue in commodities of animal origin is fat soluble.

Validated analytical methods are available in all animal commodities.

The definition for enforcement derived by the JMPR is the same in muscle, fat, milk and eggs, but differs for liver and kidney, for which the residue definition is limited to Boscalid only (FAO, 2006). However, EFSA considers that the residue definition derived by JMPR for liver and kidney is not adequate, based on the results of the available feeding studies.

7.3.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.3-8: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	2-3 days in milk
	6 days in eggs
Animal residue definition for monitoring	Boscalid in muscle, fat milk and eggs; Sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates expressed as Boscalid in liver and kidney; (Regulation n°2016/156)
Animal residue definition for risk assessment	Boscalid in muscle, fat milk and eggs; Sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates expressed as Boscalid in liver and kidney; Sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates and the bound residues (measured as M510F52 or M510F53) expressed as Boscalid in Liver (ruminant and pig); (EFSA 2014)
Conversion factor	None (DAR, 2002; EFSA, 2014)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes

7.3.3 Magnitude of residues in plants (KCA 6.3)

7.3.3.1 Summary of European data and new data supporting the intended uses

Table 7.3-9: Summary of new data supporting the intended uses of SHA 7273 A and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Sugarbeet → extrapolated to Beetroot, celery root, horseradish, Swedes, rutabagas, turnip, chicory roots	New trials	N-EU	GAP: 2 application 0.4 kg a.i./ha of boscalid, interval between application of 8 days, at BBCH 31-39, PHI= 14 days. Boscalid: 3x<LOD (0.002mg/kg) , 2x0.048, 0.074, 0.095, 0.135 3x< 0.01, 2 x 0.05, 0.07, 0.09, 0.14 mg/kg	N/A				
	Overall supporting data for cGAP	N-EU	Boscalid: 3x<LOD (0.002mg/kg) , 2x0.048, 0.074, 0.095, 0.135 3x< 0.01, 2 x 0.05, 0.07, 0.09, 0.14 mg/kg	0.05	0.135	0.2464 0.162	0.4	Yes
Tomato → extrapolated to aubergines/egg plants	New trials	N-EU	GAP: 2 application 0.4 kg a.i./ha of boscalid, interval between application of 8 days, at BBCH 20-87, PHI= 3 days (outdoor) Boscalid: 2x<LOD (0.002 mg/kg) , 0.052, 0.075, 0.076, 0.090, 0.252, 0.558 2x< 0.01, 0.05, 2x 0.08, 0.09, 0.25, 0.56 mg/kg	N/A				
	Overall supporting data for cGAP	N-EU	Boscalid: 2x<LOD (0.002 mg/kg) , 0.052, 0.075, 0.076, 0.090, 0.252, 0.558 2x< 0.01, 0.05, 2 x 0.08, 0.09, 0.25, 0.56 mg/kg	0.755	0.558	0.885 0.882	3	Yes

Onion → extrapolated to Onion “seven years old”, Shallot	New trials	N-EU	GAP: 2 application 0.4 kg a.i./ha of boscalid, interval between application of 8 days, at BBCH 43-49, PHI= 14 days Boscalid: 3x <LOD (0,002 mg/kg), 0.002 (<LOQ), 0.003 (<LOQ), 0.014, 2x 0.017 5x <0.01, 0.014, 2x 0.017 mg/kg	N/A				
	Overall supporting data for cGAP	N-EU	Boscalid: 3x <LOD (0,002 mg/kg), 0.002 (<LOQ), 0.003 (<LOQ), 0.014, 2x 0.017 5x <0.01, 0.01, 2x 0.02 mg/kg	0.0025	0.017	0.036 0.031	5	Yes
Carrot → extrapolated to radish, beet-root, celery root, horseradish, swedes, rutabagas, turnip, chicory roots, parsnip, parsley, salsifies	New trials	N-EU	GAP: 2 application 0.4 kg a.i./ha of boscalid, interval between application of 14 days, at BBCH 48, PHI= 14 days Boscalid: 2x <LOD (0,002 mg/kg), 0.046, 0.053, 0.065, 0.096, 0.135 2x <0.01, 0.05, 0.05, 0.07, 0.10, 0.14, 0.23	N/A				
	Overall supporting data for cGAP	N-EU	Boscalid: 2x <LOD (0,002 mg/kg), 0.046, 0.053, 0.065, 0.096, 0.135, 0.232 2x <0.01, 0.05, 0.05, 0.07, 0.10, 0.14, 0.23	0.059	0.232	0.384 0,378	2	Yes

7.3.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on sugar beet, tomato, carrot and onion are considered acceptable, for outdoor uses.

According to appendix D of EU guidelines, extrapolation to Beetroot, celery root, horseradish, Swedes, rutabagas, turnip, chicory roots is possible with 8 N-EU trials on Sugar beet, which is the case here.

According to appendix D of EU guidelines, extrapolation to aubergines/egg plants is possible with 8 N-EU trials on Tomato, which is the case here.

According to appendix D of EU guidelines, extrapolation to Onion “seven years old”, Shallot is possible with 8 N-EU trials on Onion, which is the case here.

According to appendix D of EU guidelines, extrapolation to radish, beetroot, celery root, horseradish, swedes, rutabagas, turnip, chicory roots, parsnip, parsley, salsifies is possible with 8 N-EU trials on Carrot, which is the case here.

To cover uses on cabbage, tomatoes in greenhouses, strawberries, cherries, raspberries and black currant, applicant refers to unprotected data on the reference product SIGNUM (Registration No. R - 33/2010, 19/04/2010).

According to appendix D of EU guidelines, extrapolation to red and white currant is possible with N-EU residue trials from reference product SIGNUM (Registration No. R - 33/2010, 19/04/2010).

The data submitted show that no exceedance of the MRL will occur.

The uses are considered acceptable.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

Table 7.3-10: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Boscalid				
Cabbage	1.10	Median residue	2.82	Highest residue
Kale	1.10	Median residue	4.10	Highest residue
Apple pomace	2.52	Median residue x PF (6) EFSA Journal 2014;12(7):3799	2.52	Median residue x PF (6)
Wheat, rye grain	0.12	Median residue	0.12	Median residue
Wheat straw	6.85	Median residue JMPR	15	Highest residue JMPR
Distiller's grain - dried	0.40	Median residue x PF (3.3)	0.56	Median residue x PF (3.3)
Wheat gluten, meal	0.22	Median residue x PF	0.31	Median residue x PF

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
		(1.8)		(1.8)
Wheat, milled by- ptds	0.84	Median residue x PF (7)	1.19	Median residue x PF (7)
Barley, oat grain	1.07	Median residue	1.07	Median residue
Brewer's grain dried	3.53	Median residue x PF (3.3)	3.53	Median residue x PF (3.3)
Barley, oat straw	15.0	Median residue	26.9	Highest residue
Rye straw	19.6	Median residue	39.5	Highest residue
Peas (dry)	0.13	Median residue	0.13	Median residue
Beans (dry)	0.13	Median residue	0.13	Median residue
Potatoes	0.05	Median residue	0.05	Highest residue
Potato, process waste	1.00	Median residue x PF (20)	2.00	Median residue x PF (20)
Potato, dried pulp	1.90	Median residue x PF (38)	3.80	Median residue x PF (38)
Turnips	0.09	Median residue	0.28	Highest residue
Rape seed meal	0.10	Median residue x PF (2)	0.10	Median residue x PF (2)
Canola, meal	0.10	Median residue x PF (2)	0.10	Median residue x PF (2)
Linseed, meal	0.10	Median residue x PF (2)	0.10	Median residue x PF (2)
Sunflower seed, meal	0.32	Median residue x PF (2)	0.32	Median residue x PF (2)
Soybean, seed	0.05	Median residue	0.05	Median residue
Soybean, meal	0.07	Median residue x PF (1.3)	0.07	Median residue x PF (1.3)
Soybean, hulls	0.65	Median residue x PF (13)	0.65	Median residue x PF (13)
Peanuts meal	0.10	Median residue x PF (2)	0.10	Median residue x PF (2)

Table 7.3-11: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: Boscalid					
Cattle (all diets)	0.309	0.469	Barley, straw	12.90	Yes
Cattle (dairy only)	0.309	0.469	Barley, straw	12.18	Yes
Sheep (all diets)	0.511	0.857	Barley, straw	21.47	Yes
Sheep (ewe only)	0.448	0.716	Barley, straw	21.47	Yes
Swine (all diets)	0.075	0.127	Kale leaves	5.51	Yes
Poultry (all diets)	0.155	0.214	Barley, straw	3.13	Yes
Poultry (layer only)	0.155	0.214	Barley, straw	3.13	Yes

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

No new data were submitted in the framework of this application.

Table 7.3-12: Overview of the values derived from livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) ^(a)	Highest residue (mg/kg) ^(b)	Calculated MRL (mg/kg)	CF for RA ^(c)
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enforce-ment		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (DAR, 2002; EFSA, 2014)												
Enforcement residue definition: <ul style="list-style-type: none">muscle, fat: boscalidkidney, liver: sum of boscalid and its hydroxy metabolite M510F01 (free and conjugated), expressed as boscalid Risk assessment residue definition: <ul style="list-style-type: none">muscle, fat: boscalidkidney: sum of boscalid and its hydroxy metabolite M510F01 (free and conjugated), expressed as boscalidliver: sum of boscalid, its hydroxy metabolite M510F01 (free and conjugated) and its bound residue (measured as M510F53 or M510F52), expressed as boscalid												
Pig meat	0.075	0.127	1.22	3	<0.025	<0.025	<0.025	<0.025	0.025	0.025	0.025*	1.00
			3.36	3	<0.025	<0.025	<0.025	<0.025				
Pig fat			1.22	9	0.15	0.22	0.15	0.22	0.025	0.05	0.05	1.00
			3.36	9	0.17	0.25	0.17	0.25				
Pig liver			1.22	3	0.09	0.11	-	-	0.005	0.05	0.05* (tentative)	1.50 ^(h)
			3.36	3	0.20	0.24	-	-				
Pig kidney			1.22	3	0.11	0.11	0.11	0.11	0.05	0.05	0.05*	1.00
			3.36	3	0.18	0.24	0.18	0.24				
Ruminant meat	0.309	0.469	1.22	3	<0.025	<0.025	<0.025	<0.025	0.025	0.025	0.025*	1.00
			3.36	3	<0.025	<0.025	<0.025	<0.025				
Ruminant fat					1.22	9	0.15	0.22	0.15	0.22	0.12	0.23

			3.36	9	0.17	0.25	0.17	0.25				
Ruminant liver			1.22	3	0.09	0.11	-	-	0.08	0.14	0.15 (tentative)	1.50 ^(h)
			3.36	3	0.20	0.24	-	-				
Ruminant kidney			1.22	3	0.11	0.11	0.11	0.11	0.09	0.14	0.15	1.00
			3.36	3	0.18	0.24	0.18	0.24				
Poultry meat	0.155	0.214	0.06	3	<0.025	<0.025	<0.025	<0.025	0.025	0.025	0.025*	1.00
			0.32	3	<0.025	<0.025	<0.025	<0.025				
			1.26	3	<0.025	<0.025	<0.025	<0.025				
Poultry fat			0.06	3	<0.025	<0.025	<0.025	<0.025	0.03	0.06	0.06	1.00
			0.32	3	0.06	0.10	0.06	0.10				
			1.26	3	0.14	0.17	0.14	0.17				
Poultry liver			0.06	3	<0.05	0.05	0.08	0.05	0.06	0.11	0.15 (tentative)	1.00
			0.32	3	0.14	0.18	0.14	0.18				
			1.26	3	0.41	0.47	0.41	0.47				
Milk	0.309	0.469	1.22	30	0.01 ^(d)	N/A	0.01 ^(d)	N/A	0.01	0.01	0.01*	1.00
			3.36	60	0.05 ^(e)	N/A	0.05 ^(e)	N/A				
Eggs	0.155	0.214	0.06	30	<0.01 ^(f)	N/A	<0.01 ^(f)	N/A	0.01	0.01	0.01*	1.00
			0.32	30	<0.01 ^(f)	N/A	<0.01 ^(f)	N/A				
			1.26	30	0.02 ^(g)	N/A	0.02 ^(g)	N/A				

N/A: Not applicable – only the mean values are considered for calculating MRLs in milk.

n.r.: Not reported

(*): Indicates that the MRL is set at the limit of analytical quantification.

(F): MRL is expressed as mg/kg of fat contained in the whole product.

(a): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).

(b): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).

(c): The median conversion factor for enforcement to risk assessment.

- (d): Mean residue level from day 1 until day 28 (3 cows, 10 sampling days).
- (e): Mean residue level from day 1 until day 28 (6 cows, 10 sampling days).
- (f): Mean residue level from day 1 until day 28 (3 hens, 10 sampling days).
- (g): Mean residue level from day 1 until day 28 (5 hens, 10 sampling days).
- (h): Tentative conversion factor derived from a separate ruminant feeding study.

Conclusion on feeding studies

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

7.3.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

7.3.5.1 Available data for all crops under consideration

No new data were submitted in the framework of this application.

Table 7.3-13: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Processing factors recommended (sufficiently supported by data)					
Apples, juice	6	0.08	1.00		PROFile
Apples, wet pomace	6	6.00	1.00	-	PROFile
Apples, dry pomace	4	18.35	1.00	-	PROFile
Apples, sauce	4	0.90	1.00		PROFile
Cherries, canned	4	0.52	1.00		EFSA, 2010
Cherries, jam	4	0.11	1.00		EFSA, 2010
Cherries, juice	4	0.39	1.00		EFSA, 2010
Plums, dried (prunes)	4	2.60	1.00		EFSA, 2010
Plums, jam	4	1.40	1.00		EFSA, 2010
Table grapes, dried (raisins)	4	2.40	1.00		DAR, 2002
Wine grapes, juice	4	0.40	1.00		DAR, 2002
Wine grapes, wet pomace	4	2.50	1.00		DAR, 2002
Strawberries, jam	4	0.44	1.00		PROFile
Strawberries, sauce	4	0.25	1.00		PROFile
Strawberries, canned	4	0.80	1.00		PROFile
Kiwi, peeled	4	0.06	1.00		PROFile
Carrots, canned	4	0.12	1.00		EFSA, 2010
Carrots, cooked	4	0.12	1.00		EFSA, 2010
Carrots, juice	4	0.12	1.00		EFSA, 2010
Tomatoes, unpeeled and canned	4	0.05	1.00		EFSA, 2010
Tomatoes, peeled and	4	0.05	1.00		EFSA, 2010

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
canned					
Tomatoes, paste	4	0.30	1.00		EFSA, 2010
Tomatoes, juice	4	0.17	1.00		EFSA, 2010
Gherkins, canned	4	0.56	1.00		EFSA, 2010
Head cabbage, cooked	4	0.07	1.00		EFSA, 2010
Head cabbage, canned	4	0.07	1.00		EFSA, 2010
Head cabbage, sauerkraut	4	0.17	1.00		EFSA, 2010
Head cabbage, sauerkraut juice	4	0.07	1.00		EFSA, 2010
Rape seed, refined oil	4	1.26	1.00		EFSA, 2010
Rape seed, meal/press cake	4	0.56	1.00		EFSA, 2010
Barley, brewing malt	4	0.48	1.00		PROFile
Barley, beer	4	0.02	1.00		PROFile
Barley, pot/pearl	4	0.34	1.00		PROFile
Wheat, whole-meal flour	4	1.21	1.00		PROFile
Wheat, whole-meal bread	4	0.81	1.00		PROFile
Wheat, white flour	4	0.34	1.00		PROFile
Wheat, bran	4	4.32	1.00		PROFile
Indicative processing factors (limited dataset)					
Peas cooked/canned	1	<0.36	1.00	-	DAR, 2002
Rape seed, crude oil	2	1.11	1.00		EFSA, 2010
Soya bean, refined oil	2	0.40	1.00		EFSA, 2010
Soya bean, meal	2	0.16	1.00		EFSA, 2010

* The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

** The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

7.3.5.2 Conclusion on processing studies

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

Studies investigating the magnitude of residues in processed commodities of grapes and peas were also reported in the framework of the peer review (DAR, 2002). After boscalid was included in Annex I to Directive 91/414/EEC, studies investigating the magnitude of residues in processed commodities of apples, cherries, plums, strawberries, kiwi, carrots, tomatoes, gherkins, head cabbage, rape seed, soya bean, barley and wheat were evaluated by EFSA or by the RMS.

It is acknowledged that for most of the studies the exact details on the processing conditions are not available (meaning that the available studies might not be representative for any type of processing). Nevertheless, data are considered acceptable to derive robust processing factors for all processed commodities, except for some processed commodities of soya bean, rape seed and peas, where the number of available studies is not adequate; a minimum of 3 processing studies is normally required.

Meanwhile, further processing studies are not required for the time being as they are not expected to affect the outcome of the risk assessment.

7.3.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Data dealing with magnitude of residues in succeeding crops are available and are summarized hereafter.

7.3.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.

Table 7.3-14: Summary of available studies in field rotational crops

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
EU data					
Lettuce followed by green beans	2.1 kg a.s./ha (2 x 0.3 kg a.s./ha followed by 3 x 0.5 kg a.s./ha)	Cereals	Spring wheat	365, 365, 365 (3-year crop rotation)	H. Funk, C. Mackenroth, 2001 Report No. 2001/10000989 DAR, 2002 EFSA, 2014
Carrots followed by cauliflower	1.7 kg a.s./ha (3 x 0.3 kg a.s./ha followed by 2 x 0.4 kg a.s./ha)	Cereals	Spring wheat	365, 365, 365 (3-year crop rotation)	
Winter rape	0.25 kg a.s./ha	Cereals	Winter wheat*	365	

* Sampling not performed under GLP

Conclusion on rotational crops studies

Occurrence of Boscalid residues in rotational crops was already investigated during the peer review.

7.3.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of Boscalid 26.7 + Pyraclostrobin 6.7% WG. Therefore, other special studies are not needed.

7.3.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

As ARfD was not deemed necessary, acute risk assessment is not relevant.

7.3.8.1 Input values for the consumer risk assessment

Table 7.3-15: Input values for the consumer risk assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment (EFSA, 2014)
Risk assessment residue definition: Boscalid		
Tree nuts except pistachios, pine nuts and coconuts	0.05	Median residue
Pistachios	0.27	Median residue
Apples, Pears, Quinces	0.42	Median residue
Apricots	0.77	Median residue (tentative)
Cherries	1.51	Median residue
Peaches	0.77	Median residue
Plums	0.29	Median residue
Table and wine grapes	1.42	Median residue
Strawberries	1.90	Median residue
Cane fruits	2.47	Median residue
Other small fruit and berries, except rose hips, mulberries and elderberries	3.60	Median residue
Rose hips, mulberries and elderberries	2.60	Median residue
Kiwi	0.08	Median residue × PF
Bananas	0.05	Median residue
Potatoes, Sweet potatoes, Yams, Arrowroot	0.05	Median residue
Beetroot	0.33	Median residue
Carrots, Horseradish	0.19	Median residue × PF
Celeriac	0.34	Median residue
Jerusalem artichokes	2.00	Median residue
Parsnips, Parsley root, Salsify, Turnips	0.09	Median residue
Radishes	0.28	Median residue
Garlic, Onions, Shallots	0.20	Median residue
Spring onions	2.30	EU MRL

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment (EFSA, 2014)
Tomatoes, Aubergines (egg plants)	0.35	Median residue
Peppers	0.51	Median residue
Cucurbits with edible peel	0.68	Median residue
Cucurbits with inedible peel	0.35	Median residue
Broccoli	1.55	Median residue
Cauliflower	1.55	Median residue
Brussels sprouts	0.30	Median residue
Head cabbage	1.10	Median residue
Chinese cabbage	1.10	Median residue
Kale	1.10	Median residue (tentative)
Kohlrabi	0.04	Median residue
Lettuce and similar	5.60	Median residue
Spinach	5.60	Median residue
Beet leaves (chard)	30.0	Median residue
Witloof	1.16	Median residue
Fresh herbs, except basil	5.60	Median residue
Basil	14.5	Median residue
Beans (fresh, with pods)	0.64	EU MRL
Beans (fresh, without pods)	0.11	Median residue
Peas (fresh, with pods)	0.64	Median residue
Peas (fresh, without pods)	0.11	Median residue
Lentils (fresh)	3.00	Median residue
Asparagus	0.05	Median residue (tentative)
Celery	2.18	Median residue
Fennel	2.18	Median residue
Globe artichokes	1.18	Median residue
Leek	2.30	Median residue
Beans (dry)	0.13	Median residue
Lentils (dry)	0.13	Median residue
Peas (dry)	0.13	Median residue
Linseed	0.05	Median residue
Peanuts	0.05	Median residue
Poppy seed	0.05	Median residue
Sunflower seed	0.16	Median residue

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment (EFSA, 2014)
Rape seed	0.15	Median residue
Soya bean	0.05	Median residue
Mustard seed	0.05	Median residue
Borage	0.05	Median residue
Gold of pleasure	0.05	Median residue
Barley grain, Oats grain	1.07	Median residue
Wheat grain, Rye grain	0.12	Median residue
Herbal infusions (dried, roots)	0.95	Median residue (tentative)
Hops (dried)	24.5	Median residue (tentative)

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.3-16: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo 3.1	398% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo 3.1	84 % (based on NL toddler)
IENTI (% ARfD) according to EFSA PRIMo*	Not relevant
NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

* include raw and processed commodities if both values are required for PRIMo

** if national model is available

The ~~proposed~~ accepted uses of Boscalid in the formulation Boscalid 26.7% + Pyraclostrobin 6.7% WG do not represent unacceptable chronic risks for the consumer.

7.4 Combined exposure and risk assessment

From a scientific point of view, it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised “scientific methods accepted by the Authority to assess such effects are available.”

Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

Not relevant. The product is a mixture of two active substances, but for only one of them has an acute reference dose been allocated .

7.5 References

Germany, 2001. Draft Assessment Report of Pyraclostrobin. 01 August 2001

European Commission, 2004. Review report for the active substance Pyraclostrobin. SANCO/1420/2001-Final, 8 September 2004

EFSA, 2011. Review of the existing Maximum Residue Levels (MRLs) for Pyraclostrobin according to Article 12 of Regulation 396/2005. EFSA Journal 2011;9(8):2344

Germany, 2002. Draft Assessment Report of Boscalid. 8 November 2002.

