REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: A22773A

Product name(s): Orondis Evo

Chemical active substance(s):

Azoxystrobin, 250 g/L
Oxathiapiprolin, 12 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(New authorization)

Applicant: Syngenta

Submission date: November 2021, updated April 2023

MS Finalisation date: July 2022 (initial Core Assessment), June 2023 (final Core Assessment)

Version history

When	What
November 2021	Part B - Section 7 - Core Assessment - Central Zone
February 2022	7.1.1 Critical GAP table edited to match central B0 GAP table
July 2022	KCA1 6.1 & KCA1 6.10: Stability data for the storage of azoxystrobin residues in honey, along with honey residue data from a new study, have been added to section 7.2.1, 7.2.7 and Appendix 2.
July 2022	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through and shaded for transparency~~.
April 2023	Table 7.1-1 has been updated to display the most critical GAP table relevant to the metabolism and residue risk assessment. Code numbers have been included in accordance with Annex I to Regulation (EU) No 396/2005.
June 2023	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow.

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

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 A22773A are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central Zone for tomato, eggplant, bell pepper, cucumber and zucchini (courgette), melon, watermelon, pumpkin and squash, lettuce, salad plants, sweet basil and spinach, leek, spring onion and hops.

A list of all intended uses within the Central Zone is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedances of the current MRLs for azoxystrobin and oxathiapiprolin as laid down in Reg. (EU) 396/2005 are not expected.

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

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

According to available data, no specific mitigation measures should apply.

Data gaps

Noticed data gaps are: None

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~~	~~11~~	~~12~~	~~13~~	~~14~~	~~15~~
~~Use-No.~~ [e]	~~Member state(s)~~	~~Crop and/ or situation~~ ~~(crop destination / purpose of crop)~~	~~F, Fn, Fpn G, Gn, Gpn or I~~	~~Pests or Group of pests controlled~~ ~~(additionally: developmental stages of the pest or pest group)~~	~~Application~~				~~Application rate~~				~~PHI (days)~~	~~Remarks:~~ ~~e.g. g safener/synergist per ha~~ [f]	
					~~Method / Kind~~	~~Timing / Growth stage of crop & season~~	~~Max. number a) per use b) per crop/ season~~	~~Min. interval between applications (days)~~	~~L A22773A / ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g OXTP/ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g AZT/ha a) max. rate per appl. b) max. total rate per crop/season~~	~~Water L/ha~~ ~~min / max~~			
~~Zonal uses (field or outdoor uses, certain types of protected crops)~~															
~~BE-2~~	~~Belgium~~	~~lettuce~~	~~F~~	~~*Bremia lactucae*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~14~~	~~maximum 2 application per year on the same field~~	~~A~~
~~BE-3~~	~~Belgium~~	~~leek~~	~~F~~	~~*Alternaria porri*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~7~~		~~A~~
~~BE-4~~	~~Belgium~~	~~leek~~	~~F~~	~~*Phytophthora porri*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~7~~		~~A~~
~~BE-5~~	~~Belgium~~	~~leek~~	~~F~~	~~*Puccinia allii*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~7~~		~~A~~
~~BE-6~~	~~Belgium~~	~~leek~~	~~F~~	~~*Puccinia porri*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~7~~		~~A~~
~~CZ-1~~	~~Czech Republic~~	~~cucumber~~	~~F~~	~~*Cladosporium sp.*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~CZ-2~~	~~Czech Republic~~	~~cucumber~~	~~F~~	~~*Pseudoperonospora cubensis*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~CZ-3~~	~~Czech Republic~~	~~cucumber~~	~~F~~	~~*Didymella bryoniae*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~CZ-4~~	~~Czech Republic~~	~~hop~~	~~F~~	~~*Pseudoperonospora humuli*~~	~~foliar~~	~~BBCH 21-89~~	~~a) 2 b) 2~~	~~12-16~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~700-3300~~	~~28~~		~~A~~
~~CZ-5~~	~~Czech Republic~~	~~leek~~	~~F~~	~~*Alternaria porri*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~7~~		~~A~~
~~CZ-6~~	~~Czech Republic~~	~~leek~~	~~F~~	~~*Phytophthora porri*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~7~~	~~-~~	~~A~~

~~1~~	~~2~~	~~3~~	~~4~~	~~5~~	~~6~~	~~7~~	~~8~~	~~9~~	~~10~~	~~11~~	~~11~~	~~12~~	~~13~~	~~14~~	~~15~~
~~**Use-No.** (e)~~	~~**Member state(s)**~~	~~**Crop and/ or situation** **(crop destination / purpose of crop)**~~	~~**F, Fn, Fpn G, Gn, Gpn or I**~~	~~**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)~~	~~**Application**~~				~~**Application rate**~~				~~**PHI** (days)~~	~~**Remarks:** e.g. g safener/synergist per ha (f)~~	
					~~Method / Kind~~	~~Timing / Growth stage of crop & season~~	~~Max. number a) per use b) per crop/ season~~	~~Min. interval between applications (days)~~	~~L A22773A / ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g OXTP/ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g AZT/ha a) max. rate per appl. b) max. total rate per crop/season~~	~~Water L/ha min / max~~			
~~CZ-7~~	~~Czech Republic~~	~~leek~~	~~F~~	~~*Puccinia allii*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~7~~	~~-~~	~~A~~
~~CZ-8~~	~~Czech Republic~~	~~leek~~	~~F~~	~~*Puccinia porri*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~7~~	~~-~~	~~A~~
~~CZ-9~~	~~Czech Republic~~	~~lettuce~~	~~F~~	~~*Bremia lactucae*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~14~~	~~maximum 2 application per year on the same field~~	~~A~~
~~CZ-10~~	~~Czech Republic~~	~~squash, pumpkin~~	~~F~~	~~*Cladosporium sp.*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~CZ-11~~	~~Czech Republic~~	~~squash, pumpkin~~	~~F~~	~~*Pseudoperonospora cubensis*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~CZ-12~~	~~Czech Republic~~	~~squash, pumpkin~~	~~F~~	~~*Didymella bryoniae*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~CZ-13~~	~~Czech Republic~~	~~tomato~~	~~F~~	~~*Alternaria sp.*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	~~-~~	~~A~~
~~CZ-14~~	~~Czech Republic~~	~~tomato~~	~~F~~	~~*Phytophthora infestans*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	~~-~~	~~A~~
~~CZ-15~~	~~Czech Republic~~	~~zucchini~~	~~F~~	~~*Cladosporium sp.*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~CZ-16~~	~~Czech Republic~~	~~zucchini~~	~~F~~	~~*Pseudoperonospora cubensis*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~CZ-17~~	~~Czech Republic~~	~~zucchini~~	~~F~~	~~*Didymella bryoniae*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~CZ-29~~	~~Czech Republic~~	~~bell pepper~~	~~F~~	~~*Alternaria sp.*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	~~-~~	~~A~~

~~1~~	~~2~~	~~3~~	~~4~~	~~5~~	~~6~~	~~7~~	~~8~~	~~9~~	~~10~~	~~11~~	~~11~~	~~12~~	~~13~~	~~14~~	~~15~~
~~**Use-No.** (e)~~	~~**Member state(s)**~~	~~**Crop and/ or situation** **(crop destination / purpose of crop)**~~	~~**F, Fn, Fpn G, Gn, Gpn or I**~~	~~**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)~~	~~**Application**~~				~~**Application rate**~~				~~**PHI** (days)~~	~~**Remarks:** e.g. g safener/synergist per ha (f)~~	
					~~Method / Kind~~	~~Timing / Growth stage of crop & season~~	~~Max. number a) per use b) per crop/ season~~	~~Min. interval between applications (days)~~	~~L A22773A / ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g OXTP/ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g AZT/ha a) max. rate per appl. b) max. total rate per crop/season~~	~~Water L/ha min / max~~			
~~CZ-30~~	~~Czech Republic~~	~~spring onion~~	~~F~~	~~*Phytophthora porri*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~7~~	~~-~~	~~A~~
~~CZ-31~~	~~Czech Republic~~	~~salad plants~~	~~F~~	~~*Bremia lactucae*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~14~~	~~maximum 2 application per year on the same field~~	~~A~~
~~DE-1~~	~~Germany~~	~~hop~~	~~F~~	~~*Pseudoperonospora humuli*~~	~~foliar~~	~~BBCH 21-89~~	~~a) 2 b) 2~~	~~12-16~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~700-3300~~	~~28~~	~~Apr-Oct only~~	~~A~~
~~DE-15~~	~~Germany~~	~~hop~~	~~F~~	~~*Pseudoperonospora humuli*~~	~~foliar~~	~~BBCH 21-89~~	~~a) 1 b) 1~~	~~-~~	~~a) 1 b) 1~~	~~a) 12 b) 12~~	~~a) 250 b) 250~~	~~700-3300~~	~~28~~	~~Apr-Oct only~~	~~A~~
~~DE-2~~	~~Germany~~	~~leek~~	~~F~~	~~*Alternaria porri*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 1 b) 1~~	~~-~~	~~a) 1 b) 1~~	~~a) 12 b) 12~~	~~a) 250 b) 250~~	~~200-800~~	~~7~~	~~On drained soil, application from April to October only~~	~~A~~
~~DE-3~~	~~Germany~~	~~leek~~	~~F~~	~~*Phytophthora porri*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 1 b) 1~~	~~-~~	~~a) 1 b) 1~~	~~a) 12 b) 12~~	~~a) 250 b) 250~~	~~200-800~~	~~7~~	~~On drained soil, application from April to October only~~	~~A~~
~~DE-4~~	~~Germany~~	~~leek~~	~~F~~	~~*Puccinia allii*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 1 b) 1~~	~~-~~	~~a) 1 b) 1~~	~~a) 12 b) 12~~	~~a) 250 b) 250~~	~~200-800~~	~~7~~	~~On drained soil, application from April to October only~~	~~A~~
~~DE-5~~	~~Germany~~	~~leek~~	~~F~~	~~*Puccinia porri*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 1 b) 1~~	~~-~~	~~a) 1 b) 1~~	~~a) 12 b) 12~~	~~a) 250 b) 250~~	~~200-800~~	~~7~~	~~On drained soil, application from April to October only~~	~~A~~
~~DE-16~~	~~Germany~~	~~lettuce~~	~~F~~	~~*Bremia lactucae*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 1 b) 1~~	~~-~~	~~a) 1 b) 1~~	~~a) 12 b) 12~~	~~a) 250 b) 250~~	~~200-800~~	~~14~~	~~On drained soil, application from April to October only~~	~~A~~

1	2	3	4	5	6	7	8	9	10	11	11	12	13	14	15
Use-No. [e]	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate				PHI (days)	Remarks: e.g. g safener/synergist per ha [f]	
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DE-6	Germany	lettuce	F	*Bremia lactucae*	foliar	BBCH 41–49	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-800	14	On drained soil, application from April to October only. max 2 application per year on same field	A
HU-1	Hungary	bell pepper	F	*Phytophthora capsici*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1200	3		A
HU-2	Hungary	cucumber	F	*Cladosporium sp.*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3	-	A
HU-3	Hungary	cucumber	F	*Pseudoperonospora cubensis*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3	-	A
HU-11	Hungary	tomato	F	*Alternaria sp.*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1200	3		A
HU-12	Hungary	tomato	F	*Phytophthora infestans*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1200	3	-	A
HU-13	Hungary	water melon	F	*Cladosporium sp.*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3	-	A
HU-14	Hungary	water melon	F	*Pseudoperonospora cubensis*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3	-	A
HU-15	Hungary	water melon	F	*Didymella bryoniae*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3	-	A
IE-1	Ireland	hop	F	*Pseudoperonospora humuli*	foliar	BBCH 21-89	a) 2 b) 2	12-16	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	700-3300	28	-	A
IE-2	Ireland	leek	F	*Alternaria porri*	foliar	BBCH 11–49	a) 2 b) 2	12-14	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-800	7	-	A

1	2	3	4	5	6	7	8	9	10	11	11	12	13	14	15
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IE-3	Ireland	leek	F	*Phytophthora porri*	foliar	BBCH 11–49	a) 2 b) 2	12-14	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-800	7	-	A
IE-4	Ireland	leek	F	*Puccinia allii*	foliar	BBCH 11–49	a) 2 b) 2	12-14	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-800	7	-	A
IE-5	Ireland	leek	F	*Puccinia porri*	foliar	BBCH 11–49	a) 2 b) 2	12-14	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-800	7	-	A
IE-6	Ireland	lettuce	F	*Bremia lactucae*	foliar	BBCH 11–49	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-800	14	maximum 2 application per year on the same field	A
NL-2	Netherlands	leek	F	*Alternaria porri*	foliar	BBCH 11–49	a) 1 b) 1	-	a) 1 b) 1	a) 12 b) 12	a) 250 b) 250	200-800	7	-	A
NL-3	Netherlands	leek	F	*Phytophthora porri*	foliar	BBCH 11–49	a) 1 b) 1	-	a) 1 b) 1	a) 12 b) 12	a) 250 b) 250	200-800	7	-	A
NL-4	Netherlands	leek	F	*Puccinia allii*	foliar	BBCH 11–49	a) 1 b) 1	-	a) 1 b) 1	a) 12 b) 12	a) 250 b) 250	200-800	7	-	A
NL-5	Netherlands	leek	F	*Puccinia porri*	foliar	BBCH 11–49	a) 1 b) 1	-	a) 1 b) 1	a) 12 b) 12	a) 250 b) 250	200-800	7	-	A
NL-6	Netherlands	lettuce	F	*Bremia lactucae*	foliar	BBCH 11–49	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-800	14	max 2 application on the same field	A
PL-17	Poland	hop	F	*Pseudoperonospora humuli*	foliar	BBCH 21-89	a) 2 b) 2	12-16	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	700-3300	28		A
PL-20	Poland	lettuce	F	*Bremia lactucae*	foliar	BBCH 11–49	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-800	14	maximum 2 application per year on the same field	A

~~1~~	~~2~~	~~3~~	~~4~~	~~5~~	~~6~~	~~7~~	~~8~~	~~9~~	~~10~~	~~11~~	~~11~~	~~12~~	~~13~~	~~14~~	~~15~~
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					~~Method / Kind~~	~~Timing / Growth stage of crop & season~~	~~Max. number a) per use b) per crop/ season~~	~~Min. interval between applications (days)~~	~~L A22773A / ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g OXTP/ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g AZT/ha a) max. rate per appl. b) max. total rate per crop/season~~	~~Water L/ha min / max~~			
~~PL-33~~	~~Poland~~	~~leek~~	~~F~~	~~*Puccinia porri*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~7~~	-	~~A~~
~~PL-29~~	~~Poland~~	~~tomato~~	~~F~~	~~*Phytophthora infestans*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	-	~~A~~
~~RO-1~~	~~Romania~~	~~bell pepper~~	~~F~~	~~*Phytophthora capsici*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	-	~~A~~
~~RO-2~~	~~Romania~~	~~cucumber~~	~~F~~	~~*Cladosporium sp.*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	-	~~A~~
~~RO-3~~	~~Romania~~	~~cucumber~~	~~F~~	~~*Pseudoperonospora cubensis*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	-	~~A~~
~~RO-11~~	~~Romania~~	~~tomato~~	~~F~~	~~*Alternaria sp.*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	-	~~A~~
~~RO-12~~	~~Romania~~	~~tomato~~	~~F~~	~~*Phytophthora infestans*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	-	~~A~~
~~RO-13~~	~~Romania~~	~~water melon~~	~~F~~	~~*Cladosporium sp.*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	-	~~A~~
~~RO-14~~	~~Romania~~	~~water melon~~	~~F~~	~~*Pseudoperonospora cubensis*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	-	~~A~~
~~RO-15~~	~~Romania~~	~~water melon~~	~~F~~	~~*Didymella bryoniae*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	-	~~A~~
~~SI-1~~	~~Slovenia~~	~~bell pepper~~	~~F~~	~~*Phytophthora capsici*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	-	~~A~~
~~SI-2~~	~~Slovenia~~	~~cucumber~~	~~F~~	~~*Cladosporium sp.*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	-	~~A~~
~~SI-3~~	~~Slovenia~~	~~cucumber~~	~~F~~	~~*Pseudoperonospora cubensis*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	-	~~A~~

~~1~~	~~2~~	~~3~~	~~4~~	~~5~~	~~6~~	~~7~~	~~8~~	~~9~~	~~10~~	~~11~~	~~11~~	~~12~~	~~13~~	~~14~~	~~15~~
~~Use-No.~~ ~~(e)~~	**~~Member state(s)~~**	**~~Crop and/ or situation~~** **~~(crop destination / purpose of crop)~~**	**~~F, Fn, Fpn G, Gn, Gpn or I~~**	**~~Pests or Group of pests controlled~~** ~~(additionally: developmental stages of the pest or pest group)~~	**~~Application~~**				**~~Application rate~~**				**~~PHI~~** ~~(days)~~	**~~Remarks:~~** ~~e.g. g safener/synergist per ha~~ ~~(f)~~	
					~~Method / Kind~~	~~Timing / Growth stage of crop & season~~	~~Max. number a) per use b) per crop/ season~~	~~Min. interval between applications (days)~~	~~L A22773A / ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g OXTP/ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g AZT/ha a) max. rate per appl. b) max. total rate per crop/season~~	~~Water L/ha min / max~~			
~~SI-4~~	~~Slovenia~~	~~eggplant~~	~~F~~	~~*Alternaria sp.*~~	~~foliar~~	~~BBCH 11 – 89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	~~-~~	~~A~~
~~SI-5~~	~~Slovenia~~	~~eggplant~~	~~F~~	~~*Oidium neolycopersici*~~	~~foliar~~	~~BBCH 11 – 89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	~~-~~	~~A~~
~~SI-6~~	~~Slovenia~~	~~eggplant~~	~~F~~	~~*Phytophthora infestans*~~	~~foliar~~	~~BBCH 11 – 89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	~~-~~	~~A~~
~~SI-12~~	~~Slovenia~~	~~lettuce~~	~~F~~	~~*Bremia lactucae*~~	~~foliar~~	~~BBCH 11 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~14~~	~~maximum 2 application per year on the same field~~	~~A~~
~~SI-13~~	~~Slovenia~~	~~melon~~	~~F~~	~~*Cladosporium sp.*~~	~~foliar~~	~~BBCH 11 – 89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~SI-14~~	~~Slovenia~~	~~melon~~	~~F~~	~~*Pseudoperonospora cubensis*~~	~~foliar~~	~~BBCH 11 – 89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~SI-15~~	~~Slovenia~~	~~melon~~	~~F~~	~~*Didymella bryoniae*~~	~~foliar~~	~~BBCH 11 – 89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~SI-16~~	~~Slovenia~~	~~tomato~~	~~F~~	~~*Alternaria sp.*~~	~~foliar~~	~~BBCH 11 – 89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	~~-~~	~~A~~
~~SI-17~~	~~Slovenia~~	~~tomato~~	~~F~~	~~*Phytophthora infestans*~~	~~foliar~~	~~BBCH 11 – 89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	~~-~~	~~A~~
~~SI-18~~	~~Slovenia~~	~~water melon~~	~~F~~	~~*Cladosporium sp.*~~	~~foliar~~	~~BBCH 11 – 89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~SI-19~~	~~Slovenia~~	~~water melon~~	~~F~~	~~*Pseudoperonospora cubensis*~~	~~foliar~~	~~BBCH 11 – 89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~SI-20~~	~~Slovenia~~	~~water melon~~	~~F~~	~~*Didymella bryoniae*~~	~~foliar~~	~~BBCH 11 – 89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~

~~1~~	~~2~~	~~3~~	~~4~~	~~5~~	~~6~~	~~7~~	~~8~~	~~9~~	~~10~~	~~11~~	~~11~~	~~12~~	~~13~~	~~14~~	~~15~~
~~**Use-No.** [(e)]~~	~~**Member state(s)**~~	~~**Crop and/ or situation**~~ ~~**(crop destination / purpose of crop)**~~	~~**F, Fn, Fpn G, Gn, Gpn or I**~~	~~**Pests or Group of pests controlled**~~ ~~(additionally: developmental stages of the pest or pest group)~~	~~**Application**~~				~~**Application rate**~~				~~**PHI** (days)~~	~~**Remarks:**~~ ~~e.g. g safener/synergist per ha~~ [(f)]	
					~~Method / Kind~~	~~Timing / Growth stage of crop & season~~	~~Max. number a) per use b) per crop/ season~~	~~Min. interval between applications (days)~~	~~L A22773A / ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g OXTP/ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g AZT/ha a) max. rate per appl. b) max. total rate per crop/season~~	~~Water L/ha min / max~~			
~~SI-21~~	~~Slovenia~~	~~zucchini~~	~~F~~	~~*Cladosporium sp.*~~	~~foliar~~	~~BBCH 11 – 89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~SI-22~~	~~Slovenia~~	~~zucchini~~	~~F~~	~~*Pseudoperonospora cubensis*~~	~~foliar~~	~~BBCH 11 – 89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~SI-23~~	~~Slovenia~~	~~zucchini~~	~~F~~	~~*Didymella bryoniae*~~	~~foliar~~	~~BBCH 11 – 89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~**Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)**~~															
~~None~~															
~~**Minor uses according to Article 51 (zonal uses)**~~															
~~AT-1~~	~~Austria~~	~~hop~~	~~F~~	~~*Pseudoperonospora humuli*~~	~~foliar~~	~~BBCH 21-89~~	~~a) 2 b) 2~~	~~12-16~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~700-3300~~	~~28~~	~~-~~	~~A~~
~~AT-2~~	~~Austria~~	~~leek~~	~~F~~	~~*Alternaria porri*~~	~~foliar~~	~~BBCH 11 – 49~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~7~~	~~-~~	~~A~~
~~AT-3~~	~~Austria~~	~~leek~~	~~F~~	~~*Phytophthora porri*~~	~~foliar~~	~~BBCH 11 – 49~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~7~~		~~A~~
~~AT-4~~	~~Austria~~	~~leek~~	~~F~~	~~*Puccinia allii*~~	~~foliar~~	~~BBCH 11 – 49~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~7~~		~~A~~
~~AT-5~~	~~Austria~~	~~leek~~	~~F~~	~~*Puccinia porri*~~	~~foliar~~	~~BBCH 11 – 49~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~7~~		~~A~~
~~AT-6~~	~~Austria~~	~~lettuce~~	~~F~~	~~*Bremia lactucae*~~	~~foliar~~	~~BBCH 11 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~14~~	~~maximum 2 application per year on the same field~~	~~A~~
~~BE-1~~	~~Belgium~~	~~hop~~	~~F~~	~~*Pseudoperonospora humuli*~~	~~foliar~~	~~BBCH 21-89~~	~~a) 2 b) 2~~	~~12-16~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~700-3300~~	~~28~~		~~A~~

~~1~~	~~2~~	~~3~~	~~4~~	~~5~~	~~6~~	~~7~~	~~8~~	~~9~~	~~10~~	~~11~~	~~11~~	~~12~~	~~13~~	~~14~~	~~15~~
~~**Use-No.** [e]~~	~~**Member state(s)**~~	~~**Crop and/ or situation** **(crop destination / purpose of crop)**~~	~~**F, Fn, Fpn G, Gn, Gpn or I**~~	~~**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)~~	~~**Application**~~				~~**Application rate**~~				~~**PHI** (days)~~	~~**Remarks:** e.g. g safener/synergist per ha [f]~~	
					~~Method / Kind~~	~~Timing / Growth stage of crop & season~~	~~Max. number a) per use b) per crop/ season~~	~~Min. interval between applications (days)~~	~~L A22773A / ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g OXTP/ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g AZT/ha a) max. rate per appl. b) max. total rate per crop/season~~	~~Water L/ha min / max~~			
~~BE-7~~	~~Belgium~~	~~spring onion~~	~~F~~	~~*Phytophthora porri*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~7~~		~~A~~
~~HU-4~~	~~Hungary~~	~~eggplant~~	~~F~~	~~*Alternaria sp.*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	~~-~~	~~A~~
~~HU-5~~	~~Hungary~~	~~eggplant~~	~~F~~	~~*Oidium neolycopersici*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	~~-~~	~~A~~
~~HU-6~~	~~Hungary~~	~~eggplant~~	~~F~~	~~*Phytophthora infestans*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	~~-~~	~~A~~
~~HU-7~~	~~Hungary~~	~~hop~~	~~F~~	~~*Pseudoperonospora humuli*~~	~~foliar~~	~~BBCH 21-89~~	~~a) 2 b) 2~~	~~12-16~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~700-3300~~	~~28~~	~~-~~	~~A~~
~~HU-8~~	~~Hungary~~	~~melon~~	~~F~~	~~*Cladosporium sp.*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~HU-9~~	~~Hungary~~	~~melon~~	~~F~~	~~*Pseudoperonospora cubensis*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~HU-10~~	~~Hungary~~	~~melon~~	~~F~~	~~*Didymella bryoniae*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~		~~A~~
~~HU-16~~	~~Hungary~~	~~zucchini~~	~~F~~	~~*Cladosporium sp.*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~HU-17~~	~~Hungary~~	~~zucchini~~	~~F~~	~~*Pseudoperonospora cubensis*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~HU-18~~	~~Hungary~~	~~zucchini~~	~~F~~	~~*Didymella bryoniae*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~NL-1~~	~~Netherlands~~	~~hop~~	~~F~~	~~*Pseudoperonospora humuli*~~	~~foliar~~	~~BBCH 21-89~~	~~a) 2 b) 2~~	~~12-16~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~700-3300~~	~~28~~		~~A~~
~~NL-8~~	~~Netherlands~~	~~spring onion~~	~~F~~	~~*Phytophthora porri*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 1 b) 1~~	~~-~~	~~a) 1 b) 1~~	~~a) 12 b) 12~~	~~a) 250 b) 250~~	~~200-800~~	~~7~~	~~-~~	~~A~~

1	2	3	4	5	6	7	8	9	10	11	11	12	13	14	15
Use-No. [e]	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate				PHI (days)	Remarks: e.g. g safener/synergist per ha [f]	
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L A22773A / ha a) max. rate per appl. b) max. total rate per crop/season	g OXTP/ha a) max. rate per appl. b) max. total rate per crop/season	g AZT/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
PL-1	Poland	cucumber	F	*Cladosporium sp.*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3	-	A
PL-2	Poland	cucumber	F	*Pseudoperonospora cubensis*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3	-	A
PL-3	Poland	cucumber	F	*Didymella bryoniae*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3	-	A
PL-4	Poland	zucchini	F	*Cladosporium sp.*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3	-	A
PL-5	Poland	zucchini	F	*Pseudoperonospora cubensis*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3	-	A
PL-6	Poland	zucchini	F	*Didymella bryoniae*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3	-	A
PL-7	Poland	melon	F	*Cladosporium sp.*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3	-	A
PL-8	Poland	melon	F	*Alternaria cucumerina*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3	-	A
PL-9	Poland	melon	F	*Pseudoperonospora cubensis*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3	-	A
PL-10	Poland	melon	F	*Didymella bryoniae*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3	-	A
PL-11	Poland	squash, pumpkin	F	*Cladosporium sp.*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3	-	A
PL-12	Poland	squash, pumpkin	F	*Pseudoperonospora cubensis*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3	-	A
PL-13	Poland	squash, pumpkin	F	*Didymella bryoniae*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3	-	A

~~1~~	~~2~~	~~3~~	~~4~~	~~5~~	~~6~~	~~7~~	~~8~~	~~9~~	~~10~~	~~11~~	~~11~~	~~12~~	~~13~~	~~14~~	~~15~~
~~Use-No.~~ [(e)]	~~Member state(s)~~	~~Crop and/ or situation (crop destination / purpose of crop)~~	~~F, Fn, Fpn G, Gn, Gpn or I~~	~~Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)~~	~~Application~~				~~Application rate~~				~~PHI (days)~~	~~Remarks: e.g. g safener/synergist per ha~~ [(f)]	
					~~Method / Kind~~	~~Timing / Growth stage of crop & season~~	~~Max. number a) per use b) per crop/ season~~	~~Min. interval between applications (days)~~	~~L A22773A / ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g OXTP/ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g AZT/ha a) max. rate per appl. b) max. total rate per crop/season~~	~~Water L/ha min / max~~			
~~PL-14~~	~~Poland~~	~~water melon~~	~~F~~	~~*Cladosporium sp.*~~	~~foliar~~	~~BBCH 11 – 89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	-	~~A~~
~~PL-15~~	~~Poland~~	~~water melon~~	~~F~~	~~*Pseudoperonospora cubensis*~~	~~foliar~~	~~BBCH 11 – 89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	-	~~A~~
~~PL-16~~	~~Poland~~	~~water melon~~	~~F~~	~~*Didymella bryoniae*~~	~~foliar~~	~~BBCH 11 – 89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	-	~~A~~
~~PL-18~~	~~Poland~~	~~salad plants~~	~~F~~	~~*Bremia lactucae*~~	~~foliar~~	~~BBCH 11 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~14~~	~~for baby leaf only BBCH 11-19 maximum 2 application per year on the same field~~	~~A~~
~~PL-19~~	~~Poland~~	~~salad plants~~	~~F~~	~~*botrytis cinerea*~~	~~foliar~~	~~BBCH 11 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~14~~	~~for baby leaf only BBCH 11-19 maximum 2 application per year on the same field~~	~~A~~
~~PL-21~~	~~Poland~~	~~lettuce~~	~~F~~	~~*botrytis cinerea*~~	~~foliar~~	~~BBCH 11 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~14~~	~~maximum 2 application per year on the same field~~	~~A~~
~~PL-38~~	~~Poland~~	~~spinach and similar leaves~~	~~F~~	~~*Peronospora farinosa f. sp. spinaciae*~~	~~foliar~~	~~BBCH 11 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~14~~	~~maximum 2 application per year on the same field~~	~~A~~

~~1~~	~~2~~	~~3~~	~~4~~	~~5~~	~~6~~	~~7~~	~~8~~	~~9~~	~~10~~	~~11~~	~~11~~	~~12~~	~~13~~	~~14~~	~~15~~
~~**Use-No.** [e]~~	~~**Member state(s)**~~	~~**Crop and/ or situation** **(crop destination / purpose of crop)**~~	~~**F, Fn, Fpn G, Gn, Gpn or I**~~	~~**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)~~	~~**Application**~~				~~**Application rate**~~				~~**PHI** (days)~~	~~**Remarks:** e.g. g safener/synergist per ha [f]~~	
					~~Method / Kind~~	~~Timing / Growth stage of crop & season~~	~~Max. number a) per use b) per crop/ season~~	~~Min. interval between applications (days)~~	~~L A22773A / ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g OXTP/ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g AZT/ha a) max. rate per appl. b) max. total rate per crop/season~~	~~Water L/ha min / max~~			
~~PL-39~~	~~Poland~~	~~sweet basil~~	~~F~~	~~*Peronospora belbahrii*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~14~~	~~maximum 2 application per year on the same field~~	~~A~~
~~PL-40~~	~~Poland~~	~~sweet basil~~	~~F~~	~~*Peronospora belbahrii*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~14~~	~~maximum 2 application per year on the same field~~	~~A~~
~~PL-30~~	~~Poland~~	~~leek~~	~~F~~	~~*Alternaria porri*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~7~~	~~-~~	~~A~~
~~PL-31~~	~~Poland~~	~~leek~~	~~F~~	~~*Phytophthora porri*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~7~~	~~-~~	~~A~~
~~PL-32~~	~~Poland~~	~~leek~~	~~F~~	~~*Puccinia allii*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~7~~	~~-~~	~~A~~
~~PL-23~~	~~Poland~~	~~bell pepper~~	~~F~~	~~*Alternaria sp.*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	~~-~~	~~A~~
~~PL-24~~	~~Poland~~	~~bell pepper~~	~~F~~	~~*Phytophthora capsici*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	~~-~~	~~A~~
~~PL-25~~	~~Poland~~	~~eggplant~~	~~F~~	~~*Alternaria sp.*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	~~-~~	~~A~~
~~PL-26~~	~~Poland~~	~~eggplant~~	~~F~~	~~*Oidium neolycopersici*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	~~-~~	~~A~~
~~PL-27~~	~~Poland~~	~~eggplant~~	~~F~~	~~*Phytophthora infestans*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	~~-~~	~~A~~
~~PL-28~~	~~Poland~~	~~tomato~~	~~F~~	~~*Alternaria sp.*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	~~-~~	~~A~~
~~PL-71~~	~~Poland~~	~~spring onion~~	~~F~~	~~*Phytophthora porri*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~7~~	~~-~~	~~A~~

~~1~~	~~2~~	~~3~~	~~4~~	~~5~~	~~6~~	~~7~~	~~8~~	~~9~~	~~10~~	~~11~~	~~11~~	~~12~~	~~13~~	~~14~~	~~15~~
~~**Use-No.** [(e)]~~	~~**Member state(s)**~~	~~**Crop and/ or situation**~~ ~~**(crop destination / purpose of crop)**~~	~~**F, Fn, Fpn G, Gn, Gpn or I**~~	~~**Pests or Group of pests controlled**~~ ~~(additionally: developmental stages of the pest or pest group)~~	~~**Application**~~				~~**Application rate**~~				~~**PHI** (days)~~	~~**Remarks:**~~ ~~e.g. g safener/synergist per ha~~ [(f)]	
					~~Method / Kind~~	~~Timing / Growth stage of crop & season~~	~~Max. number a) per use b) per crop/ season~~	~~Min. interval between applications (days)~~	~~L A22773A / ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g OXTP/ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g AZT/ha a) max. rate per appl. b) max. total rate per crop/season~~	~~Water L/ha min / max~~			
~~RO-4~~	~~Romania~~	~~eggplant~~	~~F~~	~~*Alternaria sp.*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	~~-~~	~~A~~
~~RO-5~~	~~Romania~~	~~eggplant~~	~~F~~	~~*Oidium neolycopersici*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	~~-~~	~~A~~
~~RO-6~~	~~Romania~~	~~eggplant~~	~~F~~	~~*Phytophthora infestans*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	~~-~~	~~A~~
~~RO-7~~	~~Romania~~	~~hop~~	~~F~~	~~*Pseudoperonospora humuli*~~	~~foliar~~	~~BBCH 21-89~~	~~a) 2 b) 2~~	~~12-16~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~700-3300~~	~~28~~	~~-~~	~~A~~
~~RO-8~~	~~Romania~~	~~melon~~	~~F~~	~~*Cladosporium sp.*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~RO-9~~	~~Romania~~	~~melon~~	~~F~~	~~*Pseudoperonospora cubensis*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~RO-10~~	~~Romania~~	~~melon~~	~~F~~	~~*Didymella bryoniae*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~RO-16~~	~~Romania~~	~~zucchini~~	~~F~~	~~*Cladosporium sp.*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~RO-17~~	~~Romania~~	~~zucchini~~	~~F~~	~~*Pseudoperonospora cubensis*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~RO-18~~	~~Romania~~	~~zucchini~~	~~F~~	~~*Didymella bryoniae*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~RO-34~~	~~Romania~~	~~Lettuce (LACSA)~~	~~F~~	~~Bremia lactucae~~	~~foliar~~	~~BBCH 11–49~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~14~~	~~maximum 2 application per year on the same field~~	~~A~~
~~RO-35~~	~~Romania~~	~~Leek (ALLPO)~~	~~F~~	~~Alternaria porri~~	~~foliar~~	~~BBCH 11–49~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~7~~	~~-~~	~~A~~

1	2	3	4	5	6	7	8	9	10	11	11	12	13	14	15
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**				**PHI (days)**	**Remarks:** e.g. g safener/synergist per ha [f]	
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L A22773A / ha a) max. rate per appl. b) max. total rate per crop/season	g OXTP/ha a) max. rate per appl. b) max. total rate per crop/season	g AZT/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
RO-36	Romania	Leek (ALLPO)	F	Phytophthora porri	foliar	BBCH 11–49	a) 2 b) 2	12-14	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-800	7	-	A
RO-37	Romania	Leek (ALLPO)	F	Puccinia allii	foliar	BBCH 11–49	a) 2 b) 2	12-14	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-800	7	-	A
RO-38	Romania	Leek (ALLPO)	F	Puccinia porri	foliar	BBCH 11–49	a) 2 b) 2	12-14	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-800	7	-	A
RO-39	Romania	spring onion	F	Phytophthora porri	foliar	BBCH 11–49	a) 2 b) 2	12-14	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-800	7		A
RO-40	Romania	squash, pumpkin	F	Cladosporium sp.	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3		A
RO-41	Romania	squash, pumpkin	F	Pseudoperonospora cubensis	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3		A
RO-42	Romania	squash, pumpkin	F	Didymella bryoniae	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3		A
SK-1	Slovakia	cucumber	F	*Cladosporium sp.*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3	-	A
SK-2	Slovakia	cucumber	F	*Pseudoperonospora cubensis*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3	-	A
SK-3	Slovakia	eggplant	F	*Alternaria sp.*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1200	3	-	A
SK-4	Slovakia	eggplant	F	*Oidium neolycopersici*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1200	3	-	A
SK-5	Slovakia	eggplant	F	*Phytophthora infestans*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1200	3	-	A
SK-6	Slovakia	leek	F	*Alternaria porri*	foliar	BBCH 11–49	a) 2 b) 2	12-14	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-800	7	-	A

~~1~~	~~2~~	~~3~~	~~4~~	~~5~~	~~6~~	~~7~~	~~8~~	~~9~~	~~10~~	~~11~~	~~11~~	~~12~~	~~13~~	~~14~~	~~15~~
~~**Use-No.** [e]~~	~~**Member state(s)**~~	~~**Crop and/ or situation**~~ ~~**(crop destination / purpose of crop)**~~	~~**F, Fn, Fpn G, Gn, Gpn or I**~~	~~**Pests or Group of pests controlled**~~ ~~(additionally: developmental stages of the pest or pest group)~~	~~**Application**~~				~~**Application rate**~~				~~**PHI** (days)~~	~~**Remarks:**~~ ~~e.g. g safener/synergist per ha~~ ~~[f]~~	
					~~Method / Kind~~	~~Timing / Growth stage of crop & season~~	~~Max. number a) per use b) per crop/ season~~	~~Min. interval between applications (days)~~	~~L A22773A / ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g OXTP/ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g AZT/ha a) max. rate per appl. b) max. total rate per crop/season~~	~~Water L/ha min / max~~			
~~SK-7~~	~~Slovakia~~	~~leek~~	~~F~~	~~*Phytophthora porri*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~7~~	~~-~~	~~A~~
~~SK-8~~	~~Slovakia~~	~~leek~~	~~F~~	~~*Puccinia allii*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~7~~	~~-~~	~~A~~
~~SK-9~~	~~Slovakia~~	~~leek~~	~~F~~	~~*Puccinia porri*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~7~~	~~-~~	~~A~~
~~SK-10~~	~~Slovakia~~	~~lettuce~~	~~F~~	~~*Bremia lactucae*~~	~~foliar~~	~~BBCH 11–49~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-800~~	~~14~~	~~maximum 2 application per year on the same field~~	~~A~~
~~SK-11~~	~~Slovakia~~	~~melon~~	~~F~~	~~*Cladosporium sp.*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~SK-12~~	~~Slovakia~~	~~melon~~	~~F~~	~~*Pseudoperonospora cubensis*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~SK-13~~	~~Slovakia~~	~~tomato~~	~~F~~	~~*Alternaria sp.*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	~~-~~	~~A~~
~~SK-14~~	~~Slovakia~~	~~tomato~~	~~F~~	~~*Phytophthora infestans*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1200~~	~~3~~	~~-~~	~~A~~
~~SK-15~~	~~Slovakia~~	~~water melon~~	~~F~~	~~*Cladosporium sp.*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~		~~A~~
~~SK-16~~	~~Slovakia~~	~~water melon~~	~~F~~	~~*Pseudoperonospora cubensis*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~SK-17~~	~~Slovakia~~	~~zucchini~~	~~F~~	~~*Cladosporium sp.*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~
~~SK-18~~	~~Slovakia~~	~~zucchini~~	~~F~~	~~*Pseudoperonospora cubensis*~~	~~foliar~~	~~BBCH 11–89~~	~~a) 2 b) 2~~	~~7~~	~~a) 1 b) 2~~	~~a) 12 b) 24~~	~~a) 250 b) 500~~	~~200-1000~~	~~3~~	~~-~~	~~A~~

1	2	3	4	5	6	7	8	9	10	11	11	12	13	14	15
Use-No. [(e)]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**				**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [(f)]	
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L A22773A / ha a) max. rate per appl. b) max. total rate per crop/season	g OXTP/ha a) max. rate per appl. b) max. total rate per crop/season	g AZT/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
SK-35	Slovakia	bell pepper	F	*Alternaria sp.*	foliar	BBCH 11–89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1200	3	-	A
SK-36	Slovakia	spring onion	F	*Phytophthora porri*	foliar	BBCH 11–49	a) 2 b) 2	12-14	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-800	7	-	A
SK-37	Slovakia	salad plants	F	*Bremia lactucae*	foliar	BBCH 11–49	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-800	14	maximum 2 application per year on the same field	A
SK-39	Slovakia	spinach and similar leaves	F	*Peronospora farinosa f. sp. spinaciae*	foliar	BBCH 11–49	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-800	14	maximum 2 application per year on the same field	A
SI-7	Slovenia	hop	F	*Pseudoperonospora humuli*	foliar	BBCH 21-89	a) 2 b) 2	12-16	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	700-3300	28	-	A
SI-8	Slovenia	leek	F	*Alternaria porri*	foliar	BBCH 11–49	a) 2 b) 2	12-14	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-800	7	-	A
SI-9	Slovenia	leek	F	*Phytophthora porri*	foliar	BBCH 11–49	a) 2 b) 2	12-14	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-800	7	-	A
SI-10	Slovenia	leek	F	*Puccinia allii*	foliar	BBCH 11–49	a) 2 b) 2	12-14	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-800	7	-	A
SI-11	Slovenia	leek	F	*Puccinia porri*	foliar	BBCH 11–49	a) 2 b) 2	12-14	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-800	7	-	A
Minor uses according to Article 51 (interzonal uses)															
None															

1	2	3	4	5	6	7	8	9	10	11	11	12	13	14	15
Use-No. [(e)]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**				**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [(f)]	**Conclusion:**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L A22773A / ha a) max. rate per appl. b) max. total rate per crop/season	g OXTP/ha a) max. rate per appl. b) max. total rate per crop/season	g AZT/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
BE-2	Belgium	Lettuce [0251020]	F	*Bremia lactucae*	foliar	BBCH 11 - 49	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-800	14	maximum 2 application per year on the same field	A
BE-3	Belgium	Leek [0270060]	F	*Alternaria porri*	foliar	BBCH 11 - 49	a) 2 b) 2	12-14	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-800	7		A
CZ-1	Czech Republic	Cucumber [0232010]	F	*Cladosporium sp.*	foliar	BBCH 11 - 89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3		A
CZ-4	Czech Republic	Hops [0700000]	F	*Pseudoperonospora humuli*	foliar	BBCH 21-89	a) 2 b) 2	12-16	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	700-3300	28		A
CZ-10	Czech Republic	Squash [0233020-001] Pumpkin [0233020]	F	*Cladosporium sp.*	foliar	BBCH 11 - 89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3		A
CZ-13	Czech Republic	Tomato [0231010]	F	*Alternaria sp.*	foliar	BBCH 11 - 89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1200	3		A
CZ-15	Czech Republic	Zucchini [0232030]	F	*Cladosporium sp.*	foliar	BBCH 11 - 89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3		A
CZ-29	Czech Republic	Bell pepper [0231020]	F	*Alternaria sp.*	foliar	BBCH 11 - 89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1200	3		A
CZ-30	Czech Republic	Spring onion [0220040]	F	*Phytophthora porri*	foliar	BBCH 11 - 49	a) 2 b) 2	12-14	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-800	7		A
CZ-31	Czech Republic	Salad plants [0251000]	F	*Bremia lactucae*	foliar	BBCH 11 - 49	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-800	14	maximum 2 application per year on the same field	A
HU-13	Hungary	Watermelon [0233030]	F	*Cladosporium sp.*	foliar	BBCH 11 - 89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3		A

1	2	3	4	5	6	7	8	9	10	11	11	12	13	14	15
Use-No. [(e)]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**				**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [(f)]	**Conclusion:**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L A22773A / ha a) max. rate per appl. b) max. total rate per crop/season	g OXTP/ha a) max. rate per appl. b) max. total rate per crop/season	g AZT/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
SI-4	Slovenia	Eggplant [0231020]	F	*Alternaria sp.*	foliar	BBCH 11 - 89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1200	3		A
SI-13	Slovenia	Melon [0233010]	F	*Cladosporium sp.*	foliar	BBCH 11 - 89	a) 2 b) 2	7	a) 1 b) 2	a) 12 b) 24	a) 250 b) 500	200-1000	3		A

n/a: not applicable

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 an non-professional greenhouse use, I: indoor application

Explanation for Column 15 “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 A22773A is composed of azoxystrobin and oxathiapiprolin.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of azoxystrobin and oxathiapiprolin

Reference value	Source	Year	Value	Study relied upon	Safety factor
Azoxystrobin					
ADI	EFSA	2010	0.2 mg/kg bw/day	Rat, 2 year study	100
ARfD	EFSA	2010	Not necessary		
Oxathiapiprolin					
ADI	EFSA	2016	0.14	1 year dog study	100
ARfD	EFSA	2016	Not necessary		

7.1.2.1 Summary for Azoxystrobin

Table 7.1-3: Summary for Azoxystrobin

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?
CZ-13, CZ-14, HU-11, HU-12, PL-28, PL-29, RO-11, RO-12, SK-13, SK-14, SI-16, SI-17	Tomato [0231010]	Yes	Yes (12 trials)	Yes	Yes	Yes	No	Not relevant
HU-4, HU-5, HU-6, PL-25, PL-26, PL-27, RO-4, RO-5, RO-6, SK-3, SK-4, SK-5, SI-4, SI-5, SI-6,	Aubergine/eggplant [0231020]	Yes	Yes (12 trials on tomato-extrapolation)	Yes	Yes	Yes		Not relevant
CZ-29, HU-1, PL-23, PL-24, RO-1, SK-35, SI-1	Bell pepper [0231020]	Yes	Yes (8 trials)	Yes	Yes	Yes		Not relevant
CZ-1, CZ-2, CZ-3, HU-2, HU-3, PL-1, PL-2, PL-3, RO-2, RO-3, SK-1, SK-2, SI-2, SI-3	Cucumber [0232010]	Yes	Yes (16 trials on cucurbits)	Yes	Yes	Yes		Not relevant
CZ-15, CZ-16, CZ-17, HU-16, HU-17, HU-18, PL-4, PL-5,	Zucchini (courgette) – [0232030]	Yes	Yes (16 trials on cucurbits)	Yes	Yes	Yes		Not relevant

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?
PL-6, RO-16, RO-17, RO-18, SK-17, SK-18, SI-21, SI-22, SI-23								
HU-8, HU-9, HU-10, PL-7, PL-8, PL-9, PL-10, RO-8, RO-9, RO-10, SK-11, SK-12, SI-13, SI-14, SI-15	Melon [0233010]	Yes	Yes (10 trials)	Yes	Yes	Yes		Not relevant
HU-13, HU-14, HU-15, PL-14, PL-15, PL-16, RO-13, RO-14, RO-15, SK-15, SK-16, SI-18, SI-19, SI-20	Watermelon [0233030]	Yes	Yes (10 trials on melon - extrapolation)	Yes	Yes	Yes		Not relevant
CZ-10, CZ-11, CZ-12, PL-11, PL-12, PL-13, RO-40, RO-41, RO-42	Pumpkin [0233020]	Yes	Yes (10 trials on melon - extrapolation)	Yes	Yes	Yes		Not relevant
CZ-10, CZ-11, CZ-12, PL-11, PL-12, PL-13 RO-40, RO-41, RO-42	Squash [0233020-001]	Yes	Yes (10 trials on melon - extrapolation)	Yes	Yes	Yes		Not relevant
AT-6, BE-2, CZ-9, DE-16, DE-6, IE-6, NL-6, PL-20, PL-21, SK-10, SI-12, RO-34	Lettuce [0251020]	Yes	Yes (9 trials)	Yes	Yes	Yes		Not relevant
CZ-31, PL-18, PL-19, SK-37	Salad plants [0251000]	Yes	Yes (9 trials on lettuce-extrapolation)	Yes	Yes	Yes		Not relevant
PL-38, SK-39	Spinach [0252010]	Yes	Yes (9 trials on lettuce-extrapolation)	Yes	Yes	Yes		Not relevant
PL-39, PL-40	Sweet basil [0256080]	Yes	Yes 9 trials on lettuce-extrapolation)	Yes	Yes	Yes		Not relevant

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?
AT-2, AT-3, AT-4, AT-5, BE-3, BE-4, BE-5, BE-6, CZ-5, CZ-6, CZ-7, CZ-8, DE-2, DE-3, DE-4, DE-5, IE-2, IE-3, IE-4, IE-5, NL-2, NL-3, NL-4, NL-5, PL-30, PL-31, PL-32, PL-33, SK-6, SK-7, SK-8, SK-9, SI-8, SI-9, SI-10, SI-11, RO-35, RO-36, RO-37, RO-38	Leek [0270060]	Yes	Yes (8 trials)	Yes	Yes	Yes		Not relevant
BE-7, CZ-30, NL-8, PL-71, SK-36, RO-39	Spring onion [0220040]	Yes	Yes (8 trials on leek - extrapolation)	Yes	Yes	Yes		Not relevant
AT-1, BE-1, CZ-4, DE-1, DE-15, HU-7, IE-1, NL-1, PL-17, RO-7, SI-7	Hops [0700000]	Yes	Yes (8 trials)	Yes	Yes	Yes		Not relevant

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

Studies to assess the magnitude of azoxystrobin residues during processing have been assessed in the framework of the peer review and the Article 12 MRL review and processing factors were derived for several crops (EFSA, 2010, 2013). The magnitude of residues in processed commodities relevant for crops under consideration has been sufficiently addressed to support the proposed uses of the product A22773A.

The magnitude of residues in rotational crops has been sufficiently addressed in the available studies to support the proposed uses of the product A22773A. EFSA concluded in EFSA Journal 2022;20(1):7051 that *The possible transfer of azoxystrobin residues to crops that are grown in crop rotation has been assessed in the EU pesticides peer review and the MRL review (EFSA, 2010, 2013). In the context of the MRL review, it was concluded that no residues above the LOQ (0.01 mg/kg) are expected in crop parts intended for human consumption and that residues are very low in commodities intended for feed purposes (0.05 mg/kg in wheat forage and 0.04 mg/kg in wheat straw) (EFSA, 2013).*
Since the maximum annual application rate for the crops under consideration (i.e. 0.5 kg a.s./ha) is lower than the maximum seasonal application rate assessed during the MRL review (i.e. 1 kg a.s./ha), the previous conclusion remains valid, provided that the active substance is applied according to the proposed GAP.

During the peer review under Directive 91/414/EEC, the magnitude of azoxystrobin residues in livestock was investigated in feeding studies with lactating cows and laying hens (United Kingdom, 2009). The requested uses and 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 (~~Reg. (EU) 2022/476~~ Reg. (EU) 2023/129).

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

7.1.2.2 Summary for Oxathiapiprolin

Table 7.1-4: Summary for Oxathiapiprolin

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?
CZ-13, CZ-14, HU-11, HU-12, PL-28, PL-29, RO-11, RO-12, SK-13, SK-14, SI-16, SI-17	Tomato [0231010]	Yes	Yes (16 trials)	Yes	Yes	Yes	No	Not relevant
HU-4, HU-5, HU-6, PL-25, PL-26, PL-27, RO-4, RO-5, RO-6, SK-3, SK-4, SK-5, SI-4, SI-5, SI-6,	Aubergine/eggplant [0231020]	Yes	Yes (16 trials on tomato-extrapolation)	Yes	Yes	Yes		Not relevant
CZ-29, HU-1, PL-23, PL-24, RO-1, SK-35, SI-1	Bell pepper [0231020]	Yes	Yes (8 trials)	Yes	Yes	Yes		Not relevant
CZ-1, CZ-2, CZ-3, HU-2, HU-3, PL-1, PL-2, PL-3, RO-2, RO-3, SK-1, SK-2, SI-2, SI-3	Cucumber [0232010]	Yes	Yes (8 trials)	Yes	Yes	Yes		Not relevant
CZ-15, CZ-16, CZ-17, HU-16, HU-17, HU-18, PL-4, PL-5, PL-6, RO-16, RO-17, RO-18, SK-17, SK-18, SI-21, SI-22, SI-23	Zucchini (courgette) – [0232030]	Yes	Yes (8 trials on cucumber-extrapolation)	Yes	Yes	Yes		Not relevant
HU-8, HU-9, HU-10, PL-7, PL-8, PL-9, PL-10, RO-8, RO-9, RO-10, SK-11,	Melon [0233010]	Yes	Yes (8 trials)	Yes	Yes	Yes		Not relevant

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?
SK-12, SI-13, SI-14, SI-15								
HU-13, HU-14, HU-15, PL-14, PL-15, PL-16, RO-13, RO-14, RO-15, SK-15, SK-16, SI-18, SI-19, SI-20	Watermelon [0233030]	Yes	Yes (8 trials on melon-extrapolation)	Yes	Yes	Yes		Not relevant
CZ-10, CZ-11, CZ-12, PL-11, PL-12, PL-13, RO-40, RO-41, RO-42	Pumpkin [0233020]	Yes	Yes (8 trials on melon-extrapolation)	Yes	Yes	Yes		Not relevant
CZ-10, CZ-11, CZ-12, PL-11, PL-12, PL-13 RO-40, RO-41, RO-42	Squash [0233020-001]	Yes	Yes (8 trials on melon-extrapolation)	Yes	Yes	Yes		Not relevant
AT-6, BE-2, CZ-9, DE-16, DE-6, IE-6, NL-6, PL-20, PL-21, SK-10, SI-12, RO-34	Lettuce [0251020]	Yes	Yes (8 trials)	Yes	Yes	Yes		Not relevant
CZ-31, PL-18, PL-19, SK-37	Salad plants [0251000]	Yes	Yes (8 trials on lettuce-extrapolation)	Yes	Yes	Yes		Not relevant
PL-38, SK-39	Spinach [0252010]	Yes	Yes 8 trials on lettuce-extrapolation)	Yes	Yes	Yes		Not relevant
PL-39, PL-40	Sweet basil [0256080]	Yes	Yes (8 trials on lettuce-extrapolation)	Yes	Yes	Yes		Not relevant
AT-2, AT-3, AT-4, AT-5, BE-3, BE-4, BE-5, BE-6, CZ-5, CZ-6, CZ-7, CZ-8, DE-2, DE-3, DE-4, DE-5, IE-2, IE-3, IE-4, IE-5, NL-2, NL-3, NL-4, NL-5, PL-30, PL-	Leek [0270060]	Yes	Yes (8 trials)	Yes	Yes	Yes		Not relevant

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?
31, PL-32, PL-33, SK-6, SK-7, SK-8, SK-9, SI-8, SI-9, SI-10, SI-11, RO-35, RO-36, RO-37, RO-38								
BE-7, CZ-30, NL-8, PL-71, SK-36, RO-39	Spring onion [0220040]	Yes	Yes (8 trials on leek-extrapolation)	Yes	Yes	Yes		Not relevant
AT-1, BE-1, CZ-4, DE-1, DE-15, HU-7, IE-1, NL-1, PL-17, RO-7, SI-7	Hops [0700000]	Yes	Yes (5 trials)	Yes	Yes	Yes		Not relevant

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

The nature and magnitude of residues in processed commodities relevant to these crops were evaluated in the Oxathiapiprolin Draft Assessment Report, Volume 3, CA, Annex B.7 (2016) and by Ireland (EFSA, 2019). These studies showed that oxathiapiprolin is hydrolytically stable under standard processing conditions. The processing studies are not expected to significantly affect the consumer risk assessment.