European Commission, 2008. Review report for the active substance Boscalid. SANCO/3919/2007-rev. 5, 21 January 2008

EFSA, 2014. Review of the existing Maximum Residue Levels (MRLs) for Boscalid according to Article 12 of Regulation 396/2005. EFSA Journal 2014;12(7):3799

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 8.3.1.1	Serena Kull	2019	Residue study (Decline) in sugarbeet following two sequential applications with Pyraclostrobin 6.7% + Boscalid 26.7% WG in Germany 2018 – field part. Study No. CT18-1-19. CropTrials GmbH Unpublished GLP	N	Sharda
KCP 8.3.1.2	Zofia Hordyjewicz-Baran	2019	Pyraclostrobin and boscalid residues in sugarbeet after application of pyraclostrobin 6.7% + boscalid 26.7% WG – analytical part. Study No. 45/2019. Institute of Heavy Organic Synthesis “Blachownia” Unpublished GLP	N	Sharda
KCP 8.3.1.3	K. Łukaszewski	2019	Magnitude of the residue of Pyraclostrobin and Boscalid in sugarbeet (Raw Agricultural Commodity) after two applications of Pyraclostrobin 6.7% and Boscalid 26.7% WG – two harvest trials in Poland – 2018 – field part Report No. 18SGS17 SGS Polska Unpublished GLP	N	Sharda
KCP	Zofia Hordyjewicz-	2019	Magnitude of the residue of pyraclostrobin + boscalid in sugar beet (Raw Agricultural Commodity –	N	Sharda

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
8.3.1.4	Baran		RAC) grown in open field conditions after two applications of pyraclostrobin 6.7% + boscalid 26.7% - two harvest trials in Poland, 2018. Study No. 18/2019 Institute of Heavy Organic Synthesis “Blachownia” Unpublished GLP		
KCP 8.3.1.5	Rafal Figurski	2019	Magnitude of the residue of pyraclostrobin + boscalid in sugar beet (Raw Agricultural Commodity – RAC) grown in open field conditions after two applications of formulated product pyraclostrobin 6.7% + boscalid 26.7% - two harvest trials in North Europe – Poland, 2018. Study No. PB-2018-10 Fertico Sp. z o.o. Unpublished GLP	N	Sharda
KCP 8.3.1.6	Zofia Hordyjewicz-Baran	2019	Pyraclostrobin and boscalid residues in sugar beets after application of pyraclostrobin 6.7 + boscalid 26.7% WG. Study No. 4/2019 Institute of Heavy Organic Synthesis “Blachownia” Unpublished GLP	N	Sharda
KCP 8.3.1.7-01	Martin Sumerfield	2020	Decline residue of pyraclo 6.7 + boscalid 26.7 % WG in sugar beet. Raw Agricultural commodity in the United Kingdom, 2018. Study No. ACE18-054 Unpublished GLP	N	Sharda
KCP 8.3.1.7	Zofia Hordyjewicz-Baran	2019	Decline residue of pyraclo 6.7 + boscalid 26.7 % WG in sugar beet. Raw Agricultural commodity in the United Kingdom, 2018. Study No. 50/2019 Institute of Heavy Organic Synthesis “Blachownia” Unpublished GLP	N	Sharda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 8.3.2.1	Rafal Figurski	2019	Magnitude of the residue of pyraclostrobin + boscalid in tomato (raw agricultural commodity – RAC) grown in open field conditions after two applications of formulated product pyraclostrobin 6.7% + boscalid 26.7% WG – two harvest trials in Northern Europe – Poland, 2018. Study No. PB-2018-11 Fertico Sp. z o.o. Unpublished GLP	N	Sharda
KCP 8.3.2.2	Zofia Hordyjewicz-Baran	2019	Pyraclostrobin and boscalid residues in tomatoes after application of Pyraclostrobin 6.7 + boscalid 26.7 % WG – analytical part. Study No. 5/2019 Institute of Heavy Organic Synthesis “Blachownia” Unpublished GLP	N	Sharda
KCP 8.3.2.3	K. Łukaszewski	2019	Magnitude of the residue of pyraclostrobin + boscalid in tomato (Raw Agricultural Commodity) after two applications of Pyraclostrobin 6.7% + Boscalid 26.7% WG – two harvest trials and one decline curve trial in Poland – 2018 – Field part Study No. 18SGS18 SGS Polska Unpublished GLP	N	Sharda
KCP 8.3.2.4	Zofia Hordyjewicz-Baran	2019	Magnitude of the residue of pyraclostrobin + boscalid in tomato (raw agricultural commodity) after two applications of pyraclostrobin 6.7% + boscalid 26.7% WG – two harvest trials and one decline curve trial in Poland – 2018. Study No. 22/2019 Institute of Heavy Organic Synthesis “Blachownia” Unpublished GLP	N	Sharda
KCP 8.3.2.5	P. Iszak	2020	Determination of the residues of Boscalid + Pyraclostrobin in/on tomato (outdooe) after two applications of Boscalid 26.7% + Pyraclostrobin 6.7% WG in Northern Europe – Hungary in 2019 – Field part Study No. 034SRHU19R27	N	Sharda

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
			Suntech Research Hungary Unpublished GLP		
KCP 8.3.2.6	M. Zarębska	2020	Determination of the residue of boscalid + pyraclostrobin in/on tomato (outdoor) after two foliar applications of Boscalid 26.7% + Pyraclostrobin 6.7% WG in northern Europe – Hungary in 2019 – analytical part Study No. 173/2019 Unpublished GLP	N	Sharda
KCP 8.3.3.1	Rafal Figurski	2019	Magnitude of the residue of pyraclostrobin + boscalid in onion (raw agricultural commodity – RAC) grown in open field conditions after two applications of formulated product pyraclostrobin 6.7 % + boscalid 26.7% WG – two harvest trials in Northern Europe – Poland, 2018. Study No. PB-2018-12. Fertico Sp. z o.o. Unpublished GLP	N	Sharda
KCP 8.3.3.2	Zofia Hordyjewicz-Baran	2019	Pyraclostrobin and boscalid residues in onion after application of pyraclostrobin 6.7 + boscalid 26.7 % WG – analytical part. Study No. 3/2019 Institute of Heavy Organic Synthesis “Blachownia” Unpublished GLP	N	Sharda
KCP 8.3.3.3	K. Łukaszewski	2019	Magnitude of the residue of pyraclostrobin + boscalid in onion (Raw Agricultural Commodity) after two applications of Pyraclostrobin 6.7% + Boscalid 26.7% WG – two harvest trials and two decline curve trials in Poland – 2018 – field part Study No. 18SGS19 SGS Polska Unpublished GLP	N	Sharda
KCP	Zofia Hordyjewicz-	2019	Magnitude of the residue of pyraclostrobin + boscalid in onion (raw agricultural commodity) after two	N	Sharda

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
8.3.3.4	Baran		applications of pyraclostrobin 6.7% + boscalid 26.7% WG – two harvest trials and one decline curve trial in Poland -2018 – analytical phase. Study No. 20/2019 Institute of Heavy Organic Synthesis “Blachownia” Unpublished GLP		
KCP 8.3.3.5	P. Iszak	2020	Determination of the residues of boscalid + pyraclostrobin in/on onion after two applications of Boscalid 26.7% + Pyraclostrobin 6.7% WG in Northern Europe – Hungary in 2019 – field part Study No. 034SRHU19R28 Syntech Research Hungary Unpublished GLP	N	Sharda
KCP 8.3.3.6	M. Zarębska	2020	Determination of the residue of boscalid + pyraclostrobin in/on onion after two foliar applications of Boscalid 26.7% + Pyraclostrobin 6.7% WG in northern Europe – Hungary in 2019 – analytical part Study No. 175/2019 Institute of Heavy Organic Synthesis “Blachownia” Unpublished GLP	N	Sharda
KCP 8.3.4.1	K. Łukaszewski	2019	Magnitude of the residue of Pyraclostrobin + Boscalid in carrot (Raw Agricultural Commodity) after two applications of Pyraclostrobin 6.7% + Boscalid 26.7% WG – two harvest trials and two decline curve trials in Poland – 2018 – Field part Study No. 18SGS20 SGS Polska Unpublished GLP	N	Sharda
KCP 8.3.4.2	Zofia Hordyjewicz-Baran	2019	Magnitude of the residue of pyraclostrobin and boscalid in carrot (raw agricultural commodity) after two applications of pyraclostrobin 6.7% and boscalid 26.7% WG – two harvest trials and two decline curve trials in Poland – 2018. – analytical phase. Study No. 21/2019 Institute of Heavy Organic Synthesis “Blachownia”	N	Sharda

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
			Unpublished GLP		
KCP 8.3.4.3	Rafal Figurski	2019	Magnitude of the residue of pyraclostrobin + boscalid in carrot (raw agricultural commodity – RAC) grown in open field conditions after two applications of formulated product pyraclostrobin 6.7 % + boscalid 26.7% WG – two harvest trials in Northern Europe – Poland, 2018. Study No. PB-2018-13 Fertico Sp. z o.o. Unpublished GLP	N	Sharda
KCP 8.3.4.4	Zofia Hordyjewicz-Baran	2019	Pyraclostrobin and boscalid residues in carrots after application of pyraclostrobin 6.7 + boscalid 26.7 % WG – analytical part. Study No. 6/2019 Institute of Heavy Organic Synthesis “Blachownia” Unpublished GLP	N	Sharda
KCP 8.3.4.5	Zofia Hordyjewicz-Baran	2019	Decline residue of pyraclo 6.7 + boscalid 26.7% WG. Raw agricultural commodity in the United Kingdom, 2018. Study No. 54/2019. Unpublished GLP	N	Sharda
KCP 8.3.4.6	Á. Horváth	2020	Determination of the residues of Boscalid + Pyraclostrobin in/on carrot after two applications of Boscalid 26.7% + Pyraclostrobin 6.7% WG in northern Europe – Hungary in 2019 – Field Part Study No. 034SRHU19R29 Syntech Research Hungary Unpublished GLP	N	Sharda
KCP 8.3.4.7	M. Zarębska	2020	Determination of the residue of boscalid + pyraclostrobin in/on carrot after two foliar applications of Boscalid 26.7% + Pyraclostrobin 6.7% WG in northern Europe – Hungary in 2019 – analytical part Study No. 174/2019 Insitite of Heavy Organic Synthesis “Blachownia”	N	Sharda

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
			Unpublished GLP		

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

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

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Pyraclostrobin

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

No new data were submitted in the framework of this application.

A 2.1.1.1.2 Storage stability of residues in animal products

No new data were submitted in the framework of this application. Nature of residues in plants, livestock and processed commodities

A 2.1.1.2 Nature of residue in plants

A 2.1.1.2.1 Nature of residue in primary crops

No new data were submitted in the framework of this application.

A 2.1.1.2.2 Nature of residue in rotational crops

No new data were submitted in the framework of this application.

A 2.1.1.2.3 Nature of residues in processed commodities

No new data were submitted in the framework of this application

A 2.1.1.3 Nature of residues in livestock

No new data were submitted in the framework of this application

A 2.1.1.4 Sugarbeet

Table A 1: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (1)	2	0.1 Kg pyraclostrobin/ha + 0.4 kg Boscalid/ha	8 days	BBCH 39	14

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

A 2.1.1.4.1 Study 1

zRMS Comment: Study is accepted

Procedural recoveries at the fortification levels 0.01 mg/kg for both ion mass transition of pyraclostrobin and boscalid were all in range of 70-110% and thus comply with the standard acceptance criteria of the guidance documents: SANCO/825/00 rev. 8.1, SANCO/3029/99 rev. 4 and SANTE/2020/12830, Rev.1
All precision values were <20%

Reference: KCP 8.3.1.1

Report Residue study (Decline) in sugarbeet following two sequential applications with Pyraclostrobin 6.7% + Boscalid 26.7% WG in Germany 2018 – field part. Serena Kull, 2019. Study No. CT18-1-19.

Guideline(s): Yes

- OECD Guidelines for the testing of chemicals, No 509: Crop Field Trials (2009)
- EEC document 7029/V1/95 rev. 5, 1997, Appendix B working document 1607/V1/97, rev. 2, 1999: General recommendation for the design, preparation and realisation of residue trials
- The Principles of Good Laboratory Practice, ChemG 25.07.1994, §19, Annex 1 (BGBL 21, I, 2001, p. 843-855)
- OECD-Principles of Good Laboratory Practice, No. 4: Quality Assurance and GLP (as revised in 1999), ENV/JM/MONO (1999) 20, Paris 2002
- The Application of the GLP Principles to Field Studies, OECD Consensus Document, 6, revised, ENV/JM/MONO (1999) 22, Paris 2002
- The Application of the OECD Principles of GLP to the Organisation and Management of Multi-site Studies, OECD Consensus Document, 13, ENV/JM/MONO (2002) 9
- Rückstandsversuche, Teil 1 Prüfungen an Pflanzen, A: Allgemeiner Teil, B: Spezieller Teil, IVA-Guideline, Industrieverband Agrar e. V. 1992

Deviations: No

GLP: Yes

Acceptability: Yes

The trial CT18-1-19DE1 was carried out on open field on the crop sugar beet. One untreated control plot (U = plot 1) and one treated plot (T = plot 2) were laid out and labelled. The plot size (30 m²) was chosen large enough to provide representative specimens for the sampling date. Drift of spray solution during the applications was avoided by choosing an adequate distance between the untreated and treated plot (10 m). A buffer zone of 5 m was set up around the plots of the trial.

Two applications of the test item were performed in August 2018. The first application was performed 22 days and the second application 14 days before the time of commercial harvest. The applications were conducted with a knapsack sprayer with boom, running by compressed air. The spraying equipment was cleaned with water before and after use. The output of the nozzles of the spraying boom was checked for uniformity before start of each application. The speed of walk was adapted to the output of the spraying boom and test runs were performed before start of each application. The application rate of the test item Pyraclostrobin 6.7% + Boscalid 26.7% WG was 1.5 kg/ha at both application timings. The water volume was 400 L/ha.

At the day of the second application and 3, 7 and 14 days after the second application, roots were collected over the central area of the plots. 12 roots were collected per specimen and quartered with a knife. Two opposite quarters of each of the 12 roots were taken for one specimen.

Reference: KCP 8.3.1.2

Report Pyraclostrobin and boscalid residues in sugarbeet after application of pyraclostrobin 6.7% + boscalid 26.7% WG – analytical part. Zofia Hordyjewicz-Baran, 2019. Study No. 45/2019.

Guideline(s): Yes

- Council Regulation (EC) No 440/2008, ICSO Procedure BA-AB/SPO-1 and research method No. BA-AB/MS/MB-5 and BA-AB/MS/MB-6
- Directive 2004/10/EC of the European Parliament and of the Council of 11th February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of the applications for test on chemical substances.
- The Minister of Health Regulations of 22nd May 2013 on Good Laboratory Practice and performance of studies in compliance with the principles of GLP (Dz. U. Z 2013 poz. 665)
- Act of 25th February 2011 on the chemical substances and their mixtures (The Republic of Poland Journal of Law of 2011, No. 63, item 322 with subsequent amendments)
- OECD Environmental Health and Safety Publications, Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 1 OECD Principles of Good Laboratory Practice, 1997.
- SANCO/825/00 rev. 8.1
- SANCO/3029/99 rev. 4

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods:

During the growing season of 2018, a total of one trial was conducted in sugarbeet in Northern Europe (Germany) to determine the magnitude of decline residues of Pyraclostrobin and Boscalid in or on raw agricultural commodities (RAC).

The determination of Pyraclostrobin and Boscalid residues has been performed by liquid chromatography, and consists in an separation on a reversed-phase column and detection by tandem mass spectrometry (MS/MS) by electrospray (ESI) operating with optimized conditions.

The characteristics of the analytical method was as follows:

Preparation of stock solution of Pyraclostrobin for calibration

Reference Item	Purity of reference item* (%)	Weighed amount of reference item (mg)	Amount of analyte corrected for purity (mg)	Final volume (mL)	Solvent used for dilution	Equivalent conc. (mg/mL)	Reference of standard solution produced
Pyraclostrobin	99.9	20.04	20	10	Acetonitrile	2	1S1

Preparation of stock solution of Boscalid for calibration

Reference Item	Purity of reference item* (%)	Weighed amount of reference item (mg)	Amount of analyte corrected for purity (mg)	Final volume (mL)	Solvent used for dilution	Equivalent conc. (mg/mL)	Reference of standard solution produced
Boscalid	99.5	20.21	20	10	Acetonitrile	2	1S2

Preparation of working solutions of Pyraclostrobin

Reference of standard solution used	Concentration Pyraclostrobin (µg/mL)	Volume taken (mL)	Final volume (mL)	Equivalent concentration (µg/mL)	Reference of standard solution produced (mixture)
IS1	2000	0.5	50	20	ISW1
ISW1	20	2	10	4	ISW2
ISW1	20	1	10	2	ISW3
ISW1	20	0.5	10	1	ISW4
ISW1	20	0.2	10	0.4	ISW5
ISW1	20	0.1	10	0.2	ISW6
ISW3	2	0.5	10	0.1	ISW7
ISW3	2	0.2	10	0.04	ISW8
ISW3	2	0.1	10	0.02	ISW9

Preparation of working solutions of Boscalid

Reference of standard solution used	Concentration Boscalid (µg/mL)	Volume taken (mL)	Final volume (mL)	Equivalent concentration (µg/mL)	Reference of standard solution produced (mixture)
IS2	2000	0.5	50	20	ISW1
ISW1	20	2	10	4	ISW2
ISW1	20	1	10	2	ISW3
ISW1	20	0.5	10	1	ISW4
ISW1	20	0.2	10	0.4	ISW5
ISW1	20	0.1	10	0.2	ISW6
ISW3	2	0.5	10	0.1	ISW7
ISW3	2	0.2	10	0.04	ISW8
ISW3	2	0.1	10	0.02	ISW9

Sample preparation

The detailed stepwise procedure was as follows:

- Preparation of Sample Matrix

A. Portion of dry ice was added to a homogenizer apparatus (Laboratory mill). Subsequent appropriate amount of sample was added to the apparatus in small portions. Sample was blended after each addition until a homogeneous mixture was obtained.

B. Contents of the apparatus were poured into polyethylene bags and stored in a freezer until the last traces of dry ice have sublimed.

- Sample Extraction

A. 10.00 g ± 0.1 g of homogenized matrix was weighed into a 50 mL PP centrifuge tube. Sample weight was recorded.

B. If necessary fortification of the concurrent recovery sample(s) by aliquoting the fortification standard of Pyraclostrobin and Boscalid mixture onto the matrix was carried out at this step. Fortification details are given below:

Fortification level	Standard dilution	Concentration of individual standard (µg/mL)	Volume used (µL)
LOQ (0.01 mg/kg)	ISW3	2	50

C. For extraction using an automatic pipette 10 mL of acetonitrile was added.

D. The PP centrifuge tube was closed tightly and shake for 1 min automatically.

- Liquid-Liquid Partition

A. Buffer-salt mixture (4 g ± 0.2 g of magnesium sulfate anhydrous, 1 g ± 0.05 g of sodium chloride, 0.5 g ± 0.03 g NaCitrate dibasic sesquihydrate, 1 g ± 0.05 g NaCitrate tribasic dehydrate) was added and the centrifuge tube was closed and shaken by vortex for 1 min.

B. The extract was centrifuged at >3000 g for 5 min.

- Sample Purification

A. Using an automatic pipette 6 ml of sample extract supernatant was trans-

ferred to Dispersive SPE 12 ml centrifuge tubes containing 150 mg Supelclean PSA and 900 mg MgSO₄. The tube was shaken automatically for 30 sec.

- Sample Dilution

A. An aliquot of 0.5 mL of purified sample extract was transferred to new Eppendorf safe-lock tube and subsequently diluted with 0.4 mL of Water, 0.05 mL acetonitrile (+1% Vol. formic acid) and 0.05 mL of acetonitrile.

B. Content was vortex gently and filtered through the 0.22 µm Teflon filter attached to a syringe direct into amber HPLC vial.

C. Vial was labelled so that it may be identified.

- Final Determination

A. Final determination was performed using LC-MS/MS.

Results:

No residue above the LOD were detected in the control samples. The analytical results in mg per kg are summarized in Table A.2:

Table A 2: Summary of the study

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treat- ment			Dates of treatment or no. of treatments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pyraclostrobin	Boscalid		
(a)	(a)	(b)				(c)					(d)	(e)
CT18-1-19DE1/ GERMANY / NEU / 2018	Sugarbeet/Lisianna	1) 11.04.2018 2) N/A 3) 27.09.2018	A1: 98.7 A2: 102.3 393.4 407.6	400 400		13.08.2018 21.08.2018	BBCH 39 BBCH 39	Roots	<LOD (0.002) <LOD (0.002) <LOD (0.002) <LOD (0.002)	<LOD (0.002) <LOD (0.002) <LOD (0.002) <LOD (0.002)	0 3 7 14	Test site code: LOQ Pyraclostrobin = 0.010 mg/kg (sugarbeets) LOD Pyraclostrobin = 0.002 mg/kg (sugarbeets) LOQ Boscalid = 0.010 mg/kg (sugarbeets) LOD Boscalid = 0.002 mg/kg (sugarbeets) Time between harvest and extraction: 6 months

A1 – pyraclostrobin

A2 - boscalid

- (a) According to CODEX Classification / Guide
- (b) Only if relevant
- (c) Year must be indicated
- (d) Days after last application (Label pre-harvest interval, PHI, underline)
- (e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.1.4.2 Study 2

zRMS Comment: Study is accepted

Clarifications regarding the independence of the following trials:

Łukaszewski K., Report No. 18SGS17 (Ożarów Mazowiecki) and Rafal Figurski, 2019. Study No. PB-2018-10 (Ożarów Mazowiecki)

Trials can be considered as independent as:

-were done in two different places - the distance is about 20 km.

18SGS017 PL01 – post code 05-830

D-2018-10-F01 – post code 05-850

- different kind of soil

18SGS017 PL01 – silt loam (1.5% of organic matter)

D-2018-10-F01 – sandy loam (2.21 % of organic matter)

Procedural recoveries at the fortification levels 0.01 mg/kg for both ion mass transition of pyraclostrobin and boscalid were all in range of 70-110% and thus comply with the standard acceptance criteria of the guidance documents: SANCO/825/00 rev. 8.1, SANCO/3029/99 rev. 4 and SANTE/2020/12830, Rev.1

All precision values were <20%

Reference: KCP 8.3.1.3

Report Magnitude of the residue of pyraclostrobin + boscalid in sugar beet (Raw Agricultural Commodity – RAC) grown in open field conditions after two applications of pyraclostrobin 6.7% + boscalid 26.7% - two harvest trials in Poland - 2018. K. Łukaszewski, Report No. 18SGS17

Guideline(s): Yes

- Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

- Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue trials, July 22, 1997

- OECD Environmental Health and Safety Publications, Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 1 OECD Principles of Good Laboratory Practice, 1997.

- SANCO/825/00 rev. 8.1

- SANCO/3029/99 rev. 4

Deviations: No

GLP: Yes

Acceptability: Yes

The objective of the study was to generate specimens of sugarbeet, Raw Agricultural Commodity (RAC) following two application of Pyraclostrobin 6.7% + Boscalid 26.7% WG and quantify residues of pyraclostrobin and boscalid under cultural practice typical for sugarbeet production.

Two field trials were established on sugarbeet in two different locations.

The sites were representative for sugarbeet production, grown in a typical way in the test countries. Each trial consisted of one untreated plot U and on treated plot T. Plots were of sufficient size to generate the desired specimen quantities. In each trial, the untreated plot was separated by a buffer zone of at least 10

m from the treated plot.

The application equipment consisted of boom sprayer. The foliar applications closely simulated commercial-type treatments.

Pyraclostrobin 6.7% + Boscalid 26.7% WG was only mixed with water. No adjuvant was added to the spray mixture. The target dose rate of the test item for the study was 1.5 kg/ha of formulated product per application, equivalent to 100.5 g as/kg Pyraclostrobin and 400.5 g as/kg boscalid. Applications were made at a target volume of 200-600 litres per hectare of mixture according to Good Agricultural Practice.

Reference: KCP 8.3.1.4

Report Magnitude of the residue of pyraclostrobin + boscalid in sugar beet (Raw Agricultural Commodity – RAC) grown in open field conditions after two applications of pyraclostrobin 6.7% + boscalid 26.7% - two harvest trials in Poland, 2018. Zofia Hordyjewicz-Baran, 2019. Study No. 18/2019

Guideline(s): Yes

- Council Regulation (EC) No 440/2008, ICSO Procedure BA-AB/SPO-1 and research method No. BA-AB/MS/MB-5 and BA-AB/MS/MB-6
- Directive 2004/10/EC of the European Parliament and of the Council of 11th February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of the applications for test on chemical substances.
- The Minister of Health Regulations of 22nd May 2013 on Good Laboratory Practice and performance of studies in compliance with the principles of GLP (Dz. U. Z 2013 poz. 665)
- Act of 25th February 2011 on the chemical substances and their mixtures (The Republic of Poland Journal of Law of 2011, No. 63, item 322 with subsequent amendments)
- OECD Environmental Health and Safety Publications, Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 1 OECD Principles of Good Laboratory Practice, 1997.
- SANCO/825/00 rev. 8.1
- SANCO/3029/99 rev. 4

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods:

During the growing season of 2018, a total of two trials were conducted in sugarbeet in ~~Southern~~ Northern Europe (Poland) to determine the magnitude of residues of Pyraclostrobin and Boscalid in or on raw agricultural commodities (RAC).