Considering the livestock dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

The nature and magnitude of residues in rotational crop commodities were evaluated in the Oxathiapiprolin Draft Assessment Report, Volume 3, Annex B7, Residue Data (2016). According the Conclusion on the peer review of the pesticide risk assessment of the active substance oxathiapiprolin. EFSA Journal 2016;14(7):4504, 19 pp. (European Food Safety Authority), 2016, numerous field rotational crop studies were submitted to confirm that residues of pyrazole metabolites (IN-SXS67 and IN-E8S72) are not expected to be detected in significant levels in rotational crops when the active substance is applied at a maximum seasonal application rate of 90 g/ha, therefore residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

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

7.1.2.3 Summary for A22773A

Table 7.1-5: Information on A22773A (KCA 6.8)

Crop	PHI for A22773A proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for A22773A proposed by zRMS	zRMS Comments (if different PHI proposed)
		Azoxystrobin	Oxathiapiprolin		
Tomato	3 days	Yes	Yes	3 days	-
Eggplant	3 days	Yes	Yes	3 days	-

Crop	PHI for A22773A proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for A22773A proposed by zRMS	zRMS Comments (if different PHI proposed)
		Azoxystrobin	Oxathiapiprolin		
Bell pepper	3 days	Yes	Yes	3 days	-
Cucumber	3 days	Yes	Yes	3 days	-
Zucchini	3 days	Yes	Yes	3 days	-
Melon	3 days	Yes	Yes	3 days	-
Squash, pumpkin	3 days	Yes	Yes	3 days	-
Watermelon	3 days	Yes	Yes	3 days	-
Lettuce	14 days	Yes	Yes	14 days	-
Sweet basil	14 days	Yes	Yes	14 days	-
Spinach	14 days	Yes	Yes	14 days	-
Leek	7 days	Yes	Yes	7 days	-
Spring onion	7 days	Yes	Yes	7 days	-
Hops	28 days	Yes	Yes	28 days	-

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 A22773A
Crop group	Led by azoxystrobin	Led by oxathiapiprolin	
All crops	Not required	Not required	There is no required waiting period before planting succeeding crops.

NR: not relevant

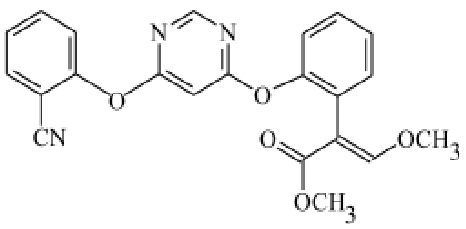
Assessment

7.2 Azoxystrobin

General data on azoxystrobin are summarized in the table below (last updated 2021/05/03)

According to EU pesticide database, Commission Regulation (EU) No 2022/476 is not applicable and changed in the meantime. The current MRL regulation for azoxystrobin is Reg. (EU) 2023/129.

Table 7.2-1: General information on azoxystrobin

Active substance (ISO Common Name)	Azoxystrobin
IUPAC	methyl (*E*)-2-{2[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate
Chemical structure	
Molecular formula	$C_{22}H_{17}N_3O_5$
Molar mass	403.4
Chemical group	Strobilurin
Mode of action (if available)	Inhibition of mitochondrial respiration in fungi
Systemic	Yes
Company	Syngenta
Rapporteur Member State (RMS)	United Kingdom
Approval status	Approved Date of 01/01/2012 Commission Regulation (EU) No 703/2011
Restriction	Restricted to uses as fungicide
Review Report	SANCO/11027/2011 – rev. 3 20/03/2015
Current MRL regulation	Commission Regulation (EU) No ~~2019/552 2022/476~~ 2023/129
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal: Conclusion on the peer review	EFSA, 2010
EFSA Journal: Conclusion on Article 12 review	EFSA 2013 EFSA, 2020 (confirmatory data following Article 12 review)
Current MRL applications on intended uses	An Evaluation Report has been prepared and submitted to Germany for review in accordance with Article 6 of Regulation (EC) No 396/2005 in order to modify the existing maximum residue level (MRL) for azoxystrobin in hops.

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

Reference: United Kingdom, 2009

The potential for degradation of residues during storage has been previously assessed in the framework of the peer review for azoxystrobin. Storage stability of azoxystrobin was demonstrated for the following

periods in the commodities listed in the table below when stored frozen (≤ −18°C).
No new data submitted in the framework of this application.

Table 7.2-2: Summary of stability data achieved at ≤ - 18°C

Commodity category	Commodity	Acceptable maximum storage period	Report Reference	Source
EU reviewed data				
Plant products				
High Water Content	Apple	733 days	Burke 1997, RJ2404B	United Kingdom, 2009
	Peach	733 days	Burke 1997, RJ2404B	United Kingdom, 2009
	Banana	728 days	Burke 1997, RJ2404B	United Kingdom, 2009
	Cucumber	729 days	Burke 1997, RJ2404B	United Kingdom, 2009
	Tomato	721 days	Burke 1997, RJ2404B	United Kingdom, 2009
	Lettuce	731 days	Gill, Burke, 2002, RJ3170B	United Kingdom, 2009
	Wheat forage	733 days	Gill, Burke, 2002, RJ3170B	United Kingdom, 2009
High Oil Content	Oilseed rape	734 days	Burke 1997, RJ2404B	United Kingdom, 2009
	Peanut	739 days	Burke 1997, RJ2404B	United Kingdom, 2009
	Pecan	739 days	Burke 1997, RJ2404B	United Kingdom, 2009
High Starch Content	Wheat grain	717 days	Burke 1997, RJ2404B	United Kingdom, 2009
	Carrot	731 days	Gill, Burke, 2002, RJ3170B	United Kingdom, 2009
High Acid Content	Grape	723 days	Burke 1997, RJ2404B	United Kingdom, 2009
No group (dry)	Wheat straw	717 days	Burke 1997, RJ2404B	United Kingdom, 2009
Processed fraction	Wine	723 days	Burke 1997, RJ2404B	United Kingdom, 2009
	Wheat bran	372 days	Burke, 1996, RJ2221B	United Kingdom, 2009
	Tomato juice	362 days	Burke, 1996, RJ2221B	United Kingdom, 2009
	Tomato paste	362 days	Burke, 1996, RJ2221B	United Kingdom, 2009
	Peanut oil	371 days	Burke, 1996, RJ2221B	United Kingdom, 2009
	Peanut meal	365 days	Burke, 1996, RJ2221B	United Kingdom, 2009
	Corn grit	734 days	Gill, Burke, 2002, RJ3170B	United Kingdom, 2009
	Soybean meal	733 days	Gill, Burke, 2002, RJ3170B	United Kingdom, 2009

Commodity category	Commodity	Acceptable maximum storage period	Report Reference	Source
	Orange oil	732 days	Gill, Burke, 2002, RJ3170B	United Kingdom, 2009
	Orange juice	735 days	Gill, Burke, 2002, RJ3170B	United Kingdom, 2009
	Orange pulp	734 days	Gill, Burke, 2002, RJ3170B	United Kingdom, 2009
Animal Products				
Meat	Ruminant	300 days	Sapiets, 1997, RJ2352B	United Kingdom, 2009
Fat	Ruminant	294 days	Sapiets, 1997, RJ2352B	United Kingdom, 2009
Liver	Ruminant	292 days	Sapiets, 1997, RJ2352B	United Kingdom, 2009
Kidney	Ruminant	274 days	Sapiets, 1997, RJ2352B	United Kingdom, 2009
Milk	Ruminant	272 days	Sapiets, 1997, RJ2352B	United Kingdom, 2009
Eggs	Poultry	258 days	Sapiets, 1997, RJ2352B	United Kingdom, 2009
Other	Honey	81 days	Appeltauer, 2022 S21-01128	New Data, Appeltauer, 2022 Appendix 2

Summary of storage stability studies reported in the EU
Reference: EFSA, 2010
"Azoxystrobin and R230310 stable for up to two years when stored at approximately –18°C in: grapes, wine, apples, orange oil, orange juice, orange pulp, bananas, peaches, tomatoes (juice and paste), cucumbers, lettuce, carrot root, cereal straw, cereal grain, soybean meal, oilseed rape, pecans and peanut (oil and nut meat).
Azoxystrobin stable for up to ten months when stored at approximately –18°C in animal tissues, eggs and milk."

Conclusion on stability of residues during storage
The storage stability of azoxystrobin has been investigated in different crop groups, including high water, high oil, high starch, high acid content commodities, dry commodities, various processed commodities for at least 12 months and animal tissues, milk and eggs or at least 10 months. The storage stability of azoxystrobin in honey has been investigated for at least 81 days. Sufficient stability has been demonstrated to support the residue data presented in the submission.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

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

Conclusion on stability of residues in sample extracts
Procedural recoveries obtained during residue analysis demonstrate the stability of residues of azoxystrobin in sample extracts and fully support the residue data presented in the submission.

zRMS comments: In EFSA Journal 2013;11(12):3497 it is stated that *The potential degradation of residues during storage of the residue trials samples was also assessed. In the framework of the peer review, storage stability of azoxystrobin was demonstrated for a period of 24 months at -18°C in commodities with high water content (banana, peach, tomato,*

cucumber, lettuce, carrot), high acid content (grape, apple, orange), high oil content (soybean meal, oilseed rape, pecans, peanut), dry commodities (cereal grain) as well as cereal straw (United Kingdom, 2009a).
(…) The storage stability of azoxystrobin residues in animal products was evaluated under the peer review of Directive 91/414/EEC (United Kingdom, 2009a). Studies demonstrated storage stability of azoxystrobin in milk, muscle, fat, liver and kidney, eggs for up to 10 months when stored deep frozen.

Additionally the Applicant submitted a new study on storage stability of azoxystrobin in honey (Appeltauer, 2022; S21-01128). Azoxystrobin and R230310 have been shown to be stable in honey for at least 81 days when stored frozen at -18ºC.

The residue data are valid with regard to storage stability.
No additional data are required.

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

Reference: United Kingdom, 2009

The metabolism of azoxystrobin was investigated for foliar application on fruits and fruiting vegetables (grape), pulses and oilseeds (peanut) and cereals (wheat) using [^{14}C-pyrimidinyl], [^{14}C-cyanophenyl] and [^{14}C-phenylacrylate] labelled-azoxystrobin. These studies are summarised in the table below.
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				Report Reference	Source
			Method, F or G(a)	Rate (kg a.s./ha)	No	Sampling (DAT)		
EU reviewed data								
Fruits and fruiting vegetables	Grape	^{14}C-pyrimidinyl, ^{14}C-cyanophenyl or ^{14}C-phenyl-acrylate	Foliar, F	0.25, 1.0, 1.0, 0.25	4	21	Earl, Hadfield, 1994, RJ1676B	United Kingdom, 2009
Pulses and oilseeds	Peanut	^{14}C-pyrimidinyl, ^{14}C-cyanophenyl or ^{14}C-phenyl-acrylate	Foliar, F	0.85, 0.85, 0.3	3	10	Emburey et al, 1995, RJ1807B	
Cereals	Wheat	^{14}C-pyrimidinyl, ^{14}C-cyanophenyl or ^{14}C-phenyl-acrylate	Foliar, F	0.5	2	Forage: 13 Mature crop: 61-62	Wilkinson et al, 1994, RJ1682B	
		^{14}C-pyrimidinyl	Foliar, F	0.284	1	28	Allin et al, 1995, RJ1888B	

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

Summary of plant metabolism studies reported in the EU

Reference: EFSA, 2013

"The metabolism pattern was similar in all plant groups, parent azoxystrobin being the major compound, accounting for 17-43% TRR in cereal grain and straw, 35-65% TRR in grapes, and 14-48% TRR in peanut hulls and hay. Azoxystrobin was not detected in peanut nuts, where radioactivity was found to be mainly incorporated in fatty acids (up to 49% TRR), but no individual metabolite was present in peanut kernels at a level greater than 1%. In the other crops, the major metabolites identified were M28, resulting from the cleavage of the ester link between the phenylacrylate and pyrimidyl ring, and metabolite M09 (*Z*-isomer of azoxystrobin), both mostly below 10% TRR. Other metabolites were identified but they were all present in very small amounts."

Conclusion on metabolism in primary crops

The metabolism of azoxystrobin in plants following foliar application is sufficiently addressed to support the proposed foliar uses of the product A22773A.

zRMS comments:

According to the OECD 501 a metabolism in crops study should be submitted for each type of crop group for which use is proposed. In order to extrapolate metabolism of a pesticide to all crop groupings, metabolism studies on a minimum of three representative crops (from the five different crop categories) should be conducted. If the results of these three studies indicate a comparable metabolic route, then additional studies will not be needed.

In EFSA Journal 2022;20(1):7051 it is stated that *The metabolism of azoxystrobin following foliar applications was investigated in crops belonging to the groups of fruit crops (grapes), cereals/grass (wheat) and pulses/oilseeds (peanuts). The metabolism pattern was similar in all plant groups with the parent azoxystrobin being the major compound, accounting for 17–43% total radioactive residue (TRR) in cereal grain and straw, 35–65% TRR in grapes and 14–48% TRR in peanut hulls and hay.*

*Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies and the capabilities of enforcement analytical methods, **the residue definition for enforcement and risk assessment in all plant commodities following foliar application was proposed as 'azoxystrobin'** (EFSA, 2010, 2013). The same residue definition is applicable to rotational crops and processed products. The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above mentioned residue definition.*

For the intended uses, the metabolic behaviour in primary crops is sufficiently addressed.
No additional data are required.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

Reference: *United Kingdom, 2009*

The metabolism of azoxystrobin in rotational crops was investigated in lettuce, radish and wheat using [^{14}C-pyrimidinyl], [^{14}C-cyanophenyl] and [^{14}C-phenylacrylate] labelled-azoxystrobin. Three confined rotational crop studies investigating the nature of residues following different plant-back intervals are available; these studies are summarised in the table below.
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				Report reference	Source
			Method, F or G(a)	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)		
EU reviewed data								
Leafy vegetables	Lettuce	^{14}C-pyrimidinyl, ^{14}C-cyanophenyl or ^{14}C-phenyl-acrylate	Bare soil, G	2.2	30, 200, 365	Maturity	Goldsby *et al*, 1995, RR 95-034B Miller, Wilson, 1995, R 95-017B Tambling, 1995, RR 95-011B	United Kingdom, 2009
Root and tuber vegetables	Radish							
Cereals	Wheat							

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

Summary of metabolism studies in rotational crops reported in the EU

Reference: *EFSA, 2013*

"The TRR in soil declined on average from 0.74–1.0 mg/kg at treatment to 0.79, 0.67 and 0.24 mg/kg at 30, 200, and 365 days after treatment, respectively. The metabolism of azoxystrobin in rotational crops was complex with a large number of conjugated metabolites formed. The residues declined significantly at longer plant back intervals. Radioactive residues in the 365-day crops were generally in concentrations below 0.01 mg/kg. As in the primary crops, parent azoxystrobin represented the major residue detected in all rotational crops (up to 17–44% TRR); with very low residue levels in the tested crops (<0.01–0.08 mg/kg at 30 days and <0.01–0.01 mg/kg at 200 days). In wheat forage and wheat straw at 30 days, TRRs were 0.15–0.34 and 1.4–1.9 mg/kg, respectively, which declined significantly at the longer plant back intervals of 200 days (0.02–0.05 and 0.06– 0.12 mg/kg, respectively) and 365 days (<0.01 mg/kg). Azoxystrobin residues in wheat grain were <0.01 mg/kg even in wheat planted 30 days after the treatment. Compounds G2, M42, N1, N2, O2 and O3, which are the principal metabolites in rotated crops, are glucose conjugates and were also found in the primary crops in both free and conjugated forms. These metabolites are not more toxicologically significant than parent."

Conclusion on metabolism in rotational crops
Metabolism in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.

zRMS comments:
According to the soil degradation studies evaluated in the framework of the peer review, the DT_{50} value of azoxystrobin is 262 days (EFSA, 2010). DT_{90} value is expected to be higher than the trigger value of 100 days (EFSA, 2010), and therefore, studies investigating the nature of residues in rotational crops are required.
In EFSA Journal 2016;14(5):4459 it is stated that *The nature and magnitude of azoxystrobin residues in rotational crops were investigated during the peer review. On the basis of studies conducted in lettuce, radish and wheat at a maximum dose rate of 2,200 g/ha, it was concluded that the metabolism of azoxystrobin is similar to that of the primary crops and that residues above 0.05 mg/kg are not expected in the rotational crops (EFSA, 2013).*

The peer-review concluded that the metabolism of azoxystrobin in succeeding crops is almost similar for all the analysed crops and also similar to that observed in the primary crops. The relevant residue in rotational crops should therefore be defined as parent azoxystrobin.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

Reference: United Kingdom, 2009

The effect of processing on the nature of azoxystrobin 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). The results are summarised in the table below.
No new data submitted in the framework of this application.

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

Conditions	Identified compound(s) (%)	Report reference	Source
EU reviewed data			
Pasteurisation (20 minutes, 90°C, pH 4)	Azoxystrobin (99.7-102.1)	Grout, 2002, RJ3296B	United Kingdom, 2009
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Azoxystrobin (95.5-96.8)		
Sterilisation (20 minutes, 120°C, pH 6)	Azoxystrobin (95.9-98.6)		

Summary of high temperature studies reported in the EU

Reference: *EFSA, 2013*

"The effect of processing on the nature of azoxystrobin 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 processing by pasteurization, baking/brewing/boiling and sterilization is not expected to have a significant impact on the composition of residues in matrices of plant origin (United Kingdom, 2009). The relevant residue for enforcement and risk assessment in processed commodities is therefore expected to be the same as for primary crops."

Conclusion on nature of residues in processed commodities

The nature of residues of azoxystrobin in processed products has been investigated. Azoxystrobin is hydrolytically stable under the representative processing conditions and the same residue definitions as for raw agricultural commodities apply.

zRMS comments: Standard hydrolysis studies simulating the effect on the nature of azoxystrobin residues under processing conditions representative of pasteurisation, boiling and sterilisation were assessed in the peer review and it was concluded that the compound is hydrolytically stable (EFSA, 2010). Thus, for processed commodities, the same residue definition as for raw agricultural commodities is applicable. Studies to assess the magnitude of azoxystrobin residues during processing have been assessed in the framework of the peer review and the Article 12 MRL review and processing factors were derived for several crops (EFSA, 2010, 2013). No further data are required to support the proposed uses.

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	Cereals (wheat), Fruit crops (grapes), Oilseeds/Pulses (peanuts) – foliar treatment
Rotational crops covered	Cereals (wheat), Root vegetables (radish), Leafy vegetables (lettuce) – application to bare soil
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Azoxystrobin is stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Azoxystrobin (EFSA, 2010, Reg. (EU) 2023/129)
Plant residue definition for risk assessment	Azoxystrobin (EFSA, 2010)
Conversion factor from enforcement to RA	None

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

Available data

Reference: United Kingdom, 2009

The metabolism of azoxystrobin was investigated in lactating goats and laying hens using [^{14}C-pyrimidinyl], [^{14}C-cyanophenyl] and [^{14}C-phenylacrylate] labelled-azoxystrobin. These studies are summarised in the table below.

No new data submitted in the framework of this application.

Table 7.2-7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Report reference	Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling		
EU reviewed data									
Lactating ruminants	Goat	^{14}C-pyrimidinyl, ^{14}C-cyanophenyl or ^{14}C-phenyl-acrylate	1[(a)]	0.93-1.04	7	Milk	Twice daily	Webb et al, 1996, RJ2083B	United Kingdom, 2009
						Urine & faeces	Daily		
						Tissues	At sacrifice (18h)		
		^{14}C-cyanophenyl	1	0.88	7	Milk	Twice daily	Turner, Bramley, 1995, RJ1957B	
						Urine & faeces	Daily		
						Tissues	At sacrifice (17.5h)		
Laying poultry	Hen	^{14}C-pyrimidinyl, ^{14}C-cyano-phenyl or ^{14}C-phenyl-acrylate	10[(a)]	0.77-0.81	10	Eggs	Twice daily	Bramley, Turner, 1996, RJ2084B	United Kingdom, 2009
						Excreta	Daily		
						Tissues	At sacrifice (23h)		

(a): per radiolabel

Summary of animal metabolism studies reported in the EU

Reference: *EFSA, 2013*

"All studies showed that azoxystrobin was rapidly excreted in both lactating goats and laying hens. The transfer in tissues was limited, the TRRs in muscle, fat, milk and egg white being <0.02 mg/kg. Thus, characterisation of residues was only performed in goat liver and kidney, and in poultry liver and egg yolk, where the TRRs were in the range of 0.05 to 1.19 mg/kg. In these matrices, the metabolism was shown to be very extensive, more than 20 compounds being identified/characterised, each accounting mostly for less than 5% of the TRR. Some metabolites (M28, M20, L4…) were however observed in higher proportions in some matrices, depending on the ^{14}C-label. The parent compound was less than 2% of the TRR, except in egg yolk (12% TRR for the cyanophenyl label). 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

The metabolism of azoxystrobin in livestock is sufficiently addressed to support the proposed uses of the product A22773A.

zRMS comments:

Information given by the Applicant is sufficient.

In EFSA Journal 2010; 8(4):1542 it is stated that *Azoxystrobin was rapidly excreted in the metabolism studies performed on goats (2N dose) and poultry (8N dose). The transfer in tissues was limited, the TRRs in muscle, fat, milk and egg white being <0.02 mg/kg. Thus, characterisation of residues was only performed in goat liver and kidney, and in poultry liver and egg yolk, where the TRRs were in the range of 0.05 to 1.19 mg/kg. In these matrices, the metabolism was shown to be very extensive, more than 20 compounds being identified/characterised, each accounting mostly for less than 5% of the TRR. Some metabolites (M28, M20, L4…) were however observed in higher proportions in some matrices, depending on the 14C-label. The parent compound was less than 2% of the TRR, except in egg yolk (12% TRR for the cyanophenyl label). None of these compounds were considered as a sufficient marker for the residue in animal matrices, and* ***the residue for monitoring and risk assessment was then defined by default as azoxystrobin only****. However, the definition for risk assessment has to be considered provisional, pending additional information on the toxicological relevance of metabolites L1, L4 and L9.*

According to the EFSA Journal 2020;18(8):6231 – "Evaluation of confirmatory data following the Article 12 and modification of the existing MRLs for azoxystrobin" *In the framework of the MRL review, EFSA identified data*

gaps related to the toxicological relevance of metabolites L1, L4 and L9, which were identified in ruminant liver and kidney (data gap number 35). In order to address this data gap, the applicant provided, in the framework of the current assessment, information that allowed to conclude that the genotoxic potential of these three compounds can be ruled out (see Section 1). However, the applicant did not provide data on the general toxicity of these metabolites. Instead, calculations were provided to demonstrate that the expected dietary exposure of consumers to these metabolites (from the intake of liver and kidney) is low and would therefore not be of toxicological concern.
(…) Regarding the toxicological assessment of livestock metabolites L1, L4 and L9, the submitted data allowed to conclude that the genotoxic potential of these three compounds can be ruled out.
(…) general toxicity of these metabolites was not addressed.

Metabolism studies, methods of analysis and residue definitions in livestock (EFSA, 2020):

Livestock (available studies)	Animal	Dose (mg/kg diet)	Duration (days)	Comment/Source
	Laying hen	11	10	Studies performed on goat using ^{14}C-pyrimidinyl ^{14}C-cyanophenyl and ^{14}C-phenylacrylate radiolabels
		12.5	10	
	Lactating ruminants	23.2–32.7	7	Study performed on goat using ^{14}C-pyrimidinyl ^{14}C-cyanophenyl and ^{14}C-phenylacrylate radiolabels
		25	7	Study performed on goat using ^{14}C-cyanophenyl radiolabel

Time needed to in milk and eggs (days)	Milk: not relevant	TRR in milk is ranging between 0.004–0.01 mg eq/L
	Eggs: 6–8	Observed in egg yolk (United Kingdom, 2009)
Metabolism in rat and ruminant similar	Yes	The general metabolic pathways in rodents and ruminants were found to be comparable
Can a general residue definition be proposed for animals?	Yes	–
Animal residue definition for monitoring (RD-Mo)	Azoxystrobin	
Animal residue definition for risk assessment (RD-RA)	Azoxystrobin (tentative, EFSA, 2010, 2013) [genotoxicity of metabolites L1, L4 and L9 can be ruled out but general toxicity of these metabolites was not addressed]	
Fat soluble residues	No	Log $P_{o/w}$ < 3
Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs)	GC-NPD (United Kingdom, 2009): Milk: LOQ 0.001 mg/kg. Eggs, Muscle, Fat, Liver/kidney: 0.01 mg/kg ILV available but confirmatory method missing. HPLC–MS/MS (validated method in FAO, 2008): LOQ: 0.01 mg/kg in all tissues, milk and eggs	

TRR: total radioactive residue; $P_{o/w}$: partition coefficient between n-octanol and water; GC-NPD: gas chromatography with nitrogen phosphorous detector; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

No further data are required to support the proposed uses.

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	Eggs: not assessed (limited transfer) Milk: not assessed (limited transfer)
Animal residue definition for monitoring	Azoxystrobin (EFSA, 2010, Reg. (EU) 2023/129)
Animal residue definition for risk assessment	Azoxystrobin (EFSA, 2010; EFSA, 2013) Reference: *EFSA, 2010* "The residue in plants was defined as azoxystrobin for monitoring and risk assessment. The same residue definition was set by default for animal products, azoxystrobin being extensively metabolised in animals. However, the definition for risk assessment has to be considered provisional, pending additional information on the toxicological relevance of metabolites L1, L4 and L9." Reference: *EFSA, 2013* "However, no conclusion could be drawn on the toxicological profile of metabolites L127, L4 and L928 (EFSA, 2010). Additional data on the toxicological relevance of metabolites L1, L4 and L9 are therefore required. Meanwhile, it is proposed, on a tentative basis, to also define the residue for risk assessment as azoxystrobin only." Reference: *EFSA, 2020* "Regarding the toxicological assessment of livestock metabolites L1, L4 and L9, the submitted data allowed to conclude that the genotoxic potential of these three compounds can be ruled out. However, data addressing the general toxicity of these compounds were not provided. Based on calculations to demonstrate that the expected dietary exposure of consumers to these metabolites was lower than the TTC, the RMS concluded that further data addressing the general toxicity of these compounds were not needed and thus proposed to confirm the residue definition for risk assessment in animal commodities as azoxystrobin alone. EFSA highlighted that the TTC approach cannot be applied in this context. EFSA concludes that the data gap identified in the framework of the MRL review was only partially addressed. Further risk management considerations should be given to decide whether the argument of the low exposure calculated for metabolites L1, L4, L9 and K1 (conjugate of L1) is acceptable to waive the need to submit data on the general toxicity of L1, L4 and L9. Meanwhile, the residue definition for risk assessment in animal commodities is still deemed tentative."
Conversion factor	None
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

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

New studies on the magnitude of residues in plants have been submitted by the applicant in the framework of this application. Reference is also made to previously evaluated data. The studies are summarized in the Table below. The detailed assessment of the new studies is presented in Appendix 2. The residue trials included in this submission support the intended use.

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of A22773A and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[a] 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
Tomato → extrapolated to eggplant	**Intended GAP**	**N-EU**	**2 x 250 g a.s./ha, BBCH 11-89, 7 d interval, PHI 3**	-				
	Zonal cGAP (Art. 12; EFSA, 2013)	**N-EU**	**N/A**	-				
	EU reviewed**	N-EU	Trials GAP: 3 x 238-268 g a.s./ha, BBCH 71-88, 7d interval, PHI 3 E/RA: 0.04, 0.07, 0.08, 0.25	-				
	New data	N-EU	Trials GAP: 2 x 242-256 g a.s./ha, BBCH 63-82, 7-8 d interval, PHI 3 E/RA: 0.04, 0.05, 0.08[c], 0.11	-				
			Trials GAP: 3 x 238-268 g a.s./ha, BBCH 71-89, 7-8 d interval, PHI 3 E/RA: 0.06, 0.09, 0.11[b][c], 0.12	-				
	Overall supporting data for intended GAP	N-EU	E/RA: 2 x 0.04, 0.05, 0.06, 0.07, 2 x 0.08, 0.09, 2 x 0.11, 0.12, 0.25	0.08	0.25	0.318	3	Yes

N/A Not available
* Source of EU MRL: Regulation (EU) ~~2019/552 2022/476~~ Reg. (EU) 2023/129
** Studies were submitted for the Article 12 review, but were not presented in the EFSA Reasoned Opinion (EFSA, 2013) as they were less critical than the EU critical GAP
(a) Definition of residue for enforcement and risk assessment are the same: azoxystrobin (EFSA, 2010)
(b) Mean of replicates; individual residue values: 0.107, 0.112, 0.104
(c) Residue value from PHI 7 presented, as the residue level from this later PHI 7 was higher than the residue level at PHI 3

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of A22773A and conformity to existing MRL continued

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[(a)] 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
Bell pepper	**Intended GAP**	**N-EU**	**2 x 250 g a.s./ha, BBCH 11-89, 7 d interval, PHI 3**	-				
	Zonal cGAP (Art. 12; EFSA, 2013)	**N-EU**	**N/A**	-				
	EU reviewed**	N-EU	Trials GAP: 2 x 228-273 g a.s./ha, BBCH 62-89, 7-8 d interval, PHI 3 E/RA: 0.17, 0.18, 0.19, 0.2, 2 x 0.21, 0.26, 0.51	-				
	Overall supporting data for intended cGAP	N-EU	E/RA: 0.17, 0.18, 0.19, 0.2, 2 x 0.21, 0.26, 0.51	0.205	0.51	0.724	3	Yes

N/A Not available
* Source of EU MRL: Regulation (EU) ~~2019/552 2022/476~~ Reg. (EU) 2023/129
** Studies were submitted for the Article 12 review, but were not presented in the EFSA Reasoned Opinion (EFSA, 2013) as they were less critical than the EU critical GAP
(a) Definition of residue for enforcement and risk assessment are the same: azoxystrobin (EFSA, 2010)

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of A22773A and conformity to existing MRL continued

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[(a)] 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
Cucumber and zucchini (courgette)	**Intended GAP**	**N-EU**	**2 x 250 g a.s./ha, BBCH 11-89, 7 d interval, PHI 3**	-				
	Zonal cGAP (Art. 12; EFSA, 2013)	**N-EU**	**2 x 250 g a.s./ha, 8-12 d interval, PHI 3**	-				
	New data	N-EU	Trials GAP: 2 x 228-264 g a.s./ha, BBCH 65-78, 6-8 d interval, PHI 3 E/RA: 2 x 0.01, 0.02, 0.03, 0.04, 0.06[(c)], 0.07, 0.12[(d)]	-				
	EU reviewed**	N-EU	Trials GAP: 3 x 192-204 g a.s./ha, BBCH 81-89, 8 d interval, PHI 3 E/RA: *0.08*[(b)], 0.16	-				
			Trials GAP: 3 x 245-270 g a.s./ha, BBCH 61-86, 8 d interval, PHI 3 E/RA: *<0.01*[(b)], *0.05*[(b)]	-				
			Trials GAP: 4 x 250 g a.s./ha, BBCH 31-79, 7-8 d interval, PHI 3 E/RA: **0.04**[(b)], **0.05**[(b)]	-				
			Trials GAP: 3 x 293-308 g a.s./ha, BBCH 65-87, 6-8 d interval, PHI 3 E/RA: **0.11**[(b)], **0.19**[(b)]	-				
	Overall supporting data for intended GAP	N-EU	E/RA: *<0.01*, 2 x 0.01, 0.02, 0.03, 0.04, **0.04**, **0.05**, *0.05*, 0.06, 0.07, *0.08*, **0.11**, 0.12, 0.16, **0.19**	0.050	0.19	0.282	1.0	Yes

* Source of EU MRL: Regulation (EU) ~~2019/552 2022/476~~ Reg. (EU) 2023/129

** Studies were submitted for the Article 12 review, but were not presented in the EFSA Reasoned Opinion (EFSA, 2013) as they were less critical than the EU critical GAP

(a) Definition of residue for enforcement and risk assessment are the same: azoxystrobin (EFSA, 2010)

(b) Data from trials on courgette highlighted in italic text, data from trials on gherkin highlighted in bold, all other data is from trials on cucumber

(c) Residue value from PHI 7 presented, as the residue level from this later PHI 7 was higher than the residue level at PHI 3

(d) There was control contamination in this trial (0.03 mg/kg) which does not appear to have impacted the residue levels in the treated samples (i.e. the residue fall within the range of the residues from the other trials) and hence no correction for control contamination has been made

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of A22773A and conformity to existing MRL continued

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[(a)] 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
Melon → extrapolated watermelon, pumpkin, squash	**Intended GAP**	**N-EU**	**2 x 250 g a.s./ha, BBCH 11-89, 7 d interval, PHI 3**	-				
	Zonal cGAP (Art. 12; EFSA, 2013)	**N-EU**	**N/A**	-				
	EU reviewed**	N-EU	Trials GAP: 3 x 198-215 g a.s./ha, BBCH 66-78, 7-8 d interval, PHI 3 Whole fruit: E/RA: 0.02, 0.05 Pulp: E/RA: <0.01, 0.01	-				
	New data	N-EU	Trials GAP: 2 x 237-261 g a.s./ha, BBCH 65-89, 7-8 d interval, PHI 3 Whole fruit: E/RA: <0.01, 0.03, 2 x 0.05, 2 x 0.06, 0.09[(b)], 0.17 Pulp: E/RA: 8 x <0.01					
	Overall supporting data for intended GAP	N-EU	E/RA: <0.01, 0.02, 0.03, 3 x 0.05, 2 x 0.06, 0.09[(b)], 0.17	0.050	0.17	0.239	1.0	Yes

N/A Not available
* Source of EU MRL: Regulation (EU) ~~2019/552 2022/476~~ Reg. (EU) 2023/129
** Studies were submitted for the Article 12 review, but were not presented in the EFSA Reasoned Opinion (EFSA, 2013) as they were less critical than the EU critical GAP
(a) Definition of residue for enforcement and risk assessment are the same: azoxystrobin (EFSA, 2010)
(b) Residue value from PHI 7 presented, as the residue level from this later PHI 7 was higher than the residue level at PHI 3

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of A22773A and conformity to existing MRL continued

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[(a)] 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
Lettuce → extrapolated to salad plants, sweet basil, and spinach	**Intended GAP****	**N-EU**	**2 x 250 g a.s./ha, BBCH 11-49, 7 d interval, PHI 14**	-				
	Zonal cGAP (Art. 12; EFSA, 2013)	**N-EU**	**4 x 250 g a.s./ha, PHI 14 (proposed NEU GAP: 2 x 250 g a.s./ha, PHI 14 (EFSA, 2020))**	-				
	EU reviewed	N-EU	Trials GAP: 2 x 232-278 g a.s./ha, BBCH 16-49, 7-8 d interval, PHI 14 E/RA: *2 x <0.01*[(b)], 0.03. 0.13, 0.17. 0.22, 0.24, 0.46, 0.49	-				
	Overall supporting data for intended cGAP	N-EU	E/RA: *2 x <0.01*, 0.03. 0.13, 0.17. 0.22, 0.24, 0.46, 0.49	0.17	0.49	0.917	~~15~~ 10 for lettuces and salad plants 15 for spinaches and similar leaves 70 for basil	Yes

* Source of EU MRL: Regulation (EU) ~~2019/552 2022/476~~ Reg. (EU) 2023/129

** A GAP with 1 application (all other parameters are identical) is also included as an intended GAP for evaluation in this submission. This additional GAP is supported by the data supporting the intended cGAP. Another GAP use is proposed, with identical parameters to the intended GAP discussed above, with the exception of a reduced application interval, BBCH 41-49. As this use is less critical, it is considered covered by the intended GAP.

(a) Definition of residue for enforcement and risk assessment are the same: azoxystrobin (EFSA, 2010)

(b) Values in italics: not considered to be true open head lettuce varieties (EFSA, 2020)

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of A22773A and conformity to existing MRL continued

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[(a)] 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
Leek → extrapolated to spring onion	**Intended GAP****	**N-EU**	**2 x 250 g a.s./ha, BBCH 11-49, 12-14 d interval, PHI 7**	-				
	Zonal cGAP (Art. 12; EFSA, 2013)	**N-EU**	**4 x 250 g a.s./ha, PHI 21**	-				
	New data	N-EU	Trials GAP: 2 x 231-257, BBCH 45-49, 10-13 d interval, PHI 7-8 E/RA: 3 x 0.1[(b)], 0.31, 0.45, 2 x 0.51, 1.16	-				
	Overall supporting data for intended GAP	N-EU	E/RA: 3 x 0.1, 0.31, 0.45, 2 x 0.51, 1.16	0.380	1.16	1.825	10	Yes

* Source of EU MRL: Regulation (EU) ~~2019/552 2022/476~~ Reg. (EU) 2023/129

** A GAP with 1 application (all other parameters are identical) is also included for central zone as an intended GAP for evaluation in this submission. This additional GAP is supported by the data supporting the intended cGAP.

(a) Definition of residue for enforcement and risk assessment are the same: azoxystrobin (EFSA, 2010)

(b) In one N-EU trial and in one S-EU trial, the residue value from PHI 10/9, respectively, is presented, as the residue level from this later PHI 10/9 was higher than the residue level at PHI 7

(c) There was control contamination in this trial (0.25 mg/kg); this residue was negligible (in excess of 10-fold lower) when compared to the residue in the corresponding treated sample. Hence, the contamination observed in the untreated sample is not considered to impact the integrity of the trial and no correction for control contamination was made

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of A22773A and conformity to existing MRL continued

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)(a) 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
Hops	**Intended GAP*** **	**N-EU**	**2 x 250 g a.s./ha, BBCH 21-89, 12-16 d interval, PHI 28**	-				
	Zonal cGAP (Art. 12; EFSA, 2013)	**N-EU**	**2 x 400 g a.s./ha, BBCH 31-89, 14-28d interval, PHI 28**	-				
	New data (supplementary data)	N-EU	*Trials GAP: 2 x 382-440 g a.s./ha, BBCH 65-78, 6-8 d interval, PHI 26-28* *E/RA: 1.13, 5.25(d), 5.86(d), 7.03(d), 8.37, 17.3(d), 20.8(c)*	-				
	EU reviewed		Trials GAP: 2 x 400 g a.s./ha(b), BBCH 37-71, 5-14 d interval, PHI 26-28 E/RA: 1.1 (d), 1.2, 1.3, 2.5, 5.7(d), 2 x 11(d), 12(d)	-				
	Overall supporting data for intended GAP	N-EU	E/RA: 1.1, 1.13, 1.2, 1.3, 2.5, 5.25, 5.7, 5.86, 7.03, 8.37, 2 x 11, 12, 17.3, 20.8	5.86	20.8	31.679	30	~~No**~~ Yes**

N/A Not available
* Source of EU MRL: Regulation (EU) ~~2019/552 2022/476~~ Reg. (EU) 2023/129
** An Evaluation Report has been prepared and will be submitted to Germany for review in accordance with Article 6 of Regulation (EC) No 396/2005 in order to modify the existing maximum residue level (MRL) for azoxystrobin in hops. Evaluation of the MRL will begin during Q4 2021 / Q1 2022 by the EMS and should be completed by end of 2022.
Since the HR is 20.8 mg/kg, zRMS-PL believes that the residues arising from the proposed use will not exceed the MRLs established for azoxystrobin for hops of 30 mg/kg in Reg. (EU) 2023/129.
*** A GAP with 1 application (all other parameters are identical) is also included for central zone as an intended GAP for evaluation in this submission. This additional GAP is supported by the data supporting the intended cGAP
(a) Definition of residue for enforcement and risk assessment are the same: azoxystrobin (EFSA, 2010)
(b) In the trials reviewed by EFSA during the Article 12 review (EFSA, 2013) 6 applications were made (application rate = 210 – 480 g a.s./ha). In all cases, the final 2 applications were conducted at 400 g a.s./ha (± 25%)
(c) Mean of experimental replicates: two trials with identical application and sample timings were conducted within 0.5 km of each other; these are therefore considered to be experimental replicates (EFSA, 2015a)
(d) In these trials residues were found in control samples of dried cone (0.01-0.23 mg/kg). In all cases, the residue in the untreated (control) sample was negligible (in excess of 20-fold lower) when compared to the residue in the corresponding treated sample. Hence, the contamination observed in some of the untreated samples is not considered to impact the integrity of the trials and no correction for control contamination was made

7.2.3.2 Conclusion on the magnitude of residues in plants

Tomato, extrapolated to eggplant

Tomato is a major crop in northern and southern Europe (SANTE/2019/12752) and therefore normally requires eight northern trials and eight southern trials to support an EU MRL. According to the Commission Technical Guideline SANTE/2019/12752, application rates within ±25% are considered to give comparable residue levels. Additionally, the OECD Crop Field Trial Guideline (OECD 509) highlights the acceptability of ±10% deviation from nominal GAP parameters as a result of natural variability.
The intended GAP is 2 x 250 g a.s./ha, BBCH 11-89, 7 d interval, PHI 3.

A total of twelve trials were conducted on tomato. The application rate was 250 g a.s./ha ±10% in all trials. The application interval was 7 days in all trials with the exception of two, which had an application interval of 8 days. This application interval can be considered to be within the acceptable deviation range of ±10% of nominal when rounded (i.e. 7 days ±10%). Four trials are considered to have been conducted according to the intended GAP for A22773A (2 x 250 g a.s./ha, BBCH 11-89, 7 d interval, PHI 3) whereas eight trials were conducted at a more critical GAP (a nominal application rate of 3 x 250 g a.s./ha, BBCH 11-89, 7 d interval, PHI 3), thus covering the intended use. Residues in untreated tomato fruit samples collected at normal commercial harvest (PHI 3 days) were below the limit of quantification (0.01 mg/kg).
Therefore, sufficient trials are available to support the proposed use on tomato (foliar application; outdoor uses). The available data submitted show that no exceedance of the existing EU MRL will occur. The proposed use of azoxystrobin in A22773A on outdoor tomato is therefore considered acceptable.
According to the Commission Technical Guideline SANTE/2019/12752, residue data from tomato trials can be extrapolated to aubergine/eggplant for which the same EU MRL applies as for tomato. Sufficient trials are available to support the proposed use on eggplant (foliar application; outdoor uses). Therefore, the proposed use of azoxystrobin in A22773A on outdoor eggplant is considered acceptable.

zRMS comments:
Information given by the Applicant is sufficient.
Tomato is the major crop in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of eight trials are required. Residue data on tomato (0231010) can be extrapolated to aubergines/eggplants (0211030) before and after forming of the edible part.

The intended GAP for azoxystrobin for tomatoes in Central Europe is 2x250 g a.s./ha with interval between applications of 7 days at BBCH 11-89 with PHI of 3 days.

New studies on the magnitude of residue have been submitted by the Applicant in the framework of this application. The trials are supported by valid storage stability data for tomatoes and validated analytical methods.
A total of 8 new supervised residue trials were performed in Northern Europe:
1. Souchier M. (2017), Report No. S16-03843 - the tested application rates and timings, corresponded to the intended GAPs for A22773A.
Residues of azoxystrobin in tomato samples taken at 3 DALA, normal commercial harvest (NCH) were between 0.04 and 0.11 mg/kg.
2. Andrews G., Coleman H. (2016), Report No. NC15017 – three applications at 250 g ai/ha were applied to tomatoes. Timings corresponded to the intended GAPs for A22773A.
Residues of azoxystrobin in tomato samples taken at 3 DALA, normal commercial harvest (NCH) were between 0.06 and 0.12 mg/kg.

The residues arising from the proposed uses will not exceed the MRLs established for azoxystrobin for tomatoes and aubergines/eggplants of 3 mg/kg in ~~Reg. (EU) 2022/476~~ Reg. (EU) 2023/129.
The uses are considered acceptable.

Bell pepper

Bell pepper is a major crop in northern and southern Europe (SANTE/2019/12752) and therefore normally requires eight northern trials and eight southern trials to support an EU MRL. According to the Commission Technical Guideline SANTE/2019/12752, application rates within ±25% are considered to give comparable residue levels. Additionally, the OECD Crop Field Trial Guideline (OECD 509) highlights the acceptability of ±10% deviation from nominal GAP parameters as a result of natural variability.

The intended GAP is 2 x 250 g a.s./ha, BBCH 11-89, 7 d interval, PHI 3.

A total of eight trials were conducted on bell pepper according to the intended GAP. The application rate was 250 g ai/ha ± 10% in all trials. The application interval was 7 days in all trials with the exception of one which had an interval of 8 days. This application interval can be considered to be within the acceptable deviation range of ±10% of nominal when rounded (i.e. 7 days ±10%). All trials are considered to have been conducted according to the intended GAP for A22773A (2 x 250 g a.s./ha, BBCH 11-89, 7 d interval, PHI 3). Residues in untreated pepper fruit samples collected at normal commercial harvest (PHI 3 days) were below the limit of quantification (0.01 mg/kg).
Therefore, sufficient trials are available to support the proposed use on bell pepper (foliar application; outdoor uses). The available data submitted show that no exceedance of the existing EU MRL will occur. The proposed use of azoxystrobin in A22773A on outdoor bell pepper is therefore considered acceptable.

zRMS comments:
Information given by the Applicant is sufficient.
Pepper is the major crop in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of eight trials are required.

The intended GAP for azoxystrobin for bell pepper in Central Europe is 2x250 g a.s./ha with interval between applications of 7 days at BBCH 11-89 with PHI of 3 days.

No new studies on the magnitude of residue have been submitted by the Applicant in the framework of this application. The studies reviewed at EU level were conducted in North France (2008, 2009 and 2011) and in Hungary (2012). For all the trials, two applications of 'A12705B' were applied at a nominal rate of 0.25 kg as/ha. The interval between applications was 7-8 days.

The trials were supported by valid storage stability data for pepper and validated analytical methods.
No residues were found in control samples above the stated LOQ of 0.01 mg/kg.

Residues of azoxystrobin in peppers samples taken at 3 DALA, normal commercial harvest (NCH) were between 0.17 and 0.51 mg/kg.

The residues arising from the proposed uses will not exceed the MRLs established for azoxystrobin for sweet peppers/bell peppers of 3 mg/kg in ~~Reg. (EU) 2022/476~~ Reg. (EU) 2023/129.
The use is considered acceptable.

Cucumber and zucchini (courgette)
Cucumber is a major crop in northern Europe and courgette is a major crop in southern Europe (SANTE/2019/12752) and therefore normally eight northern trials and eight southern trials are required either on cucumber/courgette to support an EU MRL. According to the Commission Technical Guideline SANTE/2019/12752, application rates within ±25% are considered to give comparable residue levels. Additionally, the OECD Crop Field Trial Guideline (OECD 509) highlights the acceptability of ±10% deviation from nominal GAP parameters as a result of natural variability.
The intended GAP is 2 x 250 g a.s./ha, BBCH11-89, 7 d interval, PHI 3.

A total of sixteen trials were conducted on cucurbits. Eight trials (one on cucumber, four on gherkin and three on courgette) were conducted according to a GAP (a nominal application rate of 3-4 x 200-300 g a.s/ha, BBCH 31-89, 6-8 d interval, PHI 3) which is more critical than the zonal critical GAP (i.e. 2 applications at 250 g a.s./ha, 8-12 d interval, PHI 3). Although at least one additional application was made compared to the zonal cGAP, sufficient data are available to demonstrate that the outdoor use on cucurbits is less critical than the protected use, on which the EU MRL is set. Additionally, it has been demonstrated in a range of crops that residues of azoxystrobin rapidly decline between applications (EFSA, 2013). Hence, the additional application is considered to have a negligible impact on residues. Although the application rate in two of the residue trials was less than 250 g a.s./ha, the actual application rate in all trials was within ±25% of the target application rate and all other application parameters are considered meet the intended GAP (within ±10% nominal). Hence, in accordance with SANTE/2019/12752, all trials are considered acceptable for supporting an application rate of 250 g a.s./ha. A further eight trials (all on cucumber) were

conducted according to the intended GAP. The application rate was 250 g ai/ha ±10% in all trials. The application interval was 6-8 days which is within the acceptable deviation range of ±10% of nominal 7 days.
Residues in untreated cucurbit fruit samples collected at normal commercial harvest (PHI 3 days) were below the limit of quantification (0.01 mg/kg) except in one trial (residue in control 0.03 mg/kg). This is still considered acceptable, because the residue result in the treated sample was in line with the results from other trials. No correction for control contamination was performed.
Additional trials are presented in Appendix 2, but two cucumber trials were excluded from the MRL calculation because one of the applications was outside of the ±25% acceptability range. One gherkin trial was also excluded because the second interval was 9 days.
The intended GAP for A22773A (2 x 250 g a.s./ha, BBCH 11-89, 7 d interval, PHI 3) is within the risk envelope of the zonal cGAP for the northern residue zone, and is less critical than the trials GAP. As detailed above, the actual application rate in all trials was within ±25% of the target application rate. Additionally, the application and sample timings were within ±10% of nominal when compared to the intended GAP.
Therefore, sufficient trials are available to support the proposed use on cucumber and zucchini (courgette) (foliar application; outdoor uses). The available data submitted show that no exceedance of the existing EU MRL will occur. The proposed uses of azoxystrobin in A22773A on outdoor cucumber and zucchini are therefore considered acceptable.

zRMS comments:
Information given by the Applicant is sufficient.
Cucumber is the major crop in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of eight trials are required. Zucchini (courgette) is the minor crop in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of four trials are required.
Residue data on cucumbers (0232010) and/or courgettes (0232030) can be extrapolated to Whole subgroup (b) cucurbits with edible peel before and after forming of the edible part.

The intended GAP for azoxystrobin for cucumber and zucchini (courgette) in Central Europe is 2x250 g a.s./ha with interval between applications of 7 days at BBCH 11-89 with PHI of 3 days.

New studies on the magnitude of residue have been submitted by the Applicant in the framework of this application. The trials are supported by valid storage stability data for cucumbers and gherkins and validated analytical methods.
A total of 10 new supervised residue trials were performed in Northern Europe:
1. Giles A. (2021), Report No. 684120- the tested application rates and timings, corresponded to the intended GAPs for A22773A.
Residues of azoxystrobin in cucumbers samples taken at 3 DALA, normal commercial harvest (NCH) were between <0.01 and 0.12 mg/kg.
2. Gill J.P., Chamier O.D. (1998) Report No. RJ2589B – four applications at 250 g ai/ha were applied to gherkins. Timings corresponded to the intended GAPs for A22773A.
Residues of azoxystrobin in gherkins samples taken at 3 DALA, normal commercial harvest (NCH) were between 0.04 and 0.05 mg/kg.

The residues arising from the proposed uses will not exceed the MRLs established for azoxystrobin for cucumbers, gherkins and courgettes of 1 mg/kg in ~~Reg. (EU) 2022/476~~ Reg. (EU) 2023/129.
The uses are considered acceptable.

Melon, extrapolated to watermelon, pumpkin and squash
Melon is a major crop in southern Europe and a minor crop in northern Europe (SANTE/2019/12752) and therefore normally eight southern trials and four northern trials on melon are required to support an EU MRL. Watermelon is a major crop in both northern and southern Europe and therefore eight trials on melon or watermelon are required to support an EU MRL. According to the Commission Technical Guideline SANTE/2019/12752, application rates within ±25% are considered to give comparable residue levels. Additionally, the OECD Crop Field Trial Guideline (OECD 509) highlights the acceptability of ±10% deviation from nominal GAP parameters as a result of natural variability.
The intended GAP is 2 x 250 g a.s./ha, BBCH 11-89, 7 d interval, PHI 3.

A total of ten trials were conducted on melon. Two trials were conducted according to a GAP (3 applications

at a nominal application rate of 200 g a.s./ha, BBCH 66-78, 7-8 d interval, PHI 3) which can be considered to be more critical than the intended GAP (2 applications at 250 g a.s./ha, BBCH 11-89, 7 d interval, PHI 3) when taking into account the ±25% rule in accordance with SANTE/2019/12752. Eight trials were conducted according to the intended GAP. The application rate was 250 g ai/ha ± 10% in all trials. The application interval was 7 days in all trials with the exception of two which had an interval of 8 days. This application interval can be considered to be within the acceptable deviation range of ±10% of nominal when rounded (i.e. 7 days ±10%). All trials are considered to have been conducted according to the intended GAP for A22773A (2 x 250 g a.s./ha, BBCH 11-89, 7 d interval, PHI 3). Residues in untreated melon whole fruit samples calculated from residue values in pulp and peel collected at normal commercial harvest (PHI 3 days) were below the limit of quantification (0.01 mg/kg).
Therefore, sufficient trials are available to support the proposed use on melon (foliar application; outdoor uses). The available data submitted show that no exceedance of the existing EU MRL will occur. The proposed use of azoxystrobin in A22773A on outdoor melon is therefore considered acceptable.
According to the Commission Technical Guideline SANTE/2019/12752, residue data from melon trials can be extrapolated to watermelons, pumpkin and squash for which the same EU MRL applies as for melon. Sufficient trials are available to support the proposed use on watermelon, pumpkin and squash (foliar application; outdoor uses). Therefore, the proposed use of azoxystrobin in A22773A on outdoor watermelon, pumpkin and squash is considered acceptable.

zRMS comments:
Information given by the Applicant is sufficient.
Watermelon is the major crop in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of eight trials are required. Melon is the minor crop in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of four trials are required.
Residue data on melons (0233010) can be extrapolated to Whole subgroup (c) cucurbits with inedible peel before and after forming of the edible part.

The intended GAP for azoxystrobin for melon, watermelon, pumpkin and squash in Central Europe is 2x250 g a.s./ha with interval between applications of 7 days at BBCH 11-89 with PHI of 3 days.

New studies on the magnitude of residue have been submitted by the Applicant in the framework of this application. A total of 8 new supervised residue trials were performed in Northern Europe:
1. Giles A. (2021), Report No. 684125- the tested application rates and timings, corresponded to the intended GAPs for A22773A. The trials are supported by valid storage stability data for melons and validated analytical methods. Residues of azoxystrobin in melons pulp samples taken at 3 DALA, normal commercial harvest (NCH) were <0.01 mg/kg.

The residues arising from the proposed uses will not exceed the MRLs established for azoxystrobin for cucurbits with inedible peel (melons, pumpkins amd watermelons) of 1 mg/kg in ~~Reg. (EU) 2022/476~~ Reg. (EU) 2023/129. The uses are considered acceptable.

Lettuce, extrapolated to salad plants, sweet basil and spinach
Lettuce is a major crop in northern and southern Europe (SANTE/2019/12752) and therefore normally requires eight northern trials and eight southern trials to support an EU MRL. According to the Commission Technical Guideline SANTE/2019/12752, application rates within ±25% are considered to give comparable residue levels. Additionally, the OECD Crop Field Trial Guideline (OECD 509) highlights the acceptability of ±10% deviation from nominal GAP parameters as a result of natural variability.
The intended GAP is 2 x 250 g a.s./ha, BBCH 11-49, 7 d interval, PHI 14.

A total of nine trials were conducted on lettuce according to the intended GAP. The application rate was 250 g ai/ha ± 10% in all trials with the exception of one application which had an application rate of 278 g ai/ha (+11.2%). This deviation is considered acceptable based on the 25% rule in accordance with SANTE/2019/12752. The application interval was 7 days in all trials with the exception of one which had an interval of 8 days which is within the acceptable deviation range of ±10% of nominal 7 days. All trials are considered to have been conducted according to the intended GAP for A22773A (2 x 250 g a.s./ha, 7 d interval, PHI 14). Residues in untreated lettuce samples collected at normal commercial harvest (PHI 14 days) were below the limit of quantification (0.01 mg/kg). Additional plots were included in these trials and are presented in Appendix 2; only the highest residue values from the side-by-side plots were taken for assessment.

These trials have been recently EU reviewed and considered acceptable to support the proposed use on lettuce. During peer review, it was acknowledged that two of the trials were conducted on close leaf varieties, and hence only seven trials are available on open leaf varieties. EFSA concluded that *"while the guidance document on extrapolation typically requires eight trials on open leaf varieties to allow extrapolation from lettuce trials to all crops belonging to the group of lettuce and other salad plants (crop group code 251000)[.....] considering that the northern outdoor GAPs and the southern outdoor GAPs result in significantly lower MRLs compared to the indoor GAP, one additional trial on open leaf varieties in NEU and one additional trial on open leaf varieties in SEU are not required [……] Regarding the magnitude of residues in lettuce and other salad plants, the data gaps identified in the framework of the MRL review were addressed."*

Therefore, sufficient trials are available to support the proposed use on lettuce (foliar application; outdoor uses). The available data submitted show that no exceedance of the existing EU MRL will occur. The proposed use of azoxystrobin in A22773A on outdoor lettuce is therefore considered acceptable.

An alternative GAP with 1 application (all other parameters are identical) is also included as an intended GAP for evaluation in this submission. This additional GAP is supported by the data supporting the intended cGAP.

Another GAP use is proposed, with identical parameters to the intended GAP discussed above, with the exception of a reduced application interval, BBCH 41-49. As this use is less critical, it is considered covered by the intended GAP.

According to the Commission Technical Guideline SANTE/2019/12752, residue data from lettuce trials can be extrapolated to salad plants, sweet basil and spinach for which the same EU MRL applies as for lettuce. Sufficient trials are available to support the proposed use on salad plants, sweet basil and spinach (foliar application; outdoor uses). Therefore, the proposed use of azoxystrobin in A22773A on outdoor salad plants, sweet basilnd spinach is considered acceptable.

zRMS comments:

Information given by the Applicant is sufficient and accepted.

Lettuce is the major crop in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of eight trials are required. Salad plants, sweet basil and spinach are the minor crops in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of four trials are required.

Residue data on lettuces (0251020) (trials from open leaf varieties) can be extrapolated to Whole subgroup (a) lettuces and salad plants (0251000), to Whole subgroup (b) spinaches and similar leaves (0252000) and to Whole subgroup (f) herbs and edible flowers (0256000) before and after forming of the edible part.

The intended GAP for azoxystrobin for lettuce, salad plants, sweet basil and spinach in Central Europe is 2x250 g a.s./ha with interval between applications of 7 days at BBCH 11-49 with PHI of 14 days.

No new studies on the magnitude of residue have been submitted by the Applicant in the framework of this application. Nine trials were reviewed at EU level. For all the trials, two applications were applied at a nominal rate of 0.25 kg as/ha. The interval between applications was 7-8 days with PHI of 14 days.

The trials were supported by valid storage stability data for lettuce and validated analytical methods.

No residues were found in control samples above the stated LOQ of 0.01 mg/kg.

Residues of azoxystrobin in lettuce samples taken at 14 DALA, normal commercial harvest (NCH) were between <0.01 and 0.49 mg/kg.

The residues arising from the proposed uses will not exceed the MRLs established for azoxystrobin for lettuces and salad plants of 10 mg/kg and spinaches and similar leaves of 15 mg/kg and basil of 70 mg/kg in ~~Reg. (EU) 2022/476~~ Reg. (EU) 2023/129.

The uses are considered acceptable.

<u>*Leek, extrapolated to spring onion*</u>

Leek is a major crop in northern Europe and minor crop in southern Europe (SANTE/2019/12752) and therefore normally requires eight northern trials and four southern trials to support an EU MRL. According

to the Commission Technical Guideline SANTE/2019/12752, application rates within ±25% are considered to give comparable residue levels. Additionally, the OECD Crop Field Trial Guideline (OECD 509) highlights the acceptability of ±10% deviation from nominal GAP parameters as a result of natural variability.
The intended GAP is 2 x 250 g a.s./ha, BBCH 11-49, 12-14 d interval, PHI 7.

A total of eight trials were conducted on leek according to the intended GAP. The application rate was 250 g ai/ha ± 10% in all trials. The application interval was 11-13 days in all trials which is within the acceptable deviation range of ±10%, except in one trial where the interval was 10 days which is still considered acceptable because it is more critical than the minimum intended interval of 12 days. All trials are considered to have been conducted according to the intended GAP for A22773A (2 x 250 g a.s./ha, 12-14 d interval, PHI 7). Residues in untreated leek samples collected at normal commercial harvest (PHI 7 days) were below the limit of quantification (0.01 mg/kg).
Therefore, sufficient trials are available to support the proposed use on leek (foliar application; outdoor uses). The available data submitted show that no exceedance of the existing EU MRL will occur. The proposed use of azoxystrobin in A22773A on outdoor leek is therefore considered acceptable.
A GAP with 1 application (all other parameters are identical) is also included as an intended GAP for evaluation in this submission. This additional GAP is supported by the data supporting the intended cGAP.
According to the Commission Technical Guideline SANTE/2019/12752, residue data from leek trials can be extrapolated to spring onion for which the same EU MRL applies as for leek. Sufficient trials are available to support the proposed use on spring onion (foliar application; outdoor uses). Therefore, the proposed use of azoxystrobin in A22773A on outdoor spring onion is considered acceptable.

zRMS comments:
Information given by the Applicant is sufficient.
Leek is the major crop in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of eight trials are required. Spring onion is the minor crop in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of four trials are required.
Residue data on leeks (0270060) can be extrapolated to spring onions/green onions and Welsh onions (0220040) before and after forming of the edible part.

The intended GAP for azoxystrobin for leek and spring onions in Central Europe is 2x250 g a.s./ha with interval between applications of 12-14 days at BBCH 11-49 with PHI of 7 days.

New study on the magnitude of residue have been submitted by the Applicant in the framework of this application. A total of 8 new supervised residue trials were performed in Northern Europe during 2020.
1. Giles A. (2021), Report No. 684141- the tested application rates and timings, corresponded to the intended GAPs for A22773A. The trials are supported by valid storage stability data for leek and validated analytical methods. Residues of azoxystrobin in leek samples taken at 7-8 DALA, normal commercial harvest (NCH) were between 0.09-1.16 mg/kg.

The residues arising from the proposed uses will not exceed the MRLs established for azoxystrobin for leek and spring onions of 10 mg/kg in ~~Reg. (EU) 2022/476~~ Reg. (EU) 2023/129.
The uses are considered acceptable.

Hops
Hops is a minor crop in northern and southern Europe (SANTE/2019/12752) and therefore normally requires four northern trials and four southern trials to support an EU MRL. According to the Commission Technical Guideline SANTE/2019/12752, application rates within ±25% are considered to give comparable residue levels. Additionally, the OECD Crop Field Trial Guideline (OECD 509) highlights the acceptability of ±10% deviation from nominal GAP parameters as a result of natural variability.
The intended GAP is 2 x 250 g a.s./ha, BBCH 21-89, 12-16 d interval, PHI 28.

A total of sixteen trials were conducted on hops according to a more critical GAP than the intended GAP. Eight trials were conducted on hops according to the zonal critical GAP (i.e. 2 applications at a nominal application rate of 400 g a.s./ha, BBCH 31-89, 14-28 d interval, PHI 28). Although the trials were conducted using 6 applications of azoxystrobin, and the application rates varied due to the height of the crop, the last two applications were conducted according to the zonal cGAP in all cases, with the exception of the application intervals. The application intervals were outside of the desired range, but were more critical or equivalent to the intended range in all cases (i.e. 5-14 days rather than 12-16 days). These trials have been previously EU reviewed (EFSA, 2013).

Eight additional trials were conducted on hops using 2 applications and a more critical GAP than the intended GAP (GAP: 2 applications at a nominal application rate of 400 g a.s./ha, BBCH 65-78, 6-8 d interval, PHI 26-28). These have not been previously EU reviewed and are provided as supplementary data as they demonstrate that, in accordance with the conclusions drawn during the Article 12 review (EFSA, 2013), residues from the applications performed prior to the last two applications do not have a significant impact on the residues. Two of these trials can be considered to be co-located, as they were conducted in the same year, were only separated by 0.5 km, and had identical application and sample timings. As a consequence, in accordance with the EFSA guidance on ‘Residue trials and MRL calculations’ (EFSA, 2015a), the mean residue value from these two trials is presented (individual residue values = 29.2 mg/kg and 12.4 mg/kg; mean = 20.8 mg/kg). An additional two trials were also conducted in the same year as each other but, although only separated by 0.5 km, are not considered to be co-located as all other aspects were notably different (i.e. the variety, application timing and sample timings).

Residues in untreated hops cone samples collected at normal commercial harvest (PHI 26-28 days) were above the limit of quantification (0.01 mg/kg) in four of the previously EU reviewed trials and five of the non-EU reviewed trials. In all cases, the residue in the untreated sample was negligible (in excess of 20-fold lower) when compared to the residue in the corresponding treated sample. Hence, the contamination observed in some of the untreated samples is not considered to impact the integrity of the trials.

The intended GAP for A22773A (2 x 250 g a.s./ha, 12-16 d interval, PHI 28) is within the risk envelope of the zonal cGAP for the northern residue zone. Based on the available data, sufficient trials are considered to be available to support the proposed use on hops (foliar application; outdoor uses).

It is acknowledged that, although the trials provided as supplementary data afford a HR which is lower than the current EU MRL (HR = 20.8 mg/kg, current EU MRL = 30 mg/kg), hence demonstrating that the current EU MRL is sufficiently protective and unlikely to be exceeded, when the residue data from this supplementary data are used to calculate an unrounded OECD calculator MRL value, an MRL of 40 mg/kg is afforded. The existing, previously EU reviewed data, and the new, non-EU reviewed data, can be considered to be statistically comparable according to the Mann-Whitney U-Test and, hence, the two datasets can be combined in accordance with the EFSA guidance on ‘Residue trials and MRL calculations’ (EFSA, 2015a). An MRL of 40 mg/kg is afforded from the combined datasets. As a consequence, an Evaluation Report has been prepared and will be submitted to Germany for review in accordance with Article 6 of Regulation (EC) No 396/2005 in order to modify the existing maximum residue level (MRL) for azoxystrobin in hops. Evaluation of the MRL will begin during Q4 2021 / Q1 2022 by the EMS and should be completed by end of 2022.

A GAP with 1 application (all other parameters are identical) is also included as an intended GAP for evaluation in this submission. This additional GAP is supported by the data supporting the intended cGAP.

zRMS comments:

Information given by the Applicant is sufficient.

Hops is the minor crop in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of four trials are required.

The intended GAP for azoxystrobin for hops in Central Europe is 2x250 g a.s./ha with interval between applications of 12-16 days at BBCH 21-89 with PHI of 28 days.

Eight trials were conducted on hops according to the zonal critical GAP (i.e. 2 applications at a nominal application rate of 400 g a.s./ha, BBCH 31-89, 14-28 d interval, PHI 28). These trials have been previously EU reviewed (EFSA, 2013). Treated dried samples produced from 28 DALA hops samples gave residues of azoxystrobin in the range 1.1 to 12 mg/kg.

The residues arising from the proposed uses will not exceed the MRLs established for azoxystrobin for hops of 30 mg/kg in ~~Reg. (EU) 2022/476~~ Reg. (EU) 2023/129.

Additionally, new study on the magnitude of residue have been submitted by the Applicant in the framework of this application. These above two studies have not been previously EU reviewed and are provided as supplementary

data. A total of 8 new supervised residue trials were performed in Northern Europe during 2020. 1. two trials - Wormald S. (2011), Report No. T009307-07-REG – the tested application rates were higher than the intended GAPs for A22773A: 2x400 g ai/ha with 8 day interval intsed of 12-16 days. The trials are supported by valid storage stability data for hops and validated analytical methods. For one trial residues of azoxystrobin were found at 0.04 mg/kg in the untreated fresh and dried hops samples. Treated dried samples produced from 28 DALA hops samples gave residues of azoxystrobin in the range 1.13 to 7.03 mg/kg. This study can only be considered as informative. 2. six trials - Wormald S. (2011), Report No. FSGD-063-REG - the tested application rates were higher than the intended GAPs for A22773A: 2x400 g ai/ha with 6-8 day interval intsed of 12-16 days. The trials are supported by valid storage stability data for hops and validated analytical methods. For some trial residues of azoxystrobin and R230310 were found beetwen <0.01 mg/kg and 0.23 mg/kg in the untreated fresh and dried hops samples. Treated dried samples produced from 28 DALA hops samples gave residues of azoxystrobin in the range 5.25 to 29.2 mg/kg. This study can only be considered as informative. Taking into account evaluated residue studies on hops at EU level, the uses are considered acceptable.

Ornamentals (Pot plants, Tree and Shrubs), Afforestation, Forest tree plantation, Reforestation

zRMS comments: The intended uses on ornamentals are not relevant in terms of consumer health protection. The submission of supervised residue trials is not necessary. Taking into above account, the proposed uses are considered acceptable.

7.2.4 Magnitude of residues in livestock

The use of A22773A in this zone would not result in residues of azoxystrobin in animal feed items. However, the use of azoxystrobin on a wide range of crops is widespread throughout all zones in the EU. Therefore, the possible transfer of residues in animal commodities from all uses should be considered. Livestock intake calculations and feeding studies undertaken are provided below, and cover all uses of azoxystrobin in the EU. The results of these calculations have been used to derive input values for animal commodities in the consumer risk assessment presented in Section 7.2.8 and Appendix 3.

7.2.4.1 Dietary burden calculation

The median and maximum dietary burdens for livestock were calculated under the Article 12 MRL review using the animal feedstuff table listed in the EU guideline 7031/VI/95 rev.4 (European Commission, 1996) and considering livestock intake of all feed products containing residues resulting from all authorised uses of azoxystrobin in Europe (EFSA, 2013). Following the Article 12 MRL review, additional EFSA reasoned opinions which impact the livestock dietary burdens were issued (EFSA, 2016a; EFSA, 2021). Within these reasoned opinions, EFSA updated the dietary burden calculations considering the residues resulting from the additional uses of azoxystrobin on linseed, safflower and sugar beet, the feedstuff table reported in the OECD guidance 64 Series on Pesticides 32 (OECD, 2009), and the animal model calculator developed by EFSA. The input values are summarised in Table 7.2-10.

Table 7.2-10: Input values for the dietary burden calculation (considering the uses evaluated under the Article 12/Article 6 procedure)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: azoxystrobin				
1. Forages				

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Cabbage, heads	0.03	STMR (EFSA, 2013)	0.17	HR (EFSA, 2013)
Kale	1.04	STMR (EFSA, 2013)	3.50	HR (EFSA, 2013)
Sugar beet, tops	0.21	STMR (EFSA, 2013)	0.38	HR (EFSA, 2013)
Barley, oats, straw	2.3	STMR (EFSA, 2013)	5.5	HR (EFSA, 2013)
Wheat, rye, triticale, straw	3.85	STMR (EFSA, 2013)	10.10	HR (EFSA, 2013)
2. Roots & Tubers				
Carrot, culls	0.10	STMR (EFSA, 2013)	0.24	HR (EFSA, 2013)
Potato, culls	0.02	STMR (EFSA, 2013)	0.03	HR (EFSA, 2013)
Swede, roots	0.05	STMR (EFSA, 2013)	0.10	HR (EFSA, 2013)
Turnip, roots	0.06	STMR (EFSA, 2013)	0.11	HR (EFSA, 2013)
3. Cereal grains/crop seeds				
Barley, oats, grain	0.10	STMR (EFSA, 2013)	0.10	STMR (EFSA, 2013)
Wheat, rye, triticale, grain	0.08	STMR (EFSA, 2013)	0.08	STMR (EFSA, 2013)
Maize, sorghum, grain	0.01	STMR (EFSA, 2013)	0.01	STMR (EFSA, 2013)
Bean, pea, seed	0.01	STMR (EFSA, 2013)	0.01	STMR (EFSA, 2013)
Lupin, seed	0.01	STMR (EFSA, 2013)	0.01	STMR (EFSA, 2013)
Soybean, seed	0.05	STMR (EFSA, 2013)	0.05	STMR (EFSA, 2013)
4. By-products				
Citrus pomace	4.75 x 10	STMR (EFSA, 2016a) x PF default	4.75 x 10	STMR (EFSA, 2016a) x PF default
Sugar beet, dried pulp	1.35	STMR (EFSA, 2021)[(a)]	1.35	STMR (EFSA, 2021)[(a)]
Sugar beet, ensiled pulp	1.35	STMR (EFSA, 2021)[(a)]	1.35	STMR (EFSA, 2021)[(a)]
Sugar beet, molasses	1.35	STMR (EFSA, 2021)[(a)]	1.35	STMR (EFSA, 2021)[(a)]
Oilseed rape, meal	0.11 x 2	STMR (EFSA, 2013) x PF default	0.11 x 2	STMR (EFSA, 2013) x PF default
Linseed, meal	0.02 x 2	STMR (EFSA, 2016a) x PF default	0.02 x 2	STMR (EFSA, 2016a) x PF default
Lupin seed, meal	0.01 x 1.1	STMR (EFSA, 2013) x PF default	0.01 x 1.1	STMR (EFSA, 2013) x PF default
Sunflower, meal	0.01 x 2	STMR (EFSA, 2013) x PF default	0.01 x 2	STMR (EFSA, 2013) x PF default
Potato, process waste	0.02 x 20	STMR (EFSA, 2013) x PF default	0.02 x 20	STMR (EFSA, 2013) x PF default
Potato, dried pulp	0.02 x 38	STMR (EFSA, 2013) x PF default	0.02 x 38	STMR (EFSA, 2013) x PF default
Wheat, gluten meal	0.08 x 1.8	STMR (EFSA, 2013) x PF default	0.08 x 1.8	STMR (EFSA, 2013) x PF default
Wheat, milled-by-products	0.08 x 7	STMR (EFSA, 2013) x PF default	0.08 x 7	STMR (EFSA, 2013) x PF default
Maize, milled-by-products	0.01 x 1	STMR (EFSA, 2013) x PF default	0.01 x 1	STMR (EFSA, 2013) x PF default

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Maize, hominy meal	0.01 x 6	STMR (EFSA, 2013) x PF default	0.01 x 6	STMR (EFSA, 2013) x PF default
Maize, gluten feed	0.01 x 2.5	STMR (EFSA, 2013) x PF default	0.01 x 2.5	STMR (EFSA, 2013) x PF default
Maize, gluten meal	0.01 x 1	STMR (EFSA, 2013) x PF default	0.01 x 1	STMR (EFSA, 2013) x PF default
Rice, bran/pollard	0.52 x 10	STMR (EFSA, 2013) x PF default	0.52 x 10	STMR (EFSA, 2013) x PF default
Brewer's grain	0.10 x 3.3	STMR (EFSA, 2013) x PF default	0.10 x 3.3	STMR (EFSA, 2013) x PF default
Distiller's grain	0.08 x 3.3	STMR (EFSA, 2013) x PF default	0.08 x 3.3	STMR (EFSA, 2013) x PF default
Safflower meal	0.02 x 2	STMR (EFSA, 2016a) x PF default	0.02 x 2	STMR (EFSA, 2016a) x PF default
Soybean meal	0.05 x 1.3	STMR (EFSA, 2013) x PF default	0.05 x 1.3	STMR (EFSA, 2013) x PF default
Soybean hulls	0.05 x 13	STMR (EFSA, 2013) x PF default	0.05 x 13	STMR (EFSA, 2013) x PF default

STMR: supervised trials median residue; HR: highest residue; PF: processing factor
(a): For sugar beet roots by-products, no default processing factor was applied because tentative PF calculated indicate that concentration of residues in these commodities is not expected

The results of the dietary burden calculations are reported in

Table 7.2-11. The calculated dietary burdens for cattle, sheep, swine and poultry were found to exceed the trigger value of 0.004 mg/kg bw per day. Further investigation of residues is therefore required in these groups of livestock.

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)
Risk assessment residue definition: azoxystrobin					
Beef cattle*	0.1017	0.185	Citrus, dried pulp	7.72	Y
Dairy cattle*	0.4604.	0.590	Citrus, dried pulp	15.35	Y
Ram/ewe	0.1061	0.204	Rye, straw	6.12	Y
Lamb	0.1096	0.237	Rye, straw	5.57	Y
Breeding swine	0.202	0.245	Citrus, dried pulp	10.60	Y
Finishing swine*	0.017	0.023	Sugar beet, dried pulp	0.75	Y
Broiler poultry	0.021	0.025	Swede, roots	0.35	Y
Layer poultry*	0.047	0.099	Wheat, straw	1.45	Y
Turkey	0.011	0.015	Swede, roots	0.21	Y

* These categories correspond to those (formerly) assessed at EU level.

zRMS comments:
Azoxystrobin is authorised for use on several crops that might be fed to livestock. The median and maximum dietary burdens has been calculated for different groups of livestock using the EFSA Animal model 2017.
The calculated dietary burden for azoxystrobin was found to exceed the trigger value of 0.1 mg/kg DM (or 0.004 mg/kg bw/d, respectively) for all groups of livestock. Therefore, further investigation of residues is required.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Feeding studies in livestock are triggered.
No new data were submitted in the framework of this application.

Available data

References: *United Kingdom, 2009; EFSA, 2013*

Livestock feeding studies for azoxystrobin have been conducted in lactating cows (Sapiets, Ryan, 1995, RJ1878B) and laying hens (Sapiets, Farrelly, 1997, RJ2349B). These were reviewed during the approval process and are considered to be acceptable.

Four groups of lactating cows, each consisting of three animals, were dosed for 30 consecutive days with azoxystrobin at levels of 5, 25, 75 and 250 mg/kg in the diet (equivalent to 0.18, 0.91, 2.73 and 9.09 mg/kg bw). Three groups of laying hens, each consisting of twelve animals were dosed for 28 consecutive days with azoxystrobin at levels of 6, 18, and 60 mg/kg in the diet (equivalent to 0.39, 1.2 and 3.9 mg/kg bw). The samples were analyzed for parent azoxystrobin. In milk and eggs, a plateau level was never reached and no residues at or above 0.01 mg/kg was found in any of the samples.

Consequently, the available data are considered sufficient for deriving MRLs in ruminants, pigs and poultry. These MRLs were derived in compliance with the latest recommendations on this matter (FAO, 2009) and are summarized in Table 7.2-12. Significant residues in tissues of ruminants, pigs and poultry, eggs and milk are not expected and exceedance of the current EU MRLs as detailed in Regulation (EU) 2019/552 is not anticipated.

Table 7.2-12: Summary of the outcome of livestock feeding studies

Matrix	STMR (mg/kg)[(a)]	HR (mg/kg)[(b)]	MRL (mg/kg)	CF for RA
Enforcement residue definition: azoxystrobin				
Poultry muscle	0.01	0.01	0.01	n/a
Poultry fat	0.01	0.01	0.01	n/a
Poultry liver	0.01	0.01	0.01	n/a
Eggs	0.01	0.01	0.01	n/a
Pig muscle	0.01	0.01	0.01	n/a
Pig fat	0.01	0.01	0.01	n/a
Pig liver	0.01	0.01	0.01	n/a
Pig kidney	0.01	0.01	0.01	n/a
Ruminant muscle	0.01	0.01	0.01	n/a
Ruminant fat	0.01	0.01	0.01	n/a
Ruminant liver	0.01	0.01	0.01	n/a
Ruminant kidney	0.01	0.01	0.01	n/a
Ruminant milk	0.01	0.01	0.01	n/a
Sheep/goat muscle	0.01	0.01	0.01	n/a
Sheep/goat fat	0.01	0.01	0.01	n/a
Sheep/goat liver	0.01	0.01	0.01	n/a
Sheep/goat kidney	0.01	0.01	0.01	n/a
Sheep/goat milk	0.01	0.01	0.01	n/a

(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) according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).
n/a: not applicable

Table 7.2-13: 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)[(c)]	Calculated MRL (mg/kg)	CF for RA[(d)]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)[(a)]	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Enforcement residue definition: azoxystrobin; **Risk assessment residue definition:** azoxystrobin												
EU reviewed data (United Kingdom, 2009)												
Pig meat	0.076	0.214	0.18	3	< 0.01	< 0.01	< 0.01	< 0.01	0.01	0.01	0.01	--
			0.91	3	< 0.01	< 0.01	< 0.01	< 0.01				
			2.73	3	< 0.01	< 0.01	< 0.01	< 0.01				
			9.09	3	< 0.01	< 0.01	< 0.01	< 0.01				
Pig fat	0.076	0.214	0.18	3	< 0.01	< 0.01	< 0.01	< 0.01	0.01	0.01	0.01	--
			0.91	3	< 0.01	< 0.01	< 0.01	< 0.01				
			2.73	3	0.02	0.02	0.02	0.02				
			9.09	3	0.02	0.02	0.02	0.02				
Pig liver	0.076	0.214	0.18	3	< 0.01	< 0.01	< 0.01	< 0.01	0.01	0.01	0.01	--
			0.91	3	0.01	0.01	0.01	0.01				
			2.73	3	0.03	0.03	0.03	0.03				
			9.09	3	0.05	0.05	0.05	0.05				
Pig kidney	0.076	0.214	0.18	3	< 0.01	< 0.01	< 0.01	< 0.01	0.01	0.01	0.01	--
			0.91	3	< 0.01	< 0.01	< 0.01	< 0.01				
			2.73	3	0.01	0.01	0.01	0.01				
			9.09	3	0.02	0.02	0.02	0.02				
Ruminant meat	0.174	0.497	0.18	3	< 0.01	< 0.01	< 0.01	< 0.01	0.01	0.01	0.01	--
			0.91	3	< 0.01	< 0.01	< 0.01	< 0.01				
			2.73	3	< 0.01	< 0.01	< 0.01	< 0.01				

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[(b)]	Highest residue (mg/kg)[(c)]	Calculated MRL (mg/kg)	CF for RA[(d)]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)[(a)]	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Enforcement residue definition: azoxystrobin; **Risk assessment residue definition:** azoxystrobin												
EU reviewed data (United Kingdom, 2009)												
			9.09	3	< 0.01	< 0.01	< 0.01	< 0.01				
Ruminant fat	0.174	0.497	0.18	3	< 0.01	< 0.01	< 0.01	< 0.01	0.01	0.01	0.01	--
			0.91	3	< 0.01	< 0.01	< 0.01	< 0.01				
			2.73	3	0.02	0.02	0.02	0.02				
			9.09	3	0.02	0.02	0.02	0.02				
Ruminant liver	0.174	0.497	0.18	3	<0.01	<0.01	< 0.01	< 0.01	0.01	0.01	0.01	--
			0.91	3	0.01	0.01	0.01	0.01				
			2.73	3	0.03	0.03	0.03	0.03				
			9.09	3	0.05	0.05	0.05	0.05				
Ruminant kidney	0.174	0.497	0.18	3	< 0.01	< 0.01	< 0.01	< 0.01	0.01	0.01	0.01	--
			0.91	3	< 0.01	< 0.01	< 0.01	< 0.01				
			2.73	3	0.01	0.01	0.01	0.01				
			9.09	3	0.02	0.02	0.02	0.02				
Ruminant Milk	0.174	0.497	0.18	3	< 0.01[(e)]	N/A	< 0.01[(e)]	N/A	0.01	0.01	0.01	--
			0.91	3	< 0.01[(f)]	N/A	< 0.01[(f)]	N/A				
			2.73	3	< 0.01[(f)]	N/A	< 0.01[(f)]	N/A				
			9.09	3	< 0.01[(f)]	N/A	< 0.01[(f)]	N/A				
Poultry meat	0.102	0.297	0.39	12	n.a.	n.a.	n.a.	n.a.	0.01	0.01	0.01	--

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)(b)	Highest residue (mg/kg)(c)	Calculated MRL (mg/kg)	CF for RA(d)
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)(a)	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Enforcement residue definition: azoxystrobin; **Risk assessment residue definition:** azoxystrobin												
EU reviewed data (United Kingdom, 2009)												
			1.2	12	n.a.	n.a.	n.a.	n.a.				
			3.9	12	< 0.01	< 0.01	< 0.01	< 0.01				
Poultry fat	0.102	0.297	0.39	12	n.a.	n.a.	n.a.	n.a.	0.01	0.01	0.01	--
			1.2	12	n.a.	n.a.	n.a.	n.a.				
			3.9	12	< 0.01	< 0.01	< 0.01	< 0.01				
Poultry liver	0.102	0.297	0.39	12	n.a.	n.a.	n.a.	n.a.	0.01	0.01	0.01	--
			1.2	12	n.a.	n.a.	n.a.	n.a.				
			3.9	12	< 0.01	< 0.01	< 0.01	< 0.01				
Eggs	0.102	0.297	0.39	12	n.a.	n.a.	n.a.	n.a.	0.01	0.01	0.01	--
			1.2	12	n.a.	n.a.	n.a.	n.a.				
			3.9	12	< 0.01	< 0.01	< 0.01	< 0.01				

N/A: Not applicable – only the mean values are considered for calculating MRLs in milk.
n.a.: Not analysed
(a): Based on a 412.5 kg/bw cow consuming 15 kg feed DM/day and based on a 1.83 kg/bw laying hen consuming 0.12 kg feed DM/day.
(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).
(c): 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.
(e): Mean residue level from day 1 until day 30 (4 cows, 9 sampling days).
(f): Mean residue level from day 1 until day 30 (4 cows, 10 sampling days).

Summary of livestock studies reported in the EU

Reference: EFSA, 2013

"During the peer review under Directive 91/414/EEC, the magnitude of azoxystrobin residues in livestock was investigated in feeding studies with lactating cows and laying hens (United Kingdom, 2009). Four groups of lactating cows, each consisting of three animals, were dosed for 30 consecutive days with azoxystrobin at levels of 5, 25, 75 and 250 mg/kg in the diet (equivalent to 0.18, 0.91, 2.73 and 9.09 mg/kg bw). Three groups of laying hens, each consisting of twelve animals were dosed for 28 consecutive days with azoxystrobin at levels of 6, 18, and 60 mg/kg in the diet (equivalent to 0.39, 1.2 and 3.9 mg/kg bw). The samples were analyzed for parent azoxystrobin. In milk and eggs, a plateau level was never reached and no residues at or above 0.01 mg/kg was found in any of the samples."

Conclusion on feeding studies

The new mode of calculation modifies the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk of the existing animal MRLs being exceeded.

zRMS comments: Data presented by Applicant in point 7.2.4.2 have been accepted and are sufficient to support the proposed uses. The requested uses and 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 (~~Reg. (EU) 2022/476~~ Reg. (EU) 2023/129). No additional data are required.

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

As residues of azoxystrobin exceeding 0.1 mg/kg are expected in a number of the treated crops, studies investigating the magnitude of residues in processed commodities are required.

Data/information on processing studies for azoxystrobin on grapes, cereals and fresh beans was reviewed during the approval of the active substance and were considered acceptable. Additionally, new processing studies have been submitted by the applicant in the framework of this application. These studies are summarized in the table below. The detailed results are presented in Appendix 2.

7.2.5.1 Available data for all crops under consideration

Available data

References: United Kingdom, 2009

Processing studies for azoxystrobin have been conducted for grapes: must, white wine, juice, dry pomace, wet pomace, wheat: whole meal flour, whole meal bread, white flour, white bread, bran, barley: brewing malt, beer, pot, bran and fresh beans with pods: tips, trimmed, blanched, canned, cooked and were reviewed during the approval process and are considered to be acceptable.

References: EFSA, 2013

Processing studies for azoxystrobin have been conducted for hops and processing factors for beer, spent hops, wort and spent yeast were derived by EFSA, 2013. These studies are summarized in the table below. The detailed results are presented in Appendix 2.

~~New~~ Processing studies have been submitted by the applicant in the framework of this application. These studies are summarized in the table below. The detailed results are presented in Appendix 2.

Table 7.2-14: Overview of the available processing studies relevant for crops under consideration

Processed commodity	No. studies	Individual PF values	Mean PF	Median PF*	Comments	Report references	Source
Enforcement residue definition: azoxystrobin; **Risk assessment residue definition**: azoxystrobin							
Tomato							
Tomato, washed fruit *New data*	2	0.33, 0.44	0.39	0.39	-	Clarke, Bonfanti, 1998, RJ2488B	~~New data~~ Data evaluated by zRMS-UK in Registration Report for A12705B in February 2017
Tomato, peeled fruit *New data*	2	<0.07, <0.06	<0.07	<0.07	-		
Tomato, peel *New data*	2	0.87, 0.88	0.88	0.88	-		
Tomato, puree *New data*	2	0.67, 0.38	0.53	0.53	-		
Tomato, ketchup *New data*	2	0.27, 0.25	0.26	0.26	-		
Tomato, juice *New data*	2	0.13,0.25	0.19	0.19	-		
Tomato, conserve *New data*	2	<0.07, <0.06	<0.07	<0.07	-		
Hops							
Hops, trub (spent hops)	3	0.03, 0.06, 0.07	0.05	0.06	-	Gill, Kappes, Renner, 1999, RJ2841B Gill, Kappes, Griehl, 2000, RJ3015B	EFSA, 2013
Hops, wort	3	0.01, 0.01, 0.01	0.01	0.01	-		
Hops, young beer	3	0.01, 0.01, 0.01	0.01	0.01	-		
Hops, spent yeast	3	0.02,0.02, 0.01	0.02	0.02	-		
Hops, beer	3	0.01, 0.01, 0.01	0.01	0.01	-		

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

7.2.5.2 Conclusion on processing studies

Summary of processing studies reported in the EU

Reference: United Kingdom, 2009

"Adequate mass balance and follow-up processing studies are available for determining transfer factors for azoxystrobin residues in processed wheat commodities. These transfer factors can be used in consumer assessments to estimate dietary exposures to azoxystrobin in the following processed wheat commodities: wheat grain into flour, wheat germ, and bread. As a result of the low incurred residues seen in the processing studies the calculated processing factors are unreliable and careful judgement should be exercised if they are used quantitatively."

Reference: EFSA, 2013

"Robust processing factors for enforcement and risk assessment were derived for peeled bananas, white wine, must, grape juice, grape pomace (wet and dry), brewing malt, beer, barley pot, barley bran, wholemeal and white flour, bread, wheat bran, fresh beans with pods cooked and canned. The processing factors reported for the other processed commodities should be considered as indicative as a minimum of 3 processing studies is normally required."

Processing factors for azoxystrobin were derived for beer.

Conclusion on processing studies
The magnitude of residues in processed commodities relevant for crops under consideration has been sufficiently addressed to support the proposed uses of the product A22773A.

zRMS comments: Data presented by Applicant in point 7.2.5 have been accepted and are sufficient to support the proposed uses. Studies on the processing of hops and tomatoes were evaluated by zRMS-UK in Registration Report for A12705B in February 2017. Based on the information presented by zRMS-UK in Registration Report for A12705B, the processing studies are not expected to significantly affect the consumer risk assessment. This conclusion was in line with that made in the EFSA Article 12 reasoned opinion on the review of the existing MRLs for azoxystrobin (EFSA Journal 2013;11(12):3497 p.45). The studies provided by the applicant have not been evaluated in detail. An overview of the studies indicates that they were conducted to GLP and measured azoxystrobin residue levels in appropriate processed fractions using suitably validated methods of analysis. Most of the processing factors determined by the trials were <1 and none of the results obtained present any reason for concern. The transfer factor for azoxystrobin residues from raw agricultural commodity to beer was 0.003 in both studies. No additional data are required.

7.2.6 Magnitude of residues in representative succeeding crops

Data dealing with magnitude of residues in succeeding crops are available/have been submitted and are summarised hereafter.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

Reference: United Kingdom, 2009a

In addition to the confined rotational crop study, several rotational crop field trials were evaluated in the framework of the peer review. Azoxystrobin was applied on lettuce, cucumber and wheat, the magnitude of residues was investigated on several succeeding crops (lettuce, beetroot, radish, turnip, mustard, millet and wheat) sown at different plant-back intervals following application of the active substance.
No new data submitted in the framework of this application.

Table 7.2-15: 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			Report reference	Source
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)		
EU reviewed data						
Lettuce	0.224	Leafy vegetables	Lettuce	31, 61, 63	Ediger, 2002, 492-01	United Kingdom, 2009a
		Root and tuber vegetables	Beetroot	31, 61, 63		
		Cereals	Wheat	32, 61		
Wheat	0.896	Root and tuber vegetables	Radish	34	Grant, 1996, RR 96-034B	United Kingdom, 2009a
			Turnip	29		
		Pulses and oilseeds	Mustard	29, 34		
		Cereals	Millet	29, 34, 45		
Cucumber	0.1792	Root and tuber vegetables	Turnip	30, 36	Roper, 1996, RR 96-092B	United Kingdom, 2009a
		Pulses and oilseeds	Mustard	30, 36		
		Cereals	Wheat	30, 36, 45, 51, 59, 61,		

Summary of field rotational crop studies reported in the EU

Reference: EFSA, 2013

"In addition to the confined rotational crop study, several rotational crop field trials were evaluated in the framework of the peer review (United Kingdom, 2009, 2009a). Azoxystrobin was applied on wheat, cucumber or lettuce at 2 x 0.896 kg a.s./ha, 7-8 x 0.224 kg a.s./ha and 6 x 0.373 kg a.s./ha, respectively. After harvest of these crops, rotational crops (mustard, lettuce, radish, turnip, beetroot and wheat) were sown at one, two or three different plant-back intervals (29 to 60 days following application of the active substance) and magnitude of residues was investigated in the different commodities thereof. Considering that all trials were overdosed, a correction factor was applied to the highest residue found in each commodity. At harvest, azoxystrobin residues were expected to be below the LOQ (0.01 mg/kg) in all mature plant parts except in wheat forage and wheat straw. The highest residues were expected to be 0.05 mg/kg and 0.04 mg/kg, respectively. However, although these residues might increase the dietary burden intake of livestock, no impact on the residue level in products of animal origin is awaited."

Conclusion on rotational crops studies

The magnitude of residues in rotational crops has been sufficiently addressed in the available studies to support the proposed uses of the product A22773A.

zRMS comments:

Data presented by Applicant in point 7.2.6 have been accepted and are sufficient to support the proposed uses.

EFSA concluded in EFSA Journal 2022;20(1):7051 that *The possible transfer of azoxystrobin residues to crops that are grown in crop rotation has been assessed in the EU pesticides peer review and the MRL review (EFSA, 2010, 2013). In the context of the MRL review, it was concluded that no residues above the LOQ (0.01 mg/kg) are expected in crop parts intended for human consumption and that residues are very low in commodities intended for feed purposes (0.05 mg/kg in wheat forage and 0.04 mg/kg in wheat straw) (EFSA, 2013).*

Since the maximum annual application rate for the crops under consideration (i.e. 0.5 kg a.s./ha) is lower than the maximum seasonal application rate assessed during the MRL review (i.e. 1 kg a.s./ha), the previous conclusion remains valid, provided that the active substance is applied according to the proposed GAP.

No additional data are required.

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

A22773A may be used on crops which can be considered to be melliferous (Commission Services, 2018). Therefore, the possible transfer of residues to honey from the relevant uses should be considered. Two studies were conducted to investigate azoxystrobin residues in honey following exposure of bees to treated winter oil-seed rape (Bocksch, 2008; T011298-06-REG and Appeltauer, 2022; S21-01128). These studies are briefly summarised; the detailed assessment is presented in Appendix 2.

<u>*Bocksch, 2008; T011298-06-REG*</u>
The study contained three trials during 2007 in Northern and Southern Germany. In each trial tunnels were placed in oil seed rape fields to maximise the exposure of the bee colonies to the treated rape plants. Each trial consisted of four tunnels (one control and three treated). To each of the three treated tunnels a single foliar application of azoxystrobin (ICl5504, A 12750B, 250 SC) and cyproconazole (SAN619, A9898A, 100 SL) as a tank mixture was made to oil-seed rape at the onset of flowering. Honey was then collected for analysis of azoxystrobin and cyproconazole.
The health effects on the bee colonies were also monitored.
Samples were analysed for azoxystrobin, its metabolite R230310 and cyproconazole; due to low amounts of honey in trial G07N013B both ship and retain samples were sent for analysis.
The methods were validated in compliance with European guidelines for residue analytical methods SANCO/825/00 Rev.7 (17/03/2004) and SANCO/3029/99 Rev.4 (11/07/2000) and are also in compliance with the new guideline for residue analytical methods SANTE/2020/12830, Rev.1 (24/02/2021).
At each fortification level, the mean recoveries for each analyte were in the range 71-103% and the relative standard deviation less than 20%. The specificity of the method was demonstrated with the two transitions described in the methods, with no significant interference being detected in any of the blank and unfortified specimens. The linearity of the detector was checked using calibration solutions. The calibration curves obtained were linear with correlation coefficients above 0.990.
In two tunnels from one of the trials (G07N011B), residues of azoxystrobin were found to be at the limit of quantification (0.01 mg/kg), all other residues were below LOQ.

<u>*Appeltauer, 2022; S21-01128*</u>
The study contained four trials conducted during 2021 in Germany, Austria and Spain. In each trial tunnels were placed in oilseed rape fields to maximise the exposure of the bee colonies to the treated rape plants. Each trial consisted of two tunnels (one control and one treated). To each of the treated tunnels two foliar applications of azoxystrobin (A12750B, 250 SC) were made to oilseed rape during flowering, at BBCH 62 and BBCH 63-65, separated by a 5-7 day interval. Mature honey was then collected 2-18 days after last application (DALA).

The health effects on the bee colonies were also monitored.

Samples were analysed for azoxystrobin and its metabolite R230310.

Samples were analysed using method RAM 305/03, an LC-MS./MS method to determine residues of azoxystrobin and its metabolite R230310. Acceptable concurrent recoveries were reported for honey at fortification levels of 0.01 and 0.1 mg/kg, thus validating the method. The limit of quantification (LOQ) was 0.01 mg/kg.

The stability of azoxystrobin and R230310 during storage in honey was assessed within the study; azoxystrobin and R230310 were demonstrated to be stable for up to 81 days when stored at -18°C in honey.

Residues of azoxystrobin in mature honey ranged from < 0.01 mg/kg to 0.02 mg/kg. Residues of R230310 in mature honey were below the limit of quantification (LOQ; 0.01 mg/kg).

Table 7.2-16: Summary of Residue Data and Related MRLs

Region	Residue Data (mg/kg)	Highest Residue (mg/kg)	Existing EU MRL (mg/kg)
EU	0.01, <0.01, <0.01<0.01, <0.01, <0.01, 0.02	0.02	0.05

An MRL of 0.05 mg/kg has already been established for azoxystrobin in honey in the EU (Regulation (EC) No. 396/2005) which is higher than the highest residue value observed in the residue trials, shown in the table above. Therefore, no change to the existing EU MRL is proposed and no MRL exceedances are anticipated as a result of the use of A22773A on melliferous crops.

zRMS comments:
Data presented by Applicant in point 7.2.7 have been accepted and are sufficient to support the proposed uses.

Appeltauer, 2022; S21-01128
The study contained five field trials (four were performed successfully) on winter oilseed rape was conducted in northern/southern Europe. Azoxystrobin was applied to winter oilseed rape as A12705B, an SC formulation containing nominally 250 g azoxystrobin per litre. Two applications, (applied at growth stage 62-65 BBCH), separated by a 5-7 day interval were made at a nominal rate of 250 g ai/ha. Mature honey was then collected 2-18 days after last application (DALA).
The ranges of residues of azoxystrobin were <0.01 – 0.02 mg/kg and R230310 were <0.01 mg/kg.
No residues of azoxystrobin and its metabolite R230310 at or above the limit of quantification of 0.01 mg/kg were found in any of the untreated honey samples.
Samples were stored frozen for a maximum period of 76 days from sampling to extraction. The residue data are valid with regard to storage stability.

The residues arising from the proposed uses will not exceed the MRLs established for azoxystrobin for honey of 0.05 mg/kg in ~~Reg. (EU) 2022/476~~ Reg. (EU) 2023/129.
No additional data are required.

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

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population (EFSA, 2018).
Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see section 7.1.2).
As an ARfD was not deemed necessary, therefore an acute risk assessment is not relevant.

7.2.8.1 Input values for the consumer risk assessment

For the chronic intake assessment, the TMDI (Theoretical Maximum Daily Intake) was calculated using EFSA PRIMo rev. 3.1 and the MRLs as defined in ~~Reg. (EU) No. 2019/552~~ Reg. (EU) 2023/129 as input values. ~~Additionally, a refined chronic risk assessment was conducted by assessing the International Estimated Daily Intake (IEDI) relative to the azoxystrobin acceptable daily intake (ADI) based on the EFSA PRIMo rev. 3.1 model.~~ The input values for the ~~IEDI~~ TDMI calculation are provided in **Błąd! Nie można odnaleźć źródła odwołania.**.
An acute consumer exposure assessment was not performed, as the setting of an ARfD was concluded to be unnecessary for azoxystrobin (EFSA, 2010).

Table 7.2-17: Input values for the consumer risk assessment

~~Commodity code~~	~~Commodity~~	~~Chronic risk assessment~~	
		~~Input value (mg/kg) STMR~~	~~Reference~~
~~Risk assessment residue definition: Azoxystrobin~~			
~~0110010~~	~~Grapefruits~~	~~4.9 x 0.37~~	~~STMR x PFpeel/pulp (FAO, 2008, 2008a)~~

~~Commodity code~~	~~Commodity~~	~~Chronic risk assessment~~	
		~~Input value (mg/kg) STMR~~	~~Reference~~
~~0110020~~	~~Oranges~~	~~4.9 x 0.37~~	~~STMR x PFpeel/pulp (FAO, 2008, 2008a)~~
~~0110030~~	~~Lemons~~	~~4.9 x 0.37~~	~~STMR x PFpeel/pulp (FAO, 2008, 2008a)~~
~~0110040~~	~~Limes~~	~~4.9 x 0.37~~	~~STMR x PFpeel/pulp (FAO, 2008, 2008a)~~
~~0110050~~	~~Mandarins~~	~~4.9 x 0.37~~	~~STMR x PFpeel/pulp (FAO, 2008, 2008a)~~
~~0110990~~	~~Other citrus fruit~~	~~4.9 x 0.37~~	~~STMR x PFpeel/pulp (FAO, 2008, 2008a)~~
~~0120010~~	~~Almonds~~	~~0.01~~	~~STMR (FAO, 2008, 2008a)~~
~~0120020~~	~~Brazil nuts~~	~~0.01~~	~~STMR (FAO, 2008, 2008a)~~
~~0120030~~	~~Cashew nuts~~	~~0.01~~	~~STMR (FAO, 2008, 2008a)~~
~~0120040~~	~~Chestnuts~~	~~0.01~~	~~STMR (FAO, 2008, 2008a)~~
~~0120050~~	~~Coconuts~~	~~0.01~~	~~STMR (FAO, 2008, 2008a b)~~
~~0120060~~	~~Hazlenuts/cobnuts~~	~~0.01~~	~~STMR (FAO, 2008, 2008a)~~
~~0120070~~	~~Macadamia~~	~~0.01~~	~~STMR (FAO, 2008, 2008a)~~
~~0120080~~	~~Pecans~~	~~0.01~~	~~STMR (FAO, 2008, 2008a)~~
~~0120090~~	~~Pine nuts~~	~~0.01~~	~~STMR (FAO, 2008, 2008a)~~
~~0120100~~	~~Pistachios~~	~~0.44~~	~~STMR (FAO, 2008, 2008a b)~~
~~0120110~~	~~Walnuts~~	~~0.01~~	~~STMR (FAO, 2008, 2008a)~~
~~0140010~~	~~Apricots~~	~~0.74~~	~~STMR (FAO, 2008, 2008a)~~
~~0140020~~	~~Cherries~~	~~0.74~~	~~STMR (FAO, 2008, 2008a)~~
~~0140030~~	~~Peaches~~	~~0.74~~	~~STMR (FAO, 2008, 2008a)~~
~~0140040~~	~~Plums~~	~~0.74~~	~~STMR (FAO, 2008, 2008a)~~
~~0140990~~	~~Other stone fruit~~	~~0.74~~	~~STMR (FAO, 2008, 2008a b)~~
~~0151010~~	~~Table grapes~~	~~0.72~~	~~STMR (EFSA, 2016)~~
~~0151020~~	~~Wine grapes~~	~~0.72~~	~~STMR (EFSA, 2016)~~
~~0152000~~	~~Strawberries~~	~~1.3~~	~~STMR (FAO, 2008, 2008a)~~
~~0153010~~	~~Blackberries~~	~~1~~	~~STMR (FAO, 2008, 2008a)~~
~~0153020~~	~~Dewberries~~	~~1~~	~~STMR (FAO, 2008, 2008a)~~
~~0153030~~	~~Raspberries~~	~~1~~	~~STMR (FAO, 2008, 2008a)~~
~~0153990~~	~~Other cane fruit~~	~~1~~	~~STMR (FAO, 2008, 2008a)~~
~~0154010~~	~~Blueberries~~	~~1~~	~~STMR (FAO, 2008, 2008a)~~
~~0152020~~	~~Cranberries~~	~~0.23~~	~~STMR (FAO, 2008, 2008a)~~
~~0154030~~	~~Currants (black, red and white)~~	~~1~~	~~STMR (FAO, 2008, 2008a)~~
~~0154040~~	~~Gooseberries (green, red and yellow)~~	~~1~~	~~STMR (FAO, 2008, 2008a)~~
~~0154050~~	~~Rose hips~~	~~1~~	~~STMR (FAO, 2008, 2008a)~~
~~0154060~~	~~Mulberries~~	~~1~~	~~STMR (FAO, 2008, 2008a)~~
~~0154070~~	~~Azarole (mediteranean medlar)~~	~~5~~	~~STMR EFSA (2013)~~
~~0154080~~	~~Elderberries~~	~~1~~	~~STMR (FAO, 2008, 2008a)~~
~~0154990~~	~~Other small fruit & berries~~	~~1~~	~~STMR (FAO, 2008, 2008a)~~
~~0161050~~	~~Carambola~~	~~0.023~~	~~STMR (FAO, 2013, 2013a)~~

~~Commodity code~~	~~Commodity~~	~~Chronic risk assessment~~	
		~~Input value (mg/kg) STMR~~	~~Reference~~
~~0162030~~	~~Passionfruits~~	~~1.1~~	~~STMR (EC No. 822/2009)~~
~~0163020~~	~~Bananas~~	~~0.03~~	~~STMR (FAO, 2008, 2008a)~~
~~0163030~~	~~Mangoes~~	~~0.28~~	~~STMR (EFSA, 2010)~~
~~0163040~~	~~Papaya~~	~~0.09~~	~~STMR (FAO, 2008, 2008a)~~
~~0211000~~	~~Potatoes~~	~~2.3~~	~~STMR (FAO, 2014, 2014a)~~
~~0212010~~	~~Cassava~~	~~0.23~~	~~STMR (FAO, 2008, 2008a)~~
~~0212020~~	~~Sweet potatoes~~	~~0.23~~	~~STMR (FAO, 2008, 2008a)~~
~~0212030~~	~~Yams~~	~~0.23~~	~~STMR (FAO, 2008, 2008a)~~
~~0212040~~	~~Arrowroot~~	~~0.23~~	~~STMR (FAO, 2008, 2008a)~~
~~0212990~~	~~Other tropical root and tuber vegetables~~	~~0.23~~	~~STMR (FAO, 2008, 2008a)~~
~~0213010~~	~~Beetroots~~	~~0.23~~	~~STMR (FAO, 2008, 2008a)~~
~~0213020~~	~~Carrots~~	~~0.23~~	~~STMR (FAO, 2008, 2008a)~~
~~0213030~~	~~Celeriacs/turnip rooted celeries~~	~~0.23~~	~~STMR (FAO, 2008, 2008a)~~
~~0213040~~	~~Horseradishes~~	~~0.23~~	~~STMR (FAO, 2008, 2008a)~~
~~0213050~~	~~Jerusalem artichokes~~	~~0.23~~	~~STMR (FAO, 2008, 2008a)~~
~~0213060~~	~~Parsnips~~	~~0.23~~	~~STMR (FAO, 2008, 2008a)~~
~~0213070~~	~~Parsley roots~~	~~0.23~~	~~STMR (FAO, 2008, 2008a)~~
~~0213080~~	~~Radishes~~	~~0.3~~	~~STMR (EFSA, 2013)~~
~~0213090~~	~~Salsifies~~	~~0.23~~	~~STMR (FAO, 2008, 2008a)~~
~~0213100~~	~~Swedes/rutabagas~~	~~0.23~~	~~STMR (FAO, 2008, 2008a)~~
~~0213110~~	~~Turnips~~	~~0.23~~	~~STMR (FAO, 2008, 2008a)~~
~~0213990~~	~~Other root and tuber vegtables~~	~~0.23~~	~~STMR (FAO, 2008, 2008a)~~
~~0220010~~	~~Garlic~~	~~2.2~~	~~STMR (FAO, 2008, 2008a)~~
~~0220020~~	~~Onions~~	~~2.2~~	~~STMR (FAO, 2008, 2008a)~~
~~0220030~~	~~Shallots~~	~~2.2~~	~~STMR (FAO, 2008, 2008a)~~
~~0220040~~	~~Spring onions~~	~~2.2~~	~~STMR (FAO, 2008, 2008a)~~
~~0220990~~	~~Other bulb vegetables~~	~~2.2~~	~~STMR (FAO, 2008, 2008a)~~
~~0231010~~	~~Tomatoes~~	~~0.48~~	~~STMR (EFSA, 2013)~~
~~0231020~~	~~Sweet peppers/bell peppers~~	~~0.71~~	~~STMR (EFSA, 2013)~~
~~0231030~~	~~Aubergines/eggplants~~	~~0.48~~	~~STMR (EFSA, 2013)~~
~~0231040~~	~~Okra, lady's finders~~	~~0.71~~	~~STMR (EFSA, 2013)~~
~~0231990~~	~~Other solanacea~~	~~0.71~~	~~STMR (EFSA, 2013)~~
~~0232010~~	~~Cucumbers~~	~~0.19~~	~~STMR (EFSA, 2013)~~
~~0232020~~	~~Gherkins~~	~~0.19~~	~~STMR (EFSA, 2013)~~
~~0232030~~	~~Courgette~~	~~0.19~~	~~STMR (EFSA, 2013)~~
~~0232990~~	~~Other cucurbits – edible peel~~	~~0.19~~	~~STMR (EFSA, 2013)~~
~~0233010~~	~~Melons~~	~~0.17~~	~~STMR (FAO, 2008, 2008a)~~
~~0233020~~	~~Pumpkins/Marrow/Gourd~~	~~0.17~~	~~STMR (FAO, 2008, 2008a)~~