The determination of Pyraclostrobin and Boscalid residues has been performed by liquid chromatography, and consists in an separation on a reversed-phase column and detection by tandem mass spectrometry (MS/MS) by electrospray (ESI) operating with optimized conditions.

The characteristics of the analytical method was as follows:

Preparation of stock solution of Pyraclostrobin for calibration

Reference Item	Purity of reference item* (%)	Weighed amount of reference item (mg)	Amount of analyte corrected for purity (mg)	Final volume (mL)	Solvent used for dilution	Equivalent conc. (mg/mL)	Reference of standard solution produced
Pyraclostrobin	99.9	20.04	20	10	Acetonitrile	2	1S1

Preparation of stock solution of Boscalid for calibration

Reference Item	Purity of reference item* (%)	Weighed amount of reference item (mg)	Amount of analyte corrected for purity (mg)	Final volume (mL)	Solvent used for dilution	Equivalent conc. (mg/mL)	Reference of standard solution produced
Boscalid	99.5	20.21	20	10	Acetonitrile	2	1S2

Preparation of working solutions of Pyraclostrobin

Reference of standard solution used	Concentration Pyraclostrobin (µg/mL)	Volume taken (mL)	Final volume (mL)	Equivalent concentration (µg/mL)	Reference of standard solution produced (mixture)
1S1	2000	0.5	50	20	1SW1
1SW1	20	2	10	4	1SW2
1SW1	20	1	10	2	1SW3
1SW1	20	0.5	10	1	1SW4
1SW1	20	0.2	10	0.4	1SW5
1SW1	20	0.1	10	0.2	1SW6
1SW3	2	0.5	10	0.1	1SW7
1SW3	2	0.2	10	0.04	1SW8
1SW3	2	0.1	10	0.02	1SW9

Preparation of working solutions of Boscalid

Reference of standard solution used	Concentration Boscalid (µg/mL)	Volume taken (mL)	Final volume (mL)	Equivalent concentration (µg/mL)	Reference of standard solution produced (mixture)
1S2	2000	0.5	50	20	1SW1
1SW1	20	2	10	4	1SW2
1SW1	20	1	10	2	1SW3
1SW1	20	0.5	10	1	1SW4
1SW1	20	0.2	10	0.4	1SW5
1SW1	20	0.1	10	0.2	1SW6
1SW3	2	0.5	10	0.1	1SW7
1SW3	2	0.2	10	0.04	1SW8
1SW3	2	0.1	10	0.02	1SW9

Sample preparation

The detailed stepwise procedure was as follows:

- Preparation of Sample Matrix

A. Portion of dry ice was added to a homogenizer apparatus (Laboratory mill). Subsequent appropriate amount of sample was added to the apparatus in small portions. Sample was blended after each addition until a homogeneous mixture was obtained.

B. Contents of the apparatus were poured into polyethylene bags, and stored in a freezer until the last traces of dry ice have sublimed.

- Sample Extraction

A. 10.00 g ± 0.1 g of homogenized matrix was weighed into a 50 mL PP centrifuge tube. Sample weight was recorded.

B. If necessary fortification of the concurrent recovery sample(s) by aliquoting the fortification standard of Pyraclostrobin and Boscalid mixture onto the matrix was carried out at this step. Fortification details are given below:

Fortification level	Standard dilution	Concentration of individual standard (µg/mL)	Volume used (µL)
LOQ (0.01 mg/kg)	1SW3	2	50

C. For extraction using an automatic pipette 10 mL of acetonitrile was added.
D. The PP centrifuge tube was closed tightly and shake for 1 min automatically.

- Liquid-Liquid Partition

A. Buffer-salt mixture (4 g \pm 0.2 g of magnesium sulfate anhydrous, 1 g \pm 0.05 g of sodium chloride, 0,5 g \pm 0.03 g NaCitrate dibasic sesquihydrate, 1 g \pm 0.05 g NaCitrate tribasic dehydrate) was added and the centrifuge tube was closed and shaken by vortex for 1 min.

B. The extract was centrifuged at >3000 g for 5 min.

- Sample Purification

A. Using an automatic pipette 6 ml of sample extract supernatant was transferred to Dispersive SPE 12 ml centrifuge tubes containing 150 mg Supelclean PSA and 900 mg MgSO₄. The tube was shaken automatically for 30 sec.

- Sample Dilution

A. An aliquot of 0.5 mL of purified sample extract was transferred to new Eppendorf safe-lock tube and subsequently diluted with 0.4 mL of Water, 0.05 mL acetonitrile (+1% Vol. formic acid) and 0.05 mL of acetonitrile.

B. Content was vortex gently and filtered through the 0.22 μ m Teflon filter attached to a syringe direct into amber HPLC vial.

C. Vial was labelled so that it may be identified.

- Final Determination

A. Final determination was performed using LC-MS/MS.

Results:

No residue above the LOD were detected in the control samples. The analytical results in mg per kg are summarized in Table A.2:

Table A 3: Summary of the study 2

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treat- ment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pyraclostrobin	Boscalid		
18SGS17 PL01/ POLAND / CEU / 2018 Ożarów Mazowiecki	Sugarbeet/Candimax	25/03/2018 - 20/09/2018	A1: 104.25 + 415.45 A2: 100.17 + 399.17	415 398.7	-	2 29/08/2018 06/09/2018	BBCH 39	Roots	0.02018	0.09472	14	Test site code: 18SGS17 PL01 LOQ Pyraclostrobin = 0.01 mg/kg (sugarbeets) LOD Pyraclostrobin = 0.002 mg/kg (sugarbeets) LOQ Boscalid = 0.01 mg/kg (sugarbeets) LOD Boscalid = 0.002 mg/kg (sugarbeets) Time between harvest and extraction: 5 months
18SGS17 PL02/ POLAND / CEU / 2018 Bedlno łódzkie	Sugarbeet	05/04/2018 - 10/10/2018	A1: 105.32 + 419.72 A2: 103.92 + 414.12	524 517	-	2 18/09/2018 26/09/2018	BBCH 38--39	Roots	0.01683	0.04759	14	Test site code: 18SGS17 PL02 LOQ Pyraclostrobin = 0.01 mg/kg (sugarbeets) LOD Pyraclostrobin = 0.002 mg/kg (sugarbeets) LOQ Boscalid = 0.01 mg/kg (sugarbeets) LOD Boscalid = 0.002 mg/kg (sugarbeets) Time between harvest and extraction: 5 months

A1 – pyraclostrobin

A2 - boscalid

- (a) According to CODEX Classification / Guide
- (b) Only if relevant
- (c) Year must be indicated
- (d) Days after last application (Label pre-harvest interval, PHI, underline)
- (e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.1.4.3 Study 3

zRMS Comment: Study is accepted

Clarifications regarding the independence of the following trials:

Łukaszewski K., Report No. 18SGS17 (Ożarów Mazowiecki) and Rafal Figurski, 2019. Study No. PB-2018-10 (Ożarów Mazowiecki)

Trials can be considered as independent as:

-were done in two different places - the distance is about 20 km.

18SGS017 PL01 – post code 05-830

D-2018-10-F01 – post code 05-850

- different kind of soil

18SGS017 PL01 – silt loam (1.5% of organic matter)

D-2018-10-F01 – sandy loam (2.21 % of organic matter)

Procedural recoveries at the fortification levels 0.01 mg/kg for both ion mass transition of pyraclostrobin and boscalid were all in range of 70-110% and thus comply with the standard acceptance criteria of the guidance documents: SANCO/825/00 rev. 8.1, SANCO/3029/99 rev. 4 and SANTE/2020/12830, Rev.1

All precision values were <20%

Reference: KCP 8.3.1.5

Report Magnitude of the residue of pyraclostrobin + boscalid in sugar beet (Raw Agricultural Commodity – RAC) grown in open field conditions after two applications of formulated product pyraclostrobin 6.7% + boscalid 26.7% - two harvest trials in North Europe – Poland, 2018. Rafal Figurski, 2019. Study No. PB-2018-10.

Guideline(s): Yes

- Regulation (EC) No 1107/2009 of 21 October 2009
- 7029/VI/95-rev 5., 22.07.97 and amendments
- ENV/MC/CHEM(98)17
- ENV/JM/MONO(99)22
- SANCO/3029/99 rev.4
- ENV/JM/MONO(2007)17

Deviations: No

GLP: Yes

Acceptability: Yes

A study on the magnitude of the residue of pyraclostrobin and boscalid in sugar beet raw Agricultural Commodity (RAC) was conducted in Poland following two foliar applications of formulated product Pyraclostrobin 6.7% + Boscalid 26.7% WG containing 6.7 g/kg of pyraclostrobin and 26.7 g/kg of boscalid. Two harvest trials were set up on sugar beet in Poland. Trials consisted of one untreated plot U and one treated plot T. Foliar applications of Pyraclostrobin 6.7% + Boscalid 26.7% WG were performed on the treated plot at the target dose rate of 1.5 kg/ha (equivalent to 100 g as/ha of pyraclostrobin and 400 g as/ha of boscalid). The target spray of water volume was 200 – 600 litres per hectare.

Applications were performed following the target schedule:

- 1st application performed 22±1 days before harvest
- 2nd application performed 14±1 days before harvest

In the trials, RAC specimens for analyses (roots) were collected following the target schedule below:

- At 14±1 days after last application (PHI)

All RAC specimens were deep frozen on the day of collection and stored at the target temperature below -

18°C. All specimens remained deep frozen during storage at the test sites, during shipment to the analytical laboratory.

Reference: KCP 8.3.1.6

Report Pyraclostrobin and boscalid residues in sugar beets after application of pyraclostrobin 6.7 + boscalid 26.7% WG. Zofia Hordyjewicz-Baran, 2019. Study No. 4/2019.

Guideline(s): Yes

- Council Regulation (EC) No 440/2008, ICSO Procedure BA-AB/SPO-1 and research method No. BA-AB/MS/MB-5 and BA-AB/MS/MB-6
- Directive 2004/10/EC of the European Parliament and of the Council of 11th February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of the applications for test on chemical substances.
- The Minister of Health Regulations of 22nd May 2013 on Good Laboratory Practice and performance of studies in compliance with the principles of GLP (Dz. U. Z 2013 poz. 665)
- Act of 25th February 2011 on the chemical substances and their mixtures (The Republic of Poland Journal of Law of 2011, No. 63, item 322 with subsequent amendments)
- OECD Environmental Health and Safety Publications, Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 1 OECD Principles of Good Laboratory Practice, 1997.
- SANCO/825/00 rev. 8.1
- SANCO/3029/99 rev. 4

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods:

During the growing season of 2018, a total of two trials were conducted in sugarbeet in Northern Europe (Poland) to determine the magnitude of harvest residues of Pyraclostrobin and Boscalid in or on raw agricultural commodities (RAC).

The determination of Pyraclostrobin and Boscalid residues has been performed by liquid chromatography, and consists in an separation on a reversed-phase column and detection by tandem mass spectrometry (MS/MS) by electrospray (ESI) operating with optimized conditions.

The characteristics of the analytical method was as follows:

Preparation of Stock Standard Solutions

Preparation of stock solution of Pyraclostrobin for calibration

Reference Item	Purity of reference item* (%)	Weighed amount of reference item (mg)	Amount of analyte corrected for purity (mg)	Final volume (mL)	Solvent used for dilution	Equivalent conc. (mg/mL)	Reference of standard solution produced
Pyraclostrobin	99.9	20.04	20	10	Acetonitrile	2	1S1

Preparation of stock solution of Boscalid for calibration

Reference Item	Purity of reference item* (%)	Weighed amount of reference item (mg)	Amount of analyte corrected for purity (mg)	Final volume (mL)	Solvent used for dilution	Equivalent conc. (mg/mL)	Reference of standard solution produced
Boscalid	99.5	20.21	20	10	Acetonitrile	2	1S2

Preparation of Working, Fortification and Stability Testing Standard Solutions

Preparation of working solutions of Pyraclostrobin

Reference of standard solution used	Concentration Pyraclostrobin (µg/mL)	Volume taken (mL)	Final volume (mL)	Equivalent concentration (µg/mL)	Reference of standard solution produced (mixture)
1S1	2000	0.5	50	20	1SW1
1SW1	20	2	10	4	1SW2
1SW1	20	1	10	2	1SW3
1SW1	20	0.5	10	1	1SW4
1SW1	20	0.2	10	0.4	1SW5
1SW1	20	0.1	10	0.2	1SW6
1SW3	2	0.5	10	0.1	1SW7
1SW3	2	0.2	10	0.04	1SW8
1SW3	2	0.1	10	0.02	1SW9

Preparation of working solutions of Boscalid

Reference of standard solution used	Concentration Boscalid (µg/mL)	Volume taken (mL)	Final volume (mL)	Equivalent concentration (µg/mL)	Reference of standard solution produced (mixture)
1S2	2000	0.5	50	20	1SW1
1SW1	20	2	10	4	1SW2
1SW1	20	1	10	2	1SW3
1SW1	20	0.5	10	1	1SW4
1SW1	20	0.2	10	0.4	1SW5
1SW1	20	0.1	10	0.2	1SW6
1SW3	2	0.5	10	0.1	1SW7
1SW3	2	0.2	10	0.04	1SW8
1SW3	2	0.1	10	0.02	1SW9

Sample preparation

Preparation of Sample Matrix

- Portion of dry ice was added to a homogenizer apparatus (Laboratory mill). Subsequent appropriate amount of sample was added to the apparatus in small portions. Sample was blended after each addition until a homogeneous mixture was obtained.
- Contents of the apparatus were poured into polyethylene bags, and stored in a freezer until the last traces of dry ice have sublimed.

Sample Extraction

- 10.00 g \pm 0.1 g of homogenized matrix was weighed into a 50 mL PP centrifuge tube. Sample weight was recorded.
- If necessary fortification of the concurrent recovery sample(s) by aliquoting the fortification standard of Pyraclostrobin and Boscalid mixture onto the matrix was carried out at this step. Fortification details are given below:

Fortification level	Standard dilution	Concentration of individual standard (µg/mL)	Volume used (µL)
LOQ (0.01 mg/kg)	1SW3	2	50

- For extraction using an automatic pipette 10 mL of acetonitrile was added.
- The PP centrifuge tube was closed tightly and shake for 1 min automatically.

Liquid-Liquid Partition

- Buffer-salt mixture (4 g \pm 0.2 g of magnesium sulfate anhydrous, 1 g \pm 0.05 g of sodium chloride, 0.5 g \pm 0.03 g NaCitrate dibasic sesquihydrate, 1 g

± 0.05 g NaCitrate tribasic dehydrate) was added and the centrifuge tube was closed and shaken by vortex for 1 min.
B. The extract was centrifuged at >3000 g for 5 min.

Sample purification

A. Using an automatic pipette 6 ml of sample extract supernatant was transferred to Dispersive SPE 12 ml centrifuge tubes containing 150 mg Supelclean PSA and 900 mg MgSO_4 . The tube was shaken automatically for 30 sec.

Sample Dilution

A. An aliquot of 0.5 mL of purified sample extract was transferred to new Eppendorf safe-lock tube and subsequently diluted with 0.4 mL of Water, 0.05 mL acetonitrile (+1% Vol. formic acid) and 0.05 mL of acetonitrile.
B. Content was vortex gently and filtered through the $0.22\ \mu\text{m}$ Teflon filter attached to a syringe direct into amber HPLC vial.
C. Vial was labelled so that it may be identified.

Final Determination

A. Final determination was performed using LC-MS/MS.

Results:

No residue above the LOD were detected in the control samples. The analytical results in mg per kg are summarized in Table A.2:

Table A 4: Summary of the study

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pyraclostrobin	Boscalid		
(a)	(a)	(b)				(c)					(d)	(e)
D-2018-10-F01/ Poland / NEU / 2018 Ożarów Mazowiecki	Sugarbeet/ Cadimax	1) 31/03/2018 2) NA 3) 16/11/2018	A1: 98.36 101.77 A2: 391.96 405.57	5873 6077		23/08/2018 31/08/2018	BBCH 39 BBCH 39	Roots	<LOD (0.002)	<LOD (0.002)	14	Test site code: D-2018-10 LOQ Pyraclostrobin = 0.01 mg/kg (sugarbeet) LOD Pyraclostrobin = 0.002 mg/kg (sugarbeet) LOQ Boscalid = 0.01 mg/kg (sugarbeet) LOD Boscalid = 0.002 mg/kg (sugarbeet) Time between harvest and extraction: 76 days
D-2018-10-F02/ Poland / NEU / 2018 Raciąż	Sugarbeet/ Sukcesja	1) 04/04/2018 2) NA 3) 04/09/2018	4 A1: 99.09 102.11 A2: 394.89 406.91	5920 6097		09/08/2018 17/08/2018	BBCH 39 BBCH 39	Roots	<LOD (0.002)	<LOD (0.002)	14	Test site code: D-2018-10 LOQ Pyraclostrobin = 0.01 mg/kg (sugarbeet) LOD Pyraclostrobin = 0.002 mg/kg (sugarbeet) LOQ Boscalid = 0.01 mg/kg (sugarbeet) LOD Boscalid = 0.002 mg/kg (sugarbeet) Time between harvest and extraction: 149 days

A1 – pyraclostrobin

A2 - boscalid

- (a) According to CODEX Classification / Guide
- (b) Only if relevant
- (c) Year must be indicated
- (d) Days after last application (Label pre-harvest interval, PHI, underline)
- (e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.1.4.4 Study 4

zRMS Comment: Study is accepted

Two applications at nominal rate 1.5 L product/ha were made.

Longest storage time: 184 days

Procedural recoveries at the fortification levels 0.01 mg/kg for both ion mass transition of pyraclostrobin and boscalid were all in range of 70-110% and thus comply with the standard acceptance criteria of the guidance documents: SANCO/825/00 rev. 8.1, SANCO/3029/99 rev. 4 and SANTE/2020/12830, Rev.1
All precision values were <20%

Reference: KCP 8.3.1.7-01

Report Decline residue of pyraclo 6.7 + boscalid 26.7 % WG in sugar beet. Raw Agricultural commodity in the United Kingdom, 2018. Martin Sumerfield, 2020. Study No. ACE18-054

Guideline(s): Yes

Deviations: No

GLP: Yes

Acceptability: Yes

Reference: KCP 8.3.1.7

Report Decline residue of pyraclo 6.7 + boscalid 26.7 % WG in sugar beet. Raw Agricultural commodity in the United Kingdom, 2018. Zofia Hordyjewicz-Baran, 2019. Study No. 50/2019

Guideline(s): Yes

- Council Regulation (EC) No 440/2008, ICSO Procedure BA-AB/SPO-1 and research method No. BA-AB/MS/MB-5 and BA-AB/MS/MB-6
- Directive 2004/10/EC of the European Parliament and of the Council of 11th February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of the applications for test on chemical substances.
- The Minister of Health Regulations of 22nd May 2013 on Good Laboratory Practice and performance of studies in compliance with the principles of GLP (Dz. U. Z 2013 poz. 665)
- Act of 25th February 2011 on the chemical substances and their mixtures (The Republic of Poland Journal of Law of 2011, No. 63, item 322 with subsequent amendments)
- OECD Environmental Health and Safety Publications, Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 1 OECD Principles of Good Laboratory Practice, 1997.
- SANCO/825/00 rev. 8.1
- SANCO/3029/99 rev. 4

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods:

During the growing season of 2018, a total of three trials were conducted in

sugarbeet in Northern Europe (United Kingdom) to determine the magnitude of decline residues of Pyraclostrobin and Boscalid in or on raw agricultural commodities (RAC).

The determination of Pyraclostrobin and Boscalid residues has been performed by liquid chromatography, and consists in an separation on a reversed-phase column and detection by tandem mass spectrometry (MS/MS) by electrospray (ESI) operating with optimized conditions.

The characteristics of the analytical method was as follows:

Preparation of stock solution of Pyraclostrobin for calibration

Reference Item	Purity of reference item* (%)	Weighed amount of reference item (mg)	Amount of analyte corrected for purity (mg)	Final volume (mL)	Solvent used for dilution	Equivalent conc. (mg/mL)	Reference of standard solution produced
Pyraclostrobin	99.9	20.04	20	10	Acetonitrile	2	1S1

Preparation of stock solution of Boscalid for calibration

Reference Item	Purity of reference item* (%)	Weighed amount of reference item (mg)	Amount of analyte corrected for purity (mg)	Final volume (mL)	Solvent used for dilution	Equivalent conc. (mg/mL)	Reference of standard solution produced
Boscalid	99.5	20.21	20	10	Acetonitrile	2	1S2

Preparation of working solutions of Pyraclostrobin

Reference of standard solution used	Concentration Pyraclostrobin (µg/mL)	Volume taken (mL)	Final volume (mL)	Equivalent concentration (µg/mL)	Reference of standard solution produced (mixture)
1S1	2000	0.5	50	20	1SW1
1SW1	20	2	10	4	1SW2
1SW1	20	1	10	2	1SW3
1SW1	20	0.5	10	1	1SW4
1SW1	20	0.2	10	0.4	1SW5
1SW1	20	0.1	10	0.2	1SW6
1SW3	2	0.5	10	0.1	1SW7
1SW3	2	0.2	10	0.04	1SW8
1SW3	2	0.1	10	0.02	1SW9

Preparation of working solutions of Boscalid

Reference of standard solution used	Concentration Boscalid (µg/mL)	Volume taken (mL)	Final volume (mL)	Equivalent concentration (µg/mL)	Reference of standard solution produced (mixture)
1S2	2000	0.5	50	20	1SW1
1SW1	20	2	10	4	1SW2
1SW1	20	1	10	2	1SW3
1SW1	20	0.5	10	1	1SW4
1SW1	20	0.2	10	0.4	1SW5
1SW1	20	0.1	10	0.2	1SW6
1SW3	2	0.5	10	0.1	1SW7
1SW3	2	0.2	10	0.04	1SW8
1SW3	2	0.1	10	0.02	1SW9

Sample preparation

The detailed stepwise procedure was as follows:

- Preparation of Sample Matrix

A. Portion of dry ice was added to a homogenizer apparatus (Laboratory mill). Subsequent appropriate amount of sample was added to the apparatus in small portions. Sample was blended after each addition until a homogeneous mixture was obtained.

B. Contents of the apparatus were poured into polyethylene bags, and stored in a freezer until the last traces of dry ice have sublimed.

- Sample Extraction

A. 10.00 g \pm 0.1 g of homogenized matrix was weighed into a 50 mL PP centrifuge tube. Sample weight was recorded.

B. If necessary fortification of the concurrent recovery sample(s) by aliquoting the fortification standard of Pyraclostrobin and Boscalid mixture onto the matrix was carried out at this step. Fortification details are given below:

Fortification level	Standard dilution	Concentration of individual standard ($\mu\text{g/mL}$)	Volume used (μL)
LOQ (0.01 mg/kg)	1SW3	2	50

C. For extraction using an automatic pipette 10 mL of acetonitrile was added.

D. The PP centrifuge tube was closed tightly and shake for 1 min automatically.

- Liquid-Liquid Partition

A. Buffer-salt mixture (4 g \pm 0.2 g of magnesium sulfate anhydrous, 1 g \pm 0.05 g of sodium chloride, 0,5 g \pm 0.03 g NaCitrate dibasic sesquihydrate, 1 g \pm 0.05 g NaCitrate tribasic dehydrate) was added and the centrifuge tube was closed and shaken by vortex for 1 min.

B. The extract was centrifuged at >3000 g for 5 min.

- Sample Purification

A. Using an automatic pipette 6 ml of sample extract supernatant was transferred to Dispersive SPE 12 ml centrifuge tubes containing 150 mg Supelclean PSA and 900 mg MgSO₄. The tube was shaken automatically for 30 sec.

- Sample Dilution

A. An aliquot of 0.5 mL of purified sample extract was transferred to new Eppendorf safe-lock tube and subsequently diluted with 0.4 mL of Water, 0.05 mL acetonitrile (+1% Vol. formic acid) and 0.05 mL of acetonitrile.

B. Content was vortex gently and filtered through the 0.22 μm Teflon filter attached to a syringe direct into amber HPLC vial.

C. Vial was labelled so that it may be identified.

- Final Determination

A. Final determination was performed using LC-MS/MS.

Results:

No residue above the LOD were detected in the control samples. The analytical results in mg per kg are summarized in Table A.2:

Table A 5: Summary of the study

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pyraclostrobin	Boscalid		
(a)	(a)	(b)				(c)					(d)	(e)
ACE 18-054a/ UK / NEU / 2018 Halesworth, Suffolk	Sugarbeet/	1) 2) 3)	Pyraclostrobin: 102.0 99.2 Boscalid: 412.8 401.3	200		20.08.2018 28.08.2018	BBCH 40	Roots Roots Roots Roots	0.027 0.025 0.029 0.017	0.110 0.084 0.095 0.048	0 3 7 14	Analytical phase report: 50/2019 LOD Pyraclostrobin = 0.002 mg/kg (sugarbeets) LOD Boscalid = 0.002 mg/kg (sugarbeets) Time between harvest and extraction:
ACE 18-054b/ UK / NEU / 2018 Exning Suffolk	Sugarbeet/	1) 2) 3)	Pyraclostrobin: 100.4 97.2 Boscalid: 406.3 393.6	200		20.08.2018 28.08.2018	BBCH 40-41	Roots Roots Roots Roots	0.032 0.019 0.050 0.036	0.090 0.055 0.203 0.135	0 3 7 14	Analytical phase report: 50/2019 LOD Pyraclostrobin = 0.002 mg/kg (sugarbeets) LOD Boscalid = 0.002 mg/kg (sugarbeets) Time between harvest and extraction:
ACE 18-054c/ UK / NEU / 2018 Lawford Essex	Sugarbeet/	1) 2) 3)	Pyraclostrobin: 96.4 101.2 Boscalid: 390.1 409.6	200		23.08.2018 31.08.2018	BBCH 40-41	Roots Roots Roots Roots	0.025 0.020 0.035 0.030	0.056 0.062 0.075 0.074	0 3 7 14	Analytical phase report: 50/2019 LOD Pyraclostrobin = 0.002 mg/kg (sugarbeets) LOD Boscalid = 0.002 mg/kg (sugarbeets) Time between harvest and extraction:

- (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.1.5 Tomato

Table A 6: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (1)	2	0.1 Kg a.i./ha of pyraclostrobin + 0.4 kg a.i./ha of boscalid,	8	20-87	3

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

A 2.1.1.5.1 Study 5

zRMS Comment: Study is accepted

Procedural recoveries at the fortification levels 0.01 mg/kg for both ion mass transition of pyraclostrobin and boscalid were all in range of 70-110% and thus comply with the standard acceptance criteria of the guidance documents: SANCO/825/00 rev. 8.1, SANCO/3029/99 rev. 4 and SANTE/2020/12830, Rev.1
All precision values were <20%

Reference: KCP 8.3.2.1

Report Magnitude of the residue of pyraclostrobin + boscalid in tomato (raw agricultural commodity – RAC) grown in open field conditions after two applications of formulated product pyraclostrobin 6.7% + boscalid 26.7% WG – two harvest trials in Northern Europe – Poland, 2018. Rafal Figurski, 2019. Study No. PB-2018-11

Guideline(s): Yes
- Regulation (EC) No 1107/2009 of 21 October 2009
- 7029/VI/95-rev 5., 22.07.97 and amendments
- ENV/MC/CHEM(98)17
- ENV/JM/MONO(99)22
- SANCO/3029/99 rev.4
- ENV/JM/MONO(2007)17

Deviations: No

GLP: Yes

Acceptability: Yes

A study on the magnitude of the residue of pyraclostrobin and boscalid in tomato raw Agricultural Commodity (RAC) was conducted in Poland following two foliar applications of formulated product Pyraclostrobin 6.7% + Boscalid 26.7% WG containing 67 g/kg of pyraclostrobin and 267 g/kg of boscalid. Two harvest trials were set up on tomato in Poland. Trials consisted of one untreated plot U and on treated plot T. Foliar applications of Pyraclostrobin 6.7% + Boscalid 26.7% WG were performed on the treated plot at the target dose rate of 1.5 kg/ha (equivalent to 100 g as/ha of pyraclostrobin and 400 g as/ha of boscalid). The target spray of water volume was 500-1000 litres per hectare.

Applications were performed following the target schedule:

- 1st application performed at 11±1 days before harvest

- 2nd application performed at 3±1 days before harvest.

In the trials RAC specimens for analyses (fruit) were collected following the target schedule:

- At commercial harvest (BBCH 89): 3±1 days after last application

All RAC specimens were deep frozen on the day of collection and stored at the target temperature below -18°C. All specimens remained deep frozen during storage at the test sites, during shipment to the analytical laboratory.

Reference: KCP 8.3.2.2

Report Pyraclostrobin and boscalid residues in tomatoes after application of Pyraclostrobin 6.7 + boscalid 26.7 % WG – analytical part. Zofia Hordyjewicz-Baran, 2019. Study No. 5/2019

Guideline(s): Yes

- Council Regulation (EC) No 440/2008, ICSO Procedure BA-AB/SPO-1 and research method No. BA-AB/MS/MB-5 and BA-AB/MS/MB-6
- Directive 2004/10/EC of the European Parliament and of the Council of 11th February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of the applications for test on chemical substances.
- The Minister of Health Regulations of 22nd May 2013 on Good Laboratory Practice and performance of studies in compliance with the principles of GLP (Dz. U. Z 2013 poz. 665)
- Act of 25th February 2011 on the chemical substances and their mixtures (The Republic of Poland Journal of Law of 2011, No. 63, item 322 with subsequent amendments)
- OECD Environmental Health and Safety Publications, Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 1 OECD Principles of Good Laboratory Practice, 1997.
- SANCO/825/00 rev. 8.1
- SANCO/3029/99 rev. 4

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods:

During the growing season of 2018, a total of two trials were conducted in tomato in Northern Europe (Poland) to determine the magnitude of harvest residues of Pyraclostrobin and Boscalid in or on raw agricultural commodities (RAC).

The determination of Pyraclostrobin and Boscalid residues has been performed by liquid chromatography, and consists in an separation on a reversed-phase column and detection by tandem mass spectrometry (MS/MS) by electrospray (ESI) operating with optimized conditions.

The characteristics of the analytical method was as follows:

Preparation of Stock Standard Solutions

Preparation of stock solution of Pyraclostrobin for calibration

Reference Item	Purity of reference item* (%)	Weighed amount of reference item (mg)	Amount of analyte corrected for purity (mg)	Final volume (mL)	Solvent used for dilution	Equivalent conc. (mg/mL)	Reference of standard solution produced
Pyraclostrobin	99.9	20.04	20	10	Acetonitrile	2	1S1

Preparation of stock solution of Boscalid for calibration

Reference Item	Purity of reference item* (%)	Weighed amount of reference item (mg)	Amount of analyte corrected for purity (mg)	Final volume (mL)	Solvent used for dilution	Equivalent conc. (mg/mL)	Reference of standard solution produced
Boscalid	99.5	20.21	20	10	Acetonitrile	2	1S2

Preparation of Working, Fortification and Stability Testing Standard Solutions

Preparation of working solutions of Pyraclostrobin

Reference of standard solution used	Concentration Pyraclostrobin (µg/mL)	Volume taken (mL)	Final volume (mL)	Equivalent concentration (µg/mL)	Reference of standard solution produced (mixture)
1S1	2000	0.5	50	20	1SW1
1SW1	20	2	10	4	1SW2
1SW1	20	1	10	2	1SW3
1SW1	20	0.5	10	1	1SW4
1SW1	20	0.2	10	0.4	1SW5
1SW1	20	0.1	10	0.2	1SW6
1SW3	2	0.5	10	0.1	1SW7
1SW3	2	0.2	10	0.04	1SW8
1SW3	2	0.1	10	0.02	1SW9

Preparation of working solutions of Boscalid

Reference of standard solution used	Concentration Boscalid (µg/mL)	Volume taken (mL)	Final volume (mL)	Equivalent concentration (µg/mL)	Reference of standard solution produced (mixture)
1S2	2000	0.5	50	20	1SW1
1SW1	20	2	10	4	1SW2
1SW1	20	1	10	2	1SW3
1SW1	20	0.5	10	1	1SW4
1SW1	20	0.2	10	0.4	1SW5
1SW1	20	0.1	10	0.2	1SW6
1SW3	2	0.5	10	0.1	1SW7
1SW3	2	0.2	10	0.04	1SW8
1SW3	2	0.1	10	0.02	1SW9

Sample preparation

Preparation of Sample Matrix

- Portion of dry ice was added to a homogenizer apparatus (Laboratory mill). Subsequent appropriate amount of sample was added to the apparatus in small portions. Sample was blended after each addition until a homogeneous mixture was obtained.
- Contents of the apparatus were poured into polyethylene bags, and stored in a freezer until the last traces of dry ice have sublimed.

Sample Extraction

- 10.00 g \pm 0.1 g of homogenized matrix was weighed into a 50 mL PP centrifuge tube. Sample weight was recorded.
- If necessary fortification of the concurrent recovery sample(s) by aliquoting the fortification standard of Pyraclostrobin and Boscalid mixture onto the matrix was carried out at this step. Fortification details are given below:

Fortification level	Standard dilution	Concentration of individual standard (µg/mL)	Volume used (µL)
LOQ (0.01 mg/kg)	1SW3	2	50

- For extraction using an automatic pipette 10 mL of acetonitrile was added.
- The PP centrifuge tube was closed tightly and shake for 1 min automatically.

Liquid-Liquid Partition

- Buffer-salt mixture (4 g \pm 0.2 g of magnesium sulfate anhydrous, 1 g \pm 0.05 g of sodium chloride, 0.5 g \pm 0.03 g NaCitrate dibasic sesquihydrate, 1 g

± 0.05 g NaCitrate tribasic dehydrate) was added and the centrifuge tube was closed and shaken by vortex for 1 min.
B. The extract was centrifuged at >3000 g for 5 min.

Sample purification

A. Using an automatic pipette 6 ml of sample extract supernatant was transferred to Dispersive SPE 12 ml centrifuge tubes containing 150 mg Supelclean PSA and 900 mg MgSO_4 . The tube was shaken automatically for 30 sec.

Sample Dilution

A. An aliquot of 0.5 mL of purified sample extract was transferred to new Eppendorf safe-lock tube and subsequently diluted with 0.4 mL of Water, 0.05 mL acetonitrile (+1% Vol. formic acid) and 0.05 mL of acetonitrile.
B. Content was vortex gently and filtered through the $0.22\ \mu\text{m}$ Teflon filter attached to a syringe direct into amber HPLC vial.
C. Vial was labelled so that it may be identified.

Final Determination

A. Final determination was performed using LC-MS/MS.

Results:

No residue above the LOD were detected in the control samples. The analytical results in mg per kg are summarized in Table A.2:

Table A 7: Summary of the study

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pyraclostrobin	Boscalid		
(a)	(a)	(b)				(c)					(d)	(e)
D-2018-11-F01/ Poland / NEU / 2018 Błonie	Tomato/ Babinicz	1) 30/05/2018 2) From 13/06/2018 to 01/08/2018 3) 12/09/2018	A1: 100.37 99.03 A2: 399.97 394.63	599.0 591.3		16/08/2018 24/08/2018	BBCH 83 BBCH 86	Fruits	<LOD (0.002)	<LOD (0.002)	3	Test site code: D-2018-11 LOQ Pyraclostrobin = 0.01 mg/kg (tomato fruit) LOD Pyraclostrobin = 0.002 mg/kg (tomato fruit) LOQ Boscalid = 0.01 mg/kg (tomato fruit) LOD Boscalid = 0.002 mg/kg (tomato fruit) Time between harvest and extraction: 147 days
D-2018-11-F02/ Poland / NEU / 2018 Błędów	Tomato/ Babinicz	1) 06/06/2018 2) From 15/06/2018 to 03/08/2018 3) 15/09/2018	A1: 102.64 98.36 A2: 409.04 391.96	612.7 587.3		16/08/2018 24/08/2018	BBCH 81 BBCH 86	Fruits	<LOD (0.002)	<LOD (0.002)	3	Test site code: D-2018-11 LOQ Pyraclostrobin = 0.01 mg/kg (tomato fruit) LOD Pyraclostrobin = 0.002 mg/kg (tomato fruit) LOQ Boscalid = 0.01 mg/kg (tomato fruit) LOD Boscalid = 0.002 mg/kg (tomato fruit) Time between harvest and extraction: 144 days

A1 – pyraclostrobin

A2 - boscalid

- (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.1.5.2 Study 6

zRMS Comment: Study is accepted

Procedural recoveries at the fortification levels 0.01 mg/kg for both ion mass transition of pyraclostrobin and boscalid were all in range of 70-110% and thus comply with the standard acceptance criteria of the guidance documents: SANCO/825/00 rev. 8.1, SANCO/3029/99 rev. 4 and SANTE/2020/12830, Rev.1
All precision values were <20%

Reference: KCP 8.3.2.3

Report Magnitude of the residue of pyraclostrobin + boscalid in tomato (Raw Agricultural Commodity) after two application of Pyraclostrobin 6.7% + Boscalid 26.7% WG – two harvest trials and one decline curve trial in Poland – 2018, K. Łukaszewski, Report No. 18SGS18

Guideline(s): Yes

- Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
- Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue trials, July 22, 1997
- OECD Environmental Health and Safety Publications, Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 1 OECD Principles of Good Laboratory Practice, 1997.
- SANCO/825/00 rev. 8.1
- SANCO/3029/99 rev. 4

Deviations: No

GLP: Yes

Acceptability: Yes

Three field trials were established on tomato in three different locations. The sites were representative for tomato production, grown in a typical way in the test countries. Each trial consisted of on untreated plot U and on treated plot T. Plots were of sufficient size to generate the desired specimen quantities. Around the treated and untreated plots a buffer zone of at least 10 m was set up. Tomato was cultivated according to normal local agronomic practises.

The application equipment consisted of boom sprayer. The foliar applications closely simulated commercial-type treatments. Pyraclostrobin 6.7% + Boscalid 26.7% WG was only mixed with water. No adjuvant was added to the spray mixture. The target dose rate of the test item was 1.5 kg/ha of formulated product per application, equivalent to 100.5 g as/ha Pyraclostrobin and 400.6 g as/ha Boscalid. Applications were made at a target water volume of 500-1000 litres per hectare of mixture according to GAP.

In all study trials (harvest trials – HS and decline curve trials – DCS), RAC specimens were collected following the target schedule:

Trial type	Number of sampling events	Timing of sampling events
HS	1	3 DALA
DCS	1	0 DALA
	2	1 DALA
	3	3 DALA

Reference: KCP 8.3.2.4

Report Magnitude of the residue of pyraclostrobin + boscalid in tomato (raw agricultural commodity) after two applications of pyraclostrobin 6.7% + boscalid 26.7% WG – two harvest trials and one decline curve trial in Poland – 2018. – analytical phase report. Zofia Hordyjewicz-Baran, 2019. Study No. 22/2019

Guideline(s): Yes

- Council Regulation (EC) No 440/2008, ICSO Procedure BA-AB/SPO-1 and research method No. BA-AB/MS/MB-5 and BA-AB/MS/MB-6
- Directive 2004/10/EC of the European Parliament and of the Council of 11th February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of the applications for test on chemical substances.
- The Minister of Health Regulations of 22nd May 2013 on Good Laboratory Practice and performance of studies in compliance with the principles of GLP (Dz. U. Z 2013 poz. 665)
- Act of 25th February 2011 on the chemical substances and their mixtures (The Republic of Poland Journal of Law of 2011, No. 63, item 322 with subsequent amendments)
- OECD Environmental Health and Safety Publications, Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 1 OECD Principles of Good Laboratory Practice, 1997.
- SANCO/825/00 rev. 8.1
- SANCO/3029/99 rev. 4

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods:

During the growing season of 2018, a total of three trials were conducted in tomato in Northern Europe (Poland) to determine the magnitude of harvest residues of Pyraclostrobin and Boscalid in or on raw agricultural commodities (RAC).

The determination of Pyraclostrobin and Boscalid residues has been performed by liquid chromatography, and consists in an separation on a reversed-phase column and detection by tandem mass spectrometry (MS/MS) by electrospray (ESI) operating with optimized conditions.

The characteristics of the analytical method was as follows:

Preparation of Stock Standard Solutions

Preparation of stock solution of Pyraclostrobin for calibration

Reference Item	Purity of reference item* (%)	Weighed amount of reference item (mg)	Amount of analyte corrected for purity (mg)	Final volume (mL)	Solvent used for dilution	Equivalent conc. (mg/mL)	Reference of standard solution produced
Pyraclostrobin	99.9	20.04	20	10	Acetonitrile	2	1S1

Preparation of stock solution of Boscalid for calibration

Reference Item	Purity of reference item* (%)	Weighed amount of reference item (mg)	Amount of analyte corrected for purity (mg)	Final volume (mL)	Solvent used for dilution	Equivalent conc. (mg/mL)	Reference of standard solution produced
Boscalid	99.5	20.21	20	10	Acetonitrile	2	1S2

Preparation of Working, Fortification and Stability Testing Standard Solutions

Preparation of working solutions of Pyraclostrobin

Reference of standard solution used	Concentration Pyraclostrobin (µg/mL)	Volume taken (mL)	Final volume (mL)	Equivalent concentration (µg/mL)	Reference of standard solution produced (mixture)
1S1	2000	0.5	50	20	1SW1
1SW1	20	2	10	4	1SW2
1SW1	20	1	10	2	1SW3
1SW1	20	0.5	10	1	1SW4
1SW1	20	0.2	10	0.4	1SW5
1SW1	20	0.1	10	0.2	1SW6
1SW3	2	0.5	10	0.1	1SW7
1SW3	2	0.2	10	0.04	1SW8
1SW3	2	0.1	10	0.02	1SW9

Preparation of working solutions of Boscalid

Reference of standard solution used	Concentration Boscalid (µg/mL)	Volume taken (mL)	Final volume (mL)	Equivalent concentration (µg/mL)	Reference of standard solution produced (mixture)
1S2	2000	0.5	50	20	1SW1
1SW1	20	2	10	4	1SW2
1SW1	20	1	10	2	1SW3
1SW1	20	0.5	10	1	1SW4
1SW1	20	0.2	10	0.4	1SW5
1SW1	20	0.1	10	0.2	1SW6
1SW3	2	0.5	10	0.1	1SW7
1SW3	2	0.2	10	0.04	1SW8
1SW3	2	0.1	10	0.02	1SW9

Sample preparation

Preparation of Sample Matrix

A. Portion of dry ice was added to a homogenizer apparatus (Laboratory mill). Subsequent appropriate amount of sample was added to the apparatus in small portions. Sample was blended after each addition until a homogeneous mixture was obtained.

B. Contents of the apparatus were poured into polyethylene bags, and stored in a freezer until the last traces of dry ice have sublimed.

Sample Extraction

A. 10.00 g ± 0.1 g of homogenized matrix was weighed into a 50 mL PP centrifuge tube. Sample weight was recorded.

B. If necessary fortification of the concurrent recovery sample(s) by aliquoting the fortification standard of Pyraclostrobin and Boscalid mixture onto the matrix was carried out at this step. Fortification details are given below:

Fortification level	Standard dilution	Concentration of individual standard (µg/mL)	Volume used (µL)
LOQ (0.01 mg/kg)	1SW3	2	50

C. For extraction using an automatic pipette 10 mL of acetonitrile was added.

D. The PP centrifuge tube was closed tightly and shake for 1 min automatically.

Liquid-Liquid Partition

A. Buffer-salt mixture (4 g ± 0.2 g of magnesium sulfate anhydrous, 1 g ± 0.05 g of sodium chloride, 0.5 g ± 0.03 g NaCitrate dibasic sesquihydrate, 1 g ± 0.05 g NaCitrate tribasic dehydrate) was added and the centrifuge tube was closed and shaken by vortex for 1 min.

B. The extract was centrifuged at >3000 g for 5 min.

Sample purification

A. Using an automatic pipette 6 ml of sample extract supernatant was transferred to Dispersive SPE 12 ml centrifuge tubes containing 150 mg Supelclean PSA and 900 mg MgSO₄. The tube was shaken automatically for 30 sec.

Sample Dilution

- A. An aliquot of 0.5 mL of purified sample extract was transferred to new Eppendorf safe-lock tube and subsequently diluted with 0.4 mL of Water, 0.05 mL acetonitrile (+1% Vol. formic acid) and 0.05 mL of acetonitrile.
B. Content was vortex gently and filtered through the 0.22 µm Teflon filter attached to a syringe direct into amber HPLC vial.
C. Vial was labelled so that it may be identified.

Final Determination

- A. Final determination was performed using LC-MS/MS.

Results:

No residue above the LOD were detected in the control samples. The analytical results in mg per kg are summarized in Table A.2:

Table A 8: Summary of the study

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pyraclostrobin	Boscalid		
(a)	(a)	(b)				(c)					(d)	(e)
18SGS18 PL01/ Poland / NEU / 2018 Kaczkowo Kujawsko Pomor- skie	Toma- to/Asterix	29/05/2018 25/06- 28/07/2018 07/09/2018	A1: 106.93 + 426.13 A2: 93.47 + 372.47	745 651	-	2 27/08/2018 94/09/2018	BBCH 85-87	Fruits	0.065	0.558	3	Analytical phase report: 22/2019 LOD Pyraclostrobin = 0.002 mg/kg (tomato) LOD Boscalid = 0.002 mg/kg (tomato) Time between harvest and extraction: 160 days
18SGS18 PL02/ Poland / NEU / 2018 Zduny Wieś Łódzkie	Toma- to/Dyno F1	30/04/2018 14/06- 12/08/2018 01/08- 15/09/2018	A1: 98.09 + 390.89 A2: 103.31 + 411.71	683 720	-	2 14/08/2018 21/08/2018	BBCH 82-85	Fruits	0.040	0.252	3	Analytical phase report: 22/2019 LOD Pyraclostrobin = 0.002 mg/kg (tomato) LOD Boscalid = 0.002 mg/kg (tomato) Time between harvest and extraction: 173 days
18SGS18 PL03/ Poland / NEU / 2018 Świecice Mazowieckie	Toma- to/Babinicz	05/05/2018 01//06- 25/06/2018 07/09/2018	A1: 102.18 + 407.18 A2: 98.89 + 394.09	610 590	-	2 28/08/2018 04/09/2018	BBCH 83-85	Fruits Fruits Fruits	0.043 0.028 0.016	0.216 0.163 0.076	0 1 3	Analytical phase report: 22/2019 LOD Pyraclostrobin = 0.002 mg/kg (tomato) LOD Boscalid = 0.002 mg/kg (tomato) Time between harvest and extraction: 162 days

- (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.1.5.3 Study 7

zRMS Comment: Study is accepted

Reference:	KCP 8.3.2.5
Report	Determination of the residues of Boscalid + Pyraclostrobin in/on tomato (outdoor) after two applications of Boscalid 26.7% + Pyraclostrobin 6.7% WG in Northern Europe – Hungary in 2019. P. Iszak, Report No. 034SRHU19R27
Guideline(s):	Yes - Regulations (EU) No. 283/2013 and 284/2013 implementing Regulation (EC) No. 1107/2009 of the European Parliament. - "Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997. - OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Three trials were conducted in Hungary in 2019. The field phase was performed in Kőszeg (SRHU19-192-034FR), in Vép (SRHU19-193-034FR), and in Szatymaz (SRHU19-194-034FR).