~~Commodity code~~	~~Commodity~~	~~Chronic risk assessment~~	
		~~Input value (mg/kg) STMR~~	~~Reference~~
~~0233030~~	~~Watermelons~~	~~0.17~~	~~STMR (FAO, 2008, 2008a)~~
~~0233990~~	~~Other cucurbits – inedible peel~~	~~0.17~~	~~STMR (FAO, 2008, 2008a)~~
~~0241010~~	~~Broccoli~~	~~1.2~~	~~STMR (FAO, 2008, 2008a)~~
~~0241020~~	~~Cauliflowers~~	~~1.2~~	~~STMR (FAO, 2008, 2008a)~~
~~0241990~~	~~Other flowering brassicas~~	~~1.2~~	~~STMR (FAO, 2008, 2008a)~~
~~0242010~~	~~Brussels sprouts~~	~~1.2~~	~~STMR (FAO, 2008, 2008a)~~
~~0242020~~	~~Head cabbages~~	~~1.2~~	~~STMR (FAO, 2008, 2008a)~~
~~0242990~~	~~Other head cabbage~~	~~1.2~~	~~STMR (FAO, 2008, 2008a)~~
~~0243010~~	~~Chinese cabbages/pe-tsai~~	~~1.2~~	~~STMR (FAO, 2008, 2008a)~~
~~0243020~~	~~Kale~~	~~1.2~~	~~STMR (FAO, 2008, 2008a)~~
~~0243990~~	~~Other leafy brassica~~	~~1.2~~	~~STMR (FAO, 2008, 2008a)~~
~~0244000~~	~~Kohlrabies~~	~~1.2~~	~~STMR (FAO, 2008, 2008a)~~
~~0251010~~	~~Lamb's lettuce~~	~~3.4~~	~~STMR (EFSA, 2020)~~
~~0251020~~	~~Lettuces~~	~~3.4~~	~~STMR (EFSA, 2020)~~
~~0251030~~	~~Scarole (broad leaf endive)~~	~~3.4~~	~~STMR (EFSA, 2020)~~
~~0251040~~	~~Cresses and other sprouts and shoots~~	~~3.4~~	~~STMR (EFSA, 2020)~~
~~0251050~~	~~Land cress~~	~~3.4~~	~~STMR (EFSA, 2020)~~
~~0251060~~	~~Rocket, Rucola~~	~~3.4~~	~~STMR (EFSA, 2020)~~
~~0251070~~	~~Red mustard~~	~~3.4~~	~~STMR (EFSA, 2020)~~
~~0251080~~	~~Leaves and sprouts of Brassica sp~~	~~3.4~~	~~STMR (EFSA, 2020)~~
~~0251990~~	~~Other lettuce and other salad plants~~	~~3.4~~	~~STMR (EFSA, 2020)~~
~~0252010~~	~~Spinaches~~	~~3.4~~	~~STMR (EFSA, 2020)~~
~~0252020~~	~~Purslane~~	~~3.4~~	~~STMR (EFSA, 2020)~~
~~0252030~~	~~Beet leaves (chard)~~	~~3.4~~	~~STMR (EFSA, 2020)~~
~~0252990~~	~~Other spinach and similar~~	~~3.4~~	~~STMR (EFSA, 2020)~~
~~0250000~~	~~Witloofs/endives~~	~~0.05~~	~~STMR (EFSA, 2013)~~
~~0256010~~	~~Chervil~~	~~23~~	~~STMR (FAO, 2008, 2008a)~~
~~0256020~~	~~Chives~~	~~23~~	~~STMR (FAO, 2008, 2008a)~~
~~0256030~~	~~Celery leaves~~	~~23~~	~~STMR (FAO, 2008, 2008a)~~
~~0256040~~	~~Parsley~~	~~23~~	~~STMR (FAO, 2008, 2008a)~~
~~0256050~~	~~Sage~~	~~23~~	~~STMR (FAO, 2008, 2008a)~~
~~0256060~~	~~Rosemary~~	~~23~~	~~STMR (FAO, 2008, 2008a)~~
~~0256070~~	~~Thyme~~	~~23~~	~~STMR (FAO, 2008 a,b)~~
~~0256080~~	~~Basil~~	~~23~~	~~STMR (FAO, 2008 a,b)~~
~~0256090~~	~~Bay leaves (laurel)~~	~~23~~	~~STMR (FAO, 2008 a,b)~~
~~0256100~~	~~Tarragon~~	~~23~~	~~STMR (FAO, 2008 a,b)~~
~~0256990~~	~~Other herbs~~	~~23~~	~~STMR (FAO, 2008 a,b)~~
~~0260010~~	~~Beans (with pods)/Runner beans~~	~~1~~	~~STMR (FAO, 2008 a,b)~~

~~Commodity code~~	~~Commodity~~	~~Chronic risk assessment~~	
		~~Input value (mg/kg) STMR~~	~~Reference~~
~~0260020~~	~~Beans (without pods)~~	~~1~~	~~STMR (FAO, 2008 a,b)~~
~~0260030~~	~~Peas (with pods)~~	~~1~~	~~STMR (FAO, 2008 a,b)~~
~~0260040~~	~~Peas (without pods)~~	~~1~~	~~STMR (FAO, 2008 a,b)~~
~~0260050~~	~~Lentils (fresh)~~	~~1~~	~~STMR (FAO, 2008 a,b)~~
~~0260990~~	~~Other legume vegetables (fresh)~~	~~1~~	~~STMR (FAO, 2008 a,b)~~
~~0270020~~	~~Cardoons~~	~~1.98~~	~~STMR (EFSA, 2013)~~
~~0270030~~	~~Celery~~	~~1.98~~	~~STMR (EFSA, 2013)~~
~~0270040~~	~~Fennels~~	~~10~~	~~STMR (FAO, 2008, 2008a)~~
~~0270050~~	~~Globe artichokes~~	~~1.8~~	~~STMR (FAO, 2008, 2008a)~~
~~0270060~~	~~Leeks~~	~~2.2~~	~~STMR (FAO, 2008, 2008a)~~
~~0270070~~	~~Rhubarbs~~	~~0.1~~	~~STMR (EFSA, 2013)~~
~~0300010~~	~~Beans (Pulses)~~	~~0.01~~	~~STMR (EFSA, 2013)~~
~~0300020~~	~~Lentils (Pulses)~~	~~0.01~~	~~STMR (EFSA, 2013)~~
~~0300030~~	~~Peas (Pulses)~~	~~0.01~~	~~STMR (EFSA, 2013)~~
~~0300040~~	~~Lupins~~	~~0.01~~	~~STMR (EFSA, 2013)~~
~~0300990~~	~~Other pulses, dry~~	~~0.01~~	~~STMR (EFSA, 2013)~~
~~0401010~~	~~Linseed~~	~~0.02~~	~~STMR (EFSA, 2016a)~~
~~0401020~~	~~Peanuts~~	~~0.01~~	~~STMR (FAO, 2008, 2008a)~~
~~0401030~~	~~Poppy seed~~	~~0.06~~	~~STMR (EFSA, 2013)~~
~~0401050~~	~~Sunflower seed~~	~~0.04~~	~~STMR (FAO, 2008, 2008a)~~
~~0401060~~	~~Rape seed~~	~~0.06~~	~~STMR (EFSA, 2013)~~
~~0401070~~	~~Soya bean~~	~~0.05~~	~~STMR (EFSA, 2013)~~
~~0401080~~	~~Mustard seed~~	~~0.06~~	~~STMR (EFSA, 2013)~~
~~0401090~~	~~Cotton seed~~	~~0.01~~	~~STMR (FAO, 2008, 2008a)~~
~~0401110~~	~~Safflower~~	~~0.2~~	~~STMR (EFSA, 2016a)~~
~~0401120~~	~~Borage~~	~~0.2~~	~~STMR (EFSA, 2016a)~~
~~0401130~~	~~Gold of pleasure~~	~~0.06~~	~~STMR (EFSA, 2013)~~
~~0500010~~	~~Barley~~	~~0.1~~	~~STMR (FAO, 2014, 2014a)~~
~~0500030~~	~~Maize/corn~~	~~0.01~~	~~STMR (FAO, 2008, 2008a)~~
~~0500050~~	~~Oats~~	~~0.05~~	~~STMR (FAO, 2014, 2014a)~~
~~0500060~~	~~Rice~~	~~5~~	~~MRL (FAO, 2008, 2008a;~~ [redacted]~~)~~
~~0500070~~	~~Rye~~	~~0.08~~	~~STMR (EFSA, 2013)~~
~~0500080~~	~~Sorghum~~	~~1.85~~	~~STMR (FAO, 2014, 2014a)~~
~~0500090~~	~~Wheat~~	~~0.08~~	~~STMR (EFSA, 2013)~~
~~0620000~~	~~Coffee beans~~	~~0.10~~	~~STMR (FAO, 2014, 2014a)~~
~~0631010~~	~~Camomile flowers~~	~~10.20~~	~~STMR (EFSA, 2013)~~
~~0631020~~	~~Hybiscus flowers~~	~~10.20~~	~~STMR (EFSA, 2013)~~
~~0631030~~	~~Rose petals~~	~~10.20~~	~~STMR (EFSA, 2013)~~

~~Commodity code~~	~~Commodity~~	~~Chronic risk assessment~~	
		~~Input value (mg/kg) STMR~~	~~Reference~~
~~0631040~~	~~Jasmine flowers~~	~~10.20~~	~~STMR (EFSA, 2013)~~
~~0631050~~	~~Lime (linden)~~	~~10.20~~	~~STMR (EFSA, 2013)~~
~~0631990~~	~~Other herbal infusions (dried flowers)~~	~~10.20~~	~~STMR (EFSA, 2013)~~
~~0632010~~	~~Strawberry leaves~~	~~10.20~~	~~STMR (EFSA, 2013)~~
~~0632020~~	~~Rooibos leaves~~	~~10.20~~	~~STMR (EFSA, 2013)~~
~~0632030~~	~~Mate~~	~~10.20~~	~~STMR (EFSA, 2013)~~
~~0632990~~	~~Other herbal infusions (dried leaves)~~	~~10.20~~	~~STMR (EFSA, 2013)~~
~~0633010~~	~~Valerian root~~	~~0.3~~	~~MRL (EFSA, 2013; [redacted])~~
~~0633020~~	~~Ginseng root~~	~~0.3~~	~~MRL (EFSA, 2013; [redacted])~~
~~0633990~~	~~Other herbal infusions (dried roots)~~	~~0.3~~	~~MRL (EFSA, 2013; [redacted])~~
~~0700000~~	~~Hops (dried 0.25% of beer)~~	~~11~~	~~STMR (FAO, 2008, 2008a)~~
~~0810010~~	~~Anise~~	~~0.05~~	~~STMR (EFSA, 2012)~~
~~0810020~~	~~Black caraway~~	~~0.05~~	~~STMR (EFSA, 2012)~~
~~0810030~~	~~Celery seed~~	~~0.05~~	~~STMR (EFSA, 2012)~~
~~0810040~~	~~Coriander seed~~	~~0.05~~	~~STMR (EFSA, 2012)~~
~~0810050~~	~~Cumin seed~~	~~0.05~~	~~STMR (EFSA, 2012)~~
~~0810060~~	~~Dill seed~~	~~0.05~~	~~STMR (EFSA, 2012)~~
~~0810070~~	~~Fennel seed~~	~~0.05~~	~~STMR (EFSA, 2012)~~
~~0810080~~	~~Fenugreek~~	~~0.05~~	~~STMR (EFSA, 2012)~~
~~0810090~~	~~Nutmeg~~	~~0.05~~	~~STMR (EFSA, 2012)~~
~~0810990~~	~~Other spices (seeds)~~	~~0.05~~	~~STMR (EFSA, 2012)~~
~~0820010~~	~~Allspice~~	~~0.05~~	~~STMR (EFSA, 2012)~~
~~0820020~~	~~Anise pepper (Japan pepper)~~	~~0.05~~	~~STMR (EFSA, 2012)~~
~~0820030~~	~~Caraway~~	~~0.05~~	~~STMR (EFSA, 2012)~~
~~0820040~~	~~Cardamon~~	~~0.05~~	~~STMR (EFSA, 2012)~~
~~0820050~~	~~Juniper berries~~	~~0.05~~	~~STMR (EFSA, 2012)~~
~~0820060~~	~~Pepper, black and white~~	~~0.05~~	~~STMR (EFSA, 2012)~~
~~0820070~~	~~Vanilla pods~~	~~0.05~~	~~STMR (EFSA, 2012)~~
~~0820080~~	~~Tamarind~~	~~0.05~~	~~STMR (EFSA, 2012)~~
~~0820990~~	~~Other spices (fruit and berries)~~	~~0.05~~	~~STMR (EFSA, 2012)~~
~~0900010~~	~~Sugar beet / Refined sugar~~	~~0.01~~	~~STMR (EFSA, 2013)~~
~~0900030~~	~~Chicory roots~~	~~0.03~~	~~STMR (EFSA, 2013)~~
~~1011010 1012010 1013010 1014010 1015010 1017030~~	~~Swine/bovine/sheep/goat/ equine//others: muscle~~	~~0.01*~~	~~EU MRL (Reg. (EU) 2016/[redacted]~~
~~1011020 1012020 1013020~~	~~Swine/bovine/sheep/goat/ equine/ poultry/others: fat~~	~~0.05~~	~~EU MRL (Reg. (EU) 2016/[redacted]~~

~~Commodity code~~	~~Commodity~~	~~Chronic risk assessment~~	
		~~Input value (mg/kg) STMR~~	~~Reference~~
~~1014020 1015020 1016020 1017020~~			
~~1011030 1012030 1013030 1014030 1015030 1016030 1017030~~	~~Swine/bovine/sheep/goat/ equine/poultry/others: liver~~	~~0.07~~	~~EU MRL (Reg. (EU) 2016/)~~
~~1011040 1012040 1013040 1014040 1015040 1017040~~	~~Swine/Bovine/sheep/goat/ equine/poultry/others: kidney~~	~~0.07~~	~~EU MRL (Reg. (EU) 2016/~~
~~1016000~~	~~Poultry muscle~~	~~0.01*~~	~~EU MRL (Reg. (EU) 2016/)~~
~~1011050 1012050 1013050 1014050 1015050 1017050~~	~~Swine/Bovine/sheep/goat/ equine/others: other edible offals~~	~~0.01~~	~~EU MRL Reg. (EU) 2016/)~~
~~1016050~~	~~Poultry offal~~	~~0.01~~	~~EU MRL (Reg. (EU) 2016/)~~
~~1020000~~	~~Milk~~	~~0.01*~~	~~EU MRL (Reg. (EU) 2016/)~~
~~1030000~~	~~Birds Eggs~~	~~0.01*~~	~~EU MRL (Reg. (EU) 2016/)~~

Commodity code	Commodity	Chronic risk assessment	
		Input value (mg/kg) STMR	Reference
Risk assessment residue definition: Azoxystrobin			
110000	Citrus fruits	15	EU MRL (Reg. (EU) 2023/129)
110010	Grapefruits	15	
110020	Oranges	15	
110030	Lemons	15	
110040	Limes	15	
110050	Mandarins	15	
110990	Others (2)	15	
120000	Tree nuts		
120010	Almonds	0.01	
120020	Brazil nuts	0.01	
120030	Cashew nuts	0.01	
120040	Chestnuts	0.01	
120050	Coconuts	0.01	
120060	Hazelnuts/cobnuts	0.01	

Commod-ity code	Commodity	Chronic risk assessment	
		Input value (mg/kg) STMR	Reference
120070	Macadamias	0.01	
120080	Pecans	0.01	
120090	Pine nut kernels	0.01	
120100	Pistachios	1	
120110	Walnuts	0.01	
120990	Others (2)	0.01	
130000	Pome fruits	0.01*	
130010	Apples	0.01*	
130020	Pears	0.01*	
130030	Quinces	0.01*	
130040	Medlars	0.01*	
130050	Loquats/Japanese medlars	0.01*	
130990	Others (2)	0.01*	
140000	Stone fruits	2	
140010	Apricots	2	
140020	Cherries (sweet)	2	
140030	Peaches	2	
140040	Plums	2	
140990	Others (2)	2	
150000	Berries and small fruits		
151000	(a) grapes	3	
151010	Table grapes	3	
151020	Wine grapes	3	
152000	(b) strawberries	10	
153000	(c) cane fruits	5	
153010	Blackberries	5	
153020	Dewberries	5	
153030	Raspberries (red and yellow)	5	
153990	Others (2)	5	
154000	(d) other small fruits and berries		
154010	Blueberries	5	
154020	Cranberries	0.5	
154030	Currants (black, red and white)	5	
154040	Gooseberries (green, red and yellow)	5	
154050	Rose hips	5	
154060	Mulberries (black and white)	5	
154070	Azaroles/Mediterranean medlars	5	
154080	Elderberries	5	
154990	Others (2)	5	
160000	Miscellaneous fruitswith		
161000	(a) edible peel		

Commod-ity code	Commodity	Chronic risk assessment	
		Input value (mg/kg) STMR	Reference
161010	Dates	0.01*	
161020	Figs	0.01*	
161030	Table olives	0.01*	
161040	Kumquats	0.01*	
161050	Carambolas	.,1	
161060	Kaki/Japanese persimmons	0.01*	
161070	Jambuls/jambolans	0.01*	
161990	Others (2)	0.01*	
162000	(b) inedible peel, small		
162010	Kiwi fruits (green, red, yellow)	0.01*	
162020	Litchis/lychees	0.01*	
162030	Passionfruits/maracujas	4	
162040	Prickly pears/cactus fruits	0.3	
162050	Star apples/cainitos	0.01*	
162060	American persimmons/Virginia kaki	0.01*	
162990	Others (2)	0.01*	
163000	(c) inedible peel, large		
163010	Avocados	0.01*	
163020	Bananas	2	
163030	Mangoes	4	
163040	Papayas	0.3	
163050	Granate apples/pomegranates	0.01*	
163060	Cherimoyas	0.01*	
163070	Guavas	0.2	
163080	Pineapples	0.01*	
163090	Breadfruits	0.01*	
163100	Durians	0.01*	
163110	Soursops/guanabanas	0.01*	
163990	Others (2)	0.01*	
200000	VEGETABLES, FRESH or FROZEN		
210000	Root and tuber vegetables		
211000	(a) potatoes	7	
212000	(b) tropical root and tuber vegetables	1	
212010	Cassava roots/manioc	1	
212020	Sweet potatoes	1	
212030	Yams	1	
212040	Arrowroots	1	
212990	Others (2)	1	
213000	(c) other root and tuber vegetables except sugar beets		
213010	Beetroots	1	
213020	Carrots	1	

Commod-ity code	Commodity	Chronic risk assessment	
		Input value (mg/kg) STMR	Reference
213030	Celeriacs/turnip rooted celeries	1	
213040	Horseradishes	1	
213050	Jerusalem artichokes	1	
213060	Parsnips	1	
213070	Parsley roots/Hamburg roots parsley	1	
213080	Radishes	1.5	
213090	Salsifies	1	
213100	Swedes/rutabagas	1	
213110	Turnips	1	
213990	Others (2)	1	
220000	Bulb vegetables	10	
220010	Garlic	10	
220020	Onions	10	
220030	Shallots	10	
220040	Spring onions/green onions and Welsh onions	10	
220990	Others (2)	10	
230000	Fruiting vegetables		
231000	(a) Solanaceae and Malvaceae	3	
231010	Tomatoes	3	
231020	Sweet peppers/bell peppers	3	
231030	Aubergines/eggplants	3	
231040	Okra/lady's fingers	3	
231990	Others (2)	3	
232000	(b) cucurbits with edible peel	1	
232010	Cucumbers	1	
232020	Gherkins	1	
232030	Courgettes	1	
232990	Others (2)	1	
233000	(c) cucurbits with inedible peel	1	
233010	Melons	1	
233020	Pumpkins	1	
233030	Watermelons	1	
233990	Others (2)	1	
234000	(d) sweet corn	0.01*	
239000	(e) other fruiting vegetables	0.01*	
240000	Brassica vegetables(excluding brassica roots and brassica baby leaf crops)		
241000	(a) flowering brassica	5	
241010	Broccoli	5	
241020	Cauliflowers	5	
241990	Others (2)	5	
242000	(b) head brassica	5	

Commod-ity code	Commodity	Chronic risk assessment	
		Input value (mg/kg) STMR	Reference
242010	Brussels sprouts	5	
242020	Head cabbages	5	
242990	Others (2)	5	
243000	(c) leafy brassica	6	
243010	Chinese cabbages/pe-tsai	6	
243020	Kales	6	
243990	Others (2)	6	
244000	(d) kohlrabies	5	
250000	Leaf vegetables, herbs and edible flowers		
251000	(a) lettuces and salad plants	10	
251010	Lamb's lettuces/corn salads	10	
251020	Lettuces	10	
251030	Escaroles/broad-leaved endives	10	
251040	Cresses and other sprouts and shoots	10	
251050	Land cresses	10	
251060	Roman rocket/rucola	10	
251070	Red mustards	10	
251080	Baby leaf crops (including brassica species)	10	
251990	Others (2)	10	
252000	(b) spinaches and similar leaves	15	
252010	Spinaches	15	
252020	Purslanes	15	
252030	Chards/beet leaves	15	
252990	Others (2)	15	
253000	(c) grape leaves and similar species	0.01*	
254000	(d) watercresses	0.01*	
255000	(e) witloofs/Belgian endives	0,3	
256000	(f) herbs and edible flowers	70	
256010	Chervil	70	
256020	Chives	70	
256030	Celery leaves	70	
256040	Parsley	70	
256050	Sage	70	
256060	Rosemary	70	
256070	Thyme	70	
256080	Basil and edible flowers	70	
256090	Laurel/bay leaves	70	
256100	Tarragon	70	
256990	Others (2)	70	
260000	Legume vegetables	3	
260010	Beans (with pods)	3	

Commod-ity code	Commodity	Chronic risk assessment	
		Input value (mg/kg) STMR	Reference
260020	Beans (without pods)	3	
260030	Peas (with pods)	3	
260040	Peas (without pods)	3	
260050	Lentils	3	
260990	Others (2)	3	
270000	Stem vegetables		
270010	Asparagus	0.01*	
270020	Cardoons	15	
270030	Celeries	15	
270040	Florence fennels	10	
270050	Globe artichokes	5	
270060	Leeks	10	
270070	Rhubarbs	0,6	
270080	Bamboo shoots	0.01*	
270090	Palm hearts	0.01*	
270990	Others (2)	0.01*	
280000	Fungi, mosses and lichens	0.01*	
280010	Cultivated fungi	0.01*	
280020	Wild fungi	0.01*	
280990	Mosses and lichens	0.01*	
290000	Algae and prokaryotes organisms	0.01*	
300000	PULSES	0.15	
300010	Beans	0.15	
300020	Lentils	0.15	
300030	Peas	0.15	
300040	Lupins/lupini beans	0.15	
300990	Others (2)	0.15	
400000	OILSEEDS AND OIL FRUITS		
401000	Oilseeds		
401010	Linseeds	0.4	
401020	Peanuts/groundnuts	0.2	
401030	Poppy seeds	0.5	
401040	Sesame seeds	0.01*	
401050	Sunflower seeds	0.5	
401060	Rapeseeds/canola seeds	0.7	
401070	Soyabeans	0.5	
401080	Mustard seeds	0.5	
401090	Cotton seeds	0.7	
401100	Pumpkin seeds	0.01*	
401110	Safflower seeds	0.4	
401120	Borage seeds	0.4	

Commod-ity code	Commodity	Chronic risk assessment	
		Input value (mg/kg) STMR	Reference
401130	Gold of pleasure seeds	0.5	
401140	Hemp seeds	0.01*	
401150	Castor beans	0.01*	
401990	Others (2)	0.01*	
402000	Oil fruits		
402010	Olives for oil production	0.01*	
402020	Oil palms kernels	0.01*	
402030	Oil palms fruits	0.03	
402040	Kapok	0.01*	
402990	Others (2)	0.01*	
500000	CEREALS		
500010	Barley	1.5	
500020	Buckwheat and other pseudocereals	0.01*	
500030	Maize/corn	0.02	
500040	Common millet/proso millet	0.01*	
500050	Oat	1.5	
500060	Rice	5	
500070	Rye	0.5	
500080	Sorghum	10	
500090	Wheat	0.5	
500990	Others (2)	0.01*	
600000	TEAS, COFFEE, HERBAL INFUSIONS, COCOA AND CAROBS		
610000	Teas	0.05*	
620000	Coffee beans	0.03	
630000	Herbal infusions from		
631000	(a) flowers	60	
631010	Chamomile	60	
631020	Hibiscus/roselle	60	
631030	Rose	60	
631040	Jasmine	60	
631050	Lime/linden	60	
631990	Others (2)	60	
632000	(b) leaves and herbs	60	
632010	Strawberry	60	
632020	Rooibos	60	
632030	Mate/maté	60	
632990	Others (2)	60	
633000	(c) roots	0.3	
633010	Valerian	0.3	
633020	Ginseng	0.3	
633990	Others (2)	0.3	

Commod-ity code	Commodity	Chronic risk assessment	
		Input value (mg/kg) STMR	Reference
639000	(d) any other parts of the plant	0.05*	
640000	Cocoa beans	0.05*	
650000	Carobs/Saint John's breads	0.05*	
700000	HOPS	30	
800000	SPICES		
810000	Seed spices	0.3	
810010	Anise/aniseed	0.3	
810020	Black caraway/black cumin	0.3	
810030	Celery	0.3	
810040	Coriander	0.3	
810050	Cumin	0.3	
810060	Dill	0.3	
810070	Fennel	0.3	
810080	Fenugreek	0.3	
810090	Nutmeg	0.3	
810990	Others (2)	0.3	
820000	Fruit spices	0.3	
820010	Allspice/pimento	0.3	
820020	Sichuan pepper	0.3	
820030	Caraway	0.3	
820040	Cardamom	0.3	
820050	Juniper berry	0.3	
820060	Peppercorn (black, green and white)	0.3	
820070	Vanilla	0.3	
820080	Tamarind	0.3	
820990	Others (2)	0.3	
830000	Bark spices	0.05*	
830010	Cinnamon	0.05*	
830990	Others (2)	0.05*	
840000	Root and rhizome spices		
840010	Liquorice	0.05*	
840020	Ginger (10)		
840030	Turmeric/curcuma	0.05*	
840040	Horseradish (11)		
840990	Others (2)	0.05*	
850000	Bud spices	0.05*	
850010	Cloves	0.05*	
850020	Capers	0.05*	
850990	Others (2)	0.05*	
860000	Flower pistil spices	0.05*	
860010	Saffron	0.05*	

Commod-ity code	Commodity	Chronic risk assessment	
		Input value (mg/kg) STMR	Reference
860990	Others (2)	0.05*	
870000	Aril spices	0.05*	
870010	Mace	0.05*	
870990	Others (2)	0.05*	
900000	SUGAR PLANTS		
900010	Sugar beet roots	5	
900020	Sugar canes	0.05	
900030	Chicory roots	0.09	
900990	Others (2)	0.01*	
1000000	PRODUCTS OF ANIMAL ORIGIN -TERRESTRIAL ANIMALS		
1010000	Commodities from		
1011000	(a) swine		
1011010	Muscle	0.01*	
1011020	Fat	0.05	
1011030	Liver	0.07	
1011040	Kidney	0.07	
1011050	Edible offals (other than liver and kidney)	0.07	
1011990	Others (2)	0.01*	
1012000	(b) bovine		
1012010	Muscle	0.01*	
1012020	Fat	0.05	
1012030	Liver	0.07	
1012040	Kidney	0.07	
1012050	Edible offals (other than liver and kidney)	0.07	
1012990	Others (2)	0.01*	
1013000	(c) sheep		
1013010	Muscle	0.01*	
1013020	Fat	0.05	
1013030	Liver	0.07	
1013040	Kidney	0.07	
1013050	Edible offals (other than liver and kidney)	0.07	
1013990	Others (2)	0.01*	
1014000	d) goat		
1014010	Muscle	0.01*	
1014020	Fat	0.05	
1014030	Liver	0.07	
1014040	Kidney	0.07	
1014050	Edible offals (other than liver and kidney)	0.07	
1014990	Others (2)	0.01*	
1015000	(e) equine		
1015010	Muscle	0.01*	

Commod-ity code	Commodity	Chronic risk assessment	
		Input value (mg/kg) STMR	Reference
1015020	Fat	0.05	
1015030	Liver	0.07	
1015040	Kidney	0.07	
1015050	Edible offals (other than liver and kidney)	0.07	
1015990	Others (2)	0.01*	
1016000	(f) poultry	0.01*	
1016010	Muscle	0.01*	
1016020	Fat	0.01*	
1016030	Liver	0.01*	
1016040	Kidney	0.01*	
1016050	Edible offals (other than liver and kidney)	0.01*	
1016990	Others (2)	0.01*	
1017000	(g) other farmed terrestrial animals		
1017010	Muscle	0.01*	
1017020	Fat	0.05	
1017030	Liver	0.07	
1017040	Kidney	0.07	
1017050	Edible offals (other than liver and kidney)	0.07	
1017990	Others (2)	0.01*	
1020000	Milk	0.01*	
1020010	Cattle	0.01*	
1020020	Sheep	0.01*	
1020030	Goat	0.01*	
1020040	Horse	0.01*	
1020990	Others (2)	0.01*	
1030000	Birds eggs	0.01*	
1030010	Chicken	0.01*	
1030020	Duck	0.01*	
1030030	Geese	0.01*	
1030040	Quail	0.01*	
1030990	Others (2)	0.01*	
1040000	Honey and other apiculture products (7)	0.05*	
1050000	Amphibians and Reptiles	0.01*	
1060000	Terrestrial invertebrate animals	0.01*	
1070000	Wild terrestrial vertebrate animals	0.01*	

7.2.8.2 Conclusion on consumer risk assessment

Table 7.2-18: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo 3.1	~~70~~ ~~83~~ 82% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo 3.1	~~15% (based on NL toddler)~~ Not required

IESTI (% ARfD) according to EFSA PRIMo 3.1	Not applicable (no ARfD set)

The proposed use of azoxystrobin in A22773A does not represent unacceptable chronic risks for the consumer.

zRMS comment:

The calculation of the TMDI using EFSA model (PRIMo ver. 3.1) and MRLs according to Regulation (EU) ~~Reg. (EU) 2022/476~~ Reg. (EU) 2023/129 led to a utilisation of the ADI of ~~83~~ 82% for the NL toddler diet being the population group with the highest value. For this diet, the highest contributor is oranges with 17% of the ADI. The intended uses will not result in a consumer chronic exposure exceeding the ADI.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Azoxystrobin

LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	0,2	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2010	Year of evaluation:	2010

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 : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
83%	NL toddler	165,46	17%	Oranges	15%	Potatoes	13%	Sugar beet roots		
69%	DE child	138,29	30%	Oranges	9%	Potatoes	3%	Mandarins		
68%	NL child	135,89	21%	Sugar beet roots	12%	Potatoes	11%	Oranges		
57%	FR child 3 15 yr	113,14	26%	Oranges	9%	Sugar beet roots	5%	Potatoes		
50%	GEMS/Food G06	99,69	7%	Oranges	7%	Potatoes	5%	Tomatoes		
48%	UK toddler	95,97	15%	Oranges	12%	Potatoes	8%	Sugar beet roots		
47%	IE adult	94,02	8%	Potatoes	8%	Oranges	5%	Grapefruits		
46%	GEMS/Food G07	92,39	13%	Potatoes	10%	Oranges	2%	Wine grapes		
45%	GEMS/Food G10	90,60	10%	Potatoes	8%	Oranges	3%	Rice		
44%	FR toddler 2 3 yr	88,23	11%	Oranges	7%	Sugar beet roots	7%	Potatoes		
44%	GEMS/Food G11	87,79	14%	Potatoes	5%	Oranges	3%	Lemons		
44%	DE women 14-50 yr	87,52	14%	Oranges	11%	Sugar beet roots	4%	Potatoes		
43%	SE general	86,92	15%	Potatoes	6%	Oranges	3%	Mandarins		
41%	GEMS/Food G08	82,97	14%	Potatoes	3%	Oranges	3%	Onions		
40%	DE general	79,76	12%	Oranges	11%	Sugar beet roots	4%	Potatoes		
39%	GEMS/Food G15	78,51	12%	Potatoes	5%	Oranges	3%	Onions		
39%	PT general	77,61	19%	Potatoes	5%	Oranges	4%	Wine grapes		
38%	RO general	76,13	13%	Potatoes	4%	Onions	4%	Head cabbages		
37%	ES child	74,30	16%	Oranges	6%	Potatoes	3%	Lettuces		
37%	NL general	73,14	9%	Potatoes	8%	Oranges	7%	Sugar beet roots		
36%	UK infant	71,27	11%	Potatoes	10%	Oranges	4%	Sugar beet roots		
34%	FI 3 yr	67,05	17%	Potatoes	3%	Mandarins	2%	Onions		
27%	FI 6 yr	54,14	14%	Potatoes	2%	Mandarins	1%	Onions		
27%	ES adult	53,88	10%	Oranges	4%	Lettuces	3%	Potatoes		
23%	UK vegetarian	46,88	6%	Oranges	5%	Potatoes	1%	Sugar beet roots		
23%	FR infant	46,41	7%	Potatoes	3%	Sugar beet roots	2%	Spinaches		
23%	DK child	45,73	9%	Potatoes	1%	Rye	1%	Oranges		
22%	IT toddler	44,98	4%	Oranges	3%	Potatoes	2%	Lettuces		
22%	FR adult	43,29	4%	Oranges	3%	Wine grapes	3%	Potatoes		
20%	IT adult	40,81	3%	Lettuces	3%	Oranges	2%	Potatoes		
20%	PL general	39,56	12%	Potatoes	2%	Onions	1%	Tomatoes		
19%	UK adult	38,51	5%	Potatoes	4%	Oranges	2%	Wine grapes		
16%	LT adult	32,82	11%	Potatoes	1,0%	Head cabbages	0,9%	Tomatoes		
15%	FI adult	29,68	4%	Potatoes	3%	Oranges	1%	Lettuces		
14%	DK adult	27,40	4%	Potatoes	1%	Wine grapes	1%	Oranges		
6%	IE child	11,34	2%	Potatoes	0,7%	Rice	0,6%	Oranges		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Azoxystrobin is unlikely to present a public health concern.

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EFSA PRIMo revision 3.1; 2019/03/19

Azoxystrobin

LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	0,2	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2010	Year of evaluation:	2010

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 : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	commodities under assessment (in % of ADI)
82%	NL toddler	163,71	17%	Oranges	15%	Potatoes	13%	Sugar beet roots		
69%	DE child	137,69	30%	Oranges	9%	Potatoes	3%	Mandarins		
67%	NL child	134,82	21%	Sugar beet roots	12%	Potatoes	11%	Oranges		
56%	FR child 3 15 yr	112,53	26%	Oranges	9%	Sugar beet roots	5%	Potatoes		
49%	GEMS/Food G06	98,89	7%	Oranges	7%	Potatoes	5%	Tomatoes		
48%	UK toddler	95,87	15%	Oranges	12%	Potatoes	8%	Sugar beet roots		
47%	IE adult	93,60	8%	Potatoes	8%	Oranges	5%	Grapefruits		
45%	GEMS/Food G07	90,77	13%	Potatoes	10%	Oranges	2%	Wine grapes		
44%	GEMS/Food G10	88,40	10%	Potatoes	8%	Oranges	3%	Rice		
44%	FR toddler 2 3 yr	88,03	11%	Oranges	7%	Sugar beet roots	7%	Potatoes		
43%	DE women 14-50 yr	86,81	14%	Oranges	11%	Sugar beet roots	4%	Potatoes		
43%	GEMS/Food G11	86,73	14%	Potatoes	5%	Oranges	3%	Lemons		
42%	SE general	84,90	15%	Potatoes	6%	Oranges	3%	Mandarins		
41%	GEMS/Food G08	81,39	14%	Potatoes	3%	Oranges	3%	Onions		
40%	DE general	79,16	12%	Oranges	11%	Sugar beet roots	4%	Potatoes		
39%	GEMS/Food G15	77,84	12%	Potatoes	5%	Oranges	3%	Onions		
39%	PT general	77,09	19%	Potatoes	5%	Oranges	4%	Wine grapes		
38%	RO general	76,13	13%	Potatoes	4%	Onions	4%	Head cabbages		
36%	ES child	72,21	16%	Oranges	6%	Potatoes	2%	Lettuces		
36%	NL general	72,04	9%	Potatoes	8%	Oranges	7%	Sugar beet roots		
36%	UK infant	71,27	11%	Potatoes	10%	Oranges	4%	Sugar beet roots		
33%	FI 3 yr	66,83	17%	Potatoes	3%	Mandarins	2%	Onions		
27%	FI 6 yr	53,70	14%	Potatoes	2%	Mandarins	1%	Onions		
26%	ES adult	51,20	10%	Oranges	3%	Potatoes	3%	Lettuces		
23%	FR infant	46,40	7%	Potatoes	3%	Sugar beet roots	2%	Spinaches		
23%	UK vegetarian	46,17	6%	Oranges	5%	Potatoes	1%	Sugar beet roots		
23%	DK child	45,02	9%	Potatoes	1%	Rye	1%	Oranges		
21%	IT toddler	42,92	4%	Oranges	3%	Potatoes	2%	Tomatoes		
21%	FR adult	42,40	4%	Oranges	3%	Wine grapes	3%	Potatoes		
20%	PL general	39,50	12%	Potatoes	2%	Onions	1%	Tomatoes		
19%	IT adult	38,02	3%	Oranges	2%	Potatoes	2%	Lettuces		
19%	UK adult	37,92	5%	Potatoes	4%	Oranges	2%	Wine grapes		
16%	LT adult	32,50	11%	Potatoes	1,0%	Head cabbages	0,9%	Tomatoes		
14%	FI adult	28,97	4%	Potatoes	3%	Oranges	1%	Mandarins		
13%	DK adult	26,94	4%	Potatoes	1%	Wine grapes	1%	Oranges		
6%	IE child	11,31	2%	Potatoes	0,7%	Rice	0,6%	Oranges		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Azoxystrobin is unlikely to present a public health concern.

The refinement using STMRs is not required as the unrefined risk assessment does not represent unacceptable chronic risk to the consumer.

~~Additionally, a refined chronic risk assessment was conducted by assessing the International Estimated Daily Intake (IEDI) relative to the azoxystrobin acceptable daily intake (ADI) based on the EFSA PRIMo rev. 3.1 model. The input values for the IEDI calculation are provided in updated Table 7.2-17.~~
~~The IEDI equals 15% of ADI based on NL toddler with the highest contributor is potatoes with 5% of the ADI.~~

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EFSA PRIMo revision 3.1; 2019/03/19

Azoxystrobin

LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	0,2	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2010	Year of evaluation:	2010

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 : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	commodities under assessment (in % of ADI)
15%	NL toddler	30,39	5%	Potatoes	2%	Oranges	2%	Rice		
13%	DE child	26,33	4%	Oranges	3%	Potatoes	0,7%	Rice		
12%	GEMS/Food G06	24,56	4%	Rice	2%	Potatoes	0,9%	Oranges		
12%	GEMS/Food G10	24,19	3%	Potatoes	3%	Rice	1%	Oranges		
12%	PT general	23,01	6%	Potatoes	2%	Rice	0,9%	Wine grapes		
11%	SE general	21,22	5%	Potatoes	1%	Rice	0,7%	Lettuces		
11%	GEMS/Food G07	21,18	4%	Potatoes	1%	Oranges	0,9%	Rice		
10%	GEMS/Food G08	20,24	4%	Potatoes	0,7%	Rice	0,6%	Onions		
10%	GEMS/Food G11	20,21	4%	Potatoes	0,7%	Rice	0,7%	Oranges		
10%	IE adult	19,88	3%	Potatoes	0,9%	Oranges	0,6%	Grapefruits		
10%	NL child	19,65	4%	Potatoes	1%	Oranges	0,6%	Mandarins		
10%	GEMS/Food G15	19,44	4%	Potatoes	0,8%	Rice	0,6%	Oranges		
9%	FI 3 yr	18,55	5%	Potatoes	1%	Rice	0,4%	Onions		
9%	UK toddler	18,51	4%	Potatoes	2%	Oranges	1%	Rice		
9%	FR child 3 15 yr	18,37	3%	Oranges	2%	Potatoes	1%	Rice		
9%	RO general	18,29	4%	Potatoes	0,9%	Head cabbages	0,8%	Onions		
8%	FR toddler 2 3 yr	16,84	2%	Potatoes	1%	Rice	1%	Oranges		
8%	UK infant	16,72	4%	Potatoes	2%	Rice	1%	Oranges		
8%	ES child	15,57	2%	Potatoes	2%	Oranges	1%	Rice		
8%	FI 6 yr	15,04	4%	Potatoes	1%	Rice	0,3%	Onions		
7%	NL general	13,42	3%	Potatoes	0,9%	Oranges	0,3%	Rice		
6%	DK child	11,67	3%	Potatoes	0,7%	Rice	0,3%	Onions		
6%	DE women 14-50 yr	11,55	2%	Oranges	1%	Potatoes	0,3%	Wine grapes		
6%	PL general	11,13	4%	Potatoes	0,4%	Onions	0,2%	Head cabbages		
6%	ES adult	11,04	1%	Oranges	1%	Potatoes	0,9%	Lettuces		
5%	DE general	10,91	1%	Oranges	1%	Potatoes	0,3%	Wine grapes		
5%	IT toddler	10,51	1%	Potatoes	0,5%	Lettuces	0,5%	Rice		
5%	UK vegetarian	10,47	2%	Potatoes	1,0%	Rice	0,8%	Oranges		
5%	FR infant	10,38	2%	Potatoes	0,5%	Spinaches	0,3%	Leeks		
5%	LT adult	10,15	4%	Potatoes	0,5%	Rice	0,2%	Head cabbages		
5%	IT adult	10,08	0,7%	Potatoes	0,6%	Lettuces	0,5%	Florence fennels		
5%	UK adult	9,22	2%	Potatoes	0,9%	Rice	0,5%	Oranges		
4%	FR adult	8,97	0,8%	Potatoes	0,8%	Wine grapes	0,5%	Oranges		
4%	FI adult	7,24	1%	Potatoes	0,4%	Oranges	0,3%	Rice		
3%	DK adult	6,75	1%	Potatoes	0,3%	Wine grapes	0,2%	Rice		
2%	IE child	3,93	0,7%	Rice	0,7%	Potatoes	0,1%	Oranges		

An acute consumer risk assessment was not deemed necessary.
The proposed uses of azoxystrobin in the product A22773A do not represent unacceptable chronic risk for the consumer.

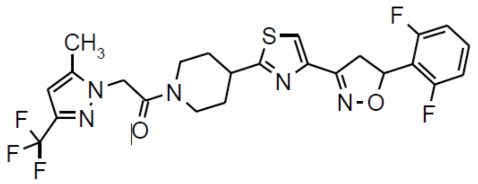
No further data are required to support the proposed uses.

7.3 Oxathiapiprolin

General data on oxathiapiprolin are summarized in the table below (last updated 2021/05/03).

According to EU pesticide database, Commission Regulation (EU) No 2021/1807 is not applicable and changed in the meantime. The current MRL regulation for oxathiapiprolin is Reg. (EU) 2023/163.

Table 7.3-1: General information on oxathiapiprolin

Active substance (ISO Common Name)	Oxathiapiprolin
IUPAC	1-(4-{4-[(5RS)-5-(2,6-difluorophenyl)-4,5-dihydro-1,2-oxazol-3-yl]-1,3-thiazol-2-yl}-1-piperidyl)-2-[5-methyl-3-(trifluoromethyl)-1H-pyrazol-1-yl]ethanone
Chemical structure	
Molecular formula	$C_{24}H_{22}F_5N_5O_2S$
Molar mass	539.53 g/mol
Chemical group	Piperidinyl thiazole isoxazoline fungicide
Mode of action (if available)	Oxathiapiprolin binds to the oxysterol binding protein resulting in inhibition of zoospore germination and mycelial growth.
Systemic	Yes
Company (ies)	Corteva Agriscience International Sàrl
Rapporteur Member State (RMS)	Ireland
Approval status	Approved 03/03/2017 COMMISSION IMPLEMENTING REGULATION (EU) 2017/239 of 10 February 2017
Restriction	None
Review Report	SANTE/11169/2016 – rev. 3 25/03/2021
Current MRL regulation	~~Commission Regulation (EU) No 2021/1807~~ Reg. (EU) 2023/163
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	~~Pending (EFSA-Q-2014-00331)~~ No
EFSA Journal : Conclusion on the peer review	Yes (EFSA, 2016)
Current MRL applications on intended uses	None

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

One new study evaluating the stability of oxathiapiprolin in honey is submitted in the framework of this application.

The potential for degradation of residues during storage has been previously assessed in the framework of the peer review for oxathiapiprolin. Storage stability of oxathiapiprolin and its metabolites IN-Q7H09, IN-RDG40, IN-E8S72, IN-RZB20, IN-RZD74, IN-SXS67 and IN-WR791 was demonstrated for the following periods in the commodities listed in the table below when frozen (approximately -20°C).

Table 7.3-2: Summary of stability data achieved for oxathiapiprolin and its metabolites at ≤ - 20°C

Commodity category	Commodity	Acceptable maximum storage period	Report Reference	Source
EU reviewed data				
Plant products				
High water content	Wheat forage	at least 18 months	Vincent, T.; 2013 Report No.: DuPont-30046	Ireland, 2015 EFSA, 2016
	Tomatoes	at least 18 months		
High oil content	Soybean seed	at least 18 months		
High protein content	Dried bean seed	at least 18 months		
High starch content	Potato tubers	at least 18 months		
	Wheat grain	at least 18 months		
High acid	Grapes	at least 18 months		
Dry matrices	Wheat straw	at least 18 months		
	Grape dry pomace	at least 18 months		
Animal Products				
Other	Honey	at least 5 months	Ford, K., 2021 Report No.: CEMR-9822, VV-924794	New Data

Summary of storage stability studies reported in the EU
Reference: EFSA, 2016
"Residue data are supported by storage stability studies where oxathiapiprolin and its metabolites IN-Q7H09, IN-RDG40, IN-E8S72, IN-R7B20, IN-RZD74, IN-SXS67 and IN-WR791 were concluded to be stable for at least 18 months in high water, high oil, high starch, high protein and high acid content matrices."
Reference: Ireland, 2015
"The data shows that residues of DPX-QGU42 and its metabolites are stable for at least 18 months in various agricultural commodities stored under frozen conditions. The commodities tested were selected across six crop groupings (high water, high starch, high acid, high protein, high oil and very dry) to represent a wide variety of crops. These conditions are consistent with the storage of actual field samples."

Conclusion on stability of residues during storage
The storage stability of oxathiapiprolin and its metabolites IN-Q7H09, IN-RDG40, IN-E8S72, IN-R7B20, IN-RZD74, IN-SXS67 and IN-WR791 has been investigated in different groups for at least 18 months. The storage stability of oxathiapiprolin in honey has been investigated for at least 5 months. Sufficient stability has been demonstrated to support the residue data presented in this submission.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data
Procedural recoveries obtained during residue analysis demonstrate the stability of residues of oxathiapiprolin in sample extracts and fully support the residue data presented in the submission.

Conclusion on stability of residues in sample extracts
Reference: Ireland, 2015
"Fortified untreated control samples were included with each analytical set and the recovery data for concurrent fortifications show good stability for the analyte in sample extracts for all periods and conditions of extract storage and analysis."
Sufficient stability has been demonstrated to support the residue data presented in the submission.

zRMS comments:

In EFSA Journal 2016;14(7):4504 it is stated that (…) *storage stability studies where oxathiapiprolin and its metabolites IN-Q7H09, IN-RDG40, IN-E8S72, IN-R7B20, IN-RZD74, IN-SXS67 and IN-WR791 were concluded to be stable for at least 18 months in high water, high oil, high starch, high protein and high acid content matrices. The active substance was shown to be stable under standard hydrolysis conditions.*

For animal matrices, the storage stability data are not required.

The Applicant submitted a new storage stability study.
Frozen storage stability of oxathiapiprolin in honey was demonstrated for a period of five months when stored at temperatures of <-18°C.

The residue data are valid with regard to storage stability.
No additional data are required.

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

The metabolism of oxathiapiprolin was investigated for foliar application on grapes, potatoes and lettuce using pyrazole-^{14}C and thiazole-^{14}C labelled-oxathiapiprolin.
The metabolism of oxathiapiprolin was investigated for soil application on courgette, potatoes and lettuce using pyrazole-^{14}C and isoxazoline-^{14}C labelled-oxathiapiprolin.
These studies are summarised in the table below.
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				Report Reference	Source
			Method, F or G $^{(a)}$	Rate (kg a.s./ha)	No	Sampling (DAT)		
EU reviewed data								
Fruits and fruiting vegetables	Grape	pyrazole-^{14}C- and thiazole-^{14}C-oxathiapiprolin	foliar treatment, G	0.07	3	Foliage: 0 DAT$_{1,2,3}$ 14 DAT$_{2,3}$ 76 DAT$_{3}$ Berries: 14 DAT$_{3}$ 76 DAT$_{3}$	Chapleo, S. and Hobbs, G; 2011 Report No.: DuPont-28070	Ireland, 2015 EFSA, 2019
	Courgette	pyrazole-^{14}C- and isoxazoline-^{14}C-oxathiapiprolin	soil application, G (preplanting)	0.60	1	44 and 79 DAT	Hobbs, G.; 2012 Report No.: DuPont-32237	Ireland, 2019 EFSA, 2019
Leafy vegetables	Lettuce	pyrazole-^{14}C- and thiazole-^{14}C-oxathiapiprolin	foliar treatment, F	0.07	3	Foliage: 0 DAT$_{1,2,3}$ 10 DAT$_{1,2}$ 3, 7, 14 DAT$_{3}$	Doig, C.; 2011 Report No.: DuPont-28069	Ireland, 2015 EFSA, 2019
		pyrazole-^{14}C- and isoxazoline-^{14}C-oxathiapiprolin	soil application, G (preplanting)	0.60	1	44 and 57 DAT	Doig, C., Inns, L.; 2012a Report No.: DuPont-31741	Ireland, 2019 EFSA, 2019
Root and tuber vegetables	Potatoes	pyrazole-^{14}C- and thiazole-^{14}C-oxathiapiprolin	foliar treatment, F	0.07	3	Foliage: 14 DAT$_{1,2,3}$ 0 DAT$_{2}$ 28 DAT$_{3}$	Doig, C.; 2013 Report No.: DuPont-	Ireland, 2015 EFSA, 2019

Crop Group	Crop	Label position	Application and sampling details				Report Reference	Source
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)		
						Tuber(b) 14 DAT2,3 28 DAT3	28068	
		pyrazole-^{14}C- and isoxazoline-^{14}C-oxathiapiprolin	soil application, G (preplanting)	0.60	1	Foliage, tubers: 37 and 72 DAT	Doig, C., Inns, L; 2012b Report No.: DuPont-31742	Ireland, 2019 EFSA, 2019

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b) Due to the low total radioactive residue (TRR) at harvest, identification of the residues was not attempted in potato tubers.

Summary of plant metabolism studies reported in the EU

Reference: EFSA, 2019

"In the framework of the EU pesticides peer review, the metabolism of oxathiapiprolin in primary crops belonging to fruit (grape), leaf (lettuce) and root (potato) crop groups has been investigated following foliar application (3 applications of 70 g/ha; radiolabelling in pyrazole and thiazole moiety) (EFSA, 2016). Due to the low total radioactive residue (TRR) at harvest, identification of the residues was not attempted in potato tubers. In grape, lettuce and potato leaves, oxathiapiprolin was observed as the major component of the TRR, accounting for 25–85%. In contrast, in mature grapes, 2 months after the last application, the main components were identified as metabolites IN-E8S72 and IN-WR791, representing 14.4% and 18.6% TRR (0.06 mg/kg), respectively. The peer review concluded that in primary crops the metabolism proceeds by hydroxylation of the molecule at the phenyl ring, the cleavage of the bond between the piperidine and pyrazole rings to form the thiazole-containing metabolites (IN-Q9L80 and IN-QPS10) or the pyrazole metabolites (IN-E8S72, IN-KJ552, IN-R7B20 and IN-WR791). Further conjugation leads to additional glucoside-conjugated metabolites (IN-SXS67) (EFSA, 2016).

Additional studies were submitted for the current assessment where the nature of oxathiapiprolin was investigated after soil application in root (potatoes), leafy (lettuce) and fruit (courgettes) crops (Ireland, 2017b). Oxathiapiprolin, labelled in pyrazole and isoxazoline moiety, was applied preplanting on bare soil at an application rate of 600 g/ha and on the same day crops were sown/planted. […]

The TRR in potato tubers and lettuce decreased over time, whereas in other matrices an increase of residues was observed. The TRR from isoxazoline study in all matrices were generally lower; in mature edible crops radioactivity was below 0.01 mg eq./kg and thus not further characterised. Parent oxathiapiprolin, if present, did not exceed 10% TRR in mature edible matrices. The main components of the TRR in immature and mature edible matrices (potatoes, lettuce and courgettes) exceeding the trigger value of 10% were metabolites IN-E8S72, IN-WR791, IN-RZB20 and IN-RZB21/IN-RZD74. The actual amounts, however, were low, being above 0.01 mg/kg only for metabolite IN-WR791 in courgettes (0.016 mg/kg). […]

All metabolites identified in the new metabolism studies have been also observed in rotational crop and, to a less extent, in primary crop metabolism studies submitted for the EU pesticides peer review.

The metabolic pathway of oxathiapiprolin in primary plants following soil treatment proceeds similarly to that in rotational crops via the cleavage of the bond between piperidine and pyrazole rings. The metabolites containing the pyrazole ring (IN-E8S72, IN-KJ552, IN-RZB20 and IN-WR791) are preferentially taken up by the plant from soil. For the intended uses, the metabolic behaviour in primary crops is sufficiently addressed."

Reference: Ireland, 2016

"Metabolites IN-Q7H09, IN-RDG40, IN-RZB20, and IN-RZD74 were rarely detected (<0.003 mg/kg) in field trials samples and consumer exposure is low. Therefore, these four metabolites are considered not relevant for monitoring or dietary risk assessment.

IN-WR791 was quantified in raw food and feed commodities at levels ≤0.10 mg/kg.[…].

IN-E8S72 is a plant, livestock and soil metabolite quantified in most food and feed commodities at levels

≤0.30 mg/kg. IN-SXS67 is a glucose-conjugate of IN-E8S72 formed in plants and quantified in food and feed commodities at levels ≤1.1 mg/kg. Because IN-SXS67 metabolizes to IN-E8S72 in livestock and is expected to similarly metabolize to IN-E8S72 in humans, the toxicological relevance of the two metabolites was considered simultaneously. IN-E8S72 was tested in a battery of genotoxicity tests and the weight of evidence is that IN-E8S72 is not genotoxic. IN-SXS67 demonstrated no evidence of genotoxicity.
[…] There will be no significant residues of oxathiapiprolin or its metabolites in milk, eggs or meat following livestock consumption of feed containing maximum expected residues of the parent oxathiapiprolin. Based on this and the evaluation of the toxicological relevance of the oxathiapiprolin metabolites, the proposed residue definition for monitoring and dietary risk assessment in crop commodities, including processed commodities, is oxathiapiprolin parent only."

Conclusion on metabolism in primary crops
The metabolism of oxathiapiprolin in plants following foliar and soil application is sufficiently addressed to support the proposed uses of the product A22773A.

zRMS comments:
Information given by Applicant is sufficient and accepted.

In EFSA Journal 2022;20(1):7049 it is stated that *The metabolism of oxathiapiprolin following foliar treatment in crops belonging to fruit, leafy and root crop groups has been investigated in the European Union (EU) pesticides peer review and following soil treatment in the framework of a previous EFSA MRL assessment. The main residue in most primary crops following foliar treatment was parent oxathiapiprolin, with exception of mature grapes, where metabolites containing the pyrazole moiety (IN-E8S72 and IN-WR791) were major residues. Following soil treatment, the main components of the total radioactive residue (TRR) in primary crops were metabolites IN-E8S72, IN-WR791, IN-RZB20 and IN-RZB21/IN-RZD74. The actual amounts, however, were low, except for metabolite IN-WR791 in courgettes.*

RAR (2016):
Based on the evaluation of the toxicological relevance of the oxathiapiprolin metabolites and the fact that oxathiapiprolin was the major residue found in grapes and lettuce, oxathiapiprolin is considered to be the best marker compound for food of plant origin.

Residue definition for monitoring: Parent oxathiapiprolin
Residue definition for risk assessment: Parent oxathiapiprolin
The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above mentioned residue definition.

For the intended uses, the metabolic behaviour in primary crops is sufficiently addressed.
No additional data are required.

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data
The metabolism of oxathiapiprolin in rotational crops was investigated in lettuce, turnip and wheat using pyrazole-^{14}C, thiazole-^{14}C and isoxazoline-^{14}C labelled-oxathiapiprolin. Two confined rotational crop studies investigating the nature of residues following different plant-back intervals are available; these studies are summarised in the table below.
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				Report reference	Source
			Method, F or G$^{(a)}$	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)		
EU reviewed data								

Leafy vegetables	Lettuce	pyrazole-^{14}C-, thiazole-^{14}C- and isoxazoline-^{14}C-oxathiapiprolin	G	1x 0.21	30, 120 and 365 DAT	harvested at intervals appropriate to the crop	Chapleo, S. and Hobbs, G.; 2013 Report No.: DuPont-28381	Ireland, 2015 EFSA, 2019
		pyrazole-^{14}C- and isoxazoline-^{14}C-oxathiapiprolin	G	1x 0.60	30, 120 and 365 DAT	harvested at intervals appropriate to the crop	Hobbs, G.; 2013 Report No.: DuPont-31739	Ireland, 2016 EFSA, 2019
Root and tuber vegetables	Turnip	pyrazole-^{14}C-, thiazole-^{14}C- and isoxazoline-^{14}C-oxathiapiprolin	G	1x 0.21	30, 120 and 365 DAT	harvested at intervals appropriate to the crop	Chapleo, S. and Hobbs, G.; 2013 Report No.: DuPont-28381	Ireland, 2015 EFSA, 2019
		pyrazole-^{14}C- and isoxazoline-^{14}C-oxathiapiprolin	G	1x 0.60	30, 120 and 365 DAT	harvested at intervals appropriate to the crop	Hobbs, G.; 2013 Report No.: DuPont-31739	Ireland, 2016 EFSA, 2019
Cereals	Wheat	pyrazole-^{14}C-, thiazole-^{14}C- and isoxazoline-^{14}C-oxathiapiprolin	G	1x 0.21	30, 120 and 365 DAT	harvested at intervals appropriate to the crop	Chapleo, S. and Hobbs, G.; 2013 Report No.: DuPont-28381	Ireland, 2015 EFSA, 2019
		pyrazole-^{14}C- and isoxazoline-^{14}C-oxathiapiprolin	G	1x 0.60	30, 120 and 365 DAT	harvested at intervals appropriate to the crop	Hobbs, G.; 2013 Report No.: DuPont-31739	Ireland, 2016 EFSA, 2019

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

Summary of metabolism studies in rotational crops reported in the EU

Reference: EFSA, 2019

"The metabolism of oxathiapiprolin in rotational crops was investigated in the EU pesticides peer review and was found to be different; residues were exclusively composed of metabolites containing pyrazole moiety (IN-E8S72 and its conjugate IN-SXS67).

In the framework of the current assessment, new primary crop metabolism studies were submitted, investigating nature of oxathiapiprolin in fruit, leafy and root crops following soil application. The new studies confirm that after soil treatment, the metabolism proceeds in a similar pathway to that in rotational crops, forming metabolites IN-E8S72, IN-WR791 and IN-RZB21/IN-RZD74. New studies investigating metabolism in rotational crops following soil treatment at higher application rates were submitted under the current assessment. The results were comparable with the previously assessed studies by the peer review. […]

Although different metabolic pathway in primary and rotational crops was observed, the peer review concluded that residue definitions for enforcement and risk assessment derived for primary crops as parent oxathiapiprolin are also applicable to rotational crops, since main rotational crop metabolites (IN-E8S72, IN-SXS67) are of a lower toxicity than oxathiapiprolin and therefore they are not proposed for the inclusion

in the plant residue definitions. The toxicological relevance of plant metabolite IN-WR791 was assessed in the current application. It was concluded that IN-WR791 is expected to have similar toxicological profile as IN-E8S72; the available data does not give an indication that this metabolite exhibits genotoxic effects."
Reference: EFSA, 2016
"In rotational crops, the metabolism was found to be different and exclusively composed of the metabolites containing the pyrazole moiety (especially metabolite IN-E8S72 and its glucose-conjugated IN-SXS67) accounting for more than 50% of the TRR. Oxathiapiprolin, metabolites denoting the structure of the parent compound and metabolites containing the thiazole moiety were almost never detected. The metabolic profile in rotational crops is mostly the result of a preferential uptake from soil of the metabolites containing the pyrazole moiety. Chiral analysis of samples indicated that the enantiomeric ratio (ca 1:1) remained unchanged in plants. Based on these studies and considering that the pyrazole metabolite IN-E8S72 was concluded by the Pesticides Peer Review Experts' Meeting 137 on toxicology of lower toxicity than oxathiapiprolin […], metabolite IN-E8S72 and its conjugate IN-SXS67 were not included in the plant residue definitions that were proposed as oxathiapiprolin for monitoring and risk assessment."

Conclusion on metabolism in rotational crops
Although different metabolic pathway in primary and rotational crops was observed, EFSA (2019) concluded that residue definitions for enforcement and risk assessment derived for primary crops as parent oxathiapiprolin are also applicable to rotational crops.

zRMS comments:
Information given by Applicant is sufficient and accepted.

In EFSA Journal 2022;20(1):7049 it is stated that *The metabolism of oxathiapiprolin in rotational crops was investigated in the EU pesticides peer review and was found to be different; residues were exclusively composed of metabolites containing pyrazole moiety (IN-E8S72 and its conjugate IN-SXS67). In the framework of a previous assessment, new metabolism studies were evaluated and the conclusions of the peer review were confirmed. The main metabolites present in rotational crops were IN-E8S72 (and IN-SXS67), IN-WR791, IN-RZB20 and IN-RZB21/IN-RZD74.*

EFSA Journal 2019;17(7):5759: *Metabolism in primary and rotational crops is different; a limited degradation of metabolism, while in the second rotational oxathiapiprolin in plants was found in primarycrop metabolism a preferential uptake of pyrazole metabolites from soil was observed. Metabolite IN-E8S72 and its conjugate IN-SXS67 were main residues in rotational crops; IN-E8S72 and its conjugate IN-SXS67 concluded to be of lower toxicity and thus both compounds were not included in the plant residue definitions (EFSA, 2016). A new metabolism study confirmed the conclusions of the peer review. The main metabolites present in rotational crops were IN-E8S72 (and IN-SXS67), IN-WR791, IN-RZB20 and IN-RZB21/IN-RZD74 (Ireland 2017a).*

No additional data are required.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data
The effect of processing on the nature of oxathiapiprolin 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). The results are summarised in the table below.
No new data submitted in the framework of this application.

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

Conditions	Identified compound(s) (%)	Report reference	Source
EU reviewed data			
Pasteurisation (20 minutes, 90°C, pH 4)	Parent (pyrazole label: 94.8%, thiazole label: 96.2%) others (0%)	Anand, H.S.; 2010 Report No.: DuPont-29273	Ireland, 2015

Conditions	Identified compound(s) (%)	Report reference	Source
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Parent (pyrazole label: 94.7%, thiazole label: 95.1%) others (0%)		
Sterilisation (20 minutes, 120°C, pH 6)	Parent (pyrazole label: 93.8 %, thiazole label: 94.2%) others (0%)		

Summary of high temperature studies reported in the EU
Reference: Ireland, 2016
"It can be concluded that DPX-QGU42 was hydrolytically stable under conditions representative of pasteurisation (pH4, 90 ºC for 20 minutes), baking/brewing/boiling (pH5, 100 ºC for 60 minutes) and sterilisation (pH6, 120 ºC at 15 psi, for 20 minutes). DPX-QGU42 is hydrolytically stable, therefore no hydrolysis pathway was proposed."

Conclusion on nature of residues in processed commodities
The nature of residues of oxathiapiprolin in processed products has been investigated. Oxathiapiprolin is stable under the representative processing conditions.

zRMS comments:
The effect of processing on the nature of parent oxathiapiprolin was investigated in the frameworkof the EU pesticides peer review (EFSA, 2016). These studies showed that oxathiapiprolin is hydrolytically stable under standard processing conditions.
The same residue definitions as for primary crops were proposed for processed products.
No further data are required to support the proposed uses.

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	Fruit crops (grapes – foliar treatment) Leafy crops (lettuce – foliar treatment) Root crops (potatoes – foliar treatment) (EFSA, 2016) Fruit crops (courgettes – soil application) Leafy crops (lettuce – soil application) Root crops (potatoes – soil application) (EFSA, 2019)
Rotational crops covered	Cereal crops (wheat, barley, maize), Root crops (turnip, carrot, onion, radish, beet) Leafy crops (lettuce, spinach, head brassica) Pulses/Oilseeds (pea, bean) (EFSA, 2016)
Metabolism in rotational crops similar to metabolism in primary crops?	Metabolism in primary and rotational crops is different; a limited degradation of metabolism, while in the second rotational oxathiapiprolin in plants was found in primary crop metabolism a preferential uptake of pyrazole metabolites from soil was observed. Metabolite IN-E8S72 and its conjugate IN-SXS67 were main residues in rotational crops; IN-E8S72 and its conjugate IN-SXS67 concluded to be of lower toxicity and thus both compounds were not included in the plant residue definitions. A new metabolism study confirmed the conclusions of the peer review. The main metabolites present in rotational crops were IN-E8S72 (and IN-SXS67), INWR791, IN-RZB20 and IN- RZB21/INRZD74. (EFSA, 2019)
Processed commodities	Oxathiapiprolin is hydrolytically stable, therefore no hydrolysis pathway was proposed (Ireland, 2016))

Residue pattern in processed commodities similar to pattern in raw commodities?	Oxathiapiprolin and metabolites are comparable in raw and processed commodities. (EFSA, 2016)
Plant residue definition for monitoring	Oxathiapiprolin (EFSA, 2016 and 2019, Reg. (EU) 2023/163)
Plant residue definition for risk assessment	Oxathiapiprolin (EFSA, 2016 and 2019)
Conversion factor from enforcement to RA	None (EFSA, 2016)

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

Available data

The metabolism of oxathiapiprolin was investigated in laying hen and lactating goat using [pyrazole-5-^{14}C] and [thiazole-5-^{14}C]oxathiapiprolin. A separate goat metabolism study with [pyrazole-5-^{14}C]IN-SXS67 (the glucoside conjugate of IN-E8S72) was also conducted. These studies are summarised in the table below. 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		Report reference	Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling		
EU reviewed data									
Lactating ruminants	Goat	[pyrazole-5-^{14}C] oxathiapiprolin	2	21.360 mg/goat/ day	7	Milk	twice daily	Anon, 2013 Report No.: Du-Pont 28213	Ireland, 2015
						Urine and faeces	daily		
		[thiazole-5-^{14}C] oxathiapiprolin		17.664 mg/goat/ day		Tissues	at sacrifice		
		[pyrazole-5-^{14}C]IN-SXS67	1	18.95 mg/kg diet (dry weight equivalent)	7	Milk	twice daily	Anon, 2013 Report No.: Du-Pont-34913	Ireland, 2015
						Urine and faeces	daily		
						Tissues	at sacrifice		
Laying poultry	Hens	[pyrazole-5-^{14}C] oxathiapiprolin	12	17.4 mg/kg diet (dry weight equivalent)	14	Eggs	twice daily	Anon, 2013 Report No.: Du-Pont-28244	Ireland, 2015
						Excreta	daily		
		[thiazole-5-^{14}C] oxathiapiprolin		17.8 mg/kg diet (dry weight equivalent)		Tissues	at sacrifice		

Summary of animal metabolism studies reported in the EU

Reference: Ireland, 2019

"In laying hens, oxathiapiprolin and its metabolites were readily eliminated in the excreta where 92-98% of the dose was recovered. Transfer of radioactive residues to the eggs was very low with <0.1% of the dose eliminated via this route. Approximately 0.02% of the dose was found in the liver, muscle and fat ca. 6 hours after the last dose indicating no bioaccumulation potential. Total radioactive residues in the liver

were 0.096 mg/kg and 0.102 mg/kg for the [pyrazole-5-^{14}C] and [thiazole-5-^{14}C]oxathiapiprolin dosed hens, respectively. Total residues were <0.03 mg/kg in eggs, muscle and fat. Given the low total radioactive residue levels even at the exaggerated dose (ca. 120N), there is no expectation of quantifiable (>0.01 mg/kg) residues in poultry tissues or eggs.
In lactating goats, oxathiapiprolin and its metabolites were readily eliminated in the urine and faeces where 84.3-86.4% of the dose (including cage wash) was recovered. Total radioactive residues (TRR) plateaued within 5 days in milk. Transfer of radioactive residues to the milk was very low with 0.2% or less of the dose eliminated via this route over the 7 days. Less than 1.2% of the dose was found in the liver, kidney, muscle and fat combined, at sacrifice 12 hours after the last dose, indicating that there is no bioaccumulation potential. Approximately 94.0-99.6% of the total dose was recovered when the radioactivity found in gastrointestinal contents (8.4-12.3% dose) was included.
Total radioactive residues in liver and kidneys were 0.966 and 0.084 mg/kg for the [pyrazole-5-14C]oxathiapiprolin dosed goat and 0.748 and 0.065 mg/kg for the [thiazole-5-^{14}C]oxathiapiprolin dosed goat, respectively. Total residues were below 0.03 mg/kg in milk, muscle and fat. Greater than 52.4% of the radioactivity in the tissues and milk was extracted, with the majority of residues identified or characterised. Residues of unmetabolised oxathiapiprolin were detected in most tissues including milk (at ca. 0.002 mg/kg). The highest residues of oxathiapiprolin were detected in liver at 0.114 and 0.048 mg/kg for the [pyrazole-5-^{14}C]oxathiapiprolin and [thiazole-5-^{14}C]oxathiapiprolin dosed goats, respectively. Given the low total radioactive residue and oxathiapiprolin levels even at the exaggerated dose (ca. 23N), there is no expectation of quantifiable (>0.01 mg/kg) residues in ruminant tissues or milk.
Metabolites present at greater than 5% TRR in the various tissues and/or milk included IN-E8S72, IN-RAB06, IN-RLB67, IN-QFD61, IN-RDG40, IN-Q7H09 and IN-Q7D41. Intact parent oxathiapiprolin was present at 59.6 and 56.4% dose in the faeces from [pyrazole-5-^{14}C] and [thiazole-5-^{14}C]oxathiapiprolin goats. Chiral analysis of faeces extracts indicated that there was no enantiomeric selectivity in metabolism of oxathiapiprolin in lactating goat.
A separate goat metabolism study with IN-SXS67, the glucoside conjugate of IN-E8S72, was also conducted. The administered IN-SXS67 was excreted quantitatively together with the only metabolite, IN-E8S72, the aglycone of IN-SXS67. There was no significant accumulation of radioactive residues in the fat, milk, and tissues.
Based on the fact that residues of oxathiapiprolin and its metabolites will not be significant (<0.01 mg/kg) in tissues, meat, milk, and eggs following consumption of feed containing residues of oxathiapiprolin and considering the evaluation of the toxicological relevance of the oxathiapiprolin metabolites, oxathiapiprolin is considered to be the best marker compound for food of animal origin. The residue definitions for monitoring and risk assessment are parent oxathiapiprolin and the MRLs, HRs and STMRs are set at the LOQ. There are no conversion factors for risk assessment."

Conclusion on metabolism in livestock
The metabolism of oxathiapiprolin in livestock and poultry is sufficiently addressed to support the proposed uses of the product A22773A.

zRMS comments:
Information given by the Applicant is sufficient.
In EFSA Journal 2016;14(7):4504 it is stated that *Livestock metabolism studies conducted on lactating goat over seven consecutive days and on poultry over 14 days at a dose rate of ca. 14 and 17 mg/kg bw were submitted. Most of the radioactivity was excreted and less than 1% of the administered dose was recovered in animal matrices. Most of the radioactive residues were identified as oxathiapiprolin and the hydroxy metabolites IN-RDG40 and IN-Q7H09. The residue definition for products of animal origin was proposed as oxathiapiprolin for monitoring and risk assessment. Having regard to the supported uses, the setting of MRLs for product of animal origin was concluded to be unnecessary.*

No further data are required to support the proposed uses.

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	Poultry (laying hens) Ruminant (lactating goat) (EFSA, 2016)
Time needed to reach a plateau concentration	Eggs (plateau reached in 6 days) Milk (plateau reached in 5 days) (EFSA, 2016)
Animal residue definition for monitoring	Oxathiapiprolin (EFSA, 2016, Reg. (EU) 2023/163)
Animal residue definition for risk assessment	Oxathiapiprolin (EFSA, 2016)
Conversion factor	None (EFSA, 2016)
Metabolism in rat and ruminant similar	Yes. In general metabolic pathways are consistent between ruminant goat, monogastric hen and rat. (EFSA, 2016)
Fat soluble residue	No. Oxathiapiprolin log $P_{O/W}$: 3.67 suggesting potential for fat solubility. However, the fish bioconcentration study showed BCF value of 87 for whole fish, suggesting that oxathiapiprolin is not bio-accumulative. (EFSA, 2016)

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

New studies on the magnitude of residues in plants have been submitted by the applicant in the framework of this application. Reference is also made to previously evaluated data. The studies are summarized in the Table below. The detailed assessment of the new studies is presented in Appendix 2. The residue trials included in this submission support the intended use.

Table 7.3-9: Summary of EU reported and new data supporting the intended uses of A22773A and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)(a) 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
Tomato → extrapolated to eggplant	**Intended GAP**	**N-EU**	**2 x 12 g a.s./ha, BBCH 11-89, 7 d interval, PHI 3**	-				
	Zonal cGAP (DAR, Ireland, 2015; EFSA, 2016)	**N-EU**	**N/A**	-				
	New data	N-EU	Trials GAP: 3 x 11-13 g a.s./ha, BBCH 65-89, 7-8 d interval, PHI 3 E/RA: <0.01, 4 x 0.01, 2 x 0.02, 0.03	- -				
			Trials GAP: 2 x 12 g a.s./ha, BBCH 73-89, 6-8 d interval, PHI 3 E/RA: 5 x <0.01, 0.011, 0.012, 0.021	- -				
	EU reviewed	NEU	-	-				
	Overall supporting data for intended/zonal GAP	NEU	E/RA: 6 x <0.01, 4 x 0.01, 0.011, 0.012, 2 x 0.02, 0.021, 0.03	0.010	0.030	0.037	~~0.2~~ 0.4	Yes

N/A Not available
* Source of EU MRL: ~~Regulation (EU) 2021/1807~~ Reg. (EU) 2023/163
(a) Definition of residue for enforcement and risk assessment are the same: oxathiapiprolin (EFSA, 2016)

Table 7.3-9: Summary of EU reported and new data supporting the intended uses of A22773A and conformity to existing MRL continued

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[(a)] 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
Bell pepper	**Intended GAP**	**N-EU**	**2 x 12 g a.s./ha, BBCH, 11-89, 7 d interval, PHI 3**	-				
	Zonal cGAP	**N-EU**	**N/A**	-				
	New data	N-EU	Trials GAP: 2 x 12 g a.s./ha, BBCH 75-88, 6-8 d interval, PHI 3 E/RA: 7 x <0.01, 0.017	-				
	Overall supporting data for intended cGAP	N-EU	E/RA: 7 x <0.01, 0.017	0.010	0.017	0.021	0.2	Yes

N/A Not available
* Source of EU MRL: ~~Regulation (EU) 2021/1807~~ Reg. (EU) 2023/163
(a) Definition of residue for enforcement and risk assessment are the same: oxathiapiprolin (EFSA, 2016)

Table 7.3-9: Summary of EU reported and new data supporting the intended uses of A22773A and conformity to existing MRL continued

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[(a)] 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
Cucumber and zucchini (courgette)	**Intended GAP**	**N-EU**	**2 x 12 g a.s./ha, BBCH, 11-89, 7 d interval, PHI 3**	-				
	Zonal cGAP (DAR, Ireland, 2015; EFSA, 2016)	**N-EU**	**N/A**	-				
	New data	N-EU	Trials GAP: 2 x 11-13 g a.s./ha, 6-8 d interval, PHI 3 E/RA: 8 x <0.01[(b)]	-				
	Overall supporting data for zonal cGAP	N-EU	E/RA: 8 x <0.01	0.010	0.010	0.010	~~0.1~~ 0.2	Yes

N/A Not available
* Source of EU MRL: ~~Regulation (EU) 2021/1807~~ Reg. (EU) 2023/163
(a) Definition of residue for enforcement and risk assessment are the same: oxathiapiprolin (EFSA, 2016)
(b) All trials were conducted on cucumber

Table 7.3-9: Summary of EU reported and new data supporting the intended uses of A22773A and conformity to existing MRL continued

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[(a)] 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
Melon → extrapolated watermelon, pumpkin, squash	**Intended GAP**	**N-EU**	**2 x 12 g a.s./ha, BBCH, 11-89, 7 d interval, PHI 3**	-				
	Zonal cGAP (DAR, Ireland, 2015; EFSA, 2016)	**N-EU**	**N/A**	-				
	New data	N-EU	Trials GAP: 2 x 11-13, BBCH 65-89, 7-8 d interval, PHI 3 Whole fruit: E/RA: 6 x <0.01, 0.02, 0.02[(b)] Pulp: E/RA: 8 x <0.01	-				
	Overall supporting data for intended GAP	N-EU	E/RA: 6 x <0.01, 2 x 0.02	0.010	0.02	0.031	0.2	Yes

N/A Not available
* Source of EU MRL: ~~Regulation (EU) 2021/1807~~ Reg. (EU) 2023/163
(a) Definition of residue for enforcement and risk assessment are the same: oxathiapiprolin (EFSA, 2016)
(b) Residue value from PHI 7 presented, as the residue level from this later PHI 7 was higher than the residue level at PHI 3.

Table 7.3-9: Summary of EU reported and new data supporting the intended uses of A22773A and conformity to existing MRL continued

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[(a)] 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
Lettuce → extrapolated to salad plants, sweet basil and spinach	**Intended GAP*** **	**N-EU**	**2 x 12 g a.s./ha, BBCH 11-49, 7 d interval, PHI 14**	-				
	Zonal cGAP (DAR, Ireland, 2015; EFSA, 2016)	**N-EU**	**2 x 15 g a.s./ha, 7 d interval, PHI 7**	-				
	EU reviewed	N-EU	Trials GAP: 2 x 15 g a.s./ha, 7 d interval, PHI 7 E/RA: 0.022, 0.035, 0.043, 0.069, 0.070, 0.130, 0.150, 0.190	-				
	Overall supporting data for intended cGAP	NEU	E/RA: 0.022, 0.035, 0.043, 0.069, 0.070, 0.130, 0.150, 0.190	0.070	0.19	0.332	5**for lettuces and salad plants 15 for spinaches and similar leaves 10 for basil	Yes

* Source of EU MRL: ~~Regulation (EU) 2021/1807~~ Reg. (EU) 2023/163
** 15 mg/kg in spinaches and similar leaves, including purslanes and MRL of 10 mg/kg in basil (~~Regulation (EU) 2021/1807~~ Reg. (EU) 2023/163).
*** A GAP with 1 application (all other parameters are the same) is also included. This additional GAP is supported by the data supporting the intended cGAP. Another GAP use is proposed, with identical parameters to the intended GAP discussed above, with the exception of a reduced application interval, BBCH 41-49. As this use is less critical, it is considered covered by the intended GAP.
(a) Definition of residue for enforcement and risk assessment are the same: oxathiapiprolin (EFSA, 2016)

Table 7.3-9: Summary of EU reported and new data supporting the intended uses of A22773A and conformity to existing MRL continued

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[(a)] 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
Leek → extrapolated to spring onion	**Intended GAP****	**N-EU**	**2 x 12 g a.s./ha, BBCH 11-49, 12-14 d interval, PHI 7**	-				
	Zonal cGAP	**N-EU**	**N/A**	-				
	New data	N-EU	Trials GAP: 2 x 11-13 g a.s./ha, 10-13 d interval, PHI 7-8 E/RA: 2 x <0.01, 0.02, 0.02[(b)], 0.04, 3 x 0.05	-				
	Overall supporting data for intended GAP	N-EU	E/RA: 2 x <0.01, 2 x 0.02, 0.04, 3 x 0.05	0.030	0.050	0.104	2	Yes

N/A Not available
* Source of EU MRL: ~~Regulation (EU) 2021/1807~~ Reg. (EU) 2023/163
** A GAP with 1 application (all other parameters are identical) is also included for central zone as an intended GAP for evaluation in this submission. This additional GAP is supported by the data supporting the intended cGAP.
(a) Definition of residue for enforcement and risk assessment are the same: oxathiapiprolin (EFSA, 2016)
(b) Residue value from PHI 10 presented, as the residue level from this later PHI 10 was higher than the residue level at PHI 7.

Table 7.3-9: Summary of EU reported and new data supporting the intended uses of A22773A and conformity to existing MRL continued

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)(a) 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
Hops	**Intended GAP****	**N-EU**	**2 x 12 g a.s./ha, BBCH 21-89, 12-16 d interval, PHI 28**	-				
	Zonal cGAP (EFSA, 2019)	**N-EU**	**2 x 50 g a.s./ha, 10 d interval, PHI 14**	-				
	EU reviewed	N-EU	Trials GAP: 2 x 50 g a.s./ha, 10 d interval, PHI 14 E/RA: 0.69, 1.3, 1.6, 3.1, 3.9	-				
	Overall supporting data for intended GAP	N-EU	E/RA: 0.69, 1.3, 1.6, 3.1, 3.9	1.600	3.900	7.453	8	Yes

N/A Not available
* Source of EU MRL: ~~Regulation (EU) 2021/1807~~ Reg. (EU) 2023/163
** A GAP with 1 application (all other parameters are the same) is also included for central zone. This additional GAP is supported by the data supporting the intended cGAP.
(a) Definition of residue for enforcement and risk assessment are the same: oxathiapiprolin (EFSA, 2016)

7.3.3.2 Conclusion on the magnitude of residues in plants

Tomato, extrapolated to eggplant

Tomato is a major crop in northern and southern Europe (SANTE/2019/12752) and therefore normally requires eight northern trials and eight southern trials to support an EU MRL. According to the Commission Technical Guideline SANTE/2019/12752, application rates within ±25% are considered to give comparable residue levels. Additionally, the OECD Crop Field Trial Guideline (OECD 509) highlights the acceptability of ±10% deviation from nominal GAP parameters as a result of natural variability.
The intended GAP is 2 x 12 g a.s./ha, BBCH 11-89, 7 d interval, PHI 3.

A total of sixteen trials in northern Europe were conducted on tomato. Eight trials were conducted according to a GAP (at a nominal application rate of 3 x 12 g a.s./ha, BBCH 65-89, 7-8 d interval, PHI 3) which is more critical than the intended GAP. Further eight trials were conducted according to the intended GAP. The application rate was 12 g a.s./ha ±10% in all trials. Application interval was 6-8 days which is within the ±10% acceptable deviation range. All trials are considered to have been conducted according to the intended GAP for A22773A. Residues in untreated tomato fruit samples collected at normal commercial harvest (PHI 3 days) were below the limit of quantification (0.01 mg/kg).
Therefore, sufficient trials are available to support the proposed use on tomato (foliar application; outdoor uses). The available data submitted show that no exceedance of the existing EU MRL will occur. The proposed use of oxathiapiprolin in A22773A on outdoor tomato is therefore considered acceptable.
According to the Commission Technical Guideline SANTE/2019/12752, residue data from tomato trials can be extrapolated to aubergine/eggplant for which the same EU MRL applies as for tomato. Sufficient trials are available to support the proposed use on eggplant (foliar application; outdoor uses). Therefore, the proposed use of oxathiapiprolin in A22773A on outdoor eggplant is considered acceptable.

zRMS comments:
Information given by the Applicant is sufficient.
Tomato is the major crop in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of eight trials are required. Residue data on tomato (0231010) can be extrapolated to aubergines/eggplants (0211030) before and after forming of the edible part.

The intended GAP for oxathiapiprolin for tomatoes in Central Europe is 2x12 g a.s./ha with interval between applications of 7 days at BBCH 11-89 with PHI of 3 days.

New studies on the magnitude of residue have been submitted by the Applicant in the framework of this application. The trials are supported by valid storage stability data for tomatoes and validated analytical methods.
A total of 16 new supervised residue trials were performed in Northern Europe:
1. Lakaschus S. (2020), Report No. S19-02717 - six trials were conducted according to a GAP at a nominal application rate of 3 x 12 g a.s./ha, BBCH 65-89, 7-8 d interval, PHI 3 which is more critical than the intended GAP.
Residues of oxathiapiprolin in tomato samples taken at 3 DALA, normal commercial harvest (NCH) were between 0.01 and 0.03 mg/kg.
2. Fritzsch S. (2020), Report No. S20-03173 – two trials, three applications at 12 g ai/ha were applied to tomatoes. Timings corresponded to the intended GAPs for A22773A.
Residues of oxathiapiprolin in tomato samples taken at 3 DALA, normal commercial harvest (NCH) were between <0.01 and 0.02 mg/kg.
3. Stolze J., Wolfgarten E. (2021), Report No. IF20-05334280 - eight trials, two applications at 12 g ai/ha were applied to tomatoes. Timings corresponded to the intended GAPs for A22773A.
Residues of oxathiapiprolin in tomato samples taken at 3 DALA, normal commercial harvest (NCH) were between <0.01 and 0.021 mg/kg.

The residues arising from the proposed uses will not exceed the MRLs established for oxathiapiprolin for tomatoes and aubergines/eggplants of 0.4 mg/kg in ~~Reg. (EU) 2021/1807~~ Reg. (EU) 2023/163.
The uses are considered acceptable.

Bell pepper

Bell pepper is a major crop in northern and southern Europe (SANTE/2019/12752) and therefore normally requires eight northern trials and eight southern trials to support an EU MRL. According to the Commission

Technical Guideline SANTE/2019/12752, application rates within ±25% are considered to give comparable residue levels. Additionally, the OECD Crop Field Trial Guideline (OECD 509) highlights the acceptability of ±10% deviation from nominal GAP parameters as a result of natural variability.
The intended GAP is 2 x 12 g a.s./ha, BBCH 11-89, 7 d interval, PHI 3.

A total of eight trials were conducted on bell pepper according to the intended GAP. The application rate was 12 g a.s./ha ± 10% in all trials. Application interval was 6-8 days in all trials which is within the ±10% acceptable deviation range. All trials are considered to have been conducted according to the intended GAP for A22773A (2 x 12 g a.s./ha, 7 d interval, PHI 3). Residues in untreated pepper fruit samples collected at normal commercial harvest (PHI 3 days) were below the limit of quantification (0.01 mg/kg). Additional plots of these trials are presented in Appendix 2, but the residue values from the plots treated with 3 x 40 g a.s./ha were not taken for assessment, because the application rate was outside of the ±25% range.
Therefore, sufficient trials are available to support the proposed use on bell pepper (foliar application; outdoor uses). The available data submitted show that no exceedance of the existing EU MRL will occur. The proposed use of oxathiapiprolin in A22773A on outdoor bell pepper is therefore considered acceptable.

zRMS comments:
Information given by the Applicant is sufficient.
Pepper is the major crop in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of eight trials are required.

The intended GAP for oxathiapiprolin for bell pepper in Central Europe is 2x12 g a.s./ha with interval between applications of 7 days at BBCH 11-89 with PHI of 3 days.

New studies on the magnitude of residue have been submitted by the Applicant in the framework of this application. The trials are supported by valid storage stability data for pepper and validated analytical methods.
A total of 8 new supervised residue trials were performed in Northern Europe:
1. Thirkell C., Wofgarten E. (2021), Report No. IF20-05334851- eight trials, the tested application rates and timings, corresponded to the intended GAPs for A22773A
No residues were found in control samples above the stated LOQ of 0.01 mg/kg.
Residues of oxathiapiprolin in peppers samples taken at 3 DALA, normal commercial harvest (NCH) were between <0.01 and 0.02 mg/kg.

The residues arising from the proposed uses will not exceed the MRLs established for oxathiapiprolin for sweet peppers/bell peppers of 0.2 mg/kg in ~~Reg. (EU) 2021/1807~~ Reg. (EU) 2023/163.
The use is considered acceptable.

Cucumber and zucchini (courgette)
Cucumber is a major crop in northern Europe and courgette is a major crop in southern Europe (SANTE/2019/12752) and therefore normally eight northern trials and eight southern trials are required either on cucumber/courgette to support an EU MRL. According to the Commission Technical Guideline SANTE/2019/12752, application rates within ±25% are considered to give comparable residue levels. Additionally, the OECD Crop Field Trial Guideline (OECD 509) highlights the acceptability of ±10% deviation from nominal GAP parameters as a result of natural variability.
The intended GAP is 2 x 12 g a.s./ha, BBCH 11-89, 7 d interval, PHI 3.

A total of eight trials were conducted on cucurbits (all on cucumber) according to the intended GAP. The application rate was 12 g ai/ha ± 10% in all trials. Application interval was 6-8 days in all trials which is within the ±10% acceptable deviation range. All trials are considered to have been conducted according to the intended GAP for A22773A (2 x 12 g a.s./ha, 7 d interval, PHI 3). Residues in untreated cucurbit fruit samples collected at normal commercial harvest (PHI 3 days) were below the limit of quantification (0.01 mg/kg).
Therefore, sufficient trials are available to support the proposed uses on cucumber and zucchini (courgette) (foliar application; outdoor uses). The available data submitted show that no exceedance of the existing EU MRL will occur. The proposed uses of oxathiapiprolin in A22773A on outdoor cucumber and zucchini are therefore considered acceptable.

zRMS comments:
Information given by the Applicant is sufficient.
Cucumber is the major crop in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of eight trials are required. Zucchini (courgette) is the minor crop in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of four trials are required.
Residue data on cucumbers (0232010) and/or courgettes (0232030) can be extrapolated to Whole subgroup (b) cucurbits with edible peel before and after forming of the edible part.

The intended GAP for oxathiapiprolin for cucumber and zucchini (courgette) in Central Europe is 2x12 g a.s./ha with interval between applications of 7 days at BBCH 11-89 with PHI of 3 days.

New studies on the magnitude of residue have been submitted by the Applicant in the framework of this application. The trials are supported by valid storage stability data for cucumbers and gherkins and validated analytical methods. A total of 8 new supervised residue trials were performed in Northern Europe:
1. Giles A. (2021), Report No. 684120- the tested application rates and timings, corresponded to the intended GAPs for A22773A.
Residues of oxathiapiprolin in cucumbers samples taken at 3 DALA, normal commercial harvest (NCH) were <0.01 mg/kg.

The residues arising from the proposed uses will not exceed the MRLs established for oxathiapiprolin for cucumbers, gherkins and courgettes of 0.2 mg/kg in ~~Reg. (EU) 2021/1807~~ Reg. (EU) 2023/163.
The uses are considered acceptable.

Melon, extrapolated to watermelon, pumpkin and squash

Melon is a major crop in southern Europe and a minor crop in northern Europe (SANTE/2019/12752) and therefore normally eight southern trials and four northern trials on melon are required to support an EU MRL. Watermelon is a major crop in both northern and southern Europe and therefore eight trials on melon or watermelon are required to support an EU MRL. According to the Commission Technical Guideline SANTE/2019/12752, application rates within ±25% are considered to give comparable residue levels. Additionally, the OECD Crop Field Trial Guideline (OECD 509) highlights the acceptability of ±10% deviation from nominal GAP parameters as a result of natural variability.
The intended GAP is 2 x 12 g a.s./ha, BBCH 11-89, 7 d interval, PHI 3.

A total of eight trials were conducted on melon according to the intended GAP. The application rate was 12 g a.s./ha ± 10% in all trials. Application interval was 7 days in all trials with the exception of two which had an interval of 8 days which is within the ±10% acceptable deviation range. All trials are considered to have been conducted according to the intended GAP for A22773A (2 x 12 g a.s./ha, 7 d interval, PHI 3). Residues in untreated melon whole fruit samples calculated from the residue values in pulp and peel collected at normal commercial harvest (PHI 3 days) were below the limit of quantification (0.01 mg/kg). Therefore, sufficient trials are available to support the proposed use on melon (foliar application; outdoor uses). The available data submitted show that no exceedance of the existing EU MRL will occur. The proposed use of oxathiapiprolin in A22773A on outdoor melon is therefore considered acceptable.
According to the Commission Technical Guideline SANTE/2019/12752, residue data from melon trials can be extrapolated to watermelons, pumpkin and squash. The available data submitted show that no exceedance of the existing EU MRL will occur. Sufficient trials are available to support the proposed use on watermelon, pumpkin and squash (foliar application; outdoor uses). Therefore, the proposed use of oxathiapiprolin in A22773A on outdoor watermelon, pumpkin and squash is considered acceptable.

zRMS comments:
Information given by the Applicant is sufficient.
Watermelon is the major crop in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of eight trials are required. Melon is the minor crop in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of four trials are required.
Residue data on melons (0233010) can be extrapolated to Whole subgroup (c) cucurbits with inedible peel before and after forming of the edible part.

The intended GAP for oxathiapiprolin for melon, watermelon, pumpkin and squash in Central Europe is 2x12 g a.s./ha with interval between applications of 7 days at BBCH 11-89 with PHI of 3 days.

New studies on the magnitude of residue have been submitted by the Applicant in the framework of this application. A total of 8 new supervised residue trials were performed in Northern Europe:
1. Giles A. (2021), Report No. 684125- the tested application rates and timings, corresponded to the intended GAPs for A22773A. The trials are supported by valid storage stability data for melons and validated analytical methods. Residues of oxathiapiprolin in melons pulp samples taken at 3 DALA, normal commercial harvest (NCH) were <0.01 mg/kg.

The residues arising from the proposed uses will not exceed the MRLs established for oxathiapiprolin for cucurbits with inedible peel (melons, pumpkins amd watermelons) of 0.2 mg/kg in ~~Reg. (EU) 2021/1807~~ Reg. (EU) 2023/163.
The uses are considered acceptable.

Lettuce, extrapolated to salad plants, sweet basil and spinach

Lettuce is a major crop in northern and southern Europe (SANTE/2019/12752) and therefore normally requires eight northern trials and eight southern trials to support an EU MRL. According to the Commission Technical Guideline SANTE/2019/12752, application rates within ±25% are considered to give comparable residue levels. Additionally, the OECD Crop Field Trial Guideline (OECD 509) highlights the acceptability of ±10% deviation from nominal GAP parameters as a result of natural variability.
The intended GAP is 2 x 12 g a.s./ha, BBCH 11-49, 7 d interval, PHI 14.

A total of eight trials were conducted on lettuce according to the zonal cGAP (at a nominal application rate of 2 x 15 g a.s./ha, 7 d interval, PHI 7), which is more critical than the intended GAP (2 x 12 g a.s./ha, 7 d interval, PHI 14). Four decline trials include also a 10-day PHI sample supporting the intended GAP with a higher PHI. Residues in untreated lettuce samples collected at normal commercial harvest (PHI 14 days) were below the limit of quantification (0.01 mg/kg). The trials available in support of the cGAP were conducted using an OD formulation. Additional studies have been carried out to show comparability of Oxathiapiprolin OD and SC formulations. This information is available in Appendix 4. Therefore it is considered valid to support the intended use with these trials.
Therefore, sufficient trials are available to support the proposed use on lettuce (foliar application; outdoor uses). The available data submitted show that no exceedance of the existing EU MRL will occur. The proposed use of oxathiapiprolin in A22773A on outdoor lettuce is therefore considered acceptable.
An alternative GAP with 1 application (all other parameters are identical) is also included as an intended GAP for evaluation in this submission. This additional GAP is supported by the data supporting the intended cGAP.
Another GAP use is proposed, with identical parameters to the intended GAP discussed above, with the exception of a reduced application interval, BBCH 41-49. As this use is less critical, it is considered covered by the intended GAP.
According to the Commission Technical Guideline SANTE/2019/12752, residue data from lettuce trials can be extrapolated to salad plants, sweet basil and spinach. According to the current MRL Regulation (EU) 2021/1807 an EU MRL has been set for for all lettuces and salad plants (5 mg/kg), spinaches and similar leaves (15 mg/kg) and basil (10 mg/kg). Sufficient trials are available to support the proposed use on salad plants, sweet basil and spinach (foliar application; outdoor uses). Therefore, the proposed use of oxathiapiprolin in A22773A on outdoor salad plants, sweet basil and spinach is considered acceptable.

zRMS comments:
Information given by the Applicant is sufficient and accepted.
Lettuce is the major crop in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of eight trials are required. Salad plants, sweet basil and spinach are the minor crops in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of four trials are required.
Residue data on lettuces (0251020) (trials from open leaf varieties) can be extrapolated to Whole subgroup (a) lettuces and salad plants (0251000), to Whole subgroup (b) spinaches and similar leaves (0252000) and to Whole subgroup (f) herbs and edible flowers (0256000) before and after forming of the edible part.

The intended GAP for oxathiapiprolin for lettuce, salad plants, sweet basil and spinach in Central Europe is 2x12 g a.s./ha with interval between applications of 7 days at BBCH 11-49 with PHI of 14 days.

No new studies on the magnitude of residue have been submitted by the Applicant in the framework of this application. Eight trials were reviewed at EU level. For all the trials, two applications were applied at a nominal rate of 0.15 kg as/ha. The interval between applications was 7-8 days with PHI of 7-10 days.

The trials were supported by valid storage stability data for lettuce and validated analytical methods.
No residues were found in control samples above the stated LOQ of 0.01 mg/kg.

Residues of oxathiapiprolin in lettuce samples taken at 7 DALA, normal commercial harvest (NCH) were between 0.022 and 0.19 mg/kg.
The residues arising from the proposed uses will not exceed the MRLs established for oxathiapiprolin for lettuces, salad plants of 5 mg/kg, for spinaches and similar leaves of 15 mg/kg and basil of 10 mg/kg in ~~Reg. (EU) 2021/1807~~ Reg. (EU) 2023/163.
The uses are considered acceptable.

Leek, extrapolated to spring onion

Leek is a major crop in northern Europe and minor crop in southern Europe (SANTE/2019/12752) and therefore normally requires eight northern trials and four southern trials to support an EU MRL. According to the Commission Technical Guideline SANTE/2019/12752, application rates within ±25% are considered to give comparable residue levels. Additionally, the OECD Crop Field Trial Guideline (OECD 509) highlights the acceptability of ±10% deviation from nominal GAP parameters as a result of natural variability.
The intended GAP is 2 x 12 g a.s./ha, BBCH 11-49, 12-14 d interval, PHI 7.

A total of eight trials were conducted on leek according to the intended GAP. The application rate was 12 g a.s./ha ± 10% in all trials. Application interval was 11-13 days in all trials which is within the ±10% acceptable deviation range with the exception of one which had an interval of 10 days. Ten days interval can be considered more critical than 12 days (minimum interval according to the intended GAP), thus this deviation can be considered acceptable. All trials are considered to have been conducted according to the intended GAP for A22773A (2 x 12 g a.s./ha, 12-14 d interval, PHI 7). Residues in untreated leek samples collected at normal commercial harvest (PHI 7 days) were below the limit of quantification (0.01 mg/kg).
Therefore, sufficient trials are available to support the proposed use on leek (foliar application; outdoor uses). The available data submitted show that no exceedance of the existing EU MRL will occur. The proposed use of oxathiapiprolin in A22773A on outdoor leek is therefore considered acceptable.
A GAP with 1 application (all other parameters are identical) is also included as an intended GAP for evaluation in this submission. This additional GAP is supported by the data supporting the intended cGAP.
According to the Commission Technical Guideline SANTE/2019/12752, residue data from leek trials can be extrapolated to spring onion. The available data submitted show that no exceedance of the existing EU MRL will occur. Sufficient trials are available to support the proposed use on spring onion (foliar application; outdoor uses). Therefore, the proposed use of oxathiapiprolin in A22773A on outdoor spring onion is considered acceptable.

zRMS comments:
Information given by the Applicant is sufficient.
Leek is the major crop in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of eight trials are required. Spring onion is the minor crop in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of four trials are required.
Residue data on leeks (0270060) can be extrapolated to spring onions/green onions and Welsh onions (0220040) before and after forming of the edible part.

The intended GAP for oxathiapiprolin for leek and spring onions in Central Europe is 2x12 g a.s./ha with interval between applications of 12-14 days at BBCH 11-49 with PHI of 7 days.

New study on the magnitude of residue have been submitted by the Applicant in the framework of this application.
A total of 8 new supervised residue trials were performed in Northern Europe during 2020.

1. Giles A. (2021), Report No. 684141- the tested application rates and timings, corresponded to the intended GAPs for A22773A. The trials are supported by valid storage stability data for leek and validated analytical methods. Residues of oxathiapiprolin in leek samples taken at 7-8 DALA, normal commercial harvest (NCH) were between <0.01-0.05 mg/kg.

The residues arising from the proposed uses will not exceed the MRLs established for oxathiapiprolin for leek and spring onions of 2 mg/kg in ~~Reg. (EU) 2021/1807~~ Reg. (EU) 2023/163.
The uses are considered acceptable.

Hops

Hop is a minor crop in northern and southern Europe (SANTE/2019/12752) and therefore normally requires four northern trials and four southern trials to support an EU MRL. According to the Commission Technical Guideline SANTE/2019/12752, application rates within ±25% are considered to give comparable residue levels. Additionally, the OECD Crop Field Trial Guideline (OECD 509) highlights the acceptability of ±10% deviation from nominal GAP parameters as a result of natural variability.
The intended GAP is 2 x 12 g a.s./ha, BBCH 21-89, 12-16 d interval, PHI 28.

A total of five trials were conducted on hop according to the zonal cGAP (at a nominal application rate of 2 x 50 g a.s./ha, 10 d interval, PHI 14) which is more critical than the intended GAP (2 x 12 g a.s./ha, 12-16 d interval, PHI 28). Residues in untreated hops samples collected at normal commercial harvest (PHI 28 days) were below the limit of quantification (0.01 mg/kg). The trials available in support of the cGAP were conducted using an OD formulation. Additional studies have been carried out to show comparability of Oxathiapiprolin OD and SC formulations. This information is available in Appendix 4. Therefore it is considered valid to support the intended use with these trials.
Therefore, sufficient trials are available to support the proposed use on hop (foliar application; outdoor uses). The available data submitted show that no exceedance of the existing EU MRL will occur. The proposed use of oxathiapiprolin in A22773A on outdoor hop is therefore considered acceptable.
A GAP with 1 application (all other parameters are identical) is also included as an intended GAP for evaluation in this submission. This additional GAP is supported by the data supporting the intended cGAP.

zRMS comments:
Information given by the Applicant is sufficient.
Hops is the minor crop in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of four trials are required.

The intended GAP for oxathiapiprolin for hops in Central Europe is 2x12 g a.s./ha with interval between applications of 12-16 days at BBCH 21-89 with PHI of 28 days.

Five trials were conducted on hops according to the zonal critical GAP (i.e. 2 applications at a nominal application rate of 50 g a.s./ha, 10 d interval, PHI 28). These trials have been previously EU reviewed. Treated dried samples produced from 28 DALA hops samples gave residues of oxathiapiprolin in the range 0.69 to 3.9 mg/kg.
The residues arising from the proposed uses will not exceed the MRLs established for oxathiapiprolin for hops of 8 mg/kg in ~~Reg. (EU) 2021/1807~~ Reg. (EU) 2023/163.
The uses are considered acceptable.

Ornamentals (Pot plants, Tree and Shrubs), Afforestation, Forest tree plantation, Reforestation

zRMS comments:
The intended uses on ornamentals are not relevant in terms of consumer health protection. The submission of supervised residue trials is not necessary.
Taking into above account, the proposed uses are considered acceptable.

7.3.4 Magnitude of residues in livestock

The use of A22773A in this zone would not result in residues of oxathiapiprolin in animal feed items. However, oxathiapiprolin is authorised for use on a number of other crops that might be fed to livestock in the EU. Therefore, the possible transfer of residues in animal commodities from all uses should be considered. Livestock intake calculations are provided below, and cover all uses of oxathiapiprolin in the

EU.

7.3.4.1 Dietary burden calculation

The median and maximum dietary burdens were calculated in EFSA 2020 Reasoned Opinion on setting of import tolerances for oxathiapiprolin in various crops. The input values are summarised in Table 7.3-10.

Table 7.3-10: Input values for the dietary burden calculation (considering the uses evaluated in EFSA Reasoned Opinion, 2020)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: oxathiapiprolin				
Sunflower seeds meal	0.01	STMR[(a)] (EFSA, 2019)	0.01	STMR[(a)] (EFSA, 2019)
Potato culls	0.01	STMR (EFSA, 2016)	0.01	STMR (EFSA, 2016)
Potato process waste	0.01	STMR[(b)] (EFSA, 2019)	0.01	STMR[(b)] (EFSA, 2019)
Potato dried pulp	0.01	STMR[(b)] (EFSA, 2019)	0.01	STMR[(b)] (EFSA, 2019)
Citrus group, dried pulp	0.012	STMR x PF[(c)]	0.012	STMR x PF[(c)]

STMR: supervised trials median residue; PF: processing factor.

(a) For sunflower seeds meal no default processing factor was applied because oxathiapiprolin is applied early in the growing season and residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.

(b) For potato process waste and potato dried pulp, the default processing factors were not applied as residues in RAC were below the LOQ and residue concentration in processed fractions are not expected.

(c) For citrus, dried pulp, in the absence of a robust processing factor supported by data, the highest processing factor of 3.7 was included in the calculation to consider the potential concentration of residues in these commodities.

The results of the calculations are reported in Table 7.3-11. The calculated dietary burdens for all groups of livestock were found not to exceed the trigger value of 0.004 mg/kg bw/day. Further investigation of residues is therefore not required in any of the commodities of animal origin.

Table 7.3-11: Results of the dietary burden calculation

Relevant groups	Dietary burden expressed in				Most critical diet[(a)]	Most critical commodity[(b)]		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004 mg/kg bw
	Median	Max.	Median	Max.				
Cattle (all diets)	0.002	0.002	0.05	0.05	Dairy cattle	Potato	process waste	No
Cattle (dairy only)	0.002	0.002	0.04	0.04	Dairy cattle	Potato	process waste	No
Sheep (all diets)	0.002	0.002	0.05	0.05	Ram/Ewe	Potato	process waste	No
Sheep (ewe only)	0.002	0.002	0.05	0.05	Ram/Ewe	Potato	process waste	No
Swine (all diets)	0.001	0.001	0.04	0.04	Swine (breeding)	Potato	process waste	No
Poultry (all diets)	0.001	0.001	0.01	0.01	Poultry broiler	Potato	culls	No
Poultry (layer only)	0.000	0.000	0.01	0.01	Poultry broiler	Potato	culls	No

(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

zRMS comments:
Oxathiapiprolin is authorised for use on several crops that might be fed to livestock. The median and maximum dietary burdens has been calculated for different groups of livestock using the EFSA Animal model 2017.

The calculated dietary burdens for oxathiapiprolin were found not to exceed the trigger value of 0.1 mg/kg DM (or 0.004 mg/kg bw/d, respectively) for all groups of livestock. Therefore, further investigation of residues is not required.

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Feeding studies in livestock are not triggered.

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

Summary of livestock studies reported in the EU
Reference: Ireland, 2016
"No feeding studies were submitted for poultry, ruminant or pig. The dose rate used in the metabolism studies for poultry and ruminant were 1353x the highest estimated dietary burden for poultry, 700x the highest estimated dietary burden for dairy cow and 350x the highest estimated dietary burden for beef cattle. The ruminant metabolism study was representative for swine and therefore the dose rate used was 350x the highest estimated swine dietary burden. These data indicate that residues of oxathiapiprolin and metabolites in poultry tissue, eggs, ruminant tissue, milk and swine tissue will be <0.01 mg/kg following consumption of feed with residues of the parent oxathiapiprolin and therefore poultry, ruminant and swine feeding studies was not considered necessary."

Conclusion on feeding studies
The requested uses do not modify the theoretical maximum daily intake for animals, and there is no risk for animal MRLs to be exceeded.

zRMS comments:
Data presented by Applicant in point 7.3.4.2 have been accepted and are sufficient to support the proposed uses.
There is no risk for animal MRLs to be exceeded.
No additional data are required.

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

As residues exceeding 0.1 mg/kg are expected in a number of commodities, studies investigating the magnitude of residues in processed commodities are required.
Data/information on processing studies for oxathiapiprolin and its metabolites for grapes, tomato and potato was reviewed during the approval of the active substance and were considered acceptable. Processing trials on hops were submitted in the framework of MRL application (EFSA, 2019). Only the results of the studies relevant for crops under consideration are summarised in the table below.

7.3.5.1 Available data for all crops under consideration

Available data
References: Ireland, 2016
Processing studies for oxathiapiprolin and its metabolites have been conducted for grape (juice, raisin, red wine and white wine), tomato (washed, sun dried, peeled, canned, juice, wet pomace, paste and puree) and potato (washed, culls, steam-peeled tubers, steam waste, abrasion peeled tubers, abrasive waste, dried flakes, chips, French fries, unpeeled French fries, boiled unpeeled, boiled peeled potatoes and microwaved unpeeled) and were reviewed during the approval process and are considered to be acceptable; the results of the studies relevant for crops under consideration are summarised in the table below.

References: Ireland, 2019

Processing study for oxathiapiprolin and its metabolites have been conducted for hops (beer) and was reviewed during MRL application process and was considered acceptable. This study is summarised in the table below.
No new data submitted in the framework of this application.