Two applications (8 days interval) of the formulated product Boscalid 26.7% + Pyraclostrobin 6.7% WG were applied at a target rate of 1.5 kg formulated product/ha to tomato, using conventional sprayer equipment, under open field condition, with the last application done 3 days before commercial harvest.

Specimens (fruits) were collected at 0, 1 and 3 days after application, frozen and shipped deep frozen to analytical facility.

Reference:	KCP 8.3.2.6
Report	Determination of the residue of boscalid + pyraclostrobin in/on tomato (outdoor) after two foliar application of Boscalid 26.7% + Pyraclostrobin 6.7% WG in northern Europe – Hungary in 2019, M. Zarębska, Report No. 173/2019
Guideline(s):	Yes

- Council Regulation (EC) No 440/2008, ICSO Procedure BA-AB/SPO-1 and research method No. BA-AB/MS/MB-5 and BA-AB/MS/MB-6
- Directive 2004/10/EC of the European Parliament and of the Council of 11th February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of the applications for test on chemical substances.
- The Minister of Health Regulations of 22nd May 2013 on Good Laboratory Practice and performance of studies in compliance with the principles of GLP (Dz. U. Z 2013 poz. 665)
- Act of 25th February 2011 on the chemical substances and their mixtures (The Republic of Poland Journal of Law of 2011, No. 63, item 322 with subsequent amendments)
- OECD Environmental Health and Safety Publications, Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 1 OECD Principles of Good Laboratory Practice, 1997.
- SANCO/825/00 rev. 8.1
- SANCO/3029/99 rev. 4

Deviations: No
GLP: Yes
Acceptability: Yes

The objective of this study was to determine the residues of Pyraclostrobin and Boscalid in raw agricultural commodities of tomatoes after application of Pyraclostrobin 6.7 + Boscalid 26.7% WG.

Materials

Mobile phase A: 0.1% (v/v) Formic acid in Water

1000 mL volumetric flask was half filled with water and 1 mL of formic acid was added. Volumetric flask was filled up to the mark with water, closed tightly and mixed by inverting several times. Solvent was transferred to amber HPLC solvent reservoir.

Mobile phase B: 0.1% (v/v) Formic acid in Acetonitrile

1000 mL volumetric flask was half filled with acetonitrile and 1 mL of formic acid was added. Volumetric flask was filled up to the mark with acetonitrile, closed tightly and mixed by inverting several times. Solvent was transferred to amber HPLC solvent reservoir.

Preparation of Sample Matrix

Portion of dry ice was added to a homogenizer apparatus (laboratory mill). Subsequent appropriate amount of sample was added to the apparatus in small portions. Sample was blended after each addition until a homogeneous mixture was obtained.

Contents of the apparatus were poured into polyethylene bags, and stored in a freezer until the last traces of dry ice have sublimed.

Sample extraction

10 g of homogenized matrix was weighed into a 50 mL PP centrifuge tube. Sample weight was recorded.

If necessary fortification of the concurrent recovery sample by aliquoting the fortification standard of Pyraclostrobin and Boscalid mixture onto the matrix was carried out at this step.

Fortification level	Standard dilution	Concentration of individual standard (µg/mL)	Volume used (µL)
LOQ (0.01 mg/kg)	1SW3	2	50
10LOQ (0.1 mg/kg)	1SW1	20	50

For extraction using an automatic pipette 10 mL of acetonitrile was added

The PP centrifuge tube was closed tightly and shake for 1 min automatically/

Liquid-Liquid Partition

Buffer-salt mixture (4 g +/- 0.2 g of magnesium sulfate anhydrous, 1 g of sodium chloride, 0.5 g NaCitrate dibasic sesquihydrate, 1 g NaCitrate tribasic dehydrate) was added and the centrifuge tube was closed and shaken by vortex for 1 min. The extract was centrifuged for 5 min.

ACCURACY and PRECISION

Analyte	Matrix	Fortification level (mg/kg)	Mean Recovery (%)	RSD (%)	n
Pyraclostrobin	Ion Mass Transition m/z 388 → 194 (Quantification)				
	Tomatoes	0.01	108	1.1	3
		0.1	109	0.8	3
	Ion Mass Transition m/z 388 → 163 (Confirmation)				
	Tomatoes	0.01	106	1.4	3
		0.1	105	2.3	3
Boscalid	Ion Mass Transition m/z 343 → 307 (Quantification)				
	Tomatoes	0.01	109	2.0	3
		0.1	106	3.6	3
	Ion Mass Transition m/z 343 → 140 (Confirmation)				
	Tomatoes	0.01	104	0.6	3
		0.1	106	2.2	3

Table A 9: Summary of the study

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pyraclostrobin	Boscalid		
(a)	(b)	(b)				€					(d)	€
SHRU19-192- 034FR/Hungary NEU / 2019 Kőszeg	Toma- to/Kecske méti 549	31/05/2019 07/2019 08/2019	A1: 399.63 + 99.91 A2: 393.59 + 98.4	749 738	-	2 06/08/2019 14/08/2019	BBCH 81 BBCH 85	Fruits Fruits Fruits	0.11 0.09 0.006	0.078 0.046 0.052	0 1 3	Analytical phase report: 173/2019 LOD Pyraclostrobin = 0.002 mg/kg (tomato) LOD Boscalid = 0.002 mg/kg (tomato) Time between harvest and extraction: 7 monrhs
SHRU19-193- 034FR/Hungary NEU / 2019 Vép	Toma- to/Kecske méti 549	03/07/2019 07/2019 08/2019	A1: 406.4 + 101.6 A2: 386.1 + 96.5	762 724	-	2 06/08/2019 14/08/2019	BBCH 83 BBCH 85	Fruits Fruits Fruits	0.049 0.034 0.011	0.278 0.170 0.075	0 1 3	Analytical phase report: 173/2019 LOD Pyraclostrobin = 0.002 mg/kg (tomato) LOD Boscalid = 0.002 mg/kg (tomato) Time between harvest and extraction: 7 monrhs
SHRU19-194- 034FR/Hungary NEU / 2019 Szatymaz	Toma- to/Kecske méti jubi- leum	31/05/2019 07/2019 08/2019	A1: 411.8 + 102.9 A2: 391.8 + 97.95	772 735	-	2 06/08/2019 14/08/2019	BBCH 83 BBCH 85	Fruits Fruits Fruits	0.027 0.006 0.017	0.138 0.025 0.090	0 1 3	Analytical phase report: 173/2019 LOD Pyraclostrobin = 0.002 mg/kg (tomato) LOD Boscalid = 0.002 mg/kg (tomato) Time between harvest and extraction: 7 monrhs

A 2.1.1.6 Onion

Table A 9: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (1)	2	0.1 Kg a.i./ha of pyraclostrobin + 0.4 kg a.i./ha of boscalid,	14	45	14

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

A 2.1.1.6.1 Study 7

zRMS Comment: Study is accepted

Procedural recoveries at the fortification levels 0.01 mg/kg for both ion mass transition of pyraclostrobin and boscalid were all in range of 70-110% and thus comply with the standard acceptance criteria of the guidance documents: SANCO/825/00 rev. 8.1, SANCO/3029/99 rev. 4 and SANTE/2020/12830, Rev.1 All precision values were <20%

Reference: KCP 8.3.3.1

Report Magnitude of the residue of pyraclostrobin + boscalid in onion (raw agricultural commodity – RAC) grown in open field conditions after two applications of formulated product pyraclostrobin 6.7 % + boscalid 26.7% WG – two harvest trials in Northern Europe – Poland, 2018. Rafal Figurski, 2019. Study No. PB-2018-12.

Guideline(s): Yes
- Regulation (EC) No 1107/2009 of 21 October 2009
- 7029/VI/95-rev 5., 22.07.97 and amendments
- ENV/MC/CHEM(98)17
- ENV/JM/MONO(99)22
- SANCO/3029/99 rev.4
- ENV/JM/MONO(2007)17

Deviations: No
GLP: Yes
Acceptability: Yes

A study on the magnitude of the residue of pyraclostrobin and boscalid in onion Raw Agricultural Commodity (RAC) was conducted in Poland following two foliar applications of formulated product Pyraclostrobin 6.7% + Boscalid 26.7% WG containing 67 g/kg of pyraclostrobin and 267 g/kg of boscalid. Two harvest trials were set up on onion in Poland. Trials consisted of one untreated plot U and one treated plot T. Foliar applications of Pyraclostrobin 6.7% + Boscalid 26.7% WG were performed on the treated plot at the target dose rate of 1.5 kg/ha (equivalent to 100 g as/ha of pyraclostrobin and 400 g as/ha of boscalid). The target spray of water volume was 200-600 litres per hectare.

Applications were performed following the target schedule:

- 1st application performed at 28 days before harvest
- 2nd application performed at 14 days before harvest.

In the trials RAC specimens for analyses (bulbs) were collected following the schedule:

- At 14 days after last application

All RAC specimens were deep frozen on the day of collection and stored at the target temperature below -18°C. All specimens remained deep frozen during storage at the test sites, during shipment to the analytical laboratory.

Reference: KCP 8.3.3.2

Report Pyraclostrobin and boscalid residues in onion after application of pyraclostrobin 6.7 + boscalid 26.7 % WG – analytical part. Zofia Hordyjewicz-Baran, 2019. Study No. 3/2019.

Guideline(s): Yes

- Council Regulation (EC) No 440/2008, ICSO Procedure BA-AB/SPO-1 and research method No. BA-AB/MS/MB-5 and BA-AB/MS/MB-6
- Directive 2004/10/EC of the European Parliament and of the Council of 11th February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of the applications for test on chemical substances.
- The Minister of Health Regulations of 22nd May 2013 on Good Laboratory Practice and performance of studies in compliance with the principles of GLP (Dz. U. Z 2013 poz. 665)
- Act of 25th February 2011 on the chemical substances and their mixtures (The Republic of Poland Journal of Law of 2011, No. 63, item 322 with subsequent amendments)
- OECD Environmental Health and Safety Publications, Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 1 OECD Principles of Good Laboratory Practice, 1997.
- SANCO/825/00 rev. 8.1

- SANCO/3029/99 rev. 4

Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods:

During the growing season of 2018, a total of two trials were conducted in onion in Northern Europe (Poland) to determine the magnitude of harvest residues of Pyraclostrobin and Boscalid in or on raw agricultural commodities (RAC).

The determination of Pyraclostrobin and Boscalid residues has been performed by liquid chromatography, and consists in an separation on a reversed-phase column and detection by tandem mass spectrometry (MS/MS) by electrospray (ESI) operating with optimized conditions.

The characteristics of the analytical method was as follows:

Preparation of Stock Standard Solutions

Preparation of stock solution of Pyraclostrobin for calibration

Reference Item	Purity of reference item* (%)	Weighed amount of reference item (mg)	Amount of analyte corrected for purity (mg)	Final volume (mL)	Solvent used for dilution	Equivalent conc. (mg/mL)	Reference of standard solution produced
Pyraclostrobin	99.9	20.04	20	10	Acetonitrile	2	1S1

Preparation of stock solution of Boscalid for calibration

Reference Item	Purity of reference item* (%)	Weighed amount of reference item (mg)	Amount of analyte corrected for purity (mg)	Final volume (mL)	Solvent used for dilution	Equivalent conc. (mg/mL)	Reference of standard solution produced
Boscalid	99.5	20.21	20	10	Acetonitrile	2	1S2

Preparation of Working, Fortification and Stability Testing Standard Solutions

Preparation of working solutions of Pyraclostrobin

Reference of standard solution used	Concentration Pyraclostrobin (µg/mL)	Volume taken (mL)	Final volume (mL)	Equivalent concentration (µg/mL)	Reference of standard solution produced (mixture)
1S1	2000	0.5	50	20	1SW1
1SW1	20	2	10	4	1SW2
1SW1	20	1	10	2	1SW3
1SW1	20	0.5	10	1	1SW4
1SW1	20	0.2	10	0.4	1SW5
1SW1	20	0.1	10	0.2	1SW6
1SW3	2	0.5	10	0.1	1SW7
1SW3	2	0.2	10	0.04	1SW8
1SW3	2	0.1	10	0.02	1SW9

Preparation of working solutions of Boscalid

Reference of standard solution used	Concentration Boscalid (µg/mL)	Volume taken (mL)	Final volume (mL)	Equivalent concentration (µg/mL)	Reference of standard solution produced (mixture)
1S2	2000	0.5	50	20	1SW1
1SW1	20	2	10	4	1SW2
1SW1	20	1	10	2	1SW3
1SW1	20	0.5	10	1	1SW4
1SW1	20	0.2	10	0.4	1SW5
1SW1	20	0.1	10	0.2	1SW6
1SW3	2	0.5	10	0.1	1SW7
1SW3	2	0.2	10	0.04	1SW8
1SW3	2	0.1	10	0.02	1SW9

Sample preparation

Preparation of Sample Matrix

A. Portion of dry ice was added to a homogenizer apparatus (Laboratory mill). Subsequent appropriate amount of sample was added to the apparatus in small portions. Sample was blended after each addition until a homogeneous mixture was obtained.

B. Contents of the apparatus were poured into polyethylene bags, and stored in a freezer until the last traces of dry ice have sublimed.

Sample Extraction

A. 10.00 g \pm 0.1 g of homogenized matrix was weighed into a 50 mL PP centrifuge tube. Sample weight was recorded.

B. If necessary fortification of the concurrent recovery sample(s) by aliquot-

ing the fortification standard of Pyraclostrobin and Boscalid mixture onto the matrix was carried out at this step. Fortification details are given below:

Fortification level	Standard dilution	Concentration of individual standard (µg/mL)	Volume used (µL)
LOQ (0.01 mg/kg)	1SW3	2	50

C. For extraction using an automatic pipette 10 mL of acetonitrile was added.

D. The PP centrifuge tube was closed tightly and shake for 1 min automatically.

Liquid-Liquid Partition

A. Buffer-salt mixture (4 g \pm 0.2 g of magnesium sulfate anhydrous, 1 g \pm 0.05 g of sodium chloride, 0,5 g \pm 0.03 g NaCitate dibasic sesquihydrate, 1 g \pm 0.05 g NaCitate tribasic dehydrate) was added and the centrifuge tube was closed and shaken by vortex for 1 min.

B. The extract was centrifuged at >3000 g for 5 min.

Sample purification

A. Using an automatic pipette 6 ml of sample extract supernatant was transferred to Dispersive SPE 12 ml centrifuge tubes containing 150 mg Supelclean PSA and 900 mg MgSO₄. The tube was shaken automatically for 30 sec.

Sample Dilution

A. An aliquot of 0.5 mL of purified sample extract was transferred to new Eppendorf safe-lock tube and subsequently diluted with 0.4 mL of Water, 0.05 mL acetonitrile (+1% Vol. formic acid) and 0.05 mL of acetonitrile.

B. Content was vortex gently and filtered through the 0.22 µm Teflon filter attached to a syringe direct into amber HPLC vial.

C. Vial was labelled so that it may be identified.

Final Determination

A. Final determination was performed using LC-MS/MS.

Results:

No residue above the LOD were detected in the control samples. The analytical results in mg per kg are summarized in Table A.2:

Table A 2: Summary of the study

Trial No./ Location/ EU zone/ Year	Commod- ity/ Varie- ty (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treat- ment			Dates of treatment or no. of treatments and last date €	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)		PHI (days) (d)	Details on trial €
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pyraclostrobin	Boscalid		
D-2018-12-F01/ Poland / NEU / 2018 Zafuski	Onion/ Supra	1) 20/04/2018 2) NA 3) 12/09/2018	A1: 95.94 103.11 A2: 382.34 415.53	572.5 615.3		24/07/2018 08/08/2018	BBCH 45 BBCH 45	Bulbs	<LOD (0.002)	<LOD (0.002)	14	Test site code: D-2018-12 LOQ Pyraclostrobin = 0.01 mg/kg (onion) LOD Pyraclostrobin = 0.002 mg/kg (onion) LOQ Boscalid = 0.01 mg/kg (onion) LOD Boscalid = 0.002 mg/kg (onion) Time between harvest and extraction: 144 days
D-2018-12-F02/ Poland / NEU / 2018 Blonie	Onion/ Supra	1) 12/04/2018 2) NA 3) 20/09/2018	A1: 97.15 105.26 A2: 387.15 419.46	580.0 628.3		24/07/2018 08/08/2018	BBCH 45 BBCH 45	Bulbs	<LOD (0.002)	<LOD (0.002)	14	Test site code: D-2018-12 LOQ Pyraclostrobin = 0.01 mg/kg (onion) LOD Pyraclostrobin = 0.002 mg/kg (onion) LOQ Boscalid = 0.01 mg/kg (onion) LOD Boscalid = 0.002 mg/kg (onion) Time between harvest and extraction: 152 days

A1 – pyraclostrobin

A2 – boscalid

(a) According to CODEX Classification / Guide

(b) Only if relevant

€ Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

€ Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.1.6.2 Study 8

zRMS Comment: Study is accepted

Procedural recoveries at the fortification levels 0.01 mg/kg for both ion mass transition of pyraclostrobin and boscalid were all in range of 70-110% and thus comply with the standard acceptance criteria of the guidance documents: SANCO/825/00 rev. 8.1, SANCO/3029/99 rev. 4 and SANTE/2020/12830, Rev.1
All precision values were <20%

Reference: KCP 8.3.3.3

Report Magnitude of the residue of pyraclostrobin + boscalid in onion (Raw Agricultural Commodity) after two application of Pyraclostrobin 6.7% + Boscalid 26.7% WG – two harvest trials and two decline curve trials in Poland – 2018, K. Łukaszewski, Report No. 18SGS19

Guideline(s): Yes

- Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
- Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue trials, July 22, 1997
- OECD Environmental Health and Safety Publications, Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 1 OECD Principles of Good Laboratory Practice, 1997.
- SANCO/825/00 rev. 8.1
- SANCO/3029/99 rev. 4

Deviations: No

GLP: Yes

Acceptability: Yes

Two harvest trials (HS) and two decline curve trials (DCS) were established in Poland. Each trial consisted of one untreated plot U and one treated plot T.

Two typical fungicide application of Pyraclostrobin 6.7% + Boscalid 26.7% WG were performed in each trial with boom sprayer on the treated plots all the target dose rate of 1.5 kg/ha. The target spray volume was 200-600 litres per hectare according to GAP. First application was performed 14 days before second application (actually was between BBCH 41 and 46). Second application was performed 41 and 49 growth stage (actually was between BBCH 47 and 49)

The spray mixture volumes remaining after the application were measured and the volumes applied to the treated plot were calculated to verify delivery rates. In all harvest trials (HS), RAC specimens for analyses (bulb) were collected at commercial harvest and 14 days after last application. In all decline curve trials (DCS), RAC specimens for analyses were collected according to list:

- 0 days after last application
- 3 days after last application
- 7 days after last application
- 14 days after last application

Reference: KCP 8.3.3.4

Report Magnitude of the residue of pyraclostrobin + boscalid in onion (raw agricultural commodity) after two applications of pyraclostrobin 6.7% + boscalid 26.7% WG – two

harvest trials and one decline curve trial in Poland -2018 – analytical phase. Zofia Hordyjewicz-Baran, 2019. Study No. 20/2019.

Guideline(s): Yes

- Council Regulation (EC) No 440/2008, ICSO Procedure BA-AB/SPO-1 and research method No. BA-AB/MS/MB-5 and BA-AB/MS/MB-6
- Directive 2004/10/EC of the European Parliament and of the Council of 11th February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of the applications for test on chemical substances.
- The Minister of Health Regulations of 22nd May 2013 on Good Laboratory Practice and performance of studies in compliance with the principles of GLP (Dz. U. Z 2013 poz. 665)
- Act of 25th February 2011 on the chemical substances and their mixtures (The Republic of Poland Journal of Law of 2011, No. 63, item 322 with subsequent amendments)
- OECD Environmental Health and Safety Publications, Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 1 OECD Principles of Good Laboratory Practice, 1997.
- SANCO/825/00 rev. 8.1
- SANCO/3029/99 rev. 4

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods:

During the growing season of 2018, a total of three trials were conducted in onion in Northern Europe (Poland) to determine the magnitude of harvest and decline of residues of Pyraclostrobin and Boscalid in or on raw agricultural commodities (RAC).

The determination of Pyraclostrobin and Boscalid residues has been performed by liquid chromatography, and consists in an separation on a reversed-phase column and detection by tandem mass spectrometry (MS/MS) by electrospray (ESI) operating with optimized conditions.

The characteristics of the analytical method was as follows:

Preparation of Stock Standard Solutions

Preparation of stock solution of Pyraclostrobin for calibration

Reference Item	Purity of reference item* (%)	Weighed amount of reference item (mg)	Amount of analyte corrected for purity (mg)	Final volume (mL)	Solvent used for dilution	Equivalent conc. (mg/mL)	Reference of standard solution produced
Pyraclostrobin	99.9	20.04	20	10	Acetonitrile	2	1S1

Preparation of stock solution of Boscalid for calibration

Reference Item	Purity of reference item* (%)	Weighed amount of reference item (mg)	Amount of analyte corrected for purity (mg)	Final volume (mL)	Solvent used for dilution	Equivalent conc. (mg/mL)	Reference of standard solution produced
Boscalid	99.5	20.21	20	10	Acetonitrile	2	1S2

Preparation of Working, Fortification and Stability Testing Standard Solutions

Preparation of working solutions of Pyraclostrobin

Reference of standard solution used	Concentration Pyraclostrobin (µg/mL)	Volume taken (mL)	Final volume (mL)	Equivalent concentration (µg/mL)	Reference of standard solution produced (mixture)
1S1	2000	0.5	50	20	1SW1
1SW1	20	2	10	4	1SW2
1SW1	20	1	10	2	1SW3
1SW1	20	0.5	10	1	1SW4
1SW1	20	0.2	10	0.4	1SW5
1SW1	20	0.1	10	0.2	1SW6
1SW3	2	0.5	10	0.1	1SW7
1SW3	2	0.2	10	0.04	1SW8
1SW3	2	0.1	10	0.02	1SW9

Preparation of working solutions of Boscalid

Reference of standard solution used	Concentration Boscalid (µg/mL)	Volume taken (mL)	Final volume (mL)	Equivalent concentration (µg/mL)	Reference of standard solution produced (mixture)
1S2	2000	0.5	50	20	1SW1
1SW1	20	2	10	4	1SW2
1SW1	20	1	10	2	1SW3
1SW1	20	0.5	10	1	1SW4
1SW1	20	0.2	10	0.4	1SW5
1SW1	20	0.1	10	0.2	1SW6
1SW3	2	0.5	10	0.1	1SW7
1SW3	2	0.2	10	0.04	1SW8
1SW3	2	0.1	10	0.02	1SW9

Sample preparation

Preparation of Sample Matrix

A. Portion of dry ice was added to a homogenizer apparatus (Laboratory mill). Subsequent appropriate amount of sample was added to the apparatus in small portions. Sample was blended after each addition until a homogeneous mixture was obtained.

B. Contents of the apparatus were poured into polyethylene bags and stored in a freezer until the last traces of dry ice have sublimed.

Sample Extraction

A. 10.00 g ± 0.1 g of homogenized matrix was weighed into a 50 mL PP centrifuge tube. Sample weight was recorded.

B. If necessary fortification of the concurrent recovery sample(s) by aliquoting the fortification standard of Pyraclostrobin and Boscalid mixture onto the matrix was carried out at this step. Fortification details are given below:

Fortification level	Standard dilution	Concentration of individual standard (µg/mL)	Volume used (µL)
LOQ (0.01 mg/kg)	1SW3	2	50

C. For extraction using an automatic pipette 10 mL of acetonitrile was added.

D. The PP centrifuge tube was closed tightly and shake for 1 min automatically.

Liquid-Liquid Partition

A. Buffer-salt mixture (4 g ± 0.2 g of magnesium sulfate anhydrous, 1 g ± 0.05 g of sodium chloride, 0.5 g ± 0.03 g NaCitrate dibasic sesquihydrate, 1 g ± 0.05 g NaCitrate tribasic dehydrate) was added and the centrifuge tube was closed and shaken by vortex for 1 min.

B. The extract was centrifuged at >3000 g for 5 min.

Sample purification

A. Using an automatic pipette 6 ml of sample extract supernatant was transferred to Dispersive SPE 12 ml centrifuge tubes containing 150 mg Supelclean PSA and 900 mg MgSO₄. The tube was shaken automatically for

30 sec.

Sample Dilution

- A. An aliquot of 0.5 mL of purified sample extract was transferred to new Eppendorf safe-lock tube and subsequently diluted with 0.4 mL of Water, 0.05 mL acetonitrile (+1% Vol. formic acid) and 0.05 mL of acetonitrile.
- B. Content was vortex gently and filtered through the 0.22 µm Teflon filter attached to a syringe direct into amber HPLC vial.
- C. Vial was labelled so that it may be identified.

Final Determination

- A. Final determination was performed using LC-MS/MS.

Results:

No residue above the LOD were detected in the control samples. The analytical results in mg per kg are summarized in Table A.2:

Table A 3: Summary of the study

Trial No./ Location/ EU zone/ Year	Commod- ity/ Varie- ty	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treat- ment			Dates of treatment or no. of treatments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pyraclostrobin	Boscalid		
(a)	(a)	(b)				(c)					(d)	(e)
18SGS19 PL01/ Poland / NEU / 2018 Sójki Łódzkie	On- ion/Majka	08/04/2018 - 15/08- 28/08/2018	A1: 106.53 + 424.53 A2: 102.51 + 408.51	424 408	-	2 25/07/2018 08/08/2018	BBCH 44 BBCH 49	Bulbs	<LOD (0.002)	0.014	14	Analytical phase report: 20/19 LOQ = 0.01 mg/kg (onion, bulbs) LOD = 0.002 mg/kg (onion, bulbs) Time between harvest and extraction: 7 months
18SGS19 PL02/ Poland / NEU / 2018 Orły Kolonia Mazowieckie	On- ion/Hystor e	20/04/2018 - 15/08- 20/08/2018	A1: 107.2 + 427.2 A2: 104.25 + 415.45	426.7 415	-	2 31/07/2018 13/08/2018	BBCH 41 BBCH 49	Bulbs	<LOD (0.002)	0.017	0 3 7 14	Analytical phase report: 20/19 LOQ = 0.01 mg/kg (onion, bulbs) LOD = 0.002 mg/kg (onion, bulbs) Time between harvest and extraction: 7 months
18SGS19 PL03/ Poland / NEU / 2018	On- ion/Wolsk a	14/04/2018 - 06/09/2018	A1: 103.38 + 411/98 A2: 107.54 + 428.54	514.4 534.9	-	2 07/08/2018 22/08/2018	BBCH 45 BBCH 47	Bulbs Bulbs Bulbs Bulbs	<LOQ (0.005) <LOD (0.002) <LOD (0.002) <LOD (0.002)	0.034 <LOQ (0.005) <LOQ (0.003) <LOD (0.002)	0 3 7 14	Analytical phase report: 20/19 LOQ = 0.01 mg/kg (onion, bulbs) LOD = 0.002 mg/kg (onion, bulbs) Time between harvest and extraction: 7 months
18SGS19 PL04/ Poland / NEU / 2018 Zakroczym Mazowieckie	Onion/Red Baron	20/03/2018 - 25/07- 08/08/2018	A1: 101.97 + 406.37 A2: 106.26 + 423.46	405.6 422.7	-	2 10/07/2018 24/07/2018	BBCH 46 BBCH 49	Bulbs Bulbs Bulbs Bulbs	<LOQ (0.005) <LOD (0.002) <LOD (0.002) <LOD (0.002)	0.041 0.026 0.017 0.017	0 3 7 14	Analytical phase report: 20/19 LOQ = 0.01 mg/kg (onion, bulbs) LOD = 0.002 mg/kg (onion, bulbs) Time between harvest and extraction: 7 months

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.1.6.3 Study 9

zRMS Comment: Study is accepted

Reference:	KCP 8.3.3.5
Report	Determination of the residues of Boscalid + Pyraclostrobin in/on onion after two applications of Boscalid 26.7% + Pyraclostrobin 6.7% WG in Northern Europe – Hungary in 2019, P. Iszak, Report No. 034SRHU19R28
Guideline(s):	Yes - Regulations (EU) No. 283/2013 and 284/2013 implementing Regulation (EC) No. 1107/2009 of the European Parliament. - "Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997. - OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Two trials were conducted in Hungary in 2019. The field phase was performed in Kőszeg (SRHU19-195-034FR), and in Vép (SRHU19-196-034FR).

Two applications (at BBCH 43 and at BBCH 49) of the formulated product Boscalid 26.7% + Pyraclostrobin 6.7% WG were applied at a target rate of 1.5 kg formulated product/ha (400 g boscalid and 100 g pyraclostrobin active ingredient/ha) onto the crop, under open field condition, with the last application done 14 days before normal commercial harvest.

Specimens (bulbs) were collected at 0, 3, 7 and 14 days after last application (DALA), frozen and shipped deep frozen to analytical facility for residue analysis.

Reference:	KCP 8.3.3.6
Report	Determination of the residue of Boscalid + Pyraclostrobin in/on onion after two foliar application of Boscalid 26.7% + Pyraclostrobin 6.7% WG in northern Europe – Hungary in 2019. M. Zarębskka, Report No. 175/2019

Guideline(s):	Yes <ul style="list-style-type: none">- Council Regulation (EC) No 440/2008, ICSO Procedure BA-AB/SPO-1 and research method No. BA-AB/MS/MB-5 and BA-AB/MS/MB-6- Directive 2004/10/EC of the European Parliament and of the Council of 11th February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of the applications for test on chemical substances.- The Minister of Health Regulations of 22nd May 2013 on Good Laboratory Practice and performance of studies in compliance with the principles of GLP (Dz. U. Z 2013 poz. 665)- Act of 25th February 2011 on the chemical substances and their mixtures (The Republic of Poland Journal of Law of 2011, No. 63, item 322 with subsequent amendments)- OECD Environmental Health and Safety Publications, Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 1 OECD Principles of Good Laboratory Practice, 1997.- SANCO/825/00 rev. 8.1- SANCO/3029/99 rev. 4
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of this study was to determine the residues of Pyraclostrobin and Boscalid in raw agricultural commodities of onions after application of Pyraclostrobin 6.7 + Boscalid 26.7% WG.

Materials

Mobile phase A: 0.1% (v/v) Formic acid in Water

1000 mL volumetric flask was half filled with water and 1 mL of formic acid was added. Volumetric flask was filled up to the mark with water, closed tightly and mixed by inverting several times. Solvent was transferred to amber HPLC solvent reservoir.

Mobile phase B: 0.1% (v/v) Formic acid in Acetonitrile

1000 mL volumetric flask was half filled with acetonitrile and 1 mL of formic acid was added. Volumetric flask was filled up to the mark with acetonitrile, closed tightly and mixed by inverting several times. Solvent was transferred to amber HPLC solvent reservoir.

Preparation of Sample Matrix

Portion of dry ice was added to a homogenizer apparatus (laboratory mill). Subsequent appropriate amount of sample was added to the apparatus in small portions. Sample was blended after each addition until a homogeneous mixture was obtained.

Contents of the apparatus were poured into polyethylene bags, and stored in a freezer until the last traces of dry ice have sublimed.

Sample extraction

10 g of homogenized matrix was weighed into a 50 mL PP centrifuge tube. Sample weight was recorded.

If necessary fortification of the concurrent recovery sample by aliquoting the fortification standard of Pyraclostrobin and Boscalid mixture onto the matrix was carried out at this step.

Fortification level	Standard dilution	Concentration of individual standard (µg/mL)	Volume used (µL)
LOQ (0.01 mg/kg)	1SW3	2	50
10LOQ (0.1 mg/kg)	1SW1	20	50

For extraction using an automatic pipette 10 mL of acetonitrile was added

The PP centrifuge tube was closed tightly and shake for 1 min automatically/

Liquid-Liquid Partition

Buffer-salt mixture (4 g +/- 0.2 g of magnesium sulfate anhydrous, 1 g of sodium chloride, 0.5 g NaCitrate dibasic sesquihydrate, 1 g NaCitrate tribasic dehydrate) was added and the centrifuge tube was closed and shaken by vortex for 1 min. The extract was centrifuged for 5 min.

ACCURACY and PRECISION

Analyte	Matrix	Fortification level (mg/kg)	Mean Recovery (%)	RSD (%)	n
Pyraclostrobin	Ion Mass Transition m/z 388 → 194 (Quantification)				
	Onions	0.01	89	6.3	3
		0.1	90	14.4	3
	Ion Mass Transition m/z 388 → 163 (Confirmation)				
	Onions	0.01	99	5.5	3
		0.1	96	15.5	3
Boscalid	Ion Mass Transition m/z 343 → 307 (Quantification)				
	Onions	0.01	88	4.1	3
		0.1	91	10.0	3

	Ion Mass Transition m/z 343 → 140 (Confirmation)				
	Onions	0.01	93	2.6	3
		0.1	93	11.2	3

Table A 12: Summary of the study

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pyraclostrobin	Boscalid		
(a)	(a)	(b)				(c)					(d)	(e)
SHRU19-195- 034FR/Hungary NEU / 2019 Kőszeg	On- ion/Sturon	20/04/2019 - 08/2019	A1: 378 + 94.9 A2: 434 + 108.9	378 434	-	2 15/07/2019 29/07/2019	BBCH 43 BBCH 47	Bulb Bulb Bulb Bulb	0.030 0.002 n.d. n.d.	0.135 0.016 0.009 0.002	0 3 7 14	Analytical phase report: 175/2019 LOD Pyraclostrobin = 0.002 mg/kg (onion) LOD Boscalid = 0.002 mg/kg (onion) Time between harvest and extraction: 7 months
SHRU19-196- 034FR/Hungary NEU / 2019 Vép	On- ion/Sturon	20/04/2019 - 08/2019	A1: 436 + 109.4 A2: 412.7 + 103.6	436 412.7	-	2 17/07/2019 31/07/2019	BBCH 43 BBCH 47	Bulb Bulb Bulb Bulb	0.006 n.d. n.d. n.d.	0.027 0.005 0.004 0.003	0 3 7 14	Analytical phase report: 175/2019 LOD Pyraclostrobin = 0.002 mg/kg (tomato) LOD Boscalid = 0.002 mg/kg (tomato) Time between harvest and extraction:

A 2.1.1.7 Carrot

Table A 4: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (1)	2	0.1 Kg pyraclostrobin/ha + 0.4 kg Boscalid/ha	14 days	BBCH 48	14

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

A 2.1.1.7.1 Study 9

zRMS Comment: Study is accepted

Procedural recoveries at the fortification levels 0.01 mg/kg for both ion mass transition of pyraclostrobin and boscalid were all in range of 70-110% and thus comply with the standard acceptance criteria of the guidance documents: SANCO/825/00 rev. 8.1, SANCO/3029/99 rev. 4 and SANTE/2020/12830, Rev.1
All precision values were <20%

Reference: KCP 8.3.4.1

Report Magnitude of the residue of Pyraclostrobin + Boscalid in carrot (Raw Agricultural Commodity) after two applications of Pyraclostrobin 6.7% + Boscalid 26.7% WG – two harvest trials and two decline curve trials in Poland – 2018, K. Łukaszewski, Report No. 18SGS20

Guideline(s): Yes

- Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
- Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue trials, July 22, 1997
- OECD Environmental Health and Safety Publications, Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 1 OECD Principles of Good Laboratory Practice, 1997.
- SANCO/825/00 rev. 8.1

- SANCO/3029/99 rev. 4

Deviations: No
GLP: Yes
Acceptability: Yes

Two harvest trials (HS) and two decline curve trials (DCS) were established in Poland. Each trial consisted of one untreated plot U and one treated plot T. Two typical for fungicide application of Pyraclostrobin 6.7% + Boscalid 26.7% WG were performed in each trial with boom sprayer on the treated plots at the target dose rate of 1.5 kg/ha. The reported spray volume was actually from 395.55 to 425.7 L/ha. First application was performed 14 days before second application (actually between BBCH 44 and 45). Second application was performed between 41 and 49 growth stage (actually between BBCH 45 and 48). The spray mixture volumes remaining after the application were measured and the volumes applied to the treated plot were calculated to verify delivery rates. In all harvest trials (HS), RAC specimens for analyses (Root) were collected at commercial harvest and 14 days after last application. In all decline curve trials (DCS), RAC specimens for analyses were collected according to list:

- 0 days after last application
- 3 days after last application
- 7 days after last application
- 14 days after last application

Reference: KCP 8.3.4.2

Report Magnitude of the residue of pyraclostrobin and boscalid in carrot (raw agricultural commodity) after two applications of pyraclostrobin 6.7% and boscalid 26.7% WG – two harvest trials and two decline curve trials in Poland – 2018. – analytical phase. Zofia Hordyjewicz-Baran, 2019. Study No. 21/2019.

Guideline(s): Yes

- Council Regulation (EC) No 440/2008, ICSO Procedure BA-AB/SPO-1 and research method No. BA-AB/MS/MB-5 and BA-AB/MS/MB-6
- Directive 2004/10/EC of the European Parliament and of the Council of 11th February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of the applications for test on chemical substances.
- The Minister of Health Regulations of 22nd May 2013 on Good Laboratory Practice and performance of studies in compliance with the principles of GLP (Dz. U. Z 2013 poz. 665)
- Act of 25th February 2011 on the chemical substances and their mixtures (The Republic of Poland Journal of Law of 2011, No. 63, item 322 with subsequent amendments)

- OECD Environmental Health and Safety Publications, Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 1 OECD Principles of Good Laboratory Practice, 1997.
- SANCO/825/00 rev. 8.1
- SANCO/3029/99 rev. 4

Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods:

During the growing season of 2018, a total of two trials were conducted in carrot in Northern Europe (Poland) to determine the magnitude of harvest residues of Pyraclostrobin and Boscalid in or on raw agricultural commodities (RAC).

The determination of Pyraclostrobin and Boscalid residues has been performed by liquid chromatography, and consists in an separation on a reversed-phase column and detection by tandem mass spectrometry (MS/MS) by electrospray (ESI) operating with optimized conditions.

The characteristics of the analytical method was as follows:

Preparation of Stock Standard Solutions

Preparation of stock solution of Pyraclostrobin for calibration

Reference Item	Purity of reference item* (%)	Weighed amount of reference item (mg)	Amount of analyte corrected for purity (mg)	Final volume (mL)	Solvent used for dilution	Equivalent conc. (mg/mL)	Reference of standard solution produced
Pyraclostrobin	99.9	20.04	20	10	Acetonitrile	2	1S1

Preparation of stock solution of Boscalid for calibration

Reference Item	Purity of reference item* (%)	Weighed amount of reference item (mg)	Amount of analyte corrected for purity (mg)	Final volume (mL)	Solvent used for dilution	Equivalent conc. (mg/mL)	Reference of standard solution produced
Boscalid	99.5	20.21	20	10	Acetonitrile	2	1S2

Preparation of Working, Fortification and Stability Testing Standard Solutions

Preparation of working solutions of Pyraclostrobin

Reference of standard solution used	Concentration Pyraclostrobin (µg/mL)	Volume taken (mL)	Final volume (mL)	Equivalent concentration (µg/mL)	Reference of standard solution produced (mixture)
1S1	2000	0.5	50	20	1SW1
1SW1	20	2	10	4	1SW2
1SW1	20	1	10	2	1SW3
1SW1	20	0.5	10	1	1SW4
1SW1	20	0.2	10	0.4	1SW5
1SW1	20	0.1	10	0.2	1SW6
1SW3	2	0.5	10	0.1	1SW7
1SW3	2	0.2	10	0.04	1SW8
1SW3	2	0.1	10	0.02	1SW9

Preparation of working solutions of Boscalid

Reference of standard solution used	Concentration Boscalid (µg/mL)	Volume taken (mL)	Final volume (mL)	Equivalent concentration (µg/mL)	Reference of standard solution produced (mixture)
1S2	2000	0.5	50	20	1SW1
1SW1	20	2	10	4	1SW2
1SW1	20	1	10	2	1SW3
1SW1	20	0.5	10	1	1SW4
1SW1	20	0.2	10	0.4	1SW5
1SW1	20	0.1	10	0.2	1SW6
1SW3	2	0.5	10	0.1	1SW7
1SW3	2	0.2	10	0.04	1SW8
1SW3	2	0.1	10	0.02	1SW9

Sample preparation

Preparation of Sample Matrix

A. Portion of dry ice was added to a homogenizer apparatus (Laboratory mill). Subsequent appropriate amount of sample was added to the apparatus in small portions. Sample was blended after each addition until a homogene-

ous mixture was obtained.

B. Contents of the apparatus were poured into polyethylene bags, and stored in a freezer until the last traces of dry ice have sublimed.

Sample Extraction

A. 10.00 g \pm 0.1 g of homogenized matrix was weighed into a 50 mL PP centrifuge tube. Sample weight was recorded.

B. If necessary fortification of the concurrent recovery sample(s) by aliquoting the fortification standard of Pyraclostrobin and Boscalid mixture onto the matrix was carried out at this step. Fortification details are given below:

Fortification level	Standard dilution	Concentration of individual standard ($\mu\text{g/mL}$)	Volume used (μL)
LOQ (0.01 mg/kg)	1SW3	2	50

C. For extraction using an automatic pipette 10 mL of acetonitrile was added.

D. The PP centrifuge tube was closed tightly and shake for 1 min automatically.

Liquid-Liquid Partition

A. Buffer-salt mixture (4 g \pm 0.2 g of magnesium sulfate anhydrous, 1 g \pm 0.05 g of sodium chloride, 0,5 g \pm 0.03 g NaCitrate dibasic sesquihydrate, 1 g \pm 0.05 g NaCitrate tribasic dehydrate) was added and the centrifuge tube was closed and shaken by vortex for 1 min.

B. The extract was centrifuged at >3000 g for 5 min.

Sample purification

A. Using an automatic pipette 6 ml of sample extract supernatant was transferred to Dispersive SPE 12 ml centrifuge tubes containing 150 mg Supelclean PSA and 900 mg MgSO₄. The tube was shaken automatically for 30 sec.

Sample Dilution

A. An aliquot of 0.5 mL of purified sample extract was transferred to new Eppendorf safe-lock tube and subsequently diluted with 0.4 mL of Water, 0.05 mL acetonitrile (+1% Vol. formic acid) and 0.05 mL of acetonitrile.

B. Content was vortex gently and filtered through the 0.22 µm Teflon filter attached to a syringe direct into amber HPLC vial.

C. Vial was labelled so that it may be identified.

Final Determination

A. Final determination was performed using LC-MS/MS.

Results:

No residue above the LOD were detected in the control samples. The analytical results in mg per kg are summarized in Table A.2:

Table A 13: Summary of the study

Trial No./ Location/ EU zone/ Year	Commod- ity/ Varie- ty	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pyraclostrobin	Boscalid		
(a)	(a)	(b)				(c)					(d)	(e)
18SGS20 PL 01/ Poland / NEU / 2018 Teresin Mazowieckie	Car- rot/Krysty na	01/06/2018 - 29/09- 05/10/2018	A1: 106.93 + 426.13 A2: 102.11 + 406.91	425.7 406.3	-	2 13/09/2018 26/09/2018	BBCH 45 BBCH 48	Roots	0.023	0.065	14±1	Analytical phase report: 21/2009 LOQ Pyraclostrobin = 0.01 mg/kg (carrot) LOD Pyraclostrobin = 0.002 mg/kg (carrot) LOQ Boscalid = 0.01 mg/kg (carrot) LOD Boscalid = 0.002 mg/kg (carrot) Time between harvest and extraction: 4 months
18SGS20 PL02/ Poland / NEU / 2018 Sójki Łódzkie	Car- rot/Sircana	13/04/2018 - 08/10- 12/10/2018	A1: 103.92 + 414.12 A2: 103.31 + 411.71	413.7 411.3	-	2 18/09/2018 02/10/2018	BBCH 45 BBCH 47	Roots	0.016	0.053	14±1	Analytical phase report: 21/2009 LOQ Pyraclostrobin = 0.01 mg/kg (carrot) LOD Pyraclostrobin = 0.002 mg/kg (carrot) LOQ Boscalid = 0.01 mg/kg (carrot) LOD Boscalid = 0.002 mg/kg (carrot) Time between harvest and extraction: 4 months
18SGS20 PL03/ Poland / NEU / 2018 Kroczewo Mazowieckie	Car- rot/Naba	15/06/2018 - 01/10- 12/10/2018	A1: 104.99 + 418.39 A2: 101.64 + 405.04	416.7 403.1	-	2 19/09/2018 02/10/2018	BBCH 45 BBCH 45	Roots Roots Roots Roots	0.016 0.019 0.027 0.015	0.035 0.050 0.070 0.046	0 3 7±1 14±1	Analytical phase report: 21/2009 LOQ Pyraclostrobin = 0.01 mg/kg (carrot) LOD Pyraclostrobin = 0.002 mg/kg (carrot) LOQ Boscalid = 0.01 mg/kg (carrot) LOD Boscalid = 0.002 mg/kg (carrot) Time between harvest and extraction: 4 months
18SGS20 PL04/ Poland / NEU / 2018 Budy Siennickie Mazowieckie	Car- rot/Baltim ore	03/06/2018 - 27/09- 09/10/2018	A1: 99.16 + 395.16 A2: 103.85 + 413.85	395.55 413.3	-	2 30/08/2018 12/09/2018	BBCH 44 BBCH 45	Roots Roots Roots Roots	0.013 0.025 0.024 0.021	0.060 0.082 0.101 0.096	0 3 7±1 14±1	Analytical phase report: 21/2009 LOQ Pyraclostrobin = 0.01 mg/kg (carrot) LOD Pyraclostrobin = 0.002 mg/kg (carrot) LOQ Boscalid = 0.01 mg/kg (carrot) LOD Boscalid = 0.002 mg/kg (carrot) Time between harvest and extraction: 4 months

- (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)

- (e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.1.7.2 Study 10

zRMS Comment: Study is accepted

Procedural recoveries at the fortification levels 0.01 mg/kg for both ion mass transition of pyraclostrobin and boscalid were all in range of 70-110% and thus comply with the standard acceptance criteria of the guidance documents: SANCO/825/00 rev. 8.1, SANCO/3029/99 rev. 4 and SANTE/2020/12830, Rev.1
All precision values were <20%

Reference: KCP 8.3.4.3

Report Magnitude of the residue of pyraclostrobin + boscalid in carrot (raw agricultural commodity – RAC) grown in open field conditions after two applications of formulated product pyraclostrobin 6.7 % + boscalid 26.7% WG – two harvest trials in Northern Europe – Poland, 2018. Rafal Figurski, 2019. Study No. PB-2018-13.

Guideline(s): Yes
- Regulation (EC) No 1107/2009 of 21 October 2009
- 7029/VI/95-rev 5., 22.07.97 and amendments
- ENV/MC/CHEM(98)17
- ENV/JM/MONO(99)22
- SANCO/3029/99 rev.4
- ENV/JM/MONO(2007)17

Deviations: No

GLP: Yes

Acceptability: Yes

A study on the magnitude of the residue of pyraclostrobin and boscalid in carrot raw Agricultural Commodity (RAC) was conducted in Poland following two foliar applications of formulated product Pyraclostrobin 6.7% + Boscalid 26.7% WG containing 6.7 g/kg of pyraclostrobin and 26.7 g/kg of boscalid.

Two harvest trials were set up on carrot in Poland. Trials consisted of one untreated plot U and one treated plot T. Foliar applications of Pyraclostrobin 6.7% + Boscalid 26.7% WG were performed on the treated plot at the target dose rate of 1.5 kg/ha (equivalent to 100 g as/ha of pyraclostrobin and 400 g as/ha of boscalid). The target spray of water volume was 200-600.