Table 7.3-12: Overview of the available processing studies relevant for crops under consideration

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Report reference	Source
EU reviewed data						
Enforcement and risk assessment residue definition: Oxathiapiprolin						EFSA, 2016 and 2019
Tomato/Washed tomato	3	0.50	1	-	Shepard, E.; 2012a Report No.: DuPont-31728	Ireland, 2016 EFSA, 2016
Tomato/Sun dried tomato	3	6.90	1	-		
Tomato/Peeled tomato	3	0.04	1	-		
Tomato/Canned tomato	3	0.04	1	-		
Tomato/Juice	3	0.20	1	-		
Tomato/Wet pomace	3	13.0	1	-		
Tomato/Paste	3	1.10	1	-		
Tomato/Puree	3	0.60	1	-		
Hops, beer	3	0.01	1	-	Spence, C., Brown, D.; 2015 Report No.: DuPont-31991	Ireland, 2019 EFSA, 2019

* 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

Summary of processing studies reported in the EU

Reference: EFSA, 2019

"Processing studies with grapes, tomatoes and potatoes have been submitted for the EU pesticides peer review where various processing factors were derived (EFSA, 2016). In the framework of the current application, the applicant submitted processing study for hops where the transfer of residues of oxathiapiprolin and its metabolites IN-E8S72 and IN-WR791 into beer was investigated. In three trials, hops were treated according to the intended use pattern and dried cones were used in the beer production. Residues of oxathiapiprolin were present in all hops samples and ranged from 0.4 to 6 mg/kg; metabolite IN-WR791 accounted for < 0.01–0.02 mg/kg. Metabolite IN-E8S71 was not detected. In beer, none of the compounds was quantified (< 0.01 mg/kg)."

Reference: Ireland, 2016

"The processing trial on tomatoes is considered acceptable. The application rate used is considerably higher than the cGAP for Europe, with the total seasonal dose at 1.263 kg as/ha/season which equates to approximately 14 times the cGAP for Europe (0.090 kg as/ha/season). Processing of the RAC with quantifiable residues of DPX-QGU42 resulted in the concentration of residues in certain tomato fractions but not in others. Residues of DPX-QGU42 concentrated in sun-dried tomatoes (median transfer factor of 6.9x and mean transfer factor of 5.7x), in wet tomato pomace (median transfer factor of 13x and mean transfer factor of 13x) and concentrated slightly in tomato paste (median transfer factor of 1.1x and mean transfer factor of 1.0x). Residues of DPX-QGU42 did not concentrate in washed tomatoes (median transfer factor of 0.5x and mean transfer factor of 0.4x), peeled tomatoes (median transfer factor of 0.01x 0.04x and mean transfer factor of 0.02x 0.04x), canned tomatoes (median transfer factor of 0.01x 0.04x and mean transfer factor of <0.01x 0.03x), tomato juice (median transfer factor of 0.2x and mean transfer factor of 0.2x) or tomato puree (median transfer factor of 0.6x and mean transfer factor of 0.5x)."

Reference: Ireland, 2015
"Distribution of the residue in pulp and peel is not relevant to the crops for the proposed authorization. However, the distribution of the residue in pulp and peel is relevant to melons, a crop included for the setting of EU MRLs.
Trials were conducted for field-grown and protected melons to determine the magnitude of residues in pulp versus whole fruit for potential use in consumer exposure assessments. […]
In the EU melon trials, all melon samples were separated into peel and pulp prior to analysis. Residues of oxathiapiprolin and all metabolites were not detected (<0.003 mg/kg) in any melon pulp samples."

Conclusion on processing studies
The magnitude of residues in processed commodities relevant for crops under consideration has been sufficiently addressed to support the proposed uses of the product A22773A.

zRMS comments:
Data presented by Applicant in point 7.3.5 have been accepted and are sufficient to support the proposed uses. Studies on the processing of various crops have been evaluated at the EU level. Based on the information presented by EFSA, the processing studies are not expected to significantly affect the consumer risk assessment. No additional data are required.

7.3.6 Magnitude of residues in representative succeeding crops
The crops under consideration can be grown in rotation.

7.3.6.1 Field rotational crop studies (KCA 6.6.2)
Available data
In addition to the confined rotational crop study, several rotational crop field trials were evaluated in the framework of the peer review. Oxathiapiprolin was applied on bare soil and on crop and the magnitude of residues was investigated on several succeeding crops (lettuce, radish, celery, carrot, barley, wheat, oat, maize, sorghum, peas, beans, soybean, mustard, canola, head cabbage, sugar beet, spring onion, strawberry, grape) sown at different plant-back intervals following application of the active substance.
No new data submitted in the framework of this application.

Table 7.3-13: Summary of field studies in rotational crops

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			Report reference	Source
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)		
EU reviewed data						
Wheat and rye	3x 0.070 (wheat: BBC: 14-69, rye BBCH: 29-61)	Leafy vegetables	Lettuce (immature, mature leaves)	29 120 270	Cairns, S. and Hammond, D.; 2012 Report No.: DuPont-30174	Ireland, 2016
			Spinach (immature, mature leaves)	30 120 317		
		Root and tuber vegetables	Radish (tops, roots)	29 120 270		
			Carrot (tops, roots)	30 120 317		
		Cereals	Barley (forage, hay, grain, straw)	30 120 317		

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			Report reference	Source
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)		
			Wheat (forage, hay, grain, straw)	29 120 270		
		Legume vegetables	Peas (whole plant without pods, immature seed with pod, mature seed)	30 120 317		
			Beans (whole plant without pods, immature seed with pod, mature seed)	29 120 270		
Bare soil	2x 0.140 (n.a.) 2x 0.280 (n.a.)	Root and tuber vegetables	Radish (tops, roots)	8-17 75-103 336-359	Shepard, E.; 2013a Report No.: DuPont-31740	Ireland, 2016
		Cereals	Oat (forage hay, grain, straw)	8-15 120-140 334-344		
			Wheat (forage, hay, grain, straw)	8-15 120-140 334-344		
		Legume vegetables	Soybean (forage, hay, immature bean with pod, mature seed)	9-21 63-77 319-359		
Bare soil	4x 0.050 (n.a.) 6x 0.020 (n.a.)	Brassica vegetables	Head cabbage (mature infloresence)	28	Spence, C. and Brown, D.; 2013a Report No.: DuPont-34687	Ireland, 2015
		Root vegetables	Sugar beet (mature leaves)	32-39		
		Cereals	Wheat (whole plant forage, straw)	14-17		
			Maize (whole green plant, immature grain on cobs, mature grain)	16-27		
		Legume vegetables	Peas (whole plant without pods, immature seed with pod)	33		
		Bulb vegetables	Spring onion (mature)	32		

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			Report reference	Source
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)		
Bare soil	2x 0.140 (n.a.)	Berries and small fruits	Strawberry (fruit)	5-8	Shepard, E.; 2013b Report No.: DuPont-33929	Ireland, 2016
		Root vegetables	Sugar beet (tops)	5-7		
		Legume vegetables	Soybean (forage, hay, immature seeds, immature pods, mature seed)	6-7		
		Oilseeds	Canola (seed)	5-9		
		Leafy vegetables	Leaf lettuce (immature leaves, mature leaves)	6-10		
			Celery (stalk)	5-6		
		Brassica vegetables	Mustard (green leaves)	7		
		Cereals	Corn and sorghum (forage and stover) Corn (ears - kernels plus cobs with husks removed)	5-7		
			Wheat (forage, hay, straw)	5-9		
Grape[(a)]	3x 0.030-0.050 (1-day and 14-day PHI)	Berries and small fruits	Grape (berry and vine leaves)	n.a.	Spence, C. and Brown, D.; 2013b Report No.: DuPont-30043	Ireland, 2015

n.a.: not applicable
(a): Carryover study conducted for DPX-QGU42 100 g/L OD in the 2012 growing season in the EU.

Summary of field rotational crop studies reported in the EU

Reference: EFSA, 2019

"Some crops from the intended European uses can be grown in a crop rotation and therefore the magnitude of residues in rotational crops was further assessed. Considering the highest residue levels observed in crops from various field studies performed with 2- to 8-fold of the intended EU application rate, it can be concluded that residues of oxathiapiprolin will be below 0.01 mg/kg in food commodities and below 0.05 mg/kg in feed commodities grown in a 30-day crop rotation. At the shortest plant-back intervals, residues of metabolites IN-E8S72 and IN-SXS67 could occur above 0.01 mg/kg in cereal grain, pulses, strawberries, legumes, lettuces, spinach, mustard greens and oilseeds and the metabolite IN-WR791 in leafy vegetables. Quantifiable residues may occur in feed commodities. In order to avoid residues in crops that have relatively short vegetation period and are rotated within short plant-back intervals, Member States granting authorisations of oxathiapiprolin might consider applying risk mitigation measures."

Reference: Ireland, 2019

"Field crop rotation studies have been evaluated in the EFSA Conclusion (2016) in support of uses in the EU. Residues of oxathiapiprolin scaled to 90 g a.s./ha were less than 0.010 mg/kg at all plantback intervals (PBI) in all commodities of representative root vegetables, green bulb vegetables, leafy vegetables, brassica vegetables, grapes, strawberries, canola seed, large-grain cereals (corn/maize, sorghum), small-grain cereals (barley, oats, wheat) and legume vegetables/pulses with one exception: legume vegetables/pulse foliage (0.012 mg/kg). Residues of the metabolite IN-WR791 scaled to 90 g a.s./ha were ≤0.01 mg/kg in all commodities of representative root vegetables, green bulb vegetables, brassica vegetables, grapes, strawberries, canola seed, large-grain cereals (corn/maize, sorghum), small-grain cereals (barley, oats, wheat), and legume vegetables/pulses with the exception of small-grain cereals (barley, oats, wheat forage) at 0.01 mg/kg and small grain cereals (barley, oats, wheat hay) at 0.012 mg/kg. Residues of the combined metabolites (IN-E8S72 + IN-SXS67, expressed as IN-E8S72) scaled to 90 g a.s./ha were ≤0.24 mg/kg in animal feed commodities and ≤0.080 mg/kg in food commodities."

Reference: Ireland, 2016
"On the basis of the findings of the nature of the residue investigations, DPX-QGU42 and seven metabolites were analysed in field crop rotation studies. The metabolites analysed in the field crop rotation studies were driven by the metabolites identified at >5% TRR in multiple commodities in the crop metabolism and confined crop rotation studies (IN-E8S72, IN-Q7H09, IN-RDG40, IN-RZB20, IN-RZD74, IN-SXS67 and IN-WR791). IN-RAB06, a soil metabolite unresolved from DPX-QGU42 in the confined crop rotation studies was not included in the field crop rotation studies. Based on the low residues of DPX-QGU42 in field rotational crops and the similar physical chemical characteristics of IN-RAB06 to DPX-QGU42, there is no expectation that residues of IN-RAB06 would be significant in field rotational crops. Likewise, IN-KJ552, a soil metabolite observed in the confined crop rotation, was not an analyte in the field crop rotation studies. However, the hydroxylated form of IN-KJ552, IN-RZD74, was monitored and was not detected (<0.003 mg/kg) in any samples."

Conclusion on rotational crops studies
Considering available data dealing with nature of residues no study dealing with magnitude of residues in succeeding crops is needed.

zRMS comments:
Data presented by Applicant in point 7.3.6 have been accepted and are sufficient to support the proposed uses.

Residues of oxathiapiprolin scaled to 50 g a.s./ha, covering the maximum seasonal application rate of 24 g a.s./ha, were less than 0.010 mg/kg at all plant-back intervals (PBI) in all commodities of representative root vegetables, green bulb vegetables, leafy vegetables, brassica vegetables, grapes, strawberries, canola seed, large-grain cereals (corn/maize, sorghum), small-grain cereals (barley, oats, wheat), legume vegetables/pulses and legume vegetables/pulse foliage.

Residues of IN-WR791 scaled to 50 g a.s./ha were ≤0.01 mg/kg in all commodities of representative root vegetables, green bulb vegetables, brassica vegetables, grapes, strawberries, canola seed, large grain cereals (corn/maize, sorghum), small-grain cereals (barley, oats, wheat), legume vegetables/pulses, small-grain cereals (barley, oats, wheat forage) and small grain cereals (barley, oats, wheat hay).

Residues of (IN-E8S72 + IN-SXS67) scaled to 50 g a.s./ha were ≤0.13 mg/kg in animal feed commodities and ≤0.044 mg/kg in food commodities.

Conclusion on rotational crops studies
Residues of oxathiapiprolin are anticipated to be <0.01 mg/kg in rotational crop commodities. No mitigation measures are required.
No additional data are required.

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

A22773A may be used on crops which can be considered to be melliferous. Therefore, the possible transfer of residues to honey from the relevant uses should be considered.
Two new studies have been submitted by the applicant in the framework of this application, using a surrogate crop with high melliferous capacity (oilseed rape). These studies have been conducted in accordance with SANTE/11956/2016 rev. 9 (Commission Services, 2018). As oxathiapiprolin is not currently registered for use on oilseed rape, the GAP followed in this study covered the most critical GAP on crops with melliferous capacity.
Residue trials, at a GAP of 2 x 60 g a.s./ha during the flowering period of OSR, were initiated on spring oilseed rape in France in 2020 or 2021 where honey was sampled following the exposure of bees to treated crop. In each trial, tunnels were placed over two plots of spring oilseed rape to maximise the exposure of

bee colonies to the treated rape plants. One trial was terminated after the crop became infested with beetles. It was not possible to sample sufficient honey for sample analysis from one trial due to bees consuming the honey due to heat stress caused by a period of very hot weather. It was not possible to sample sufficient honey for analysis from one other trials due to a lack of nectar-producing flowers during the trial. A total of six trials were successful across the two studies and demonstrated residues of oxathiapiprolin below the limit of quantification (LOQ, 0.01 mg/kg). The detailed assessment of these studies are presented in Appendix 2.

zRMS comments:
Data presented by Applicant in point 7.3.7 have been accepted and are sufficient to support the proposed uses.

Applicant submitted two new residue trials:
1. Ford, K., 2020, CEMR-9533, VV-885771
The study has been conducted to determine the magnitude of residues of oxathiapiprolin in honey collected from bees following exposure of honeybees to spring oilseed rape plants, treated with two applications of oxathiapiprolin at a rate of 60 g a.i./ha under semi-field conditions. Two residue trials (SRFR20-001-037FC09 and SRFR20-005-037FC09) were successfully conducted in northern France in 2020 and three trials were unsuccessful.

No residues of oxathiapiprolin at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in the untreated or treated honey samples.

2. Ford K (2021), Report number CEMR-9822
The study contained four trials has been conducted under confined semi-field conditions in Northern and Southern Europe to determine the magnitude of residues of oxathiapiprolin in honey following exposure of honeybees to flowering winter oilseed rape treated with two applications of A20941A (100 g/L OD) at a nominal rate of 60 g a.i./ha per application.

No residues of oxathiapiprolin at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in the untreated or treated honey samples.

Six trials demonstrated residues of oxathiapiprolin below the limit of quantification (LOQ, 0.01 mg/kg) and below the MRL value of 0.05 mg/kg (~~Reg. (EU) 2021/1807~~ Reg. (EU) 2023/163).

No additional data are required.

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

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population (EFSA, 2018).
Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see section 7.1.2).
As an ARfD was not deemed necessary, acute risk assessment is not relevant.

7.3.8.1 Input values for the consumer risk assessment

For the chronic intake assessment, the TMDI (Theoretical Maximum Daily Intake) was calculated using EFSA PRIMo rev. 3.1 and the MRLs as defined in EU MRL Reg (EU) 2021/1807 for the majority of commodities.
An acute consumer exposure assessment was not performed, as the setting of an ARfD was concluded to be unnecessary for oxathiapiprolin (EFSA, 2016).

Table 7.3-14: Input values for the consumer risk assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Citrus Fruit	0.05	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Blackberries	0.5	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Dewberries	~~0.5~~ 0.01*	~~CODEX MRL~~ EU MRL Reg. (EU) 2023/163
Raspberries (yellow and red)	0.5	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Other cane fruit	~~0.5~~ 0.01*	~~CODEX MRL~~ EU MRL Reg. (EU) 2023/163
Blueberries	0.5	~~Proposed IT~~ EU MRL Reg. (EU) 2023/163
Table grapes	0.7	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Wine grapes	0.7	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Potatoes	~~0.04~~ 0.01*	~~CODEX MRL~~ EU MRL Reg. (EU) 2023/163
Tropical root and tuber vegetables	~~0.04~~ 0.01*	~~CODEX MRL~~ EU MRL Reg. (EU) 2023/163
Garlic	0.04	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Onions	0.04	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Shallots	0.04	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Spring onions/green onions and Welsh onions	2	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Tomatoes	0.4	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Sweet peppers/bell peppers	0.2	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Aubergines/egg plants	0.4	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Okra/lady’s fingers	0.2	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Other solanacea	0.2	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Cucumbers	0.2	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Gherkins	0.2	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Courgettes	0.2	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Other cucurbits - edible peel	0.2	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Melons	0.2	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Pumpkins	0.2	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Watermelons	0.2	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Other cucurbits - inedible peel	0.2	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Broccoli	1.5	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Cauliflowers	1.5	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Other flowering brassica	1.5	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Head cabbages	0.7	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Chinese cabbage/pe-tsai	9.0	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Lamb's lettuce/corn salads	5	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Lettuces	5	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Escaroles/broad-leaved endives	5	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Cress and other sprouts and shoots	5	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Land cress	5	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Roman rocket/rucola	5	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Red mustards	5	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Baby leaf crops (including brassica species)	5	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Other lettuce and other salad plants	5	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Spinaches	15	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Purslanes	15	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Chards/beet leaves	15	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Other spinach and similar	15	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Basil and edible flowers	10	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Grape leaves and similar species	40	~~EU MRL Reg (EU) 2021/1807~~

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
		EU MRL Reg. (EU) 2023/163
Peas (with pods)	1	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Asparagus	2	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Leeks	2	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Bamboo shoots	2	~~CODEX MRL~~ EU MRL Reg. (EU) 2023/163
Ginseng root	0.15	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Hops (dried)	8	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163
Other crops/commodities	LOQ	~~EU MRL Reg (EU) 2021/1807~~ EU MRL Reg. (EU) 2023/163

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.3-15: Consumer risk assessment

TMDI (%ADI) according to EFSA PRIMo 3.1	~~11~~12% (Based on NL toddler)
IEDI (%ADI) according to EFSA PRIMo 3.1	Not required
IESTI (%ARfD) according to EFSA PRIMo 3.1*	Not applicable (no ARfD)

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

The proposed uses of oxathiapiprolin in A22773A do not represent unacceptable acute and chronic risks for the consumer.

zRMS comment:
The calculation of the TMDI using EFSA model (PRIMo ver. 3.1) and MRLs according to Regulation (EU) ~~Reg. (EU) 2021/1807~~ Reg. (EU) 2023/163 led to a utilisation of the ADI of ~~11~~12% for the NL toddler diet being the population group with the highest value. For this diet, the highest contributor is spinaches with 8% of the ADI. The intended uses will not result in a consumer chronic exposure exceeding the ADI for oxathiapiprolin.

efsa European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Oxathiapiprolin

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day): **0,14** ARfD (mg/kg bw): **not necessary**

Source of ADI: **EFSA** Source of ARfD: **EFSA**

Year of evaluation: **2016** Year of evaluation: **2016**

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

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (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 under assessment (in % of ADI)
12%	NL toddler	17,21	8%	Spinaches	0,9%	Escaroles/broad-leaved endives	0,8%	Table grapes		
5%	DE child	7,56	2%	Spinaches	0,7%	Table grapes	0,3%	Grape leaves and similar species		
5%	NL child	7,23	3%	Spinaches	0,5%	Table grapes	0,3%	Escaroles/broad-leaved endives		
5%	IT adult	7,11	1%	Lettuces	1%	Spinaches	0,7%	Other spinach and similar		
5%	SE general	7,00	1%	Lettuces	1%	Chinese cabbages/pe-tsai	0,7%	Spinaches		
5%	GEMS/Food G10	6,46	1%	Lettuces	1%	Chinese cabbages/pe-tsai	0,5%	Spinaches		
5%	ES adult	6,38	2%	Lettuces	0,9%	Chards/beet leaves	0,8%	Spinaches		
4%	FR infant	6,07	3%	Spinaches	0,4%	Leeks	0,3%	Chards/beet leaves		
4%	IE adult	5,93	1%	Spinaches	0,6%	Wine grapes	0,3%	Lettuces		
4%	ES child	5,86	1%	Lettuces	0,9%	Spinaches	0,9%	Chards/beet leaves		
4%	IT toddler	5,71	1%	Lettuces	0,6%	Chards/beet leaves	0,6%	Spinaches		
4%	GEMS/Food G06	5,70	1%	Tomatoes	0,5%	Table grapes	0,5%	Spinaches		
4%	NL general	5,36	2%	Spinaches	0,4%	Escaroles/broad-leaved endives	0,3%	Lettuces		
4%	GEMS/Food G11	5,34	1,0%	Spinaches	0,5%	Wine grapes	0,4%	Leeks		
4%	GEMS/Food G07	4,95	0,9%	Lettuces	0,7%	Wine grapes	0,4%	Spinaches		
3%	FR toddler 2 3 yr	4,81	2%	Spinaches	0,4%	Leeks	0,3%	Cauliflowers		
3%	FR child 3 15 yr	4,70	1%	Spinaches	0,4%	Other lettuce and other salad plants	0,3%	Leeks		
3%	GEMS/Food G08	4,64	0,7%	Lettuces	0,5%	Wine grapes	0,3%	Tomatoes		
3%	FR adult	4,52	1%	Wine grapes	0,6%	Spinaches	0,5%	Other lettuce and other salad plant		
3%	RO general	3,81	0,8%	Wine grapes	0,7%	Head cabbages	0,6%	Tomatoes		
3%	DE women 14-50 yr	3,80	0,5%	Spinaches	0,4%	Wine grapes	0,4%	Lettuces		
3%	GEMS/Food G15	3,77	0,5%	Wine grapes	0,4%	Head cabbages	0,4%	Lettuces		
3%	DE general	3,59	0,5%	Spinaches	0,4%	Wine grapes	0,3%	Lettuces		
2%	PT general	3,12	1%	Wine grapes	0,4%	Lettuces	0,3%	Tomatoes		
2%	UK vegetarian	2,91	0,5%	Lettuces	0,4%	Wine grapes	0,4%	Spinaches		
2%	FI 3 yr	2,67	0,7%	Spinaches	0,2%	Tomatoes	0,1%	Cucumbers		
2%	FI 6 yr	2,46	0,6%	Spinaches	0,3%	Lettuces	0,2%	Chinese cabbages/pe-tsai		
2%	UK adult	2,41	0,5%	Wine grapes	0,4%	Lettuces	0,2%	Spinaches		
2%	FI adult	2,25	0,5%	Lettuces	0,2%	Coffee beans	0,2%	Tomatoes		
2%	DK child	2,23	0,5%	Lettuces	0,2%	Cucumbers	0,2%	Tomatoes		
2%	DK adult	2,14	0,5%	Wine grapes	0,3%	Lettuces	0,1%	Tomatoes		
1%	UK toddler	1,92	0,3%	Spinaches	0,2%	Tomatoes	0,1%	Milk: Cattle		
1%	PL general	1,59	0,3%	Tomatoes	0,2%	Head cabbages	0,2%	Table grapes		
1%	UK infant	1,49	0,3%	Milk: Cattle	0,3%	Cauliflowers	0,1%	Spinaches		
0,8%	LT adult	1,11	0,2%	Lettuces	0,2%	Head cabbages	0,2%	Tomatoes		
0,3%	IE child	0,40	0,1%	Broccoli	0,0%	Spinaches	0,0%	Table grapes		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Oxathiapiprolin is unlikely to present a public health concern.

An acute consumer risk assessment was not deemed necessary.
The proposed use of oxathiapiprolin in the product A22773A do not represent unacceptable chronic risk for the consumer.
No further data are required to support the proposed uses.

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.

zRMS comment:
Information presented by Applicant in point 7.4 has been accepted.

7.5 References

7.5.1 General

European Commission Directorate-General for Health and Food Safety, 2020. Appendix D – On data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin. SANTE/2019/12752 23 November 2020. https://ec.europa.eu/food/plants/pesticides/maximum-residue-levels/guidelines-maximum-residue-levels_en

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7.5.2 Azoxystrobin

EC (European Commission), 2011. Review report for the active substance azoxystrobin. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 17 June 2011 in view of the approval of azoxystrobin as active substance in accordance with Regulation (EC) No 1107/2009 SANCO/11027/2011 Rev 3, 20 March 2015.

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FAO (Food and Agriculture Organisation of the United Nations), 2014. Azoxystrobin. In: Pesticide residues in food – 2013. Evaluations. Part I. Residues. FAO Plant Production and Protection Paper 220.
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7.5.3 Oxathiapiprolin

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FAO (Food and Agriculture Organisation of the United Nations), 2016b. Oxathiapiprolin. In: Pesticide residues in food. Evaluations. Part I. Residues. FAO Plant Production and Protection Paper 231.
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Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Azoxystrobin		
~~KCA1 6.1~~	~~Ford, K.~~	~~20/10/2021~~	~~Oxathiapiprolin - Honey Residue Study on Winter Oilseed Rape in Northern and Southern Europe in 2021~~ ~~Report No. CEMR-9822~~ ~~Document No. VV-924794~~ ~~Test Facility CEM Analytical Services Limited (CEMAS)~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~SYN~~
KCA1 6.1	Appeltauer A.	2022	Azoxystrobin - Determination of Residues of Azoxystrobin and R230310 (z-isomer) in Honey after Two Applications of A12705B to Winter Oilseed rape at 5 Sites in Northern and Southern Europe in 2021 Report No. S21-01128 Document No. VV-931501 Test Facility: Eurofins Agroscience Services Ecotox GmbH, Germany GLP Unpublished	N	SYN
KCA1 6.3	Giles, A.	30/04/2021	Azoxystrobin/Oxathiapiprolin – Residue Study on Leeks in the United Kingdom, North France, Belgium, Germany and The Netherlands, Initiated in 2020 Report No. 684141 Document No. VV-900599 Test Facility Charles River Laboratories Edinburgh, Ltd. GLP Unpublished	N	SYN
KCA1 6.3	Giles, A.	03/08/2021	Azoxystrobin/Oxathiapiprolin – Residue Study on Cucumber in North France, The Netherlands, Belgium, Germany, Poland and Czech Republic, Initiated in 2020 Report No. 684120 Document No. VV-896693 Test Facility Charles River Laboratories Edinburgh, Ltd. GLP Unpublished	N	SYN
KCA1 6.3	Giles, A.	31/03/2021	Azoxystrobin/Oxathiapiprolin – Residue Study on Melons in North France, Belgium, Poland, Germany, Czech Republic and The Netherlands, Initiated in 2020 Report No. 684125 Document No. VV-896705 Test Facility Charles River Laboratories Edinburgh, Ltd.	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCA1 6.3	Gill, J. Chamier, O.	07/07/1998	Azoxystrobin: Residue Levels in Gherkins from a Study Carried Out in Germany during 1997. Report No. RJ2589B Document No. VV-377471 , ICI5504/0499 Test Facility N/A GLP Unpublished	N	SYN
KCA1 6.3	Wormald, S.	04/02/2011	Azoxystrobin – Residue Study on Hops in Germany in 2008 Report No. T009307-07-REG Document No. VV-395720 , A12705A_10044 Test Facility The Food and Environment Research Agency (FERA) GLP Unpublished	N	SYN
KCA1 6.3	Wormald, S.	19/05/2011	Azoxystrobin – Residue Study on Hops in Northern France, the United Kingdom and Germany in 2009 Report No. FSGD-063-REG Document No. VV-396812 , A12705B_11490 Test Facility The Food and Environment Research Agency (FERA) GLP Unpublished	N	SYN
KCA1 6.3.1	Andrews, G. Coleman, H.	26/08/2016	Azoxystrobin - Residue Study on Tomato in Poland and Hungary in 2015 Report No. NC15017 Document No. VV-465709 , A12705B_13791 Test Facility Battelle UK, Ltd. GLP Unpublished	N	SYN
KCA1 6.3.1	Souchier, M.	01/08/2017	Azoxystrobin - Residue Study on Field Tomato in Northern France and Germany in 2016 Report No. S16-03843 Document No. VV-467765 , A12705B_13932 Test Facility Eurofins Agroscience Services Chem S.A.S. GLP Unpublished	N	SYN
~~KCA1 6.5.3~~	~~Clarke, D.~~ ~~Bonfanti, F.~~	~~02/06/1998~~	~~Azoxystrobin – Residue Levels in Tomatoes and Process Fractions from Trials in Italy 1997~~ ~~Report No. RJ2488B~~ ~~Document No. VV-380583 , ICI5504/0706~~ ~~Test Facility N/A~~	~~N~~	~~SYN~~

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			~~GLP~~ ~~Unpublished~~		
~~KCA1 6.5.3~~	~~Gill, J.~~ ~~Kappes, E.~~ ~~Griehl, T.~~	~~11/08/2000~~	~~Residue Levels in Hops, Beer & Processed Fractions from stuidies Carried out in Germany during 1999~~ ~~Report No. RJ3015B~~ ~~Document No. VV-377467 , ICI5504/0698~~ ~~Test Facility N/A~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~SYN~~
~~KCA1 6.5.3~~	~~Gill, J.~~ ~~Kappes, E.~~ ~~Renner, G.~~	~~01/09/1999~~	~~Azoxystrobin: Residue Levels in Hops, Beer and Process Fractions from Studies carried out in Germany during 1998~~ ~~Report No. RJ2841B~~ ~~Document No. VV-326273 , ICI5504/0694~~ ~~Test Facility N/A~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~SYN~~
KCA1 6.10	Appeltauer A.	2022	Azoxystrobin - Determination of Residues of Azoxystrobin and R230310 (z-isomer) in Honey after Two Applications of A12705B to Winter Oilseed rape at 5 Sites in Northern and Southern Europe in 2021 Report No. S21-01128 Document No. VV-931501 Test Facility: Eurofins Agroscience Services Ecotox GmbH, Germany GLP Unpublished	N	SYN
~~KCA1 6.10~~	~~Bocksch, S.~~	~~08/02/2008~~	~~Azoxystrobin (ICI5504) and Cyproconazole (SAN619) - residues in honey following exposure of bees to treated winter oil-seed rape in Germany during 2007~~ ~~Report No. T011298-06-REG~~ ~~Document No. VV-382035 , ICI5504_10398~~ ~~Test Facility GAB Biotechnologie GmbH~~ ~~Not GLP~~ ~~Unpublished~~	~~N~~	~~SYN~~
Oxathiapiprolin					
KCA2 6.1	Ford, K.	20/10/2021	Oxathiapiprolin - Honey Residue Study on Winter Oilseed Rape in Northern and Southern Europe in 2021 Report No. CEMR-9822 Document No. VV-924794 Test Facility CEM Analytical Services Limited (CEMAS) GLP Unpublished	N	SYN

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Vertebrate study Y/N	Owner
KCA2 6.3	Giles, A.	30/04/2021	Azoxystrobin/Oxathiapiprolin – Residue Study on Leeks in the United Kingdom, North France, Belgium, Germany and The Netherlands, Initiated in 2020 Report No. 684141 Document No. VV-900599 Test Facility Charles River Laboratories Edinburgh, Ltd. GLP Unpublished	N	SYN
KCA2 6.3	Giles, A.	31/03/2021	Azoxystrobin/Oxathiapiprolin – Residue Study on Melons in North France, Belgium, Poland, Germany, Czech Republic and The Netherlands, Initiated in 2020 Report No. 684125 Document No. VV-896705 Test Facility Charles River Laboratories Edinburgh, Ltd. GLP Unpublished	N	SYN
KCA2 6.3	Giles, A.	03/08/2021	Azoxystrobin/Oxathiapiprolin – Residue Study on Cucumber in North France, The Netherlands, Belgium, Germany, Poland and Czech Republic, Initiated in 2020 Report No. 684120 Document No. VV-896693 Test Facility Charles River Laboratories Edinburgh, Ltd. GLP Unpublished	N	SYN
KCA2 6.3	Hampton, M.	14/09/2015	Oxathiapiprolin OD (A20941A) and Oxathiapiprolin SC (A21008A) - Magnitude of the Residues in or on Cucumber Raw Agricultural Commodities Resulting from Foliar Application of OD and SC Formulations- - USA, 2014 Report No. TK0221427|81123 Document No. VV-511307 , A20941A_50005 Test Facility The Carringers, Inc. GLP Unpublished	N	SYN
KCA2 6.3	Hampton, M.	21/09/2015	Oxathiapiprolin OD (A20941A) and Oxathiapiprolin SC (A21008A) - Magnitude of the Residues in or on Brassica Head and Stem Vegetables Raw Agricultural Commodities Resulting from Foliar Applications of OD and SC Formulations - USA, 2014 Report No. TK0221426|81122 Document No. VV-511309 , A20941A_50007 Test Facility The Carringers, Inc. GLP Unpublished	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA2 6.3	Hampton, M.	08/10/2015	Oxathiapiprolin OD (A20941A) and Oxathiapiprolin SC (A21008A) - Magnitude of the Residues in or on Tobacco Raw Agricultural Commodities Resulting from Foliar Applications of OD and SC Formulations - USA, 2014 Report No. 81125|TK0221432 Document No. VV-511265 , A20941A_50009 Test Facility The Carringers, Inc. GLP Unpublished	N	SYN
KCA2 6.3	Hampton, M.	08/10/2015	Oxathiapiprolin SC (A21008A) and Oxathiapiprolin OD (A20941A) - Magnitude of the Residues in or on Potato Raw Agricultural Commodities Resulting from Soil and Foliar Applications - USA, 2014 Report No. 81124|TK0221431 Document No. VV-511263 , A21008A_50007 Test Facility The Carringers, Inc. GLP Unpublished	N	SYN
KCA2 6.3	Thirkell, C. Wolfgarten, E.	24/03/2021	Oxathiapiprolin - Residue Study on Pepper in Germany, Poland, Hungary and Northern France, in 2020 Report No. IF20-05334851 Document No. VV-896488 Test Facility SGS Institut Fresenius GmbH GLP Unpublished	N	SYN
KCA2 6.3.1	Fritzsch, S.	07/10/2020	Oxathiapiprolin - Residue Study on Tomato in Northern France and Germany in 2020 Report No. S20-03173 Document No. VV-875090 Test Facility Eurofins Agroscience Services Chem GmbH GLP Unpublished	N	SYN
KCA2 6.3.1	~~Reinhardt, R.~~ Lakaschus, S. Reinhardt, R.	24/04/2020	Oxathiapiprolin - Residue Study on Tomato in Northern France, Germany and Hungary in 2019 Report No. S19-02717 Document No. VV-854096 Test Facility Eurofins Agroscience Services Chem GmbH GLP Unpublished	N	SYN
KCA2 6.3.1	Stolze, J. Wolfgarten, E.	24/03/2021	Oxathiapiprolin - Residue Study on Tomato in Germany, Poland, Northern France and Hungary 2020 Report No. IF20-05334280 Document No. VV-896130 Test Facility SGS Institut Fresenius GmbH	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCA2 6.10	Ford, K.	15/12/2020	Oxathiapiprolin – Honey Residue Study on Spring Oilseed Rape in Northern and Southern Europe in 2020 Report No. CEMR-9533 Document No. VV-885771 Test Facility CEM Analytical Services Limited (CEMAS) GLP Unpublished	N	SYN

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
			Azoxystrobin		
KCA1 6.3.1	Render K.	2010	Azoxystrobin - Residue Study on Tomatoes in Northern France in 2009 Report No. FSGD-069-REG Syngenta File No. VV-394875 GLP Not Published	N	SYN
KCA1 6.3.1	Render K.	2010	Azoxystrobin - Residue Study on Field Tomato in France (North) in 2008 Report No. FSGD-014-REG Syngenta File No. VV-394328 GLP Not Published	N	SYN
KCA1 6.3.2	Yozgatli H.P., Winkler K.	2013	Azoxystrobin – Residue Study on Pepper in Northern France and Hungary in 2012 Report No. S12-01261 Syngenta File No. VV-404035 GLP Not Published	N	SYN
KCA1 6.3.2	Jones A.	2010	Azoxystrobin - Residue Study on Peppers in France (North) in 2008 Report No. T009405-07-REG Syngenta File No. VV-394626 GLP Not Published	N	SYN
KCA1 6.3.2	Render K.	2010	Azoxystrobin - Residue Study on Peppers in Northern France in 2009 Report No. FSGD-064-REG Syngenta File No. VV-393718 GLP Not Published	N	SYN
KCA1 6.3.3	Jones A.	2009	Azoxystrobin and Difenoconazole - Residue Study on Courgette in France (North) in 2008 Report No. T011466-06-REG (FSGD-039-REG) Syngenta File No. VV-384994 GLP Not Published	N	SYN
KCA1 6.3.3	Andrew G.	2011	Azoxystrobin - Residue Study on Gherkin in Northern France and Germany in 2010 Report No. NC10010-10-REG Syngenta File No. VV-396617 GLP	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Not Published		
KCA1 6.3.3	Heillaut C.	2008	Azoxystrobin (ICI5504) and Difenoconazole (CGA169374) – Residue Study on Outdoor Cucumbers in Austria, Belgium and France (North) in 2007 Report No. T011466-06-REG Syngenta File No. VV-382145 GLP Not Published	N	SYN
KCA1 6.3.3	Kelly M.	2011	Azoxystrobin and Difenoconazole - Residue Study on Courgette in Northern France and Austria in 2008 Report No. T009543-07-REG Syngenta File No. VV-396787 GLP Not Published	N	SYN
KCA1 6.3.3	Seck C.	2010	Azoxystrobin - Residue Study on Gherkin in Northern France and Germany in 2009 Report No. T001092-09-REG Syngenta File No. VV-393207 GLP Not Published	N	SYN
KCA1 6.3.4	Kelly M.	2011	Azoxystrobin and Difenoconazole - Residue Study on Melon in Northern France in 2008 and 2009 Report No. T009553-07-REG Syngenta File No. VV-397531 GLP Not Published	N	SYN
KCA1 6.3.5	Richards S., Hansen A., Atkinson D.	2001	Azoxystrobin - Residue Levels in Outdoor Lettuces from Trials conducted in the UK during 2000 Report No. RJ3145B Syngenta File No. VV-377726 GLP Not Published	N	SYN
KCA1 6.3.5	Yozgatli H.P.	2011	Azoxystrobin/Difenoconazole - Residue Study on Lettuce in Northern France, the UK and Germany in 2009 Report No. S09-01457 Syngenta File No. VV-397331 GLP Not Published	N	SYN
KCA1 6.3.5	Gill J.P., Barnaud C., Burke S.	2001	Azoxystrobin - Residue Levels in Outdoor Lettuces from Trials Conducted in Northern and Southern France during 2000 Report No. RJ3182B Syngenta File No. VV-376946	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Not Published		
KCA1 6.3.5	Yozgatli H.P., Winkler K.	2013	Azoxystrobin - Residue Study on Open Leaf Varieties of Lettuce in the United Kingdom in 2012 Report No. S12-01269 Syngenta File No. VV-404294 GLP Not Published	N	SYN
KCA1 6.3.7	Gill J.P., Hughes A.	2000	Azoxystrobin - Residue Levels in Hops from Trials Carried out in the UK During 1999 Report No. RJ2981B Syngenta File No. VV-328581 GLP Not published	N	SYN
KCA1 6.3.7	Lister N.	1998	Azoxystrobin: Residue Levels in Hops from Trials Carried out in the UK during 1998 Report No. RJ2801B Syngenta File No. VV-377468 GLP Not published	N	SYN
KCA1 6.3.7 and KCA1 6.5.3	Gill J. P., Kappes E., Renner G.	1999	Azoxystrobin: Residue Levels in Hops, Beer and Process Fractions from Studies carried out in Germany during 1998 Jealott's Hill Research Station, Zeneca Agrochemicals, UK Report No. RJ2841B Syngenta File No. VV-326273 GLP Not Published	N	SYN
KCA1 6.3.7 and KCA1 6.5.3	Gill J.P., Kappes E., Griehl T.	2000	Residue Levels in Hops, Beer & Processed Fractions from Studies Carried out in Germany during 1999 Jealott's Hill Research Station, Zeneca Agrochemicals, UK Report No. RJ3015B Syngenta File No. VV-377467 GLP Not Published	N	SYN
KCA1 6.5.3	Clarke, D. Bonfanti, F.	02/06/1998	Azoxystrobin - Residue Levels in Tomatoes and Process Fractions from Trials in Italy 1997 Report No. RJ2488B Document No. VV-380583 , ICI5504/0706 Test Facility N/A GLP Unpublished	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA1 6.5.3	Gill, J. Kappes, E. Griehl, T.	11/08/2000	Residue Levels in Hops, Beer & Processed Fractions from stuidies Carried out in Germany during 1999 Report No. RJ3015B Document No. VV-377467 , ICI5504/0698 Test Facility N/A GLP Unpublished	N	SYN
KCA1 6.5.3	Gill, J. Kappes, E. Renner, G.	01/09/1999	Azoxystrobin: Residue Levels in Hops, Beer and Process Fractions from Studies carried out in Germany during 1998 Report No. RJ2841B Document No. VV-326273 , ICI5504/0694 Test Facility N/A GLP Unpublished	N	SYN
KCA1 6.10	Bocksch, S.	08/02/2008	Azoxystrobin (ICI5504) and Cyproconazole (SAN619) - residues in honey following exposure of bees to treated winter oil-seed rape in Germany during 2007 Report No. T011298-06-REG Document No. VV-382035 , ICI5504_10398 Test Facility GAB Biotechnologie GmbH Not GLP Unpublished	N	SYN
Oxathiapiprolin					
KCA2 6.3.5	Spence C., Brown D.	2013	Decline and magnitude of residues of DPX-QGU42 and its metabolites in field lettuce (leafy vegetables) following foliar application of DPX-QGU42 100 g/L OD or DPX-QGU42 100 g/l SE – Europe, 2011-2012 Dupont-31734. Charles river study number 696296 Report No. DuPont-31734 GLP Not Published	N	DuPont (SYN LoA)
KCA2 6.3.7	Spence, C. and Brown, D.	2015	Decline and Magnitude of Residues of DPX-QGU42 and its Metabolites in Hops Following Foliar Application of DPX-QGU42 100 g/L OD – Northern Europe - 2012-2013; Report No. DuPont-31990 GLP Not Published	N	DuPont (SYN LoA)
KCA2 6.5.3	Shepard, E.	2012a	Magnitude of residues of DPX-QGU42 and its metabolites in processed commodities of tomato following applications of DPX-QGU42 100 g/L OD and DPX-QGU42 200 g/L SC at an exaggerated rate - USA and Canada, 2011. ABC Laboratories, Inc. (Missouri) Report No. DuPont-31728, MRID 49011239	N	DuPont (SYN LoA)

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
			GLP Not Published		
KCA2 6.5.3	Spence, C.; Brown, D.	2015	Magnitude of residues of oxathiapiprolin and its metabolites in processed commodities of hops following foliar application of Oxathiapiprolin (DPX-QGU42) 100 g/L OD - northern Europe, 2013. Charles River Laboratories (UK) Report No. DuPont-31991 GLP Not Published	N	DuPont (SYN LoA)

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 Azoxystrobin

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 or additional studies have been submitted.

A 2.1.1.1.2 Storage stability of residues in animal products

A 2.1.1.1.2.1 Study 1 (Report No. S21-01128) (New data)

Comments of zRMS:	The study has been conducted according to the OECD 506. The limit of quantitation (LOQ) was 0.01 mg/kg per analyte for honey. All method validation data are within the acceptable criteria: mean recovery range of 70-120% and relative standard deviation ≤ 20%. Residues of azoxystrobin and its metabolite R230310 in honey have been shown to be stable under these conditions for 81 days. The study is acceptable.

Reference	KCA1 6.1
Report	Azoxystrobin - Determination of Residues of Azoxystrobin and R230310 (z-isomer) in Honey after Two Applications of A12705B to Winter Oilseedrape at 5 Sites in Northern and Southern Europe in 2021 Appeltauer, A (2022) Report No. S21-01128, Syngenta File No. VV-931501
Guidelines	OECD 509 (September 2009) SANTE/2020/12830, Rev. 1 (2021): Guidance document on pesticide analytical methods for risk assessment and post-approval control and monitoring purposes (February 2021) EC (2018) Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey (SANTE/11956/2016 rev. 9)
Deviations	None
GLP	Yes
Acceptability	Yes

Executive Summary

Samples of honey were fortified with azoxystrobin and R230310 at a level of 0.1 mg/kg and put into storage at -18°C. One sample was prepared per matrix and per analyte. At intervals of 0 and 81 days, stored samples and freshly fortified samples were analysed for residues of azoxystrobin and R230310.

At each storage interval, azoxystrobin and R230310 were determined using method RAM 305/03. A sub sample (2.0 g) is extracted with 20 mL of acetonitrile/water (90/10, v/v) by homogenisation at high speed. After centrifugation an aliquot of 1.0 mL is evaporated to dryness and reconstituted in 10 mL of acetonitrile/water (50/50, v/v). Final determination is by a liquid chromatography system coupled with a mass selective triple quadrupole detector (LC-MS/MS). Acceptable method validation and concurrent recoveries were reported for samples of honey at fortification levels of 0.1 mg/kg (ppm), thus validating the method. The limit of quantitation (LOQ) was 0.01 mg/kg per analyte for honey.

Under these conditions, residues of azoxystrobin and R230310 were stable for 81 days.

Materials

Test Material	Azoxystrobin
Lot/Batch #:	ASJ10008-05
Purity (%):	99.8% (w/w)
IUPAC name:	methyl (E)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate
CAS number:	131860-33-8

Test Material	R230310
Lot/Batch #:	ASJ10075-04
Purity (%):	98.0% (w/w)
IUPAC name:	methyl (Z)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate
CAS number:	143130-94-3

Test commodities			
Crop	**Commodity**	**Commodity type**	**Source**
Honey	Honey	Honey	Not reported

Study Design and Methods

Test facility: Eurofins-GAB GmbH, Eutinger Str. 24, D-75223 Niefern-Öschelbronn, Germany
Study start date: 01 Mar 2021
Study end date: 26 July 2021

Homogenised sub-samples of each test commodity (2.0 g) were fortified with standard solutions of azoxystrobin and R230310 to give a fortification rate of 0.1 mg/kg. One sample was prepared per matrix and per analyte. Samples were transferred to a deep freezer at –18°C immediately after fortification. Untreated samples of each crop commodity were stored in the same freezer for use as control and procedural recovery samples.

Three replicate samples were extracted for analysis immediately after fortification. Duplicate stored samples were extracted for analysis at 81 days

After the scheduled storage periods, the required number of fortified samples were removed from frozen storage, along with a untreated control sample. Two untreated samples were fortified as concurrent recovery samples and then the set of samples (untreated, recovery and stored samples) were analysed for azoxystrobin and R230310 using method RAM 305/03, validated in honey to a limit of quantification (LOQ) of 0.01 mg/kg, and fully verified (5 recoveries at a higher level, selectivity and linearity) within this study.

Results

A summary of the procedural/concurrent recoveries of azoxystrobin and R230310 in freshly fortified commodities tested at each interval are shown in the tables below.

Residues of azoxystrobin and R230310 found in stored frozen honey tested at each interval are shown below.

There was no significant change in the levels of azoxystrobin and R230310 in any commodity over a 81 day storage period (any apparent losses were less than 30% of the initial value). These losses are not considered significant according to EU, EPA and OECD guidelines (SANCO 7032/VI/95 rev. 5, OPPTS 860.1380 and OECD Guideline 506).

Table A 1: Summary of procedural/concurrent recoveries of azoxystrobin in honey

Commodity	Storage duration (days (months))[1]	Fortification level (mg/kg)	Number of recoveries (n)	Individual recoveries (%)	Mean ± Rel. Std. Dev. (%)
Honey	0	0.1	2	105, 105	98 ± 7.9
	81 (3)		2	90, 93	

[1] Storage duration in months calculated as: (no. of days in storage/365) x 12 and reported to the nearest whole month

Table A 2: Summary of procedural/concurrent recoveries of R230310 in honey

Commodity	Storage duration (days (months))[1]	Fortification level (mg/kg)	Number of recoveries (n)	Individual recoveries (%)	Mean ± Rel. Std. Dev. (%)
Honey	0	0.1	2	105, 103	97 ± 8.9
	81 (3)		2	87, 91	

[1] Storage duration in months calculated as: (no. of days in storage/365) x 12 and reported to the nearest whole month

Table A 3: Stability of azoxystrobin residues in crop matrices during storage at -18°C

Commodity	Storage duration (days (months))[1]	Fortification Level (mg/kg)	Recovered residues (mg/kg)	Mean stored recovery (%)	Mean concurrent recovery (%)	Corrected recovery[2] (%)
Azoxystrobin						
Honey	0	0.1	0.108, 0.108, 0.108	108	105	103
	81 (3)	0.1	0.096, 0.094	95	92	103

[1] Storage duration in months calculated as: (no. of days in storage/365) x 12 and reported to the nearest whole month
[2] Corrected for concurrent recovery

Table A 4: Stability of R230310 residues in crop matrices during storage at -18°C

Commodity	Storage duration (days (months))[1]	Fortification Level (mg/kg)	Recovered residues (mg/kg)	Mean stored recovery (%)	Mean concurrent recovery (%)	Corrected recovery[2] (%)
R230310						
Honey	0	0.1	0.108, 0.105, 0.106	106	104	102
	81 (3)	0.1	0.096, 0.090	93	89	104

[1] Storage duration in months calculated as: (no. of days in storage/365) x 12 and reported to the nearest whole month
[2] Corrected for concurrent recovery

Conclusion

Azoxystrobin and R230310 have been shown to be stable in honey for at least 81 days when stored frozen at -18°C.

A 2.1.2 Nature of residues in plants, livestock and processed commodities

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

No new or additional studies have been submitted.

A 2.1.2.1.2 Nature of residue in rotational crops

No new or additional studies have been submitted.

A 2.1.2.1.3 Nature of residues in processed commodities

No new or additional studies have been submitted.

A 2.1.2.2 Nature of residues in livestock

No new or additional studies have been submitted.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Tomato (extrapolated to support eggplant)

Table A 5: 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)
cGAP N-EU (Art. 12, EFSA, 2013)	-	-	-	-	-
cGAP S-EU (Art. 12, EFSA, 2013)	4	250 g a.s./ha	-	-	3
Intended cGAP A22773A - CZ-13, CZ-14, HU-11, HU-12, PL-28, PL-29, RO-11, RO-12, SK-13, SK-14, SI-16, SI-17 Extrapolated to eggplant: HU-4, HU-5, HU-6, PL-25, PL-26, PL-27, RO-4, RO-5, RO-6, SK-3, SK-4, SK-5, SI-4, SI-5, SI-6*	2	250 g a.s./ha	7	BBCH 11-89	3

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
** Timing of applications determined primarily by growth stage
*** Minimum PHI

A 2.1.3.1.1 Study 1 (Report No. S16-03843) (New data)

Comments of zRMS:	Four residue field trials on field tomato were conducted in Northern France and Germany during 2016. Azoxystrobin were applied to tomato as A12705B, a soluble concentrate (SC) formulation containing nominally 250 g azoxystrobin per litre. Two applications, (applied at growth stage 63-82 BBCH and 66-82 BBCH respectively), separated by a 7-8 days interval were made at a nominal rate of 250 g ai/ha for azoxystrobin. Treated samples of tomato fruits were collected at 0 days before the last application (DBLA), 0, 1, 3 (normal commercial harvest, NCH) and 7 days after last application (DALA). Untreated samples of tomato fruit were collected at 3 days (normal commercial harvest, NCH) after last application (DALA). Samples were analysed for azoxystrobin as the analytes (azoxystrobin and R230310). Samples were stored frozen for a maximum period of 5 months from sampling to analysis. Analytical method: RAM 305/03 for azoxystrobin and R230310. The analytical method has been validated for analysis of azoxystrobin and R230310 on a range of crop groups and is therefore considered suitable for use on tomato fruit with LOQ=0.01 mg/kg.

The ranges of residues of azoxystrobin and R230310 are summarised in the table below.

Sampling Interval (days)	Azoxystrobin Residues in the range (mg/kg)	R230310 Residues in the range (mg/kg)
Treated Plot (P2): at a rate of 2x 250 g ai/ha		
Tomato fruit		
0 DBLA	0.01 – 0.04	< 0.01
0 DALA	0.02 – 0.40	< 0.01
1 DALA	0.05 – 0.10	< 0.01
3 DALA (NCH)	0.04 – 0.11	< 0.01
7 DALA	0.02 – 0.08	< 0.01
Control plot (C1) No residues of azoxystrobin and R230310 at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in any of the untreated tomato fruit samples.		

The study is acceptable.