Applications were performed following the schedule:

- 1st application performed 28 days before harvest
- 2nd application performed 14 days before harvest

In the trials, RAC specimens for analyses (roots) were collected following the schedule:

- At commercial harvest (BBCH 49): 14 days after last application

All RAC specimens were deep frozen on the day of collection and stored at the target temperature below -18°C. All specimens remained deep frozen during storage at the test sites, during shipment to the analytical laboratory.

Reference: KCP 8.3.4.4

Report Pyraclostrobin and boscalid residues in carrots after application of pyraclostrobin 6.7 + boscalid 26.7 % WG – analytical part. Zofia Hordyjewicz-Baran, 2019. Study No. 6/2019.

Guideline(s): Yes
- Council Regulation (EC) No 440/2008, ICSO Procedure BA-AB/SPO-1 and research

method No. BA-AB/MS/MB-5 and BA-AB/MS/MB-6

- Directive 2004/10/EC of the European Parliament and of the Council of 11th February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of the applications for test on chemical substances.
- The Minister of Health Regulations of 22nd May 2013 on Good Laboratory Practice and performance of studies in compliance with the principles of GLP (Dz. U. Z 2013 poz. 665)
- Act of 25th February 2011 on the chemical substances and their mixtures (The Republic of Poland Journal of Law of 2011, No. 63, item 322 with subsequent amendments)
- OECD Environmental Health and Safety Publications, Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 1 OECD Principles of Good Laboratory Practice, 1997.
- SANCO/825/00 rev. 8.1
- SANCO/3029/99 rev. 4

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods:

During the growing season of 2018, a total of two trials were conducted in carrot in Northern Europe (Poland) to determine the magnitude of harvest residues of Pyraclostrobin and Boscalid in or on raw agricultural commodities (RAC).

The determination of Pyraclostrobin and Boscalid residues has been performed by liquid chromatography, and consists in an separation on a reversed-phase column and detection by tandem mass spectrometry (MS/MS) by electrospray (ESI) operating with optimized conditions.

The characteristics of the analytical method was as follows:

Preparation of Stock Standard Solutions

Preparation of stock solution of Pyraclostrobin for calibration

Reference Item	Purity of reference item* (%)	Weighed amount of reference item (mg)	Amount of analyte corrected for purity (mg)	Final volume (mL)	Solvent used for dilution	Equivalent conc. (mg/mL)	Reference of standard solution produced
Pyraclostrobin	99.9	20.04	20	10	Acetonitrile	2	1S1

Preparation of stock solution of Boscalid for calibration

Reference Item	Purity of reference item* (%)	Weighed amount of reference item (mg)	Amount of analyte corrected for purity (mg)	Final volume (mL)	Solvent used for dilution	Equivalent conc. (mg/mL)	Reference of standard solution produced
Boscalid	99.5	20.21	20	10	Acetonitrile	2	1S2

Preparation of Working, Fortification and Stability Testing Standard Solutions

Preparation of working solutions of Pyraclostrobin

Reference of standard solution used	Concentration Pyraclostrobin (µg/mL)	Volume taken (mL)	Final volume (mL)	Equivalent concentration (µg/mL)	Reference of standard solution produced (mixture)
1S1	2000	0.5	50	20	1SW1
1SW1	20	2	10	4	1SW2
1SW1	20	1	10	2	1SW3
1SW1	20	0.5	10	1	1SW4
1SW1	20	0.2	10	0.4	1SW5
1SW1	20	0.1	10	0.2	1SW6
1SW3	2	0.5	10	0.1	1SW7
1SW3	2	0.2	10	0.04	1SW8
1SW3	2	0.1	10	0.02	1SW9

Preparation of working solutions of Boscalid

Reference of standard solution used	Concentration Boscalid (µg/mL)	Volume taken (mL)	Final volume (mL)	Equivalent concentration (µg/mL)	Reference of standard solution produced (mixture)
1S2	2000	0.5	50	20	1SW1
1SW1	20	2	10	4	1SW2
1SW1	20	1	10	2	1SW3
1SW1	20	0.5	10	1	1SW4
1SW1	20	0.2	10	0.4	1SW5
1SW1	20	0.1	10	0.2	1SW6
1SW3	2	0.5	10	0.1	1SW7
1SW3	2	0.2	10	0.04	1SW8
1SW3	2	0.1	10	0.02	1SW9

Sample preparation

Preparation of Sample Matrix

A. Portion of dry ice was added to a homogenizer apparatus (Laboratory mill). Subsequent appropriate amount of sample was added to the apparatus in small portions. Sample was blended after each addition until a homogeneous mixture was obtained.

B. Contents of the apparatus were poured into polyethylene bags, and stored in a freezer until the last traces of dry ice have sublimed.

Sample Extraction

A. 10.00 g ± 0.1 g of homogenized matrix was weighed into a 50 mL PP centrifuge tube. Sample weight was recorded.

B. If necessary fortification of the concurrent recovery sample(s) by aliquoting the fortification standard of Pyraclostrobin and Boscalid mixture onto the matrix was carried out at this step. Fortification details are given below:

Fortification level	Standard dilution	Concentration of individual standard (µg/mL)	Volume used (µL)
LOQ (0.01 mg/kg)	1SW3	2	50

C. For extraction using an automatic pipette 10 mL of acetonitrile was added.

D. The PP centrifuge tube was closed tightly and shake for 1 min automatically.

Liquid-Liquid Partition

A. Buffer-salt mixture (4 g ± 0.2 g of magnesium sulfate anhydrous, 1 g ± 0.05 g of sodium chloride, 0.5 g ± 0.03 g NaCitrate dibasic sesquihydrate, 1 g ± 0.05 g NaCitrate tribasic dehydrate) was added and the centrifuge tube was closed and shaken by vortex for 1 min.

B. The extract was centrifuged at >3000 g for 5 min.

Sample purification

A. Using an automatic pipette 6 ml of sample extract supernatant was trans-

ferred to Dispersive SPE 12 ml centrifuge tubes containing 150 mg Supelclean PSA and 900 mg MgSO₄. The tube was shaken automatically for 30 sec.

Sample Dilution

- A. An aliquot of 0.5 mL of purified sample extract was transferred to new Eppendorf safe-lock tube and subsequently diluted with 0.4 mL of Water, 0.05 mL acetonitrile (+1% Vol. formic acid) and 0.05 mL of acetonitrile.
- B. Content was vortex gently and filtered through the 0.22 µm Teflon filter attached to a syringe direct into amber HPLC vial.
- C. Vial was labelled so that it may be identified.

Final Determination

- A. Final determination was performed using LC-MS/MS.

Results:

No residue above the LOD were detected in the control samples. The analytical results in mg per kg are summarized in Table A.2:

Table A 14: Summary of the study

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treat- ment			Dates of treatment or no. of treatments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pyraclostrobin	Boscalid		
(a)	(a)	(b)				(c)					(d)	(e)
D-2018-13-F01/ Poland / NEU / 2018 <u>Teresin</u>	Carrot/ Karotan	1) 10/04/2018 2) NA 3) 10/09/2018	A1: 96.08 A2: 382.88 400.23	573.6 599.7		27/08/2018 10/09/2018	BBCH 46 BBCH 48	Roots	<LOD (0.002)	<LOD (0.002)	14	Test site code: D-2018-13 LOQ Pyraclostrobin = 0.01 mg/kg (carrot) LOD Pyraclostrobin = 0.002 mg/kg (carrot) LOQ Boscalid = 0.01 mg/kg (carrot) LOD Boscalid = 0.002 mg/kg (carrot) Time between harvest and extraction: 157 days
D-2018-13-F02/ Poland / NEU / 2018 <u>Zaturski</u>	Carrot/ Nerac	1) 21/04/2018 2) NA 3) 20/09/2018	A1: 105.39 A2: 419.99 381.01	629.0 570.7		02/08/2018 16/08/2018	BBCH 47 BBCH 48	Roots	<LOD (0.002)	<LOD (0.002)	14	Test site code: D-2018-13 LOQ Pyraclostrobin = 0.01 mg/kg (carrot) LOD Pyraclostrobin = 0.002 mg/kg (carrot) LOQ Boscalid = 0.01 mg/kg (carrot) LOD Boscalid = 0.002 mg/kg (carrot) Time between harvest and extraction: 147 days

A1 – pyraclostrobin

A2 - boscalid

- (a) According to CODEX Classification / Guide
- (b) Only if relevant
- (c) Year must be indicated
- (d) Days after last application (Label pre-harvest interval, PHI, underline)
- (e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.1.7.3 Study 11

zRMS Comment: Study is accepted

Information on storage time should be confirmed and Table A-15 should be completed by the applicant. Procedural recoveries at the fortification levels 0.01 mg/kg for both ion mass transition of pyraclostrobin and boscalid were all in range of 70-110% and thus comply with the standard acceptance criteria of the guidance documents: SANCO/825/00 rev. 8.1, SANCO/3029/99 rev. 4 and SANTE/2020/12830, Rev.1 All precision values were <20%

Reference: KCP 8.3.4.5

Report Decline residue of pyraclo 6.7 + boscalid 26.7% WG. Raw agricultural commodity in the United Kingdom, 2018. Zofia Hordyjewicz-Baran, 2019. Study No. 54/2019.

Guideline(s): Yes

- Council Regulation (EC) No 440/2008, ICSO Procedure BA-AB/SPO-1 and research method No. BA-AB/MS/MB-5 and BA-AB/MS/MB-6
- Directive 2004/10/EC of the European Parliament and of the Council of 11th February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of the applications for test on chemical substances.
- The Minister of Health Regulations of 22nd May 2013 on Good Laboratory Practice and performance of studies in compliance with the principles of GLP (Dz. U. Z 2013 poz. 665)
- Act of 25th February 2011 on the chemical substances and their mixtures (The Republic of Poland Journal of Law of 2011, No. 63, item 322 with subsequent amendments)
- OECD Environmental Health and Safety Publications, Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 1 OECD Principles of Good Laboratory Practice, 1997.
- SANCO/825/00 rev. 8.1
- SANCO/3029/99 rev. 4

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods:

During the growing season of 2018, a total of one trial was conducted in carrot in Northern Europe (United Kingdom) to determine the magnitude of harvest residues of Pyraclostrobin and Boscalid in or on raw agricultural commodities (RAC).

The determination of Pyraclostrobin and Boscalid residues has been performed by liquid chromatography, and consists in an separation on a reversed-phase column and detection by tandem mass spectrometry (MS/MS) by electrospray (ESI) operating with optimized conditions.

The characteristics of the analytical method was as follows:

Preparation of Stock Standard Solutions

Preparation of stock solution of Pyraclostrobin for calibration

Reference Item	Purity of reference item* (%)	Weighed amount of reference item (mg)	Amount of analyte corrected for purity (mg)	Final volume (mL)	Solvent used for dilution	Equivalent conc. (mg/mL)	Reference of standard solution produced
Pyraclostrobin	99.9	20.04	20	10	Acetonitrile	2	1S1

Preparation of stock solution of Boscalid for calibration

Reference Item	Purity of reference item* (%)	Weighed amount of reference item (mg)	Amount of analyte corrected for purity (mg)	Final volume (mL)	Solvent used for dilution	Equivalent conc. (mg/mL)	Reference of standard solution produced
Boscalid	99.5	20.21	20	10	Acetonitrile	2	1S2

Preparation of Working, Fortification and Stability Testing Standard Solutions

Preparation of working solutions of Pyraclostrobin

Reference of standard solution used	Concentration Pyraclostrobin (µg/mL)	Volume taken (mL)	Final volume (mL)	Equivalent concentration (µg/mL)	Reference of standard solution produced (mixture)
1S1	2000	0.5	50	20	1SW1
1SW1	20	2	10	4	1SW2
1SW1	20	1	10	2	1SW3
1SW1	20	0.5	10	1	1SW4
1SW1	20	0.2	10	0.4	1SW5
1SW1	20	0.1	10	0.2	1SW6
1SW3	2	0.5	10	0.1	1SW7
1SW3	2	0.2	10	0.04	1SW8
1SW3	2	0.1	10	0.02	1SW9

Preparation of working solutions of Boscalid

Reference of standard solution used	Concentration Boscalid (µg/mL)	Volume taken (mL)	Final volume (mL)	Equivalent concentration (µg/mL)	Reference of standard solution produced (mixture)
1S2	2000	0.5	50	20	1SW1
1SW1	20	2	10	4	1SW2
1SW1	20	1	10	2	1SW3
1SW1	20	0.5	10	1	1SW4
1SW1	20	0.2	10	0.4	1SW5
1SW1	20	0.1	10	0.2	1SW6
1SW3	2	0.5	10	0.1	1SW7
1SW3	2	0.2	10	0.04	1SW8
1SW3	2	0.1	10	0.02	1SW9

Sample preparation

Preparation of Sample Matrix

A. Portion of dry ice was added to a homogenizer apparatus (Laboratory mill). Subsequent appropriate amount of sample was added to the apparatus in small portions. Sample was blended after each addition until a homogeneous mixture was obtained.

B. Contents of the apparatus were poured into polyethylene bags, and stored in a freezer until the last traces of dry ice have sublimed.

Sample Extraction

A. 10.00 g ± 0.1 g of homogenized matrix was weighed into a 50 mL PP centrifuge tube. Sample weight was recorded.

B. If necessary fortification of the concurrent recovery sample(s) by aliquoting the fortification standard of Pyraclostrobin and Boscalid mixture onto the matrix was carried out at this step. Fortification details are given below:

Fortification level	Standard dilution	Concentration of individual standard (µg/mL)	Volume used (µL)
LOQ (0.01 mg/kg)	1SW3	2	50

- C. For extraction using an automatic pipette 10 mL of acetonitrile was added.
- D. The PP centrifuge tube was closed tightly and shake for 1 min automatically.

Liquid-Liquid Partition

- A. Buffer-salt mixture ($4\text{ g} \pm 0.2\text{ g}$ of magnesium sulfate anhydrous, $1\text{ g} \pm 0.05\text{ g}$ of sodium chloride, $0.5\text{ g} \pm 0.03\text{ g}$ NaCitrate dibasic sesquihydrate, $1\text{ g} \pm 0.05\text{ g}$ NaCitrate tribasic dehydrate) was added and the centrifuge tube was closed and shaken by vortex for 1 min.
- B. The extract was centrifuged at $>3000\text{ g}$ for 5 min.

Sample purification

- A. Using an automatic pipette 6 ml of sample extract supernatant was transferred to Dispersive SPE 12 ml centrifuge tubes containing 150 mg Supelclean PSA, 15 mg Supelclean ENVI-Carb and 900 mg MgSO_4 (for samples, with a high content of carotinoides, EN). The tube was shaken automatically for 2 min.

Sample Dilution

- A. An aliquot of 0.5 mL of purified sample extract was transferred to new Eppendorf safe-lock tube and subsequently diluted with 0.4 mL of Water, 0.05 mL acetonitrile (+1% Vol. formic acid) and 0.05 mL of acetonitrile.
- B. Content was vortex gently and filtered through the $0.22\text{ }\mu\text{m}$ Teflon filter attached to a syringe direct into amber HPLC vial.
- C. Vial was labelled so that it may be identified.

Final Determination

- A. Final determination was performed using LC-MS/MS.

Results:

No residue above the LOD were detected in the control samples. The analytical results in mg per kg are summarized in Table A.2:

Table A 15: Summary of the study

Trial No./ Location/ EU zone/ Year	Commodi- ty/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pyraclostrobin	Boscalid		
	(a)	(b)				(c)					(d)	(e)
ACE-18-061/ UK / NEU / 2018	Carrot/	1) 2) 3)						Roots Roots Roots Roots	<LOD (0.002) 0.014 0.026 0.026	<LOD (0.002) 0.059 0.110 0.135	0 3 7 14	Analytical phase report: 54/2019 LOD Pyraclostrobin = 0.002 mg/kg (carrot) LOD Boscalid = 0.002 mg/kg (carrot) Time between harvest and extraction: - days

- (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.1.7.4 Study 9

zRMS Comment: Study is accepted

Procedural recoveries at the fortification levels 0.01 mg/kg for both ion mass transition of pyraclostrobin and boscalid were all in range of 70-110% and thus comply with the standard acceptance criteria of the guidance documents: SANCO/825/00 rev. 8.1, SANCO/3029/99 rev. 4 and SANTE/2020/12830, Rev.1
All precision values were <20%

Reference:	KCP 8.3.4.6
Report	Determination of the residues of Boscalid + Pyraclostrobin in/on carrot after two applications of Boscalid 26.7% + Pyraclostrobin 6.7% WG in Northern Europe – Hungary in 2019, A. Horváth, Report No. 034SRHU19R29
Guideline(s):	Yes - Regulations (EU) No. 283/2013 and 284/2013 implementing Regulation (EC) No. 1107/2009 of the European Parliament. - "Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997. - OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

One trial was conducted in Hungary in 2019. The field phase was performed in Kőszeg.

Two applications (14 days interval) of the formulated product Boscalid 26.7% + Pyraclostrobin 6.7% WG were applied at a target rate of 1.5 kg / ha to carrot, using conventional sprayer equipment, under open field condition between BBCH 41 and 49.

Specimens (roots) were collected at 0, 3, 7 and 14 days after application, frozen and shipped deep frozen to analytical facility for residue analysis.

Reference:	KCP 8.3.4.7
Report	Determination of the residue of boscalid + pyraclostrobin in/on carrot after two foliar applications of Boscalid 26.7% + Pyraclostrobin 6.7% WG in northern Europe – Hungary in 2019, M. Zarębska, Report No. 174/2019

Guideline(s):	Yes <ul style="list-style-type: none">- Council Regulation (EC) No 440/2008, ICSO Procedure BA-AB/SPO-1 and research method No. BA-AB/MS/MB-5 and BA-AB/MS/MB-6- Directive 2004/10/EC of the European Parliament and of the Council of 11th February 2004 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of the applications for test on chemical substances.- The Minister of Health Regulations of 22nd May 2013 on Good Laboratory Practice and performance of studies in compliance with the principles of GLP (Dz. U. Z 2013 poz. 665)- Act of 25th February 2011 on the chemical substances and their mixtures (The Republic of Poland Journal of Law of 2011, No. 63, item 322 with subsequent amendments)- OECD Environmental Health and Safety Publications, Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 1 OECD Principles of Good Laboratory Practice, 1997.- SANCO/825/00 rev. 8.1- SANCO/3029/99 rev. 4
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of this study was to determine the residues of Pyraclostrobin and Boscalid in raw agricultural commodities of carrots after application of Pyraclostrobin 6.7 + Boscalid 26.7% WG.

Materials

Mobile phase A: 0.1% (v/v) Formic acid in Water

1000 mL volumetric flask was half filled with water and 1 mL of formic acid was added. Volumetric flask was filled up to the mark with water, closed tightly and mixed by inverting several times. Solvent was transferred to amber HPLC solvent reservoir.

Mobile phase B: 0.1% (v/v) Formic acid in Acetonitrile

1000 mL volumetric flask was half filled with acetonitrile and 1 mL of formic acid was added. Volumetric flask was filled up to the mark with acetonitrile, closed tightly and mixed by inverting several times. Solvent was transferred to amber HPLC solvent reservoir.

Preparation of Sample Matrix

Portion of dry ice was added to a homogenizer apparatus (laboratory mill). Subsequent appropriate amount of sample was added to the apparatus in small portions. Sample was blended after each addition until a homogeneous mixture was obtained.

Contents of the apparatus were poured into polyethylene bags, and stored in a freezer until the last traces of dry ice have sublimed.

Sample extraction

10 g of homogenized matrix was weighed into a 50 mL PP centrifuge tube. Sample weight was recorded.

If necessary fortification of the concurrent recovery sample by aliquoting the fortification standard of Pyraclostrobin and Boscalid mixture onto the matrix was carried out at this step.

Fortification level	Standard dilution	Concentration of individual standard (µg/mL)	Volume used (µL)
LOQ (0.01 mg/kg)	1SW3	2	50
10LOQ (0.1 mg/kg)	1SW1	20	50

For extraction using an automatic pipette 10 mL of acetonitrile was added

The PP centrifuge tube was closed tightly and shake for 1 min automatically/

Liquid-Liquid Partition

Buffer-salt mixture (4 g +/- 0.2 g of magnesium sulfate anhydrous, 1 g of sodium chloride, 0.5 g NaCitrate dibasic sesquihydrate, 1 g NaCitrate tribasic dehydrate) was added and the centrifuge tube was closed and shaken by vortex for 1 min. The extract was centrifuged for 5 min.

ACCURACY and PRECISION

Analyte	Matrix	Fortification level (mg/kg)	Mean Recovery (%)	RSD (%)	n
Pyraclostrobin	Ion Mass Transition m/z 388 → 194 (Quantification)				
	Carrots	0.01	80	14.4	3
		0.1	99	17.1	3
	Ion Mass Transition m/z 388 → 163 (Confirmation)				
	Carrots	0.01	83	12.3	3
		0.1	100	15.9	3
Boscalid	Ion Mass Transition m/z 343 → 307 (Quantification)				
	Carrots	0.01	85	9.8	3
		0.1	96	11.5	3
	Ion Mass Transition m/z 343 → 140 (Confirmation)				
	Carrots	0.01	85	10.6	3
		0.1	97	12.1	3

Table A 16: Summary of the study

Trial No./ Location/ EU zone/ Year	Commodi- ty/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)		PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Pyraclostrobin	Boscalid		
(a)	(a)	(b)				(c)					(d)	(e)
SHRU19-197- 034FR/Hungary NEU / 2018	Car- rot/Flakker	02/04/2019 - 08/2019	A1: 347.5 + 115.83 A2: 402 +136	370 429	-	2 19/07/2019 02/08/2019	BBCH 41 BBCH 45	Roots Roots Roots Roots	0.024 0.018 0.023 0.024	0.219 0.217 0.212 0.232	0 3 7 14	Analytical phase report: 174/2019 LOD Pyraclostrobin = 0.002 mg/kg (carrot) LOD Boscalid = 0.002 mg/kg (carrot) Time between harvest and extraction: 7 months

A 2.1.2 Magnitude of residues in livestock

No new data were submitted in the framework of this application.

A 2.1.3 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

A 2.1.3.1 Distribution of the residue in peel/pulp

No new data were submitted in the framework of this application

A 2.1.3.2 Processing studies on a core set of representative processes

No new data were submitted in the framework of this application.

A 2.1.4 Magnitude of residues in representative succeeding crops

No new data were submitted in the framework of this application.

A 2.1.5 Other/Special Studies

No new data were submitted in the framework of this application

A 2.2 Boscalid

A 2.2.1 Stability of residues

A 2.2.1.1 Stability of residues during storage of samples

A 2.2.1.1.1 Storage stability of residues in plant products

No new data were submitted in the framework of this application.

A 2.2.1.1.2 Storage stability of residues in animal products

No new data were submitted in the framework of this application.

A 2.2.2 Nature of residues in plants, livestock and processed commodities

A 2.2.2.1 Nature of residue in plants

A 2.2.2.1.1 Nature of residue in primary crops

No new data were submitted in the framework of this application.

A 2.2.2.1.2 Nature of residue in rotational crops

No new data were submitted in the framework of this application.

A 2.2.2.1.3 Nature of residues in processed commodities

No new data were submitted in the framework of this application.

A 2.2.2.2 Nature of residues in livestock

No new data were submitted in the framework of this application.

A 2.2.3 Magnitude of residues in plants

No additional studies were necessary/provided

A 2.2.4 Magnitude of residues in livestock

A 2.2.4.1 Livestock feeding studies

No new data were submitted in the framework of this application.

A 2.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

A 2.2.5.1 Distribution of the residue in peel/pulp

No new data were submitted in the framework of this application.

A 2.2.5.2 Processing studies on a core set of representative processes

No new data were submitted in the framework of this application.

A 2.2.6 Magnitude of residues in representative succeeding crops

No new data were submitted in the framework of this application.


A 2.2.7 Other/Special Studies

No new data were submitted in the framework of this application.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 Pyraclostrobin

A 3.1.1 TMDI calculations



European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

comments:

Pyraclostrobin (F) (F)

LOQs (mg/kg) range from: 0.01 to: 0.10

Toxicological reference values

ADI (mg/kg bw/day): 0.03 ARID (mg/kg bw): 0.03

Source of ADI: Source of ARID:

Year of evaluation: Year of evaluation:

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

		No of diets exceeding the ADI : ---								Exposure resulting from	
	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/IEDI calculation (based on average food consumption)	86%	NL toddler	25.84	18%	Apples	15%	Oranges	7%	Pears	3%	15%
	86%	DE child	25.73	27%	Oranges	21%	Apples	5%	Table grapes	1%	12%
	58%	NL child	17.31	10%	Apples	9%	Oranges	6%	Sugar beet roots	2%	14%
	53%	FR child 3-15 yr	16.01	23%	Oranges	4%	Other lettuce and other salad plants	3%	Wheat	2%	7%
	48%	GEMS/Food G07	14.52	10%	Wine grapes	9%	Oranges	3%	Wheat	1%	5%
	48%	IE adult	14.44	8%	Wine grapes	7%	Oranges	5%	Grapefruits	1%	4%
	47%	GEMS/Food G08	14.11	7%	Oranges	5%	Wheat	4%	Onions	0.5%	11%
	46%	GEMS/Food G11	13.78	7%	Wine grapes	5%	Oranges	3%	Lamb's lettuce/corn salads	0.9%	5%
	44%	GEMS/Food G10	13.19	8%	Oranges	3%	Onions	3%	Wine grapes	0.9%	8%
	44%	GEMS/Food G08	13.17	7%	Wine grapes	3%	Oranges	3%	Barley	1.0%	8%
	44%	DE women 14-50 yr	13.07	13%	Oranges	6%	Wine grapes	4%	Apples	0.8%	8%
	41%	GEMS/Food G15	12.27	7%	Wine grapes	4%	Oranges	3%	Wheat	0.9%	8%
	41%	DE general	12.18	10%	Oranges	6%	Wine grapes	4%	Apples	0.9%	7%
	39%	FR toddler 2-3 yr	11.77	10%	Oranges	5%	Apples	5%	Mandarins	2%	8%
	37%	RO general	11.09	11%	Wine grapes	4%	Onions	3%	Wheat	0.9%	11%
	37%	FR adult	11.08	15%	Wine grapes	5%	Other lettuce and other salad plants	4%	Oranges	0.8%	3%
	37%	PT general	11.00	17%	Wine grapes	4%	Oranges	3%	Wheat	0.1%	4%
	35%	UK toddler	10.54	13%	Oranges	3%	Apples	3%	Wheat	1%	8%
	34%	ES child	10.05	14%	Oranges	3%	Wheat	3%	Lettuces	2%	4%
	31%	SE general	9.36	5%	Oranges	3%	Mandarins	3%	Lettuces	1%	7%
	30%	NL general	8.99	7%	Oranges	4%	Wine grapes	2%	Apples	0.8%	5%
	29%	ES adult	8.61	9%	Oranges	4%	Lettuces	3%	Wine grapes	0.8%	3%
	28%	DK child	8.36	4%	Apples	4%	Rye	3%	Wheat	1%	5%
	27%	UK infant	8.10	9%	Oranges	3%	Apples	2%	Carrots	2%	7%
	25%	IT toddler	7.60	4%	Wheat	4%	Other lettuce and other salad plants	3%	Oranges	0.2%	4%
	24%	IT adult	7.27	5%	Other lettuce and other salad plants	3%	Wheat	3%	Lettuces	0.1%	3%
	23%	FI 3 yr	7.05	3%	Mandarins	2%	Onions	2%	Oat	0.2%	8%
	23%	UK vegetarian	6.81	6%	Oranges	5%	Wine grapes	1%	Wheat	0.2%	3%
	20%	FI adult	5.95	6%	Coffee beans	3%	Oranges	2%	Wine grapes	0.1%	3%
	20%	UK adult	5.90	7%	Wine grapes	4%	Oranges	1%	Wheat	0.4%	3%
	18%	FI 6 yr	5.40	2%	Mandarins	1%	Onions	1%	Strawberries	0.1%	6%
	18%	DK adult	5.28	6%	Wine grapes	2%	Apples	1.0%	Oranges	0.6%	3%
	17%	FR infant	5.18	3%	Apples	2%	Carrots	2%	Oranges	0.8%	5%
	13%	PL general	3.85	3%	Apples	2%	Onions	1%	Table grapes	0.0%	5%
	10%	LT adult	3.11	3%	Apples	0.7%	Rye	0.7%	Wheat	0.5%	2%
	4%	IE child	1.30	0.8%	Wheat	0.6%	Oranges	0.5%	Apples	0.2%	1%

A 3.1.2 IEDI calculations

Not relevant

A 3.1.3 IESTI calculations - Raw commodities

Show results of IESTI calculation only for crops with GAPs under assessment								
Unprocessed commodities	Results for children No. of commodities for which ARID/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARID/ADI is exceeded (IESTI):			
	3				***			
	IESTI				IESTI			
	Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	122%	Cherries (sweet)	3 / 3	37	100%	Cherries (sweet)	3 / 3	30
	114%	Onions	1.5 / 1.5	34	74%	Onions	1.5 / 1.5	22
	108%	Carrots	0.5 / 0.5	32	68%	Currants (red, black and	3 / 3	20
	92%	Raspberries (red and yellow)	3 / 3	28	56%	Head cabbages	0.4 / 0.4	17
	92%	Celeriacs/turnip rooted	0.5 / 0.5	28	54%	Raspberries (red and yellow)	3 / 3	16
	82%	Strawberries	1.5 / 1.5	25	47%	Strawberries	1.5 / 1.5	14
79%	Currants (red, black and	3 / 3	24	33%	Carrots	0.5 / 0.5	9.9	
59%	Head cabbages	0.4 / 0.4	18	27%	Aubergines/egg plants	0.3 / 0.3	8.1	
58%	Tomatoes	0.3 / 0.3	17	20%	Celeriacs/turnip rooted	0.5 / 0.5	5.9	
41%	Radishes	0.5 / 0.5	12	17%	Radishes	0.5 / 0.5	5.2	
36%	Parsnips	0.3 / 0.3	11	16%	Tomatoes	0.3 / 0.3	4.8	
25%	Aubergines/egg plants	0.3 / 0.3	7.5	14%	Parsnips	0.3 / 0.3	4.2	
19%	Beetroots	0.1 / 0.1	5.7	10%	Swedes/rutabagas	0.09 / 0.09	3.1	
16%	Swedes/rutabagas	0.09 / 0.09	4.7	8%	Beetroots	0.1 / 0.1	2.3	
11%	Turnips	0.09 / 0.09	3.2	7%	Horseradishes	0.3 / 0.3	2.2	
Expand/collapse list								
Total number of commodities exceeding the ARID/ADI in children and adult diets (IESTI calculation)				3				

A 3.1.4 IESTI calculations - Raw commodities (GAP under assessment considering STMR/HR)

Unprocessed commodities	Results for children				Results for adults			
	No. of commodities for which ARID/ADI is exceeded (IESTI):				No. of commodities for which ARID/ADI is exceeded (IESTI):			
	IESTI				IESTI			
	Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	92%	Celeriacs/turnip rooted	0.5 / 0.5	28	56%	Head cabbages	0.4 / 0.4	17
	82%	Strawberries	1.5 / 1.5	25	53%	Cherries (sweet)	3 / 1.6	16
	65%	Cherries (sweet)	3 / 1.6	20	47%	Strawberries	1.5 / 1.5	14
	59%	Head cabbages	0.4 / 0.4	18	46%	Currants (red, black and	3 / 2.1	14
	58%	Tomatoes	0.3 / 0.3	17	27%	Aubergines/egg plants	0.3 / 0.3	8.1
	55%	Currants (red, black and	3 / 2.1	17	23%	Raspberries (red and yellow)	3 / 1.3	7.0
	41%	Radishes	0.5 / 0.5	12	20%	Celeriacs/turnip rooted	0.5 / 0.5	5.9
	40%	Raspberries (red and yellow)	3 / 1.3	12	17%	Radishes	0.5 / 0.5	5.2
	36%	Parsnips	0.3 / 0.3	11	16%	Tomatoes	0.3 / 0.3	4.8
	25%	Aubergines/egg plants	0.3 / 0.3	7.5	14%	Parsnips	0.3 / 0.3	4.2
	19%	Beetroots	0.1 / 0.1	5.7	10%	Onions	1.5 / 0.21	3.1
	16%	Onions	1.5 / 0.21	4.8	10%	Swedes/rutabagas	0.09 / 0.09	3.1
	16%	Swedes/rutabagas	0.09 / 0.09	4.7	8%	Beetroots	0.1 / 0.1	2.3
	13%	Carrots	0.5 / 0.06	3.8	7%	Horseradishes	0.3 / 0.3	2.2
	11%	Turnips	0.09 / 0.09	3.2	4%	Carrots	0.5 / 0.06	1.2
	Expand/collapse list							
	Total number of commodities exceeding the ARID/ADI in children and adult diets (IESTI calculation)							

A 3.1.5 IESTI calculations - Processed commodities


Processed commodities	Results for children				Results for adults			
	No of processed commodities for which ARID/ADI is exceeded (IESTI):				No of processed commodities for which ARID/ADI is exceeded (IESTI):			
	2				1			
Processed commodities	IESTI				IESTI			
	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	288%	Currents (red, black and white	3 / 3	88	128%	Currents (red, black and	3 / 3	38
	117%	Raspberries / juice	3 / 3	35	47%	Onions / boiled	1.5 / 1.5	14
	73%	Sugar beets (root) / sugar	0.2 / 2.4	22	30%	Celeriacs / boiled	0.5 / 0.5	9.1
	60%	Carrots / juice	0.5 / 0.5	18	29%	Sugar beets (root) / sugar	0.2 / 2.4	8.8
	51%	Parsnips / boiled	0.3 / 0.3	15	21%	Parsnips / boiled	0.3 / 0.3	6.4
	24%	Celeriacs / juice	0.5 / 0.5	7.2	14%	Carrots / canned	0.5 / 0.5	4.1
	19%	Tomatoes / juice	0.3 / 0.3	5.7	13%	Beetroots / boiled	0.1 / 0.1	3.9
	16%	Shallots / boiled	0.3 / 0.3	4.9	13%	Head cabbages / canned	0.4 / 0.4	3.8
	15%	Turnips / boiled	0.09 / 0.09	4.6	8%	Tomatoes / sauce/puree	0.3 / 0.3	2.5
	15%	Beetroots / boiled	0.1 / 0.1	4.4	6%	Shallots / boiled	0.3 / 0.3	1.9
	10%	Tomatoes / sauce/puree	0.3 / 0.3	2.9	6%	Turnips / boiled	0.09 / 0.09	1.7
	9%	Salsifies / boiled	0.1 / 0.1	2.6	3%	Salsifies / boiled	0.1 / 0.1	0.82
	8%	Head cabbages / canned	0.4 / 0.4	2.3	2%	Jerusalem artichokes / boiled	0.06 / 0.06	0.49
	5%	Jerusalem artichokes / boiled	0.06 / 0.06	1.5	0.08%	Chicory roots / processed (not	0.06 / 0.06	0.02
	0.2%	Chicory roots / processed (not	0.06 / 0.06	0.06	#UICZBA!	#UICZBA!	#UICZBA!	#UICZBA!

A 3.1.6 IESTI calculations - Processed commodities (GAP under assessment considering STMR/HR)

Processed commodities	Results for children				Results for adults			
	No of processed commodities for which ARID/ADI is exceeded (IESTI):				No of processed commodities for which ARID/ADI is exceeded (IESTI):			
	---				---			
Processed commodities	IESTI				IESTI			
	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	90%	Currents (red, black and white	3 / 0.94	27	40%	Currents (red, black and	3 / 0.94	12
	73%	Sugar beets (root) / sugar	0.2 / 2.4	22	30%	Celeriacs / boiled	0.5 / 0.5	9.1
	51%	Parsnips / boiled	0.3 / 0.3	15	29%	Sugar beets (root) / sugar	0.2 / 2.4	8.8
	34%	Raspberries / juice	3 / 0.87	10	21%	Parsnips / boiled	0.3 / 0.3	6.4
	24%	Celeriacs / juice	0.5 / 0.5	7.2	13%	Beetroots / boiled	0.1 / 0.1	3.9
	19%	Tomatoes / juice	0.3 / 0.3	5.7	13%	Head cabbages / canned	0.4 / 0.4	3.8
	16%	Shallots / boiled	0.3 / 0.3	4.9	8%	Tomatoes / sauce/puree	0.3 / 0.3	2.5
	15%	Turnips / boiled	0.09 / 0.09	4.6	7%	Onions / boiled	1.5 / 0.21	2.0
	15%	Beetroots / boiled	0.1 / 0.1	4.4	6%	Shallots / boiled	0.3 / 0.3	1.9
	10%	Tomatoes / sauce/puree	0.3 / 0.3	2.9	6%	Turnips / boiled	0.09 / 0.09	1.7
	9%	Salsifies / boiled	0.1 / 0.1	2.6	3%	Salsifies / boiled	0.1 / 0.1	0.82
	8%	Head cabbages / canned	0.4 / 0.4	2.3	2%	Jerusalem artichokes / boiled	0.06 / 0.06	0.49
	5%	Jerusalem artichokes / boiled	0.06 / 0.06	1.5	1%	Carrots / canned	0.5 / 0.04	0.33
	5%	Carrots / juice	0.5 / 0.04	1.4	0.08%	Chicory roots / processed (not	0.06 / 0.06	0.02
	0.2%	Chicory roots / processed (not	0.06 / 0.06	0.06	#UICZBA!	#UICZBA!	#UICZBA!	#UICZBA!

A 3.2 Boscalid

A 3.2.1 TMDI calculations



European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Boscalid (F) (R) (F)

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw/day): 0.04 ARID (mg/kg bw): not necessary

Source of ADI: Source of ARID:

Year of evaluation: Year of evaluation:

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:


Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

			No of diets exceeding the ADI :		26				Exposure resulting from		
	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/IEDI calculation (based on average food consumption)	398%	NL toddler	159.12	90%	Spinaches	54%	Apples	31%	Escaroles/broad-leaved endives	0.4%	
	260%	DE child	104.12	62%	Apples	25%	Spinaches	20%	Oranges	0.2%	
	224%	GEMS/Food G11	89.62	34%	Sugar canes	28%	Soyabeans	20%	Potatoes	0.4%	
	223%	GEMS/Food G10	89.22	41%	Lettuces	24%	Soyabeans	23%	Sugar canes	0.3%	
	217%	NL child	86.79	31%	Spinaches	29%	Apples	17%	Potatoes	0.4%	
	216%	GEMS/Food G06	86.30	29%	Sugar canes	27%	Tomatoes	14%	Wheat	0.2%	
	214%	GEMS/Food G08	85.42	28%	Sugar canes	25%	Lettuces	20%	Potatoes	0.3%	
	210%	GEMS/Food G07	84.04	30%	Lettuces	27%	Sugar canes	19%	Potatoes	0.4%	
	187%	GEMS/Food G15	74.93	23%	Sugar canes	18%	Potatoes	14%	Lettuces	0.3%	
	184%	IE adult	73.67	18%	Sweet potatoes	16%	Wine grapes	16%	Wine grapes	0.3%	
	169%	SE general	67.42	50%	Lettuces	21%	Potatoes	8%	Spinaches	0.8%	
	145%	IT adult	57.95	47%	Lettuces	20%	Other lettuce and other salad plants	12%	Spinaches	0.0%	
	144%	ES adult	57.57	67%	Lettuces	9%	Spinaches	6%	Oranges	0.3%	
	143%	FR child 3-15 yr	57.39	17%	Oranges	14%	Other lettuce and other salad plants	13%	Spinaches	0.5%	
	140%	ES child	56.04	52%	Lettuces	11%	Oranges	10%	Spinaches	0.5%	
	132%	RO general	52.61	21%	Wine grapes	19%	Potatoes	18%	Head cabbages	0.2%	
	131%	IT toddler	52.32	36%	Lettuces	14%	Other lettuce and other salad plants	13%	Wheat	0.0%	
	131%	PT general	52.28	31%	Wine grapes	27%	Potatoes	13%	Lettuces	0.0%	
	130%	NL general	52.03	19%	Spinaches	12%	Escaroles/broad-leaved endives	12%	Potatoes	0.3%	
	127%	FR toddler 2-3 yr	50.95	20%	Spinaches	16%	Apples	10%	Beans (with pods)	0.4%	
	120%	DE women 14-50 yr	48.05	14%	Lettuces	13%	Apples	10%	Wine grapes	0.2%	
	119%	DK child	47.57	18%	Lettuces	16%	Cucumbers	12%	Potatoes	0.4%	
	115%	DE general	46.08	12%	Apples	12%	Lettuces	10%	Wine grapes	0.2%	
	112%	FI 3 yr	44.80	24%	Potatoes	10%	Cucumbers	8%	Spinaches	0.0%	
	108%	FR adult	43.27	29%	Wine grapes	19%	Other lettuce and other salad plants	7%	Spinaches	0.3%	
	102%	FR infant	40.73	33%	Spinaches	10%	Potatoes	8%	Apples	0.1%	
	102%	UK toddler	40.68	17%	Potatoes	10%	Oranges	9%	Apples	0.3%	
	92%	FI 6 yr	36.75	19%	Potatoes	10%	Lettuces	7%	Cucumbers	0.0%	
	87%	UK infant	34.89	16%	Potatoes	8%	Apples	7%	Carrots	0.3%	
	82%	UK vegetarian	32.87	18%	Lettuces	10%	Wine grapes	7%	Potatoes	0.0%	
	68%	UK adult	27.26	15%	Lettuces	14%	Wine grapes	7%	Potatoes	0.2%	
	67%	PL general	26.89	17%	Potatoes	10%	Apples	7%	Tomatoes	0.0%	
	66%	DK adult	26.26	12%	Wine grapes	11%	Lettuces	6%	Potatoes	0.2%	
	63%	FI adult	25.07	18%	Lettuces	6%	Potatoes	4%	Tomatoes	0.7%	
	60%	LT adult	23.88	16%	Potatoes	9%	Apples	8%	Lettuces	0.1%	
	18%	IE child	7.24	3%	Potatoes	2%	Wheat	2%	Apples	0.0%	

Conclusion:
The estimated TMDI/IEDI was in the range of 0 % to 397.8 % of the ADI.
For 26 diet(s) the ADI is exceeded.

A 3.2.2 IEDI calculations



European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

Boscalid (F) (R) (F)

LOOs (mg/kg) range from: **0.01** to: **0.05**

Toxicological reference values

ADI (mg/kg bw/day): **0.04** ARID (mg/kg bw): **not necessary**

Source of ADI: Source of ARID: Year of evaluation: Year of evaluation:

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

		No of diets exceeding the ADI : ---								Exposure resulting from	
	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI(NED)/IEDI calculation (based on average food consumption)	84%	NL toddler	33.54	11%	Apples	11%	Oranges	10%	Spinaches	0.1%	
	69%	GEMS/Food G11	27.55	34%	Sugar canes	4%	Oranges	4%	Wine grapes	0.1%	
	68%	DE child	27.11	20%	Oranges	13%	Apples	5%	Table grapes	0.1%	
	68%	GEMS/Food G06	27.06	29%	Sugar canes	5%	Oranges	4%	Table grapes	0.1%	
	64%	GEMS/Food G07	25.64	27%	Sugar canes	7%	Oranges	5%	Wine grapes	0.1%	
	60%	GEMS/Food G08	23.84	28%	Sugar canes	4%	Wine grapes	3%	Lettuces	0.1%	
	56%	GEMS/Food G10	22.41	23%	Sugar canes	6%	Oranges	5%	Lettuces	0.1%	
	53%	NL child	21.33	8%	Sugar beet roots	7%	Oranges	6%	Apples	0.1%	
	53%	GEMS/Food G15	21.01	23%	Sugar canes	4%	Wine grapes	3%	Oranges	0.1%	
	48%	IE adult	19.26	5%	Oranges	4%	Wine grapes	4%	Other leafy brassica	0.1%	
	42%	FR child 3-15 yr	16.72	17%	Oranges	4%	Sugar beet roots	2%	Apples	0.1%	
	37%	DE women 14-50 yr	14.63	10%	Oranges	5%	Sugar beet roots	3%	Wine grapes	0.1%	
	34%	DE general	13.56	8%	Oranges	4%	Sugar beet roots	3%	Wine grapes	0.1%	
	34%	ES child	13.49	11%	Oranges	6%	Chards/beet leaves	6%	Lettuces	0.1%	
	33%	FR toddler 2-3 yr	13.18	7%	Oranges	4%	Mandarins	3%	Apples	0.0%	
	31%	ES adult	12.58	7%	Lettuces	6%	Oranges	6%	Chards/beet leaves	0.0%	
	29%	SE general	11.74	6%	Lettuces	4%	Oranges	2%	Mandarins	0.0%	
	28%	NL general	11.22	5%	Oranges	3%	Sugar beet roots	2%	Spinaches	0.1%	
	26%	UK toddler	11.08	10%	Oranges	3%	Sugar beet roots	2%	Apples	0.0%	
	27%	IT adult	10.79	5%	Lettuces	5%	Chards/beet leaves	2%	Other lettuce and other salad plants	0.0%	
	26%	RO general	10.46	6%	Wine grapes	4%	Head cabbages	2%	Aubergines/egg plants	0.0%	
	26%	IT toddler	10.44	5%	Chards/beet leaves	4%	Lettuces	2%	Oranges	0.0%	
	24%	FR adult	9.78	8%	Wine grapes	3%	Oranges	2%	Other lettuce and other salad plants	0.1%	
	23%	PT general	9.33	9%	Wine grapes	3%	Oranges	1%	Lettuces	0.0%	
	21%	UK infant	8.26	6%	Oranges	2%	Apples	1%	Sugar beet roots	0.0%	
	20%	FR infant	8.05	4%	Spinaches	2%	Chards/beet leaves	2%	Apples	0.0%	
	19%	DK child	7.73	3%	Cucumbers	2%	Apples	2%	Lettuces	0.0%	
	19%	FI 3 yr	7.42	2%	Mandarins	2%	Cucumbers	2%	Strawberries	0.0%	
	18%	UK vegetarian	7.14	4%	Oranges	3%	Wine grapes	2%	Lettuces	0.0%	
	15%	UK adult	5.90	4%	Wine grapes	3%	Oranges	2%	Lettuces	0.0%	
15%	FI 6 yr	5.82	2%	Mandarins	1%	Strawberries	1%	Cucumbers	0.0%		
12%	FI adult	4.98	2%	Oranges	2%	Lettuces	1%	Wine grapes	0.7%		
12%	DK adult	4.89	3%	Wine grapes	1%	Lettuces	1%	Apples	0.0%		
10%	PL general	3.91	2%	Apples	1%	Table grapes	1%	Head cabbages	0.0%		
9%	LT adult	3.50	2%	Apples	1%	Head cabbages	0.9%	Lettuces	0.0%		
3%	IE child	1.29	0.4%	Oranges	0.3%	Wheat	0.3%	Apples	0.0%		

Conclusion:
The estimated long-term dietary intake (TMDI(NED)/IEDI) was below the ADI.
The long-term intake of residues of Boscalid (F) (R) (F) is unlikely to present a public health concern.

A 3.2.3 IESTI calculations - Raw commodities

Not relevant

A 3.2.4 IESTI calculations - Processed commodities

Not relevant.

Appendix 4 Additional information provided by the applicant

No additional data submitted.