Reference: KCA1 6.3

Report: Souchier M. (2017)
Azoxystrobin - Residue Study on Field Tomato in Northern France and Germany in 2016
Syngenta Report No. S16-03843
Syngenta File No. VV-467765
Unpublished

Guideline(s): Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document)
OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50
OECD Guidance Document on Overview of Residue Chemistry Studies (as revised 2009), Series on Testing and Assessment (No. 64) and Series on Pesticides (No. 32), ENV/JM/MONO(2009)31
Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009

	OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009 European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000)
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 6: Summary of the study 1 trials

Field Trials, Crop Residue (Summary): Azoxystrobin - Residue study on Field Tomato in Northern France and Germany in 2016			
Active Substance (common name):	Azoxystrobin	**Commercial Product (name):**	
Crop/Crop Group:	Tomato	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	France, Germany	**Other active substance in the formulation (common name and content):**	None
Content of active substance (g/kg or g/L):	A12705B: 250 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A12705B SC		
Analytical Method:	Azoxystrobin (Fruit) RAM 305/03; 0.01 mg/kg R230310 (Fruit) RAM 305/03; 0.01 mg/kg		
Recovery data:	Azoxystrobin Fruit Mean = 95% RSD = 8% (n = 4 in 0.01 - 10 spiking range) R230310 Fruit Mean = 96% RSD = 8% (n = 4 in 0.01 - 10 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	**(2) Commodity / Variety (a)**	**(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)**	**(4) Method of Treatment**	**(5) Application rate per treatment**			**(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)**	**(7) Growth Stage at Treatment**	**(8) Portion Analyzed**	**(9) Residue found (Uncorrected)**		**(10) PHI (d)**	**(11) Sample Date / Cut Date**	**(12) Trial Details (e)**
				Concentration	**Water**	**Rate Formulation (Additive Type, Rate)**				**Azoxystrobin (mg/kg)**	**R230310 (mg/kg)**			
S16-03843 S16-03843-01 Germany (Europe North) (69124)	Tomato / Organza	1.01 Jun 2016 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	15 Aug 2016/ -	Field SP (max days): 115
S16-03843 S16-03843-01 Germany (Europe North) (69124)	Tomato / Organza	1.01 Jun 2016 2 – 3 -	1. Foliar 2. Foliar	-	1. 496.33 L/ha 2. 496.33 L/ha	1. 247.6713 g ai/ha 2. 247.6713 g ai/ha A12705B (-)	1. 05 Aug 2016 2. 12 Aug 2016 (7)	1. BBCH 63-81 2. BBCH 66-81	Fruit	0.01 mg/kg	< 0.01 mg/kg	0	12 Aug 2016/ -	Field SP (max days): 118

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
S16-03843 S16-03843-01 Germany (Europe North) (69124)	Tomato / Organza	1.01 Jun 2016 2 – 3 -	1. Foliar 2. Foliar	-	1. 496.33 L/ha 2. 496.33 L/ha	1. 247.6713 g ai/ha 2. 247.6713 g ai/ha A12705B (-)	1. 05 Aug 2016 2. 12 Aug 2016 (7)	1. BBCH 63-81 2. BBCH 66-81	Fruit	0.06 mg/kg	< 0.01 mg/kg	0	12 Aug 2016/ -	Field SP (max days): 118
S16-03843 S16-03843-01 Germany (Europe North) (69124)	Tomato / Organza	1.01 Jun 2016 2 – 3 -	1. Foliar 2. Foliar	-	1. 496.33 L/ha 2. 496.33 L/ha	1. 247.6713 g ai/ha 2. 247.6713 g ai/ha A12705B (-)	1. 05 Aug 2016 2. 12 Aug 2016 (7)	1. BBCH 63-81 2. BBCH 66-81	Fruit	0.05 mg/kg	< 0.01 mg/kg	1	13 Aug 2016/ -	Field SP (max days): 118
S16-03843 S16-03843-01 Germany (Europe North) (69124)	Tomato / Organza	1.01 Jun 2016 2 – 3 -	1. Foliar 2. Foliar	-	1. 496.33 L/ha 2. 496.33 L/ha	1. 247.6713 g ai/ha 2. 247.6713 g ai/ha A12705B (-)	1. 05 Aug 2016 2. 12 Aug 2016 (7)	1. BBCH 63-81 2. BBCH 66-81	Fruit	0.04 mg/kg	< 0.01 mg/kg	3	15 Aug 2016/ -	Field SP (max days): 118
S16-03843 S16-03843-01 Germany (Europe North) (69124)	Tomato / Organza	1.01 Jun 2016 2 – 3 -	1. Foliar 2. Foliar	-	1. 496.33 L/ha 2. 496.33 L/ha	1. 247.6713 g ai/ha 2. 247.6713 g ai/ha A12705B (-)	1. 05 Aug 2016 2. 12 Aug 2016 (7)	1. BBCH 63-81 2. BBCH 66-81	Fruit	0.02 mg/kg	< 0.01 mg/kg	7	19 Aug 2016/ -	Field SP (max days): 118

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
S16-03843 S16-03843-02 Germany (Europe North) (71706)	Tomato / Pannovy F1	1.27 Jun 2016 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	23 Sep 2016/ -	Field SP (max days): 76
S16-03843 S16-03843-02 Germany (Europe North) (71706)	Tomato / Pannovy F1	1.27 Jun 2016 2 – 3 -	1. Foliar 2. Foliar	-	1. 409.5 L/ha 2. 406.83 L/ha	1. 255.2993 g ai/ha 2. 253.6367 g ai/ha A12705B (-)	1. 12 Sep 2016 2. 20 Sep 2016 (8)	1. BBCH 73 2. BBCH 74	Fruit	0.02 mg/kg	< 0.01 mg/kg	0	20 Sep 2016/ -	Field SP (max days): 79
S16-03843 S16-03843-02 Germany (Europe North) (71706)	Tomato / Pannovy F1	1.27 Jun 2016 2 – 3 -	1. Foliar 2. Foliar	-	1. 409.5 L/ha 2. 406.83 L/ha	1. 255.2993 g ai/ha 2. 253.6367 g ai/ha A12705B (-)	1. 12 Sep 2016 2. 20 Sep 2016 (8)	1. BBCH 73 2. BBCH 74	Fruit	0.02 mg/kg	< 0.01 mg/kg	0	20 Sep 2016/ -	Field SP (max days): 79
S16-03843 S16-03843-02 Germany (Europe North) (71706)	Tomato / Pannovy F1	1.27 Jun 2016 2 – 3 -	1. Foliar 2. Foliar	-	1. 409.5 L/ha 2. 406.83 L/ha	1. 255.2993 g ai/ha 2. 253.6367 g ai/ha A12705B (-)	1. 12 Sep 2016 2. 20 Sep 2016 (8)	1. BBCH 73 2. BBCH 74	Fruit	0.1 mg/kg	< 0.01 mg/kg	1	21 Sep 2016/ -	Field SP (max days): 79

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
S16-03843 S16-03843-02 Germany (Europe North) (71706)	Tomato / Pannovy F1	1.27 Jun 2016 2 – 3 -	1. Foliar 2. Foliar	-	1. 409.5 L/ha 2. 406.83 L/ha	1. 255.2993 g ai/ha 2. 253.6367 g ai/ha A12705B (-)	1. 12 Sep 2016 2. 20 Sep 2016 (8)	1. BBCH 73 2. BBCH 74	Fruit	0.06 mg/kg	< 0.01 mg/kg	3	23 Sep 2016/ -	Field SP (max days): 79
S16-03843 S16-03843-02 Germany (Europe North) (71706)	Tomato / Pannovy F1	1.27 Jun 2016 2 – 3 -	1. Foliar 2. Foliar	-	1. 409.5 L/ha 2. 406.83 L/ha	1. 255.2993 g ai/ha 2. 253.6367 g ai/ha A12705B (-)	1. 12 Sep 2016 2. 20 Sep 2016 (8)	1. BBCH 73 2. BBCH 74	Fruit	0.08 mg/kg	< 0.01 mg/kg	7	27 Sep 2016/ -	Field SP (max days): 79
S16-03843 S16-03843-03 France (Europe North) (91140)	Tomato / Brillante	1.20 May 2016 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	19 Sep 2016/ -	Field SP (max days): 81
S16-03843 S16-03843-03 France (Europe North) (91140)	Tomato / Brillante	1.20 May 2016 2 – 3 -	1. Foliar 2. Foliar	-	1. 410.67 L/ha 2. 389.17 L/ha	1. 256.0266 g ai/ha 2. 242.6226 g ai/ha A12705B (-)	1. 09 Sep 2016 2. 16 Sep 2016 (7)	1. BBCH 73-74 2. BBCH 74-81	Fruit	0.04 mg/kg	< 0.01 mg/kg	0	16 Sep 2016/ -	Field SP (max days): 84

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
S16-03843 S16-03843-03 France (Europe North) (91140)	Tomato / Brillante	1.20 May 2016 2 – 3 -	1. Foliar 2. Foliar	-	1. 410.67 L/ha 2. 389.17 L/ha	1. 256.0266 g ai/ha 2. 242.6226 g ai/ha A12705B (-)	1. 09 Sep 2016 2. 16 Sep 2016 (7)	1. BBCH 73-74 2. BBCH 74-81	Fruit	0.12 mg/kg	< 0.01 mg/kg	0	16 Sep 2016/ -	Field SP (max days): 84
S16-03843 S16-03843-03 France (Europe North) (91140)	Tomato / Brillante	1.20 May 2016 2 – 3 -	1. Foliar 2. Foliar	-	1. 410.67 L/ha 2. 389.17 L/ha	1. 256.0266 g ai/ha 2. 242.6226 g ai/ha A12705B (-)	1. 09 Sep 2016 2. 16 Sep 2016 (7)	1. BBCH 73-74 2. BBCH 74-81	Fruit	0.05 mg/kg	< 0.01 mg/kg	1	17 Sep 2016/ -	Field SP (max days): 84
S16-03843 S16-03843-03 France (Europe North) (91140)	Tomato / Brillante	1.20 May 2016 2 – 3 -	1. Foliar 2. Foliar	-	1. 410.67 L/ha 2. 389.17 L/ha	1. 256.0266 g ai/ha 2. 242.6226 g ai/ha A12705B (-)	1. 09 Sep 2016 2. 16 Sep 2016 (7)	1. BBCH 73-74 2. BBCH 74-81	Fruit	0.05 mg/kg	< 0.01 mg/kg	3	19 Sep 2016/ -	Field SP (max days): 84
S16-03843 S16-03843-03 France (Europe North) (91140)	Tomato / Brillante	1.20 May 2016 2 – 3 -	1. Foliar 2. Foliar	-	1. 410.67 L/ha 2. 389.17 L/ha	1. 256.0266 g ai/ha 2. 242.6226 g ai/ha A12705B (-)	1. 09 Sep 2016 2. 16 Sep 2016 (7)	1. BBCH 73-74 2. BBCH 74-81	Fruit	0.04 mg/kg	< 0.01 mg/kg	7	23 Sep 2016/ -	Field SP (max days): 84

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
S16-03843 S16-03843-04 France (Europe North) (49730)	Tomato / Petula	1.10 Jun 2016 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	01 Sep 2016/ -	Field SP (max days): 99
S16-03843 S16-03843-04 France (Europe North) (49730)	Tomato / Petula	1.10 Jun 2016 2 – 3 -	1. Foliar 2. Foliar	-	1. 485.69 L/ha 2. 500.97 L/ha	1. 242.3625 g ai/ha 2. 249.9861 g ai/ha A12705B (-)	1. 22 Aug 2016 2. 29 Aug 2016 (7)	1. BBCH 81-82 2. BBCH 81-82	Fruit	0.03 mg/kg	< 0.01 mg/kg	0	29 Aug 2016/ -	Field SP (max days): 108
S16-03843 S16-03843-04 France (Europe North) (49730)	Tomato / Petula	1.10 Jun 2016 2 – 3 -	1. Foliar 2. Foliar	-	1. 485.69 L/ha 2. 500.97 L/ha	1. 242.3625 g ai/ha 2. 249.9861 g ai/ha A12705B (-)	1. 22 Aug 2016 2. 29 Aug 2016 (7)	1. BBCH 81-82 2. BBCH 81-82	Fruit	0.4 mg/kg	< 0.01 mg/kg	0	29 Aug 2016/ -	Field SP (max days): 108
S16-03843 S16-03843-04 France (Europe North) (49730)	Tomato / Petula	1.10 Jun 2016 2 – 3 -	1. Foliar 2. Foliar	-	1. 485.69 L/ha 2. 500.97 L/ha	1. 242.3625 g ai/ha 2. 249.9861 g ai/ha A12705B (-)	1. 22 Aug 2016 2. 29 Aug 2016 (7)	1. BBCH 81-82 2. BBCH 81-82	Fruit	0.06 mg/kg	< 0.01 mg/kg	1	30 Aug 2016/ -	Field SP (max days): 108

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
S16-03843 S16-03843-04 France (Europe North) (49730)	Tomato / Petula	1.10 Jun 2016 2 – 3 -	1. Foliar 2. Foliar	-	1. 485.69 L/ha 2. 500.97 L/ha	1. 242.3625 g ai/ha 2. 249.9861 g ai/ha A12705B (-)	1. 22 Aug 2016 2. 29 Aug 2016 (7)	1. BBCH 81-82 2. BBCH 81-82	Fruit	0.11 mg/kg	< 0.01 mg/kg	3	01 Sep 2016/ -	Field SP (max days): 108
S16-03843 S16-03843-04 France (Europe North) (49730)	Tomato / Petula	1.10 Jun 2016 2 – 3 -	1. Foliar 2. Foliar	-	1. 485.69 L/ha 2. 500.97 L/ha	1. 242.3625 g ai/ha 2. 249.9861 g ai/ha A12705B (-)	1. 22 Aug 2016 2. 29 Aug 2016 (7)	1. BBCH 81-82 2. BBCH 81-82	Fruit	0.02 mg/kg	< 0.01 mg/kg	7	05 Sep 2016/ -	Field SP (max days): 108

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of 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.

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value
(DBA) Days Before Application
SP (max days): Maximum storage period

A 2.1.3.1.2 Study 2 (Report No. NC15017) (New data)

Comments of zRMS:	Four decline residue field trials on tomato were successfully conducted in Poland and Hungary during 2015. Each trial consisted of one control plot and one treated plot. Azoxystrobin was applied to tomatoes as A12705B, a suspension concentrate (SC) formulation containing nominally 250 grams of azoxystrobin per litre. Three applications were planned for 17, 10, 3 days before harvest with azoxystrobin at 250 g ai/ha. The BBCH growth stages at application were BBCH 71-76, BBCH 73-81 and BBCH 81-89 for application 1, 2 and 3 respectively. Treated tomato samples were collected at 0 DBLA (days before last application), +0, 1, 3 (normal commercial harvest, NCH) and 7 days after application (DALA). Untreated tomato samples were collected at normal commercial harvest (NCH, 3 DALA). Samples were analysed for azoxystrobin and its metabolite R230310. Analytical Method: RAM 305/03 for Azoxystrobin and R230310 The analytical method has been successfully validated and shown to be acceptable for analysis of Azoxystrobin and its metabolite R230310 in a range of crop groups including tomato and is therefore considered suitable for the analysis of tomato (fruit) with LOQ=0.01 mg/kg. No residues of azoxystrobin or its metabolite R230310 were found at or above the limit of quantification (LOQ) (0.01 mg/kg) in any of the untreated samples. Residues of azoxystrobin in tomato samples taken at 0 DBLA were between 0.03 and 0.07 mg/kg. Residues of azoxystrobin in tomato samples taken at 0 DALA were between 0.09 and 0.21 mg/kg. Residues of azoxystrobin in tomato samples taken at 1 DALA were between 0.05 and 0.13 mg/kg. Residues of azoxystrobin in tomato samples taken at 3 DALA, normal commercial harvest (NCH) were between 0.06 and 0.12 mg/kg. Residues of azoxystrobin in tomato samples taken at 7 DALA were between 0.02 and 0.11 mg/kg. Residues of R230310 in tomato samples taken at 0 DBLA, +0, 1, 3 (NCH) and 7 DALA were all below the limit of quantification (LOQ) (0.01 mg/kg). The study is acceptable.

Reference:	KCA1 6.3
Report:	Andrews G., Coleman H. (2016) Azoxystrobin - Residue Study on Tomato in Poland and Hungary in 2015 Syngenta Report No. NC15017 Syngenta File No. VV-465709 Unpublished
Guideline(s):	Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document) OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50 OECD Guidance Document on Overview of Residue Chemistry Studies (as revised 2009), Series on Testing and Assessment (No. 64) and Series on Pesticides (No. 32), ENV/JM/MONO(2009)31 Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009

	OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009 OECD Series on Testing and Assessment No. 9 “Guidance document on the conduct of studies of occupational exposure to pesticides during agricultural application”, Paris 1997 OCDE/GD(97)148. European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000) European Commission Guidance Document on Residue Analytical Method, SANCO/825/00 revision 8.1 (16 Nov 2010).
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 7: Summary of the study 2 trials

Field Trials, Crop Residue (Summary): AZOXYSTROBIN- RESIDUE STUDY ON TOMATO IN POLAND AND HUNGARY IN 2015			
Active Substance (common name):	Azoxystrobin	**Commercial Product (name):**	
Crop/Crop Group:	Tomato	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	Poland, Hungary	**Other active substance in the formulation (common name and content):**	None
Content of active substance (g/kg or g/L):	A12705B: 250 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A12705B SC		
Analytical Method:	Azoxystrobin (Fruit) RAM 305/03; 0.01 mg/kg R230310 (Fruit) RAM 305/03; 0.01 mg/kg		
Recovery data:	Azoxystrobin Fruit Mean = 100% RSD = 6% (n = 8 in 0.01 - 0.3 spiking range) R230310 Fruit Mean = 107% RSD = 6% (n = 4 in 0.01 - 0.1 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
NC15017 NC15017-01 Poland (Europe North) (98-300 Wielun)	Tomato / Hubal	1.21 May 2015 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	07 Aug 2015/ -	Field SP (max days): 299
NC15017 NC15017-01 Poland (Europe North) (98-300 Wielun)	Tomato / Hubal	1.21 May 2015 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 416.67 L/ha 2. 411.11 L/ha 3. 397.22 L/ha	1. 260.4167 g ai/ha 2. 256.9444 g ai/ha 3. 248.2639 g ai/ha A12705B (-)	1. 21 Jul 2015 2. 28 Jul 2015 3. 04 Aug 2015 (7, 7)	1. BBCH 75-76 2. BBCH 79-91 3. BBCH 86-87	Fruit	0.12 mg/kg	< 0.01 mg/kg	0	04 Aug 2015/ -	Field SP (max days): 302

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
NC15017 NC15017-01 Poland (Europe North) (98-300 Wielun)	Tomato / Hubal	1.21 May 2015 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 416.67 L/ha 2. 411.11 L/ha 3. 397.22 L/ha	1. 260.4167 g ai/ha 2. 256.9444 g ai/ha 3. 248.2639 g ai/ha A12705B (-)	1. 21 Jul 2015 2. 28 Jul 2015 3. 04 Aug 2015 (7, 7)	1. BBCH 75-76 2. BBCH 79-91 3. BBCH 86-87	Fruit	0.03 mg/kg	< 0.01 mg/kg	0	04 Aug 2015/ -	Field SP (max days): 302
NC15017 NC15017-01 Poland (Europe North) (98-300 Wielun)	Tomato / Hubal	1.21 May 2015 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 416.67 L/ha 2. 411.11 L/ha 3. 397.22 L/ha	1. 260.4167 g ai/ha 2. 256.9444 g ai/ha 3. 248.2639 g ai/ha A12705B (-)	1. 21 Jul 2015 2. 28 Jul 2015 3. 04 Aug 2015 (7, 7)	1. BBCH 75-76 2. BBCH 79-91 3. BBCH 86-87	Fruit	0.13 mg/kg	< 0.01 mg/kg	1	05 Aug 2015/ -	Field SP (max days): 302
NC15017 NC15017-01 Poland (Europe North) (98-300 Wielun)	Tomato / Hubal	1.21 May 2015 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 416.67 L/ha 2. 411.11 L/ha 3. 397.22 L/ha	1. 260.4167 g ai/ha 2. 256.9444 g ai/ha 3. 248.2639 g ai/ha A12705B (-)	1. 21 Jul 2015 2. 28 Jul 2015 3. 04 Aug 2015 (7, 7)	1. BBCH 75-76 2. BBCH 79-91 3. BBCH 86-87	Fruit	0.09 mg/kg	< 0.01 mg/kg	3	07 Aug 2015/ -	Field SP (max days): 302

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
NC15017 NC15017-01 Poland (Europe North) (98-300 Wielun)	Tomato / Hubal	1.21 May 2015 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 416.67 L/ha 2. 411.11 L/ha 3. 397.22 L/ha	1. 260.4167 g ai/ha 2. 256.9444 g ai/ha 3. 248.2639 g ai/ha A12705B (-)	1. 21 Jul 2015 2. 28 Jul 2015 3. 04 Aug 2015 (7, 7)	1. BBCH 75-76 2. BBCH 79-91 3. BBCH 86-87	Fruit	0.09 mg/kg	< 0.01 mg/kg	7	11 Aug 2015/ -	Field SP (max days): 302
NC15017 NC15017-02 Poland (Europe North) (55-100 Trzebnica)	Tomato / Jet F1	1.15 May 2015 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	08 Aug 2015/ -	Field SP (max days): 298
NC15017 NC15017-02 Poland (Europe North) (55-100 Trzebnica)	Tomato / Jet F1	1.15 May 2015 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 407.14 L/ha 2. 410.71 L/ha 3. 401.79 L/ha	1. 254.4643 g ai/ha 2. 256.6964 g ai/ha 3. 251.1161 g ai/ha A12705B (-)	1. 22 Jul 2015 2. 29 Jul 2015 3. 05 Aug 2015 (7, 7)	1. BBCH 73-75 2. BBCH 79-81 3. BBCH 85-87	Fruit	0.11 mg/kg	< 0.01 mg/kg	0	05 Aug 2015/ -	Field SP (max days): 301

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
NC15017 NC15017-02 Poland (Europe North) (55-100 Trzebnica)	Tomato / Jet F1	1.15 May 2015 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 407.14 L/ha 2. 410.71 L/ha 3. 401.79 L/ha	1. 254.4643 g ai/ha 2. 256.6964 g ai/ha 3. 251.1161 g ai/ha A12705B (-)	1. 22 Jul 2015 2. 29 Jul 2015 3. 05 Aug 2015 (7, 7)	1. BBCH 73-75 2. BBCH 79-81 3. BBCH 85-87	Fruit	0.07 mg/kg	< 0.01 mg/kg	0	05 Aug 2015/ -	Field SP (max days): 301
NC15017 NC15017-02 Poland (Europe North) (55-100 Trzebnica)	Tomato / Jet F1	1.15 May 2015 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 407.14 L/ha 2. 410.71 L/ha 3. 401.79 L/ha	1. 254.4643 g ai/ha 2. 256.6964 g ai/ha 3. 251.1161 g ai/ha A12705B (-)	1. 22 Jul 2015 2. 29 Jul 2015 3. 05 Aug 2015 (7, 7)	1. BBCH 73-75 2. BBCH 79-81 3. BBCH 85-87	Fruit	0.054 mg/kg, 0.053 mg/kg, 0.054 mg/kg (Mean=0.0537 mg/kg)	< 0.01 mg/kg	1	06 Aug 2015/ -	Field SP (max days): 301
NC15017 NC15017-02 Poland (Europe North) (55-100 Trzebnica)	Tomato / Jet F1	1.15 May 2015 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 407.14 L/ha 2. 410.71 L/ha 3. 401.79 L/ha	1. 254.4643 g ai/ha 2. 256.6964 g ai/ha 3. 251.1161 g ai/ha A12705B (-)	1. 22 Jul 2015 2. 29 Jul 2015 3. 05 Aug 2015 (7, 7)	1. BBCH 73-75 2. BBCH 79-81 3. BBCH 85-87	Fruit	0.077 mg/kg, 0.076 mg/kg, 0.077 mg/kg (Mean=0.0767 mg/kg)	< 0.01 mg/kg	3	08 Aug 2015/ -	Field SP (max days): 301

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
NC15017 NC15017-02 Poland (Europe North) (55-100 Trzebnica)	Tomato / Jet F1	1.15 May 2015 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 407.14 L/ha 2. 410.71 L/ha 3. 401.79 L/ha	1. 254.4643 g ai/ha 2. 256.6964 g ai/ha 3. 251.1161 g ai/ha A12705B (-)	1. 22 Jul 2015 2. 29 Jul 2015 3. 05 Aug 2015 (7, 7)	1. BBCH 73-75 2. BBCH 79-81 3. BBCH 85-87	Fruit	0.107 mg/kg, 0.112 mg/kg, 0.104 mg/kg (Mean=0.1077 mg/kg)	< 0.01 mg/kg	7	12 Aug 2015/ -	Field SP (max days): 301
NC15017 NC15017-03 Hungary (Europe North) (3360)	Tomato / Mobil	1.10 May 2015 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	16 Aug 2015/ -	Field SP (max days): 290
NC15017 NC15017-03 Hungary (Europe North) (3360)	Tomato / Mobil	1.10 May 2015 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 587.5 L/ha 2. 643.75 L/ha 3. 618.75 L/ha	1. 244.7917 g ai/ha 2. 268.2292 g ai/ha 3. 257.8125 g ai/ha A12705B (-)	1. 30 Jul 2015 2. 06 Aug 2015 3. 13 Aug 2015 (7, 7)	1. BBCH 71 2. BBCH 73 3. BBCH 81	Fruit	0.04 mg/kg	< 0.01 mg/kg	0	13 Aug 2015/ -	Field SP (max days): 293

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
NC15017 NC15017-03 Hungary (Europe North) (3360)	Tomato / Mobil	1.10 May 2015 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 587.5 L/ha 2. 643.75 L/ha 3. 618.75 L/ha	1. 244.7917 g ai/ha 2. 268.2292 g ai/ha 3. 257.8125 g ai/ha A12705B (-)	1. 30 Jul 2015 2. 06 Aug 2015 3. 13 Aug 2015 (7, 7)	1. BBCH 71 2. BBCH 73 3. BBCH 81	Fruit	0.09 mg/kg	< 0.01 mg/kg	0	13 Aug 2015/ -	Field SP (max days): 293
NC15017 NC15017-03 Hungary (Europe North) (3360)	Tomato / Mobil	1.10 May 2015 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 587.5 L/ha 2. 643.75 L/ha 3. 618.75 L/ha	1. 244.7917 g ai/ha 2. 268.2292 g ai/ha 3. 257.8125 g ai/ha A12705B (-)	1. 30 Jul 2015 2. 06 Aug 2015 3. 13 Aug 2015 (7, 7)	1. BBCH 71 2. BBCH 73 3. BBCH 81	Fruit	0.07 mg/kg	< 0.01 mg/kg	1	14 Aug 2015/ -	Field SP (max days): 293
NC15017 NC15017-03 Hungary (Europe North) (3360)	Tomato / Mobil	1.10 May 2015 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 587.5 L/ha 2. 643.75 L/ha 3. 618.75 L/ha	1. 244.7917 g ai/ha 2. 268.2292 g ai/ha 3. 257.8125 g ai/ha A12705B (-)	1. 30 Jul 2015 2. 06 Aug 2015 3. 13 Aug 2015 (7, 7)	1. BBCH 71 2. BBCH 73 3. BBCH 81	Fruit	0.06 mg/kg	< 0.01 mg/kg	3	16 Aug 2015/ -	Field SP (max days): 293

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
NC15017 NC15017-03 Hungary (Europe North) (3360)	Tomato / Mobil	1.10 May 2015 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 587.5 L/ha 2. 643.75 L/ha 3. 618.75 L/ha	1. 244.7917 g ai/ha 2. 268.2292 g ai/ha 3. 257.8125 g ai/ha A12705B (-)	1. 30 Jul 2015 2. 06 Aug 2015 3. 13 Aug 2015 (7, 7)	1. BBCH 71 2. BBCH 73 3. BBCH 81	Fruit	0.02 mg/kg	< 0.01 mg/kg	7	20 Aug 2015/ -	Field SP (max days): 293
NC15017 NC15017-04 Hungary (Europe North) (2765)	Tomato / Corcoran	1.14 May 2015 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	29 Aug 2015/ -	Field SP (max days): 277
NC15017 NC15017-04 Hungary (Europe North) (2765)	Tomato / Corcoran	1.14 May 2015 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 570 L/ha 2. 620 L/ha 3. 570 L/ha	1. 237.5 g ai/ha 2. 258.3333 g ai/ha 3. 237.5 g ai/ha A12705B (-)	1. 11 Aug 2015 2. 19 Aug 2015 3. 26 Aug 2015 (8, 7)	1. BBCH 73 2. BBCH 83 3. BBCH 89	Fruit	0.03 mg/kg	< 0.01 mg/kg	0	26 Aug 2015/ -	Field SP (max days): 280

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
NC15017 NC15017-04 Hungary (Europe North) (2765)	Tomato / Corcoran	1.14 May 2015 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 570 L/ha 2. 620 L/ha 3. 570 L/ha	1. 237.5 g ai/ha 2. 258.3333 g ai/ha 3. 237.5 g ai/ha A12705B (-)	1. 11 Aug 2015 2. 19 Aug 2015 3. 26 Aug 2015 (8, 7)	1. BBCH 73 2. BBCH 83 3. BBCH 89	Fruit	0.21 mg/kg	< 0.01 mg/kg	0	26 Aug 2015/ -	Field SP (max days): 280
NC15017 NC15017-04 Hungary (Europe North) (2765)	Tomato / Corcoran	1.14 May 2015 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 570 L/ha 2. 620 L/ha 3. 570 L/ha	1. 237.5 g ai/ha 2. 258.3333 g ai/ha 3. 237.5 g ai/ha A12705B (-)	1. 11 Aug 2015 2. 19 Aug 2015 3. 26 Aug 2015 (8, 7)	1. BBCH 73 2. BBCH 83 3. BBCH 89	Fruit	0.11 mg/kg	< 0.01 mg/kg	1	27 Aug 2015/ -	Field SP (max days): 280
NC15017 NC15017-04 Hungary (Europe North) (2765)	Tomato / Corcoran	1.14 May 2015 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 570 L/ha 2. 620 L/ha 3. 570 L/ha	1. 237.5 g ai/ha 2. 258.3333 g ai/ha 3. 237.5 g ai/ha A12705B (-)	1. 11 Aug 2015 2. 19 Aug 2015 3. 26 Aug 2015 (8, 7)	1. BBCH 73 2. BBCH 83 3. BBCH 89	Fruit	0.12 mg/kg	< 0.01 mg/kg	3	29 Aug 2015/ -	Field SP (max days): 280

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
NC15017 NC15017-04 Hungary (Europe North) (2765)	Tomato / Corcoran	1.14 May 2015 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 570 L/ha 2. 620 L/ha 3. 570 L/ha	1. 237.5 g ai/ha 2. 258.3333 g ai/ha 3. 237.5 g ai/ha A12705B (-)	1. 11 Aug 2015 2. 19 Aug 2015 3. 26 Aug 2015 (8, 7)	1. BBCH 73 2. BBCH 83 3. BBCH 89	Fruit	0.08 mg/kg	< 0.01 mg/kg	7	02 Sep 2015/ -	Field SP (max days): 280

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(c) Year must be indicated

(d) Minimum number of 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.

(*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^) PHI calculated using cut date

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period

A 2.1.3.1.3 Study 3 (Report No. FSGD-069-REG) (EU reviewed)

Comments of zRMS:	The study has been reviewed at EU level.

Reference:	KCA1 6.3
Report:	Render K. (2010) Azoxystrobin - Residue Study on Tomatoes in Northern France in 2009 Syngenta Report No. FSGD-069-REG Syngenta File No. VV-394875 Unpublished
Guideline(s):	FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials (Rome, 1990) Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document) Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2), 1996
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 8: Summary of the study 3 trials

Field Trials, Crop Residue (Summary): Azoxystrobin - Residue study on Tomatoes in northern France in 2009			
Active Substance (common name):	Azoxystrobin	**Commercial Product (name):**	
Crop/Crop Group:	Tomato	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	France	**Other active substance in the formulation (common name and content):**	None
Content of active substance (g/kg or g/L):	A12705B: 250 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A12705B SC		
Analytical Method:	Azoxystrobin (Fruit) RAM 305/03; 0.01 mg/kg R230310 (Fruit) RAM 305/03; 0.01 mg/kg		
Recovery data:	Azoxystrobin Fruit Mean = 88% RSD = 15% (n = 2 in 0.01 - 1 spiking range) R230310 Fruit Mean = 89% RSD = 10% (n = 2 in 0.01 - 0.1 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
FSGD-069-REG S09-01451-01 France (Europe North) (67210)	Tomato / Montfavet 63-5 F	1.15 Jun 2009 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	29 Aug 2009/ -	Field SP (max days): 59
FSGD-069-REG S09-01451-01 France (Europe North) (67210)	Tomato / Montfavet 63-5 F	1.15 Jun 2009 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 982 L/ha 2. 985 L/ha 3. 1072 L/ha	1. 245 g ai/ha 2. 246 g ai/ha 3. 268 g ai/ha A12705B (-)	1. 19 Aug 2008 2. 12 Aug 2009 3. 26 Aug 2009 (7, 7)	1. BBCH 77 2. BBCH 71 3. BBCH 79	Fruit	0.19 mg/kg	< 0.01 mg/kg	0	26 Aug 2009/ -	Field SP (max days): 424

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
FSGD-069-REG S09-01451-01 France (Europe North) (67210)	Tomato / Montfavet 63-5 F	1.15 Jun 2009 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 982 L/ha 2. 985 L/ha 3. 1072 L/ha	1. 245 g ai/ha 2. 246 g ai/ha 3. 268 g ai/ha A12705B (-)	1. 19 Aug 2008 2. 12 Aug 2009 3. 26 Aug 2009 (358, 14)	1. BBCH 77 2. BBCH 71 3. BBCH 79	Fruit	0.19 mg/kg	< 0.01 mg/kg	1	27 Aug 2009/ -	Field SP (max days): 424
FSGD-069-REG S09-01451-01 France (Europe North) (67210)	Tomato / Montfavet 63-5 F	1.15 Jun 2009 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 982 L/ha 2. 985 L/ha 3. 1072 L/ha	1. 245 g ai/ha 2. 246 g ai/ha 3. 268 g ai/ha A12705B (-)	1. 19 Aug 2008 2. 12 Aug 2009 3. 26 Aug 2009 (358, 14)	1. BBCH 77 2. BBCH 71 3. BBCH 79	Fruit	<u>0.07 mg/kg</u>	< 0.01 mg/kg	3	29 Aug 2008/ -	Field SP (max days): 424
FSGD-069-REG S09-01451-02 France (Europe North) (49650)	Tomato / Paola	1.20 May 2009 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	03 Sep 2009/ -	Field SP (max days): 54

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
FSGD-069-REG S09-01451-02 France (Europe North) (49650)	Tomato / Paola	1.20 May 2009 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 1006 L/ha 2. 1029 L/ha 3. 1024 L/ha	1. 252 g ai/ha 2. 257 g ai/ha 3. 256 g ai/ha A12705B (-)	1. 17 Aug 2009 2. 24 Aug 2009 3. 31 Aug 2009 (7, 7)	1. BBCH 79-81 2. BBCH 81-82 3. BBCH 82-84	Fruit	0.2 mg/kg	< 0.01 mg/kg	0	31 Aug 2009/ -	Field SP (max days): 57
FSGD-069-REG S09-01451-02 France (Europe North) (49650)	Tomato / Paola	1.20 May 2009 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 1006 L/ha 2. 1029 L/ha 3. 1024 L/ha	1. 252 g ai/ha 2. 257 g ai/ha 3. 256 g ai/ha A12705B (-)	1. 17 Aug 2009 2. 24 Aug 2009 3. 31 Aug 2009 (7, 7)	1. BBCH 79-81 2. BBCH 81-82 3. BBCH 82-84	Fruit	0.04 mg/kg	< 0.01 mg/kg	1	01 Sep 2009/ -	Field SP (max days): 57
FSGD-069-REG S09-01451-02 France (Europe North) (49650)	Tomato / Paola	1.20 May 2009 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 1006 L/ha 2. 1029 L/ha 3. 1024 L/ha	1. 252 g ai/ha 2. 257 g ai/ha 3. 256 g ai/ha A12705B (-)	1. 17 Aug 2009 2. 24 Aug 2009 3. 31 Aug 2009 (7, 7)	1. BBCH 79-81 2. BBCH 81-82 3. BBCH 82-84	Fruit	<u>0.04 mg/kg</u>	< 0.01 mg/kg	3	03 Sep 2009/ -	Field SP (max days): 57

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values

(c) Year must be indicated

(d) Minimum number of 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.

(^) PHI calculated using cut date

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period

A 2.1.3.1.4 Study 4 (Report No. FSGD-014-REG) (EU reviewed)

Comments of zRMS:	The study has been reviewed at EU level.

Reference:	KCA1 6.3
Report:	Render K. (2010) Azoxystrobin - Residue Study on Field Tomato in France (North) in 2008 Syngenta Report No. FSGD-014-REG Syngenta File No. VV-394328 Unpublished
Guideline(s):	FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials (Rome, 1990) Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document) Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2), 1996
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 9: Summary of the study 4 trials

Field Trials, Crop Residue (Summary): Azoxystrobin - Residue study on field Tomato in France (north) in 2008			
Active Substance (common name):	Azoxystrobin	**Commercial Product (name):**	
Crop/Crop Group:	Tomato	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	France	**Other active substance in the formulation (common name and content):**	None
Content of active substance (g/kg or g/L):	A12705B: 250 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A12705B SC		
Analytical Method:	Azoxystrobin (Fruit) RAM 305/03; 0.01 mg/kg R230310 (Fruit) RAM 305/03; 0.01 mg/kg		
Recovery data:	Azoxystrobin Fruit Mean = 91% RSD = 2% (n = 2 in 0.01 - 0.5 spiking range) R230310 Fruit Mean = 90% RSD = 4% (n = 2 in 0.01 - 0.1 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
FSGD-014-REG S08-00661-01 France (Europe North) (91140)	Tomato / Topkapi	1.30 May 2008 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	21 Aug 2008/ -	Field SP (max days): 196
FSGD-014-REG S08-00661-01 France (Europe North) (91140)	Tomato / Topkapi	1.30 May 2008 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 998.17 L/ha 2. 972.69 L/ha 3. 1006.93 L/ha	1. 249.3 g ai/ha 2. 242.9 g ai/ha 3. 251.5 g ai/ha A12705B (-)	1. 04 Aug 2008 2. 11 Aug 2008 3. 18 Aug 2008 (7, 7)	1. BBCH 81 2. BBCH 82 3. BBCH 88	Fruit	0.17 mg/kg	< 0.01 mg/kg	0	18 Aug 2008/ -	Field SP (max days): 199

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
FSGD-014-REG S08-00661-01 France (Europe North) (91140)	Tomato / Topkapi	1.30 May 2008 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 998.17 L/ha 2. 972.69 L/ha 3. 1006.93 L/ha	1. 249.3 g ai/ha 2. 242.9 g ai/ha 3. 251.5 g ai/ha A12705B (-)	1. 04 Aug 2008 2. 11 Aug 2008 3. 18 Aug 2008 (7, 7)	1. BBCH 81 2. BBCH 82 3. BBCH 88	Fruit	0.12 mg/kg	< 0.01 mg/kg	1	19 Aug 2008/ -	Field SP (max days): 199
FSGD-014-REG S08-00661-01 France (Europe North) (91140)	Tomato / Topkapi	1.30 May 2008 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 998.17 L/ha 2. 972.69 L/ha 3. 1006.93 L/ha	1. 249.3 g ai/ha 2. 242.9 g ai/ha 3. 251.5 g ai/ha A12705B (-)	1. 04 Aug 2008 2. 11 Aug 2008 3. 18 Aug 2008 (7, 7)	1. BBCH 81 2. BBCH 82 3. BBCH 88	Fruit	<u>0.08 mg/kg</u>	< 0.01 mg/kg	3	21 Aug 2008/ -	Field SP (max days): 199
FSGD-014-REG S08-00661-02 France (Europe North) (49650)	Tomato / Topkapi	1.12 Jun 2008 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 1007.63 L/ha 2. 953.68 L/ha 3. 998.42 L/ha	1. 251.66 g ai/ha 2. 238.18 g ai/ha 3. 249.36 g ai/ha A12705B (-)	1. 01 Sep 2008 2. 08 Sep 2008 3. 15 Sep 2008 (7, 7)	1. BBCH 81 2. BBCH 81-85 3. BBCH 85	Fruit	0.3 mg/kg	< 0.01 mg/kg	0	15 Sep 2008/ -	Field SP (max days): 171

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
FSGD-014-REG S08-00661-02 France (Europe North) (49650)	Tomato / Topkapi	1.12 Jun 2008 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 1007.63 L/ha 2. 953.68 L/ha 3. 998.42 L/ha	1. 251.66 g ai/ha 2. 238.18 g ai/ha 3. 249.36 g ai/ha A12705B (-)	1. 01 Sep 2008 2. 08 Sep 2008 3. 15 Sep 2008 (7, 7)	1. BBCH 81 2. BBCH 81-85 3. BBCH 85	Fruit	0.35 mg/kg	< 0.01 mg/kg	1	16 Sep 2008/ -	Field SP (max days): 171
FSGD-014-REG S08-00661-02 France (Europe North) (49650)	Tomato / Topkapi	1.12 Jun 2008 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 1007.63 L/ha 2. 953.68 L/ha 3. 998.42 L/ha	1. 251.66 g ai/ha 2. 238.18 g ai/ha 3. 249.36 g ai/ha A12705B (-)	1. 01 Sep 2008 2. 08 Sep 2008 3. 15 Sep 2008 (7, 7)	1. BBCH 81 2. BBCH 81-85 3. BBCH 85	Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	18 Sep 2008/ -	Field SP (max days): 171
FSGD-014-REG S08-00661-02 France (Europe North) (49650)	Tomato / Topkapi	1.12 Jun 2008 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 1007.63 L/ha 2. 953.68 L/ha 3. 998.42 L/ha	1. 251.66 g ai/ha 2. 238.18 g ai/ha 3. 249.36 g ai/ha A12705B (-)	1. 01 Sep 2008 2. 08 Sep 2008 3. 15 Sep 2008 (7, 7)	1. BBCH 81 2. BBCH 81-85 3. BBCH 85	Fruit	0.25 mg/kg	< 0.01 mg/kg	3	18 Sep 2008/ -	Field SP (max days): 171

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values

(c) Year must be indicated	(^) PHI calculated using cut date
(d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)	(+) Indicates calculated Residue value
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included.	(DBA) Days Before Application
	SP (max days): maximum storage period

A 2.1.3.2 Bell pepper

Table A 10: 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)
cGAP N-EU (Art. 12, EFSA, 2013)	-	-	-	-	-
cGAP S-EU (Art. 12, EFSA, 2013)	4	250 g a.s./ha	-	-	3
Intended cGAP A22773A - CZ-29, HU-1, PL-23, PL-24, RO-1, SK-35, SI-1*	2	250 g a.s./ha	7	BBCH 11-89	3

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
** Timing of applications determined primarily by growth stage
*** Minimum PHI

A 2.1.3.2.1 Study 1 (Report No. S12-01261) (EU reviewed)

Comments of zRMS:	The study has been reviewed at EU level.

Reference:	KCA1 6.3
Report:	Yozgatli H.P., Winkler K. (2013) Azoxystrobi n – Residue Study on Pepper in Northern France and Hungary in 2012 Syngenta Report No. S12-01261 Syngenta File No. VV-404035 Unpublished
Guideline(s):	FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials (Rome, 1990) Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document) Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2), 1996
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 11: Summary of the study 1 trials

Field Trials, Crop Residue (Summary): Azoxystrobin - Residue Study on Pepper in Northern France and Hungary in 2012			
Active Substance (common name):	azoxystrobin	**Commercial Product (name):**	
Crop/Crop Group:	Pepper	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	FRANCE, HUNGARY	**Other active substance in the formulation (common name and content):**	None
Content of active substance (g/kg or g/L):	A12705B: 250 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A12705B SC		
Analytical Method:	R230310 (Fruit) RAM 305/03; 0.01 mg/kg Azoxystrobin (Fruit) RAM 305/03; 0.01 mg/kg		
Recovery data:	R230310 Fruit Mean = 95% RSD = N/A (n = 2 in 0.01 - 0.1 spiking range) Azoxystrobin Fruit Mean = 89% RSD = 13% (n = 3 in 0.01 - 2 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	**(2) Commodity / Variety (a)**	**(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)**	**(4) Method of Treatment**	**(5) Application rate per treatment**			**(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)**	**(7) Growth Stage at Treatment**	**(8) Portion Analyzed**	**(9) Residue found (Uncorrected)**		**(10) PHI (d)**	**(11) Sample Date / Cut Date**	**(12) Trial Details (e)**
				Concentration	**Water**	**Rate Formulation (Additive Type, Rate)**				**Azoxystrobin (mg/kg)**	**R230310 (mg/kg)**			
S12-01261 S12-01261-01 FRANCE (Europe North) (78910)	Pepper / Lipari	1.25 May 2012 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	15 Sep 2012/ -	Field SP (max days): 48
S12-01261 S12-01261-01 FRANCE (Europe North) (78910)	Pepper / Lipari	1.25 May 2012 2 – 3 -	1. Foliar 2. Foliar	-	1. 1071.4286 L/ha 2. 1030.3571 L/ha	1. 268 g ai/ha** 2. 258 g ai/ha** A12705B (-)	1. 04 Sep 2012 2. 12 Sep 2012 (8)	1. BBCH 81-85 2. BBCH 83-86	Fruit	<u>0.19 mg/kg</u>	< 0.01 mg/kg	3	15 Sep 2012/ -	Field SP (max days): 48

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
S12-01261 S12-01261-02 FRANCE (Europe North) (49350)	Pepper / TWINGO	1.18 Jun 2012 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	13 Sep 2012/ -	Field SP (max days): 50
S12-01261 S12-01261-02 FRANCE (Europe North) (49350)	Pepper / TWINGO	1.18 Jun 2012 2 – 3 -	1. Foliar 2. Foliar	-	1. 1002.75 L/ha 2. 1023 L/ha	1. 251 g ai/ha** 2. 256 g ai/ha** A12705B (-)	1. 03 Sep 2012 2. 10 Sep 2012 (7)	1. BBCH 77-79 2. BBCH 81-85	Fruit	0.51 mg/kg	< 0.01 mg/kg	3	13 Sep 2012/ -	Field SP (max days): 50
S12-01261 S12-01261-03 HUNGARY (Europe North) (H-2347)	Pepper / Kápia F1	1.03 Jun 2012 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	25 Aug 2012/ -	Field SP (max days): 69
S12-01261 S12-01261-03 HUNGARY (Europe North) (H-2347)	Pepper / Kápia F1	1.03 Jun 2012 2 – 3 -	1. Foliar 2. Foliar	-	1. 1016.6667 L/ha 2. 1055 L/ha	1. 254 g ai/ha** 2. 264 g ai/ha A12705B (-)	1. 15 Aug 2012 2. 22 Aug 2012 (7)	1. BBCH 65-71 2. BBCH 71-79	Fruit	0.26 mg/kg	< 0.01 mg/kg	3	25 Aug 2012/ -	Field SP (max days): 69

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
S12-01261 S12-01261-04 FRANCE (Europe North) (45160)	Pepper / Lipari	1.16 Jun 2012 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	17 Aug 2012/ -	Field SP (max days): 77
S12-01261 S12-01261-04 FRANCE (Europe North) (45160)	Pepper / Lipari	1.16 Jun 2012 2 – 3 -	1. Foliar 2. Foliar	-	1. 1059.6667 L/ha 2. 1021.6667 L/ha	1. 265 g ai/ha** 2. 255 g ai/ha** A12705B (-)	1. 07 Aug 2012 2. 14 Aug 2012 (7)	1. BBCH 62-71 2. BBCH 72-85	Fruit	0.21 mg/kg	< 0.01 mg/kg	0	14 Aug 2012/ -	Field SP (max days): 80
S12-01261 S12-01261-04 FRANCE (Europe North) (45160)	Pepper / Lipari	1.16 Jun 2012 2 – 3 -	1. Foliar 2. Foliar	-	1. 1059.6667 L/ha 2. 1021.6667 L/ha	1. 24.975 g ai/hL 2. 25 g ai/hL A12705B (-)	1. 07 Aug 2012 2. 14 Aug 2012 (7)	1. BBCH 62-71 2. BBCH 72-85	Fruit	0.13 mg/kg	< 0.01 mg/kg	1	15 Aug 2012/ -	Field SP (max days): 80
S12-01261 S12-01261-04 FRANCE (Europe North) (45160)	Pepper / Lipari	1.16 Jun 2012 2 – 3 -	1. Foliar 2. Foliar	-	1. 1059.6667 L/ha 2. 1021.6667 L/ha	1. 24.975 g ai/hL 2. 25 g ai/hL A12705B (-)	1. 07 Aug 2012 2. 14 Aug 2012 (7)	1. BBCH 62-71 2. BBCH 72-85	Fruit	<u>0.2 mg/kg</u>	< 0.01 mg/kg	3	17 Aug 2012/ -	Field SP (max days): 80

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
S12-01261 S12-01261-05 FRANCE (Europe North) (49650)	Pepper / Twingo	1.18 Jun 2012 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	13 Sep 2012/ -	Field SP (max days): 50
S12-01261 S12-01261-05 FRANCE (Europe North) (49650)	Pepper / Twingo	1.18 Jun 2012 2 – 3 -	1. Foliar 2. Foliar	-	1. 1077.75 L/ha 2. 1060.25 L/ha	1. 269 g ai/ha** 2. 265 g ai/ha** A12705B (-)	1. 03 Sep 2012 2. 10 Sep 2012 (7)	1. BBCH 75-77 2. BBCH 77-85	Fruit	0.25 mg/kg	< 0.01 mg/kg	0	10 Sep 2012/ -	Field SP (max days): 53
S12-01261 S12-01261-05 FRANCE (Europe North) (49650)	Pepper / Twingo	1.18 Jun 2012 2 – 3 -	1. Foliar 2. Foliar	-	1. 1077.75 L/ha 2. 1060.25 L/ha	1. 24.975 g ai/hL 2. 24.975 g ai/hL A12705B (-)	1. 03 Sep 2012 2. 10 Sep 2012 (7)	1. BBCH 75-77 2. BBCH 77-85	Fruit	0.35 mg/kg	< 0.01 mg/kg	1	11 Sep 2012/ -	Field SP (max days): 53
S12-01261 S12-01261-05 FRANCE (Europe North) (49650)	Pepper / Twingo	1.18 Jun 2012 2 – 3 -	1. Foliar 2. Foliar	-	1. 1077.75 L/ha 2. 1060.25 L/ha	1. 24.975 g ai/hL 2. 24.975 g ai/hL A12705B (-)	1. 03 Sep 2012 2. 10 Sep 2012 (7)	1. BBCH 75-77 2. BBCH 77-85	Fruit	0.21 mg/kg	< 0.01 mg/kg	3	13 Sep 2012/ -	Field SP (max days): 53

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
S12-01261 S12-01261-06 HUNGARY (Europe North) (H-6635)	Pepper / Csángó F1	1.12 Jun 2012 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	13 Aug 2012/ -	Field SP (max days): 81
S12-01261 S12-01261-06 HUNGARY (Europe North) (H-6635)	Pepper / Csángó F1	1.12 Jun 2012 2 – 3 -	1. Foliar 2. Foliar	-	1. 974.6667 L/ha 2. 975.8333 L/ha	1. 244 g ai/ha** 2. 244 g ai/ha** A12705B (-)	1. 03 Aug 2012 2. 10 Aug 2012 (7)	1. BBCH 85-87 2. BBCH 85-89	Fruit	0.13 mg/kg	< 0.01 mg/kg	0	10 Aug 2012/ -	Field SP (max days): 84
S12-01261 S12-01261-06 HUNGARY (Europe North) (H-6635)	Pepper / Csángó F1	1.12 Jun 2012 2 – 3 -	1. Foliar 2. Foliar	-	1. 974.6667 L/ha 2. 975.8333 L/ha	1. 25 g ai/hL 2. 25 g ai/hL A12705B (-)	1. 03 Aug 2012 2. 10 Aug 2012 (7)	1. BBCH 85-87 2. BBCH 85-89	Fruit	0.12 mg/kg	< 0.01 mg/kg	1	11 Aug 2012/ -	Field SP (max days): 84
S12-01261 S12-01261-06 HUNGARY (Europe North) (H-6635)	Pepper / Csángó F1	1.12 Jun 2012 2 – 3 -	1. Foliar 2. Foliar	-	1. 974.6667 L/ha 2. 975.8333 L/ha	1. 25 g ai/hL 2. 25 g ai/hL A12705B (-)	1. 03 Aug 2012 2. 10 Aug 2012 (7)	1. BBCH 85-87 2. BBCH 85-89	Fruit	0.18 mg/kg	< 0.01 mg/kg	3	13 Aug 2012/ -	Field SP (max days): 84

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date

(d) Minimum number of 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.

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period
** Application rate g ai/ha was calculated from g ai/hL and L water/ha.

A 2.1.3.2.2 Study 2 (Report No. T009405-07-REG) (EU reviewed)

Comments of zRMS:	The study has been reviewed at EU level.

Reference:	KCA1 6.3
Report:	Jones A. (2010) Azoxystrobin - Residue Study on Peppers in France (North) in 2008 Syngenta Report No. T009405-07-REG Syngenta File No. VV-394626 Unpublished
Guideline(s):	Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document)
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 12: Summary of the study 2 trials

Field Trials, Crop Residue (Summary): Azoxystrobin - Residue study on Peppers in France (north) in 2008			
Active Substance (common name):	Azoxystrobin	**Commercial Product (name):**	
Crop/Crop Group:	Pepper	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	France	**Other active substance in the formulation (common name and content):**	None
Content of active substance (g/kg or g/L):	A12705B: 250 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A12705B SC		
Analytical Method:	Azoxystrobin (Fruit) RAM 305/03; 0.01 mg/kg R230310 (Fruit) RAM 305/03; 0.01 mg/kg		
Recovery data:	Azoxystrobin Mean = 90% RSD = N/A (n = 2 in 0.01 - 1 spiking range) R230310 Mean = 89% RSD = N/A (n = 2 in 0.01 - 0.1 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	**(2) Commodity / Variety (a)**	**(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)**	**(4) Method of Treatment**	**(5) Application rate per treatment**			**(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)**	**(7) Growth Stage at Treatment**	**(8) Portion Analyzed**	**(9) Residue found (Uncorrected)**		**(10) PHI (d)**	**(11) Sample Date / Cut Date**	**(12) Trial Details (e)**
				Concentration	**Water**	**Rate Formulation (Additive Type, Rate)**				**Azoxystrobin (mg/kg)**	**R230310 (mg/kg)**			
T009405-07-REG S08-00657-01 France (Europe North) (49650)	Pepper / Denver	1.12 Jun 2008 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	11 Sep 2008/ -	Field SP (max days): 169
T009405-07-REG S08-00657-01 France (Europe North) (49650)	Pepper / Denver	1.12 Jun 2008 2 – 3 -	1. Foliar 2. Foliar	-	1. 1044.74 L/ha 2. 955.26 L/ha	1. 272.7 g ai/ha 2. 228.3 g ai/ha A12705B (-)	1. 01 Sep 2008 2. 08 Sep 2008 (7)	1. BBCH 81 2. BBCH 81-85	Fruit	0.19 mg/kg	< 0.01 mg/kg	0	08 Sep 2008/ -	Field SP (max days): 172

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
T009405-07-REG S08-00657-01 France (Europe North) (49650)	Pepper / Denver	1.12 Jun 2008 2 – 3 -	1. Foliar 2. Foliar	-	1. 1044.74 L/ha 2. 955.26 L/ha	1. 272.7 g ai/ha 2. 228.3 g ai/ha A12705B (-)	1. 01 Sep 2008 2. 08 Sep 2008 (7)	1. BBCH 81 2. BBCH 81-85	Fruit	0.3 mg/kg	< 0.01 mg/kg	1	09 Sep 2008/ -	Field SP (max days): 172
T009405-07-REG S08-00657-01 France (Europe North) (49650)	Pepper / Denver	1.12 Jun 2008 2 – 3 -	1. Foliar 2. Foliar	-	1. 1044.74 L/ha 2. 955.26 L/ha	1. 272.7 g ai/ha 2. 228.3 g ai/ha A12705B (-)	1. 01 Sep 2008 2. 08 Sep 2008 (7)	1. BBCH 81 2. BBCH 81-85	Fruit	0.17 mg/kg	< 0.01 mg/kg	3	11 Sep 2008/ -	Field SP (max days): 172

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(c) Year must be indicated

(d) Minimum number of 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.

(*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^) PHI calculated using cut date

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period

A 2.1.3.2.3 Study 3 (Report No. FSGD-064-REG) (EU reviewed)

Comments of zRMS:	The study has been reviewed at EU level.

Reference:	KCA1 6.3
Report:	Render K. (2010) Azoxystrobin - Residue Study on Peppers in Northern France in 2009 Syngenta Report No. FSGD-064-REG Syngenta File No. VV-393718 Unpublished
Guideline(s):	FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials (Rome, 1990) Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document) Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2), 1996
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 13: Summary of the study 3 trials

Field Trials, Crop Residue (Summary): Azoxystrobin - Residue study on Peppers in northern France in 2009			
Active Substance (common name):	Azoxystrobin	**Commercial Product (name):**	
Crop/Crop Group:	Pepper, Bell	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	France	**Other active substance in the formulation (common name and content):**	None
Content of active substance (g/kg or g/L):	A12705B: 250 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A12705B SC		
Analytical Method:	Azoxystrobin (Fruit) RAM 305/03; 0.01 mg/kg R230310 (Fruit) RAM 305/03; 0.01 mg/kg		
Recovery data:	Azoxystrobin Fruit Mean = 87% RSD = 9% (n = 2 in 0.01 - 1 spiking range) R230310 Fruit Mean = 89% RSD = 1% (n = 2 in 0.01 - 0.1 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
FSGD-064-REG S09-01447-01 France (Europe North) (-)	Pepper, Bell / Denver	1.19 May 2009 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	17 Aug 2009/ -	Field SP (max days): 61
FSGD-064-REG S09-01447-01 France (Europe North) (-)	Pepper, Bell / Denver	1.19 May 2009 2 – 3 -	1. Foliar 2. Foliar	-	1. 962 L/ha 2. 1035 L/ha	1. 241 g ai/ha 2. 259 g ai/ha A12705B (-)	1. 07 Aug 2009 2. 14 Aug 2009 (7)	1. BBCH 73-74 2. BBCH 75-76	Fruit	<u>0.21 mg/kg</u>	< 0.01 mg/kg	3	17 Aug 2009/ -	Field SP (max days): 61

(a) According to Codex (or other e.g. EU) classification

(*) Indicates sample taken prior to application

(b) Only if relevant

(c) Year must be indicated

(d) Minimum number of 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.

(#) Indicates corrected Residue values

(^) PHI calculated using cut date

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period

A 2.1.3.3 Cucumber and zucchini (courgette)

Table A 14: 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)
cGAP N-EU (Art. 12, EFSA, 2013)	2	250 g a.s./ha	8-12	-	3
cGAP S-EU (Art. 12, EFSA, 2013)	4	250 g a.s./ha	-	-	3
Intended cGAP A22773A – CZ-1, CZ-2, CZ-3, HU-2, HU-3, PL-1, PL-2, PL-3, RO-2, RO-3, SK-1, SK-2, SI-2, SI-3 Extrapolated to zucchini: CZ-15, CZ-16, CZ-17, HU-16, HU-17, HU-18, PL-4, PL-5, PL-6, RO-16, RO-17, RO-18, SK-17, SK-18, SI-21, SI-22, SI-23*	2	250 g a.s./ha	7	BBCH 11-89	3

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
** Timing of applications determined primarily by growth stage
*** Minimum PHI

A 2.1.3.3.1 Study 1 (Report No. 684120) (New data)

<table>
<tr><td>Comments of zRMS:</td><td>
Eight residue field trials on cucumbers were conducted in Northern Europe during 2020.
Azoxystrobin and oxathiapiprolin were applied to cucumbers as A22773A, a suspension concentrate (SC) formulation containing nominally 250 g of azoxystrobin per litre and 12 g of oxathiapiprolin per litre. To treated plot P2, two applications, separated by a 6-8 day interval, were made at a nominal rate of 250 g ai/ha for azoxystrobin and 12 g ai/ha for oxathiapiprolin.
For the harvest trials, following the applications, treated samples of cucumber fruit were collected at normal commercial harvest (NCH), 3 days after last application (DALA). Untreated cucumber fruit samples were collected at 3 DALA (NCH).
For the decline trials, following the applications, treated samples of cucumber fruit were collected at 0, 1, 3 (NCH) and 6-8 DALA. Untreated cucumber fruit samples were collected at 3 DALA (NCH).
Samples were analysed for azoxystrobin and it’s z-isomer R230310 using method RAM 305/03, and oxathiapiprolin using method Dupont-30422, Supplement No. 1.
<table>
<tr><th>Actual Sampling Interval (days)</th><th>Azoxystrobin Residues in the range (mg/kg)</th><th>R230310 Residues in the range (mg/kg)</th><th>Oxathiapiprolin Residues in the range (mg/kg)</th></tr>
<tr><td colspan="4">Treated Plot (P2): at a rate of 2 x 250 g ai/ha for azoxystrobin, 2 x 12 g ai/ha for oxathiapiprolin</td></tr>
<tr><td colspan="4">Cucumber fruit</td></tr>
<tr><td>0 DALA</td><td><0.01 – 0.15</td><td><0.01</td><td><0.01 – 0.01</td></tr>
<tr><td>1 DALA</td><td>0.01 – 0.25</td><td><0.01</td><td><0.01 – 0.02</td></tr>
<tr><td>3 DALA (NCH)</td><td><0.01 – 0.12</td><td><0.01</td><td><0.01</td></tr>
<tr><td>6-8 DALA</td><td>0.01 – 0.06</td><td><0.01</td><td><0.01</td></tr>
<tr><td colspan="4">Control plot (C1)
No residues of azoxystrobin, R230310 or oxathiapiprolin at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in any of the untreated cucumber samples, Except the following;
The detected residue of azoxystrobin for sample 005 for Trial 8 was above the LOQ therefore the primary sample (005) and spare sample (006) were re-analysed in duplicate. The three residue values detected in the primary sample (005) were 0.03 mg/kg and the two residue values detected in the spare sample (006) were also 0.03 mg/kg. All detected values from acceptable analysis are detailed in section 4.1.</td></tr>
</table>
DALA = days after last application to the treated plot; NCH = normal commercial harvest
The study is acceptable.
</td></tr>
</table>

Reference:	KCA1 6.3
Report:	Giles A. (2021) Azoxystrobin/Oxathiapiprolin – Residue Study on Cucumber in North France, The Netherlands, Belgium, Germany, Poland and Czech Republic, Initiated in 2020 Syngenta Report No. 684120 Syngenta File No. VV-896693 Unpublished
Guideline(s):	Commission of the European Communities, General Recommendations for the Design, Preparation and Realisation of Residue Trials; 7029/VI/95 (rev. 5, working document) Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009

	OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50 OECD Guidance Document on Overview of Residue Chemistry Studies (as revised 2009), Series on Testing and Assessment (No. 64) and Series on Pesticides (No. 32), ENV/JM/MONO(2009)31 OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, adopted 7-Sep-2009 European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000) Guideline on Pesticide Residue Analytical Methods, SANCO/825/00 revision 8.1 (Nov 2010) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32). OECD (2011) Guidance Document on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66).
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 15: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) : Azoxystrobin/Oxathiapiprolin – Residue Study on Cucumber in North France, The Netherlands, Belgium, Germany, Poland and Czech Republic, Initiated in 2020			
Active Substance (common name):	azoxystrobin	**Commercial Product (name):**	
Crop/Crop Group:	Cucumber	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	GERMANY, POLAND, FRANCE, BELGIUM, CZECHIA, NETHERLANDS	**Other active substance in the formulation (common name and content):**	A22773A: oxathiapiprolin (12 g/L)
Content of active substance (g/kg or g/L):	A22773A: 250 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A22773A SC		
Analytical Method:	Azoxystrobin (Fruit) RAM 305/03; 0.01 mg/kg R230310 (Fruit) RAM 305/03; 0.01 mg/kg		
Recovery data:	Azoxystrobin Fruit Mean = 80% RSD = 7% (n = 19 in 0.01 - 0.5 spiking range) R230310 Fruit Mean = 81% RSD = 6% (n = 19 in 0.01 - 0.5 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
684120 684120 Trial 1 FRANCE (Europe North) (59450)	Cucumber / Gynial	1.03 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	17 Aug 2020/ -	Field SP (max days): 116
684120 684120 Trial 1 FRANCE (Europe North) (59450)	Cucumber / Gynial	1.03 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 606.6043 L/ha 2. 586.3357 L/ha	1. 252.4572 g ai/ha 2. 244.02179 g ai/ha A22773A (-)	1. 06 Aug 2020 2. 14 Aug 2020 (8)	1. BBCH 65-71 2. BBCH 72-76	Fruit	0.01 mg/kg	< 0.01 mg/kg	3	17 Aug 2020/ -	Field SP (max days): 116

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
684120 684120 Trial 2 BELGIUM (Europe North) (3470)	Cucumber / Delikateß	1.12 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	13 Aug 2020/ -	Field SP (max days): 120
684120 684120 Trial 2 BELGIUM (Europe North) (3470)	Cucumber / Delikateß	1.12 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 474.7556 L/ha 2. 492.5333 L/ha	1. 236.904 g ai/ha 2. 245.7751 g ai/ha A22773A (-)	1. 03 Aug 2020 2. 10 Aug 2020 (7)	1. BBCH 74- 2. BBCH 78-	Fruit	0.07 mg/kg	< 0.01 mg/kg	3	13 Aug 2020/ -	Field SP (max days): 120
684120 684120 Trial 3 POLAND (Europe North) (47-270)	Cucumber / Octopus	1.19 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	24 Jul 2020/ -	Field SP (max days): 140
684120 684120 Trial 3 POLAND (Europe North) (47-270)	Cucumber / Octopus	1.19 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 548.5787 L/ha 2. 622.4453 L/ha	1. 228.3001 g ai/ha 2. 259.04092 g ai/ha A22773A (-)	1. 13 Jul 2020 2. 21 Jul 2020 (8)	1. BBCH 71-72 2. BBCH 73-75	Fruit	0.03 mg/kg	< 0.01 mg/kg	3	24 Jul 2020/ -	Field SP (max days): 140

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
684120 684120 Trial 4 CZECHIA (Europe North) (69671)	Cucumber / Othello	1.05 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	02 Aug 2020/ -	Field SP (max days): 131
684120 684120 Trial 4 CZECHIA (Europe North) (69671)	Cucumber / Othello	1.05 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 604.312 L/ha 2. 614.712 L/ha	1. 251.4944 g ai/ha 2. 255.8226 g ai/ha A22773A (-)	1. 23 Jul 2020 2. 30 Jul 2020 (7)	1. BBCH 72- 2. BBCH 73-	Fruit	0.02 mg/kg	< 0.01 mg/kg	3	02 Aug 2020/ -	Field SP (max days): 131
684120 684120 Trial 5 NETHERLANDS (Europe North) (6599)	Cucumber / Vorgebirgstrauben	1.12 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	31 Jul 2020/ -	Field SP (max days): 133
684120 684120 Trial 5 NETHERLANDS (Europe North) (6599)	Cucumber / Vorgebirgstrauben	1.12 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 523.015 L/ha 2. 484.6667 L/ha	1. 263.9157 g ai/ha 2. 241.8496 g ai/ha A22773A (-)	1. 20 Jul 2020 2. 28 Jul 2020 (8)	1. BBCH 73- 2. BBCH 77-	Fruit	< 0.01 mg/kg	< 0.01 mg/kg	0	28 Jul 2020/ -	Field SP (max days): 136

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
684120 684120 Trial 5 NETHERLANDS (Europe North) (6599)	Cucumber / Vorgebirgstrauben	1.12 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 523.015 L/ha 2. 484.6667 L/ha	1. 263.9157 g ai/ha 2. 241.8496 g ai/ha A22773A (-)	1. 20 Jul 2020 2. 28 Jul 2020 (8)	1. BBCH 73- 2. BBCH 77-	Fruit	0.01 mg/kg	< 0.01 mg/kg	1	29 Jul 2020/ -	Field SP (max days): 136
684120 684120 Trial 5 NETHERLANDS (Europe North) (6599)	Cucumber / Vorgebirgstrauben	1.12 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 523.015 L/ha 2. 484.6667 L/ha	1. 263.9157 g ai/ha 2. 241.8496 g ai/ha A22773A (-)	1. 20 Jul 2020 2. 28 Jul 2020 (8)	1. BBCH 73- 2. BBCH 77-	Fruit	0.01 mg/kg	< 0.01 mg/kg	3	31 Jul 2020/ -	Field SP (max days): 136
684120 684120 Trial 5 NETHERLANDS (Europe North) (6599)	Cucumber / Vorgebirgstrauben	1.12 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 523.015 L/ha 2. 484.6667 L/ha	1. 263.9157 g ai/ha 2. 241.8496 g ai/ha A22773A (-)	1. 20 Jul 2020 2. 28 Jul 2020 (8)	1. BBCH 73- 2. BBCH 77-	Fruit	0.01 mg/kg	< 0.01 mg/kg	6	03 Aug 2020/ -	Field SP (max days): 136
684120 684120 Trial 6 GERMANY (Europe North) (46342)	Cucumber / Vorgebirgstrauben	1.02 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	09 Aug 2020/ -	Field SP (max days): 124

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
684120 684120 Trial 6 GERMANY (Europe North) (46342)	Cucumber / Vorgebirgstrauben	1.02 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 523.015 L/ha 2. 514.6667 L/ha	1. 263.9157 g ai/ha 2. 256.8197 g ai/ha A22773A (-)	1. 30 Jul 2020 2. 06 Aug 2020 (7)	1. BBCH 71- 2. BBCH 73-	Fruit	0.07 mg/kg	< 0.01 mg/kg	0	06 Aug 2020/ -	Field SP (max days): 127
684120 684120 Trial 6 GERMANY (Europe North) (46342)	Cucumber / Vorgebirgstrauben	1.02 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 523.015 L/ha 2. 514.6667 L/ha	1. 263.9157 g ai/ha 2. 256.8197 g ai/ha A22773A (-)	1. 30 Jul 2020 2. 06 Aug 2020 (7)	1. BBCH 71- 2. BBCH 73-	Fruit	0.03 mg/kg	< 0.01 mg/kg	1	07 Aug 2020/ -	Field SP (max days): 127
684120 684120 Trial 6 GERMANY (Europe North) (46342)	Cucumber / Vorgebirgstrauben	1.02 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 523.015 L/ha 2. 514.6667 L/ha	1. 263.9157 g ai/ha 2. 256.8197 g ai/ha A22773A (-)	1. 30 Jul 2020 2. 06 Aug 2020 (7)	1. BBCH 71- 2. BBCH 73-	Fruit	0.04 mg/kg	< 0.01 mg/kg	3	09 Aug 2020/ -	Field SP (max days): 127
684120 684120 Trial 6 GERMANY (Europe North) (46342)	Cucumber / Vorgebirgstrauben	1.02 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 523.015 L/ha 2. 514.6667 L/ha	1. 263.9157 g ai/ha 2. 256.8197 g ai/ha A22773A (-)	1. 30 Jul 2020 2. 06 Aug 2020 (7)	1. BBCH 71- 2. BBCH 73-	Fruit	0.02 mg/kg	< 0.01 mg/kg	8	14 Aug 2020/ -	Field SP (max days): 127

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
684120 684120 Trial 7 GERMANY (Europe North) (96157)	Cucumber / Diamant F1	1.05 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	10 Aug 2020/ -	Field SP (max days): 123
684120 684120 Trial 7 GERMANY (Europe North) (96157)	Cucumber / Diamant F1	1.05 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 602.244 L/ha 2. 578.644 L/ha	1. 250.4405 g ai/ha 2. 240.6266 g ai/ha A22773A (-)	1. 31 Jul 2020 2. 07 Aug 2020 (7)	1. BBCH 69- 2. BBCH 74-	Fruit	0.15 mg/kg	< 0.01 mg/kg	0	07 Aug 2020/ -	Field SP (max days): 126
684120 684120 Trial 7 GERMANY (Europe North) (96157)	Cucumber / Diamant F1	1.05 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 602.244 L/ha 2. 578.644 L/ha	1. 250.4405 g ai/ha 2. 240.6266 g ai/ha A22773A (-)	1. 31 Jul 2020 2. 07 Aug 2020 (7)	1. BBCH 69- 2. BBCH 74-	Fruit	0.19 mg/kg	< 0.01 mg/kg	1	08 Aug 2020/ -	Field SP (max days): 126
684120 684120 Trial 7 GERMANY (Europe North) (96157)	Cucumber / Diamant F1	1.05 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 602.244 L/ha 2. 578.644 L/ha	1. 250.4405 g ai/ha 2. 240.6266 g ai/ha A22773A (-)	1. 31 Jul 2020 2. 07 Aug 2020 (7)	1. BBCH 69- 2. BBCH 74-	Fruit	0.03 mg/kg	< 0.01 mg/kg	3	10 Aug 2020/ -	Field SP (max days): 126

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
684120 684120 Trial 7 GERMANY (Europe North) (96157)	Cucumber / Diamant F1	1.05 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 602.244 L/ha 2. 578.644 L/ha	1. 250.4405 g ai/ha 2. 240.6266 g ai/ha A22773A (-)	1. 31 Jul 2020 2. 07 Aug 2020 (7)	1. BBCH 69- 2. BBCH 74-	Fruit	0.06 mg/kg	< 0.01 mg/kg	7	14 Aug 2020/ -	Field SP (max days): 126
684120 684120 Trial 8 POLAND (Europe North) (62-001)	Cucumber / Krak	1.12 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	0.03 mg/kg, 0.03 mg/kg, 0.03 mg/kg (Mean=0.03 mg/kg)	< 0.01 mg/kg, < 0.01 mg/kg, < 0.01 mg/kg (Mean=0.01 mg/kg)	3	30 Jul 2020/ -	Field SP (max days): 134
684120 684120 Trial 8 POLAND (Europe North) (62-001)	Cucumber / Krak	1.12 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	0.03 mg/kg, 0.03 mg/kg (Mean=0.03 mg/kg)	< 0.01 mg/kg, < 0.01 mg/kg (Mean=0.01 mg/kg)	3	30 Jul 2020/ -	Field SP (max days): 134
684120 684120 Trial 8 POLAND (Europe North) (62-001)	Cucumber / Krak	1.12 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 622.333 L/ha 2. 623.333 L/ha	1. 258.8093 g ai/ha 2. 259.2252 g ai/ha A22773A (-)	1. 21 Jul 2020 2. 27 Jul 2020 (6)	1. BBCH 71- 2. BBCH 73-	Fruit	0.09 mg/kg	< 0.01 mg/kg	0	27 Jul 2020/ -	Field SP (max days): 137

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
684120 684120 Trial 8 POLAND (Europe North) (62-001)	Cucumber / Krak	1.12 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 622.333 L/ha 2. 623.333 L/ha	1. 258.8093 g ai/ha 2. 259.2252 g ai/ha A22773A (-)	1. 21 Jul 2020 2. 27 Jul 2020 (6)	1. BBCH 71- 2. BBCH 73-	Fruit	0.25 mg/kg	< 0.01 mg/kg	1	28 Jul 2020/ -	Field SP (max days): 137
684120 684120 Trial 8 POLAND (Europe North) (62-001)	Cucumber / Krak	1.12 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 622.333 L/ha 2. 623.333 L/ha	1. 258.8093 g ai/ha 2. 259.2252 g ai/ha A22773A (-)	1. 21 Jul 2020 2. 27 Jul 2020 (6)	1. BBCH 71- 2. BBCH 73-	Fruit	<u>0.12 mg/kg</u>	< 0.01 mg/kg	3	30 Jul 2020/ -	Field SP (max days): 137
684120 684120 Trial 8 POLAND (Europe North) (62-001)	Cucumber / Krak	1.12 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 622.333 L/ha 2. 623.333 L/ha	1. 258.8093 g ai/ha 2. 259.2252 g ai/ha A22773A (-)	1. 21 Jul 2020 2. 27 Jul 2020 (6)	1. BBCH 71- 2. BBCH 73-	Fruit	0.06 mg/kg	< 0.01 mg/kg	7	03 Aug 2020/ -	Field SP (max days): 137

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of 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.

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value
(DBA) Days Before Application
SP (max days): Maximum storage period

A 2.1.3.3.2 Study 2 (Report No. NC10010-10-REG) (EU reviewed)

Comments of zRMS:	The study has been reviewed at EU level.

Reference:	KCA1 6.3
Report:	Andrew G. (2011) Azoxystrobin - Residue Study on Gherkin in Northern France and Germany in 2010 Syngenta Report No. NC10010-10-REG Syngenta File No. VV-396617 Unpublished
Guideline(s):	FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials (Rome, 1990). Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document). Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2), 1996.
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 16: Summary of the study 2 trials

Field Trials, Crop Residue (Summary): Azoxystrobin - Residues study on gherkin in northern France and Germany 2010			
Active Substance (common name):	Azoxystrobin	**Commercial Product (name):**	-
Crop/Crop Group:	Gherkin	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	Germany, France	**Other active substance in the formulation (common name and content):**	A12705B: Azoxystrobin
Content of active substance (g/kg or g/L):	A12705B	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A12705B SC		
Analytical Method:	Azoxystrobin (Fruit) RAM 305/03; 0.01 mg/kg R230310 (Fruit) RAM 305/03; 0.01 mg/kg		
Recovery data:	Azoxystrobin Mean = 89% RSD = 8% (n = 4 in 0.01 - 0.1 spiking range) R230310 Mean = 98% RSD = 8% (n = 4 in 0.01 - 0.1 spiking range)		

(1) Report No.Trial No.Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date/Cut Date (d)	(12) Trial Details (e)
				Conc'n	**Water**	**Rate Formulation (Additive Type, Rate)**				**Azoxystrobin**			
NC10010-10-REG S10-00361-02 France (Europe North) (-)	Gherkin (Vert De Paris)	1. 06 Aug 2010 2. 30 Aug 2010 3. Oct	-	-	-	- (-)	- (-)	-	Fruit	< 0.01 mg/kg	3	11 Oct 2010	Field SP (max days): 87
			foliar	-	1207 L/ha 1196 L/ha 1207 L/ha	301 g ai/ha 299 g ai/ha 301 g ai/ha A12705B (-)	22 Sep 2010 30 Sep 2010 08 Oct 2010 (8, 8)	BBCH 65-71 BBCH 65-71 BBCH 65-79	Fruit	0.12 mg/kg	0	08 Oct 2010	Field SP (max days): 90
									Fruit	0.10 mg/kg	1	09 Oct 2010	
									Fruit	0.11 mg/kg	3	11 Oct 2010	

(1) Report No.Trial No.Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date/Cut Date (d)	(12) Trial Details (e)
				Conc'n	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin			
NC10010-10-REG S10-00361-01 Germany (Europe North) (-)	Gherkin (Amba)	1.21 Apr 2010 2 – 3. Aug-Oct	-	-	-	- (-)	- (-)	-	Fruit	< 0.01 mg/kg	3	05 Sep 2010	Field SP (max days): 123
			foliar	-	1220 L/ha 1216 L/ha 1211 L/ha	305 g ai/ha 304 g ai/ha 303 g ai/ha A12705B (-)	18 Aug 2010 27 Aug 2010 02 Sep 2010 (6, 9)	BBCH 75-82 BBCH 75-82 BBCH 76-82	Fruit	0.31 mg/kg	0	02 Sep 2010	Field SP (max days): 126
									Fruit	0.22 mg/kg	1	03 Sep 2010	
									Fruit	0.08 mg/kg	3	05 Sep 2010	

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of 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.

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value
(DBA) Days Before Application
SP (max days): Maximum storage period

A 2.1.3.3.3 Study 3 (Report No. T001092-09-REG) (EU reviewed)

Comments of zRMS:	The study has been reviewed at EU level.

Reference:	KCA1 6.3
Report:	Seck C. (2010) Azoxystrobin - Residue Study on Gherkin in Northern France and Germany in 2009 Syngenta Report No. T001092-09-REG Syngenta File No. VV-393207 Unpublished
Guideline(s):	Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document). Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2), 1996.
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 17: Summary of the study 3 trials

Field Trials, Crop Residue (Summary) :Azoxystrobin - Residue study on Gherkin in northern France and Germany in 2009			
Active Substance (common name):	Azoxystrobin	**Commercial Product (name):**	-
Crop/Crop Group:	Gherkin	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	France, Germany	**Other active substance in the formulation (common name and content):**	A12705B: Azoxystrobin
Content of active substance (g/kg or g/L):	A12705B	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A12705B SC		
Analytical Method:	Azoxystrobin (Fruit) RAM 305/03; 0.01 mg/kg		
Recovery data:	Azoxystrobin Mean = 99% RSD = 10% (n = 2 in 0.01 - 0.1 spiking range)		

(1) Report No.Trial No.Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date/Cut Date (d)	(12) Trial Details (e)
				Conc'n	Water	Rate Formulation (Additive Type,Rate)				Azoxystrobin			
T001092-09-REG S09-01441-01 France (Europe North) (49350)	Gherkin (Vert Petit De Paris)	1.01 Jun 2009 2 – 3 -	-	-	-	- (-)	- (-)	-	Fruit	< 0.01 mg/kg	3	16 Aug 2009	Field SP (max days): 87
			foliar	-	1171.666 L/ha 1200 L/ha 1233.333 L/ha	300 g ai/ha 293 g ai/ha 308 g ai/ha A12705B (-)	05 Aug 2009 13 Aug 2009 28 Jul 2009 (8, 8)	BBCH 85-86 BBCH 86-87 BBCH 73-74	Fruit	0.23 mg/kg	0	13 Aug 2009	Field SP (max days): 90
									Fruit	0.31 mg/kg	1	14 Aug 2009	
									Fruit	<u>0.19 mg/kg</u>	3	16 Aug 2009	

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of 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.

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value
(DBA) Days Before Application
SP (max days): Maximum storage period

A 2.1.3.3.4 Study 4 (Report No. RJ2589B) (New data)

Comments of zRMS:	Two trials on gherkins were conducted in Niedersachsen and Nordrhein-Westfalen between July and October 1997. In this study azoxystrobin was applied as ‘Ortiva', a suspension concentrate formulation (SC) containing 250 g/L azoxystrobin, for the control of fungi. Four applications of azoxystrobin were applied at 250 g ai/ha. Samples of the crop were taken 3 days after the final treatment and were analysed for azoxystrobin and its Z-isomer (R230310). Azoxystrobin residues in treated gherkins 3 days after the final application to trial RS-9703-B1 were 0.04 mg/kg. Azoxystrobin residues in treated gherkins 3 days after the final application to trial RS-9703-H1 were 0.05 mg/kg. No residues of azoxystrobin were found in control samples above the limit of quantication of the method (0.01 mg/kg). No measurable residues of the Z isomer were detected in any of the samples. Samples were stored frozen for up to 9 months prior to analysis. The study is acceptable.

Reference:	KCA1 6.3
Report:	Gill J.P., Chamier O.D. (1998) Azoxystrobin - Residue Levels in Gherkins from a study carried out in Germany during 1997 Syngenta Report No. RJ2589B Syngenta File No. VV-377471 Unpublished
Guideline(s):	European Council Directive 91/414/EEC
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 18: Summary of the study 4 trials

Field Trials, Crop Residue (Summary) : Azoxystrobin: Residue Levels in Gherkins from a Study Carried Out in Germany during 1997.			
Active Substance (common name):	Azoxystrobin	**Commercial Product (name):**	
Crop/Crop Group:	Gherkin	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	Germany	**Other active substance in the formulation (common name and content):**	None
Content of active substance (g/kg or g/L):	YF9247: 250 g/L	**Residues calculated as:**	
Formulation (e.g. WP):	YF9247 SC		
Analytical Method:	Azoxystrobin (Fruit) SOP RAM 243/05; 0.01 mg/kg R230310 (Fruit) SOP RAM 243/05; 0.01 mg/kg		
Recovery data:	Azoxystrobin Fruit Mean = 100% RSD = 3% (n = 4 in 0.05 - 0.05 spiking range) R230310 Fruit Mean = 109% RSD = 2% (n = 4 in 0.05 - 0.05 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
RJ2589B RS-9703-B1 Germany (Europe North) (D-29562)	Gherkin / Othello	1.10 Jun 1997 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg #	< 0.01 mg/kg #	3	04 Aug 1997/ -	Field SP (max days): 170
RJ2589B RS-9703-B1 Germany (Europe North) (D-29562)	Gherkin / Othello	1.10 Jun 1997 2 – 3 -	1. Foliar 2. Foliar 3. Foliar 4. Foliar	-	1. 600 L/ha 2. 600 L/ha 3. 600 L/ha 4. 600 L/ha	1. 250 g ai/ha 2. 250 g ai/ha 3. 250 g ai/ha 4. 250 g ai/ha YF9247 (-)	1. 11 Jul 1997 2. 18 Jul 1997 3. 25 Jul 1997 4. 01 Aug 1997 (7, 7, 7)	1. BBCH 31 2. BBCH 51 3. BBCH 65 4. BBCH 75	Fruit	0.04 mg/kg #	< 0.01 mg/kg #	3	04 Aug 1997/ -	Field SP (max days): 170

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
RJ2589B RS-9703-H1 Germany (Europe North) (D-41812)	Gherkin / Duet	1.01 May 1997 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg #, < 0.01 mg/kg # (Mean=0.01 mg/kg)	< 0.01 mg/kg #, < 0.01 mg/kg # (Mean=0.01 mg/kg)	3	05 Aug 1997/ -	Field SP (max days): 274
RJ2589B RS-9703-H1 Germany (Europe North) (D-41812)	Gherkin / Duet	1.01 May 1997 2 – 3 -	1. Foliar 2. Foliar 3. Foliar 4. Foliar	-	1. 600 L/ha 2. 600 L/ha 3. 600 L/ha 4. 600 L/ha	1. 250 g ai/ha 2. 250 g ai/ha 3. 250 g ai/ha 4. 250 g ai/ha YF9247 (-)	1. 10 Jul 1997 2. 18 Jul 1997 3. 26 Jul 1997 4. 02 Aug 1997 (8, 8, 7)	1. BBCH 72-73 2. BBCH 75-76 3. BBCH 78-79 4. BBCH 79	Fruit	0.05 mg/kg #, 0.05 mg/kg # (Mean=0.05 mg/kg)	< 0.01 mg/kg #, < 0.01 mg/kg # (Mean=0.01 mg/kg)	3	05 Aug 1997/ -	Field SP (max days): 274

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of 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.

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value
(DBA) Days Before Application
SP (max days): Maximum storage period

A 2.1.3.3.5 Study 5 (Report No. T011466-06-REG) (EU reviewed)

Comments of zRMS:	The study has been reviewed at EU level.

Reference:	KCA1 6.3
Report:	Heillaut C. (2008) Azoxystrobin (ICI5504) and Difenoconazole (CGA169374) – Residue Study on Outdoor Cucumbers in Austria, Belgium and France (North) in 2007 Syngenta Report No. T011466-06-REG Syngenta File No. VV-382145 Unpublished
Guideline(s):	FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials (Rome, 1990). Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document). Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2), 1996.
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 19: Summary of the study 5 trials

Field Trials, Crop Residue (Summary) : Azoxystrobin (ICI5504) and Difenoconazole (CGA169374) - Residue study on outdoor Cucumbers in Austria, Belgium and France (north) in 2007.			
Active Substance (common name):	Azoxystrobin	**Commercial Product (name):**	
Crop/Crop Group:	Cucumber	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	France, Belgium, Austria	**Other active substance in the formulation (common name and content):**	A13703G: Difenoconazole (125 g/L)
Content of active substance (g/kg or g/L):	A13703G: 200 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A13703G SC		
Analytical Method:	Azoxystrobin (Fruit) RAM 305/03; 0.01 mg/kg R230310 (Fruit) RAM 305/03; 0.01 mg/kg		
Recovery data:	Azoxystrobin Fruit Mean = 102% RSD = 9% (n = 4 in 0.01 - 0.5 spiking range) R230310 Fruit Mean = 100% RSD = 13% (n = 4 in 0.01 - 0.5 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
T011466-06-REG AT-FR-07-0038 Austria (Europe North) (7111)	Cucumber / Bestseller F1	1.25 May 2007 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	0	17 Aug 2007/ -	Field SP (max days): 116
T011466-06-REG AT-FR-07-0038 Austria (Europe North) (7111)	Cucumber / Bestseller F1	1.25 May 2007 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	20 Aug 2007/ -	Field SP (max days): 116

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
T011466-06-REG AT-FR-07-0038 Austria (Europe North) (7111)	Cucumber / Bestseller F1	1.25 May 2007 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 416 L/ha 2. 393 L/ha 3. 416 L/ha	1. 207.9 g ai/ha 2. 196.4 g ai/ha 3. 207.9 g ai/ha A13703G (-)	1. 01 Aug 2007 2. 08 Aug 2007 3. 17 Aug 2007 (7, 9)	1. BBCH 65-71 2. BBCH 71 3. BBCH 72	Fruit	< 0.01 mg/kg	< 0.01 mg/kg	0	17 Aug 2007/ -	Field SP (max days): 116
T011466-06-REG AT-FR-07-0038 Austria (Europe North) (7111)	Cucumber / Bestseller F1	1.25 May 2007 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 416 L/ha 2. 393 L/ha 3. 416 L/ha	1. 207.9 g ai/ha 2. 196.4 g ai/ha 3. 207.9 g ai/ha A13703G (-)	1. 01 Aug 2007 2. 08 Aug 2007 3. 17 Aug 2007 (7, 9)	1. BBCH 65-71 2. BBCH 71 3. BBCH 72	Fruit	0.04 mg/kg	< 0.01 mg/kg	0	17 Aug 2007/ -	Field SP (max days): 116
T011466-06-REG AT-FR-07-0038 Austria (Europe North) (7111)	Cucumber / Bestseller F1	1.25 May 2007 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 416 L/ha 2. 393 L/ha 3. 416 L/ha	1. 207.9 g ai/ha 2. 196.4 g ai/ha 3. 207.9 g ai/ha A13703G (-)	1. 01 Aug 2007 2. 08 Aug 2007 3. 17 Aug 2007 (7, 9)	1. BBCH 65-71 2. BBCH 71 3. BBCH 72	Fruit	0.03 mg/kg	< 0.01 mg/kg	1	18 Aug 2007/ -	Field SP (max days): 116

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
T011466-06-REG AT-FR-07-0038 Austria (Europe North) (7111)	Cucumber / Bestseller F1	1.25 May 2007 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 416 L/ha 2. 393 L/ha 3. 416 L/ha	1. 207.9 g ai/ha 2. 196.4 g ai/ha 3. 207.9 g ai/ha A13703G (-)	1. 01 Aug 2007 2. 08 Aug 2007 3. 17 Aug 2007 (7, 9)	1. BBCH 65-71 2. BBCH 71 3. BBCH 72	Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	20 Aug 2007/ -	Field SP (max days): 116
T011466-06-REG BE-FR-07-0039 Belgium (Europe North) (6210)	Cucumber / Sensation	1.12 Jul 2007 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	0	13 Sep 2007/ -	Field SP (max days): 89
T011466-06-REG BE-FR-07-0039 Belgium (Europe North) (6210)	Cucumber / Sensation	1.12 Jul 2007 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	16 Sep 2007/ -	Field SP (max days): 89

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
T011466-06-REG BE-FR-07-0039 Belgium (Europe North) (6210)	Cucumber / Sensation	1.12 Jul 2007 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 507 L/ha 2. 500 L/ha 3. 507 L/ha	1. 202.7 g ai/ha 2. 200 g ai/ha 3. 202.7 g ai/ha A13703G (-)	1. 28 Aug 2007 2. 05 Sep 2007 3. 13 Sep 2007 (8, 8)	1. BBCH 84 2. BBCH 87 3. BBCH 88-89	Fruit	0.1 mg/kg	< 0.01 mg/kg	0	13 Sep 2007/ -	Field SP (max days): 89
T011466-06-REG BE-FR-07-0039 Belgium (Europe North) (6210)	Cucumber / Sensation	1.12 Jul 2007 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 507 L/ha 2. 500 L/ha 3. 507 L/ha	1. 202.7 g ai/ha 2. 200 g ai/ha 3. 202.7 g ai/ha A13703G (-)	1. 28 Aug 2007 2. 05 Sep 2007 3. 13 Sep 2007 (8, 8)	1. BBCH 84 2. BBCH 87 3. BBCH 88-89	Fruit	0.27 mg/kg	< 0.01 mg/kg	0	13 Sep 2007/ -	Field SP (max days): 89
T011466-06-REG BE-FR-07-0039 Belgium (Europe North) (6210)	Cucumber / Sensation	1.12 Jul 2007 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 507 L/ha 2. 500 L/ha 3. 507 L/ha	1. 202.7 g ai/ha 2. 200 g ai/ha 3. 202.7 g ai/ha A13703G (-)	1. 28 Aug 2007 2. 05 Sep 2007 3. 13 Sep 2007 (8, 8)	1. BBCH 84 2. BBCH 87 3. BBCH 88-89	Fruit	0.22 mg/kg	< 0.01 mg/kg	1	14 Sep 2007/ -	Field SP (max days): 89

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
T011466-06-REG BE-FR-07-0039 Belgium (Europe North) (6210)	Cucumber / Sensation	1.12 Jul 2007 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 507 L/ha 2. 500 L/ha 3. 507 L/ha	1. 202.7 g ai/ha 2. 200 g ai/ha 3. 202.7 g ai/ha A13703G (-)	1. 28 Aug 2007 2. 05 Sep 2007 3. 13 Sep 2007 (8, 8)	1. BBCH 84 2. BBCH 87 3. BBCH 88-89	Fruit	0.16 mg/kg	< 0.01 mg/kg	3	16 Sep 2007/ -	Field SP (max days): 89
T011466-06-REG FR-FR-07-0040 France (Europe North) (71570)	Cucumber / Serit	1.29 Jun 2007 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	0	06 Sep 2007/ -	Field SP (max days): 96
T011466-06-REG FR-FR-07-0040 France (Europe North) (71570)	Cucumber / Serit	1.29 Jun 2007 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	09 Sep 2007/ -	Field SP (max days): 96

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
T011466-06-REG FR-FR-07-0040 France (Europe North) (71570)	Cucumber / Serit	1.29 Jun 2007 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 410 L/ha 2. 372 L/ha 3. 397 L/ha	1. 205.1 g ai/ha 2. 186.1 g ai/ha 3. 198.2 g ai/ha A13703G (-)	1. 22 Aug 2007 2. 30 Aug 2007 3. 06 Sep 2007 (8, 7)	1. BBCH 69-72 2. BBCH 73 3. BBCH 75-85	Fruit	0.08 mg/kg	< 0.01 mg/kg	0	06 Sep 2007/ -	Field SP (max days): 96
T011466-06-REG FR-FR-07-0040 France (Europe North) (71570)	Cucumber / Serit	1.29 Jun 2007 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 410 L/ha 2. 372 L/ha 3. 397 L/ha	1. 205.1 g ai/ha 2. 186.1 g ai/ha 3. 198.2 g ai/ha A13703G (-)	1. 22 Aug 2007 2. 30 Aug 2007 3. 06 Sep 2007 (8, 7)	1. BBCH 69-72 2. BBCH 73 3. BBCH 75-85	Fruit	0.2 mg/kg	< 0.01 mg/kg	0	06 Sep 2007/ -	Field SP (max days): 96
T011466-06-REG FR-FR-07-0040 France (Europe North) (71570)	Cucumber / Serit	1.29 Jun 2007 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 410 L/ha 2. 372 L/ha 3. 397 L/ha	1. 205.1 g ai/ha 2. 186.1 g ai/ha 3. 198.2 g ai/ha A13703G (-)	1. 22 Aug 2007 2. 30 Aug 2007 3. 06 Sep 2007 (8, 7)	1. BBCH 69-72 2. BBCH 73 3. BBCH 75-85	Fruit	0.12 mg/kg	< 0.01 mg/kg	1	07 Sep 2007/ -	Field SP (max days): 96

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
T011466-06-REG FR-FR-07-0040 France (Europe North) (71570)	Cucumber / Serit	1.29 Jun 2007 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 410 L/ha 2. 372 L/ha 3. 397 L/ha	1. 205.1 g ai/ha 2. 186.1 g ai/ha 3. 198.2 g ai/ha A13703G (-)	1. 22 Aug 2007 2. 30 Aug 2007 3. 06 Sep 2007 (8, 7)	1. BBCH 69-72 2. BBCH 73 3. BBCH 75-85	Fruit	0.03 mg/kg	< 0.01 mg/kg	3	09 Sep 2007/ -	Field SP (max days): 96
T011466-06-REG FR-FR-07-0041 France (Europe North) (71570)	Cucumber / Gynial	1.29 Jun 2007 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	0	14 Sep 2007/ -	Field SP (max days): 88
T011466-06-REG FR-FR-07-0041 France (Europe North) (71570)	Cucumber / Gynial	1.29 Jun 2007 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	17 Sep 2007/ -	Field SP (max days): 88

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
T011466-06-REG FR-FR-07-0041 France (Europe North) (71570)	Cucumber / Gynial	1.29 Jun 2007 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 382 L/ha 2. 370 L/ha 3. 325 L/ha	1. 218.4 g ai/ha 2. 211.4 g ai/ha 3. 185.5 g ai/ha A13703G (-)	1. 30 Aug 2007 2. 06 Sep 2007 3. 14 Sep 2007 (7, 8)	1. BBCH 73 2. BBCH 75-82 3. BBCH 88	Fruit	< 0.01 mg/kg	< 0.01 mg/kg	0	14 Sep 2007/ -	Field SP (max days): 88
T011466-06-REG FR-FR-07-0041 France (Europe North) (71570)	Cucumber / Gynial	1.29 Jun 2007 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 382 L/ha 2. 370 L/ha 3. 325 L/ha	1. 218.4 g ai/ha 2. 211.4 g ai/ha 3. 185.5 g ai/ha A13703G (-)	1. 30 Aug 2007 2. 06 Sep 2007 3. 14 Sep 2007 (7, 8)	1. BBCH 73 2. BBCH 75-82 3. BBCH 88	Fruit	0.13 mg/kg	< 0.01 mg/kg	0	14 Sep 2007/ -	Field SP (max days): 88
T011466-06-REG FR-FR-07-0041 France (Europe North) (71570)	Cucumber / Gynial	1.29 Jun 2007 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 382 L/ha 2. 370 L/ha 3. 325 L/ha	1. 218.4 g ai/ha 2. 211.4 g ai/ha 3. 185.5 g ai/ha A13703G (-)	1. 30 Aug 2007 2. 06 Sep 2007 3. 14 Sep 2007 (7, 8)	1. BBCH 73 2. BBCH 75-82 3. BBCH 88	Fruit	0.11 mg/kg	< 0.01 mg/kg	1	15 Sep 2007/ -	Field SP (max days): 88

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
T011466-06-REG FR-FR-07-0041 France (Europe North) (71570)	Cucumber / Gynial	1.29 Jun 2007 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 382 L/ha 2. 370 L/ha 3. 325 L/ha	1. 218.4 g ai/ha 2. 211.4 g ai/ha 3. 185.5 g ai/ha A13703G (-)	1. 30 Aug 2007 2. 06 Sep 2007 3. 14 Sep 2007 (7, 8)	1. BBCH 73 2. BBCH 75-82 3. BBCH 88	Fruit	0.14 mg/kg	< 0.01 mg/kg	3	17 Sep 2007/ -	Field SP (max days): 88

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(c) Year must be indicated

(d) Minimum number of 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.

(*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^) PHI calculated using cut date

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period

A 2.1.3.3.6 Study 6 (Report No. T011466-06-REG; FSGD-039-REG) (EU reviewed)

Comments of zRMS:	The study has been reviewed at EU level.

Reference:	KCA1 6.3
Report:	Jones A. (2009) Azoxystrobin and Difenoconazole - Residue Study on Courgette in France (North) in 2008 Syngenta Report No. T011466-06-REG (FSGD-039-REG) Syngenta File No. VV-384994 Unpublished
Guideline(s):	Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029NI/95 (rev. 5, working document).
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 20: Summary of the study 6 trials

Field Trials, Crop Residue (Summary) : Azoxystrobin and Difenoconazole - Residue study on Courgette in France (north) in 2008			
Active Substance (common name):	Azoxystrobin	**Commercial Product (name):**	
Crop/Crop Group:	Courgette	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	France	**Other active substance in the formulation (common name and content):**	A13703G: Difenoconazole (125 g/L)
Content of active substance (g/kg or g/L):	A13703G: 200 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A13703G SC		
Analytical Method:	Azoxystrobin (Fruit) RAM 305/03; 0.01 mg/kg R230310 (Fruit) RAM 305/03; 0.01 mg/kg		
Recovery data:			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
T011466-06-REG S08-02832-01 France (Europe North) (49650)	Courgette / Blitz F1	1.04 Aug 2008 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	< 0.01 mg/kg	3	20 Sep 2008/ -	Field SP (max days): 235
T011466-06 -REG S08-02832-01 France (Europe North) (49650)	Courgette / Blitz F1	1.04 Aug 2008 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 818 L/ha 2. 795 L/ha 3. 768 L/ha	1. 204 g ai/ha 2. 199 g ai/ha 3. 192 g ai/ha A13703G (-)	1. 01 Sep 2008 2. 09 Sep 2008 3. 17 Sep 2008 (8, 8)	1. BBCH 81 2. BBCH 81 3. BBCH 83	Fruit	0.17 mg/kg	< 0.01 mg/kg	0	17 Sep 2008/ -	Field SP (max days): 238

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
T011466-06 -REG S08-02832-01 France (Europe North) (49650)	Courgette / Blitz F1	1.04 Aug 2008 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 818 L/ha 2. 795 L/ha 3. 768 L/ha	1. 204 g ai/ha 2. 199 g ai/ha 3. 192 g ai/ha A13703G (-)	1. 01 Sep 2008 2. 09 Sep 2008 3. 17 Sep 2008 (8, 8)	1. BBCH 81 2. BBCH 81 3. BBCH 83	Fruit	0.16 mg/kg	< 0.01 mg/kg	1	18 Sep 2008/ -	Field SP (max days): 238
T011466-06 -REG S08-02832-01 France (Europe North) (49650)	Courgette / Blitz F1	1.04 Aug 2008 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 818 L/ha 2. 795 L/ha 3. 768 L/ha	1. 204 g ai/ha 2. 199 g ai/ha 3. 192 g ai/ha A13703G (-)	1. 01 Sep 2008 2. 09 Sep 2008 3. 17 Sep 2008 (8, 8)	1. BBCH 81 2. BBCH 81 3. BBCH 83	Fruit	<u>0.08 mg/kg</u>	0.02 mg/kg	3	20 Sep 2008/ -	Field SP (max days): 238

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(c) Year must be indicated

(d) Minimum number of 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.

(*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^) PHI calculated using cut date

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period

A 2.1.3.3.7 Study 7 (Report No. T009543-07-REG) (EU reviewed)

Comments of zRMS:	The study has been reviewed at EU level.

Reference:	KCA1 6.3
Report:	Kelly M. (2011) Azoxystrobin and Difenoconazole - Residue Study on Courgette in Northern France and Austria in 2008 Syngenta Report No. T009543-07-REG Syngenta File No. VV-396787 Unpublished
Guideline(s):	FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials (Rome, 1990) Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document) Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2), 1996
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 21: Summary of the study 7 trials

Field Trials, Crop Residue (Summary) :Azoxystrobin and Difenoconazole - Residue study on Courgette in northern France and Austria in 2008			
Active Substance (common name):	Azoxystrobin	**Commercial Product (name):**	-
Crop/Crop Group:	Courgette	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	France, Austria	**Other active substance in the formulation (common name and content):**	A12705B: Azoxystrobin A13703G: Azoxystrobin
Content of active substance (g/kg or g/L):	A12705B A13703G	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A13703G SC		
Analytical Method:	Azoxystrobin (Fruit) RAM 305/03; 0.01 mg/kg		
Recovery data:	Azoxystrobin Mean = 94% RSD = 9% (n = 9 in 0.01 - 0.5 spiking range)		

(1) Report No.Trial No.Location(Region)(Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI(d)	(11) Sample Date/Cut Date (d)	(12) Trial Details (e)
				Conc'n	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin			
T009543-07-REG SRF08-036-37FR Austria (Europe North) (-)	Courgette (Pixar F1)	1.11 Jun 2008 2 – 3 -	-	-	-	- (-)	- (-)	-	Fruit	< 0.01 mg/kg, < 0.01 mg/kg (Mean = < 0.01 mg/kg)	3	05 Sep 2008	Field SP (max days): 314
			foliar	-	435 L/ha 418.3 L/ha 416.6 L/ha	271.9 g ai/ha 260.4 g ai/ha 261.5 g ai/ha A12705B (-)	15 Aug 2008 24 Aug 2008 02 Sep 2008 (9, 9)	BBCH 65 BBCH 71 BBCH 73	Fruit	0.20 mg/kg	0	02 Sep 2008	Field SP (max days): 317
									Fruit	0.17 mg/kg	1	03 Sep 2008	
									Fruit	0.12 mg/kg	3	05 Sep 2008	
			foliar		415 L/ha 418.3 L/ha	219.1 g ai/ha 209.2 g ai/ha 207.5 g ai/ha	15 Aug 2008 24 Aug 2008 02 Sep 2008	BBCH 65 BBCH 71 BBCH 73	Fruit	0.18 mg/kg	0	02 Sep 2008	Field
									Fruit	0.13 mg/kg	1	03 Sep 2008	

(1) Report No.Trial No.Location(Region)(Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI(d)	(11) Sample Date/Cut Date (d)	(12) Trial Details (e)
				Conc'n	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin			
					438.3 L/ha	A13703G (-)	(9, 9)		Fruit	0.10 mg/kg	3	05 Sep 2008	SP (max days): 317
T009543-07-REG SRF08-013-37FR France (Europe North) (71570)	Courgette (Tarmino)	1.25 Jun 2008 2 – 3 -	-	-	-	- (-)	- (-)	-	Fruit	< 0.01 mg/kg	3	16 Aug 2008	Field SP (max days): 334
			foliar	-	455 L/ha 452 L/ha 459 L/ha	267 g ai/ha 266 g ai/ha 270 g ai/ha A12705B (-)	28 Jul 2008 05 Aug 2008 13 Aug 2008 (8, 8)	BBCH 63 BBCH 71 BBCH 83-86	Fruit	0.13 mg/kg	0	13 Aug 2008	Field SP (max days): 334
									Fruit	0.15 mg/kg	1	14 Aug 2008	
									Fruit	0.05 mg/kg	3	16 Aug 2008	
			foliar	-	434 L/ha 425 L/ha 434 L/ha	204 g ai/ha 199 g ai/ha 218 g ai/ha A13703G (-)	28 Jul 2008 05 Aug 2008 13 Aug 2008 (8, 8)	BBCH 63 BBCH 71 BBCH 83-86	Fruit	0.12 mg/kg	0	13 Aug 2008	Field SP (max days): 334
									Fruit	0.12 mg/kg	1	14 Aug 2008	

(1) Report No.Trial No.Location(Region)(Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI(d)	(11) Sample Date/Cut Date (d)	(12) Trial Details (e)
				Conc'n	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin			
									Fruit	0.03 mg/kg	3	16 Aug 2008	
T009543-07-REG SRF08-037-37FR Austria (Europe North) (4070)	Courgette (Zigal)	1.06 Jun 2008 2 – 3 -	-	-	-	- (-)	- (-)	-	Fruit	< 0.01 mg/kg, < 0.01 mg/kg (Mean = < 0.01 mg/kg)	3	17 Aug 2008	Field SP (max days): 333
			foliar		498.2 L/ha 478.4 L/ha 498.2 L/ha	199.3 g ai/ha 191.3 g ai/ha 199.3 g ai/ha A13703G (-)	07 Aug 2008 30 Jul 2008 14 Aug 2008 (8, 7)	BBCH 61-75 BBCH 61-75 BBCH 65-77	Fruit	0.11 mg/kg	0	14 Aug 2008	Field SP (max days): 336
									Fruit	0.04 mg/kg	1	15 Aug 2008	
									Fruit	< 0.01 mg/kg	3	17 Aug 2008	
			foliar		492.5 L/ha 489.1 L/ha 504.8 L/ha	244.6 g ai/ha 252.4 g ai/ha 246.3 g ai/ha A12705B	30 Jul 2008 07 Aug 2008 14 Aug 2008 (8, 7)	BBCH 61-75 BBCH 61-75 BBCH 65-77	Fruit	0.3 mg/kg	0	14 Aug 2008	Field SP (max days):
									Fruit	0.06 mg/kg	1	15 Aug 2008	

(1) Report No.Trial No.Location(Region)(Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI(d)	(11) Sample Date/Cut Date (d)	(12) Trial Details (e)
				Conc'n	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin			
						(-)			Fruit	<u>< 0.01 mg/kg</u>	3	17 Aug 2008	336
T009543-07-REG SRF08-014-37FR France (Europe North) (71960)	Courgette (Quirinal)	1.21 Aug 2008 2 – 3 -	-	-	-	- (-)	- (-)	-	Fruit	< 0.01 mg/kg	3	13 Oct 2008	Field SP (max days): 276
			foliar	-	442 L/ha 434 L/ha 431 L/ha	202 g ai/ha 207 g ai/ha 204 g ai/ha A13703G (-)	02 Sep 2008 10 Sep 2008 10 Oct 2008 (8, 30)	BBCH 51-53 BBCH 53-62 BBCH 71	Fruit	0.17 mg/kg	0	10 Oct 2008	Field SP (max days): 279
									Fruit	0.15 mg/kg	1	11 Oct 2008	
									Fruit	0.14 mg/kg	3	13 Oct 2008	
			foliar	-	464 L/ha 452 L/ha 449 L/ha	264 g ai/ha 273 g ai/ha 266 g ai/ha A12705B (-)	10 Sep 2008 02 Sep 2008 10 Oct 2008 (8, 30)	BBCH 53-62 BBCH 51-53 BBCH 71	Fruit	0.17 mg/kg	0	10 Oct 2008	Field SP (max days): 279
									Fruit	0.32 mg/kg	1	11 Oct 2008	
									Fruit	0.15 mg/kg	3	13 Oct 2008	

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value

(1) Report No.Trial No.Location(Region)(Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI(d)	(11) Sample Date/Cut Date (d)	(12) Trial Details (e)
				Conc'n	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin			

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

(DBA) Days Before Application

SP (max days): Maximum storage period

A 2.1.3.4 Melon (extrapolated to watermelon, pumpkin, squash)

Table A 22: 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)
cGAP N-EU (Art. 12, EFSA, 2013)	-	-	-	-	-
cGAP S-EU (Art. 12, EFSA, 2013)	4	250 g a.s./ha	-	-	3
Intended cGAP A22773A - HU-8, HU-9, HU-10, PL-7, PL-8, PL-9, PL-10, RO-8, RO-9, RO-10, SK-11, SK-12, SI-13, SI-14, SI-15 Extrapolated to watermelon, pumpkin, squash: CZ-10, CZ-11, CZ-12, HU-13, HU-14, HU-15, PL-11, PL-12, PL-13, PL-14, PL-15, PL-16, RO-13, RO-14, RO-15, SK-15, SK-16, SI-18, SI-19, SI-20, RO-40, RO-41, RO-42*	2	250 g a.s./ha	7	BBCH 11-89	3

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
** Timing of applications determined primarily by growth stage
*** Minimum PHI

A 2.1.3.4.1 Study 1 (Report No. T009553-07-REG) (EU reviewed)

Comments of zRMS:	The study has been reviewed at EU level.

Reference:	KCA1 6.3
Report:	Kelly M. (2011) Azoxystrobin and Difenoconazole - Residue Study on Melon in Northern France in 2008 and 2009 Syngenta Report No. T009553-07-REG Syngenta File No. VV-397531 Unpublished
Guideline(s):	FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials (Rome, 1990) Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document) Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2), 1996
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 23: Summary of the study 1 trials

Field Trials, Crop Residue (Summary): Azoxystrobin and Difenoconazole - Residue study on melon in northern France in 2008 and 2009			
Active Substance (common name):	Azoxystrobin	**Commercial Product (name):**	
Crop/Crop Group:	Melon	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	France	**Other active substance in the formulation (common name and content):**	A13703G: Difenoconazole (125 g/L)
Content of active substance (g/kg or g/L):	A13703G: 200 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A13703G SC		
Analytical Method:	Azoxystrobin (Peel, Pulp, Whole Fruit) RAM 305/03; 0.01 mg/kg R230310 (Peel, Pulp, Whole Fruit) RAM 305/03; 0.01 mg/kg		
Recovery data:	Azoxystrobin Fruit Mean = 110% RSD = 14% (n = 0 in 0 - 0 spiking range) R230310 Fruit Mean = 104% RSD = 13% (n = 0 in 0 - 0 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
T009553-07-REG SRF08-009-37FR France (Europe North) (71570)	Melon / Nogaro	1.10 Jul 2008 2 – 3 -	-	-	-	(-)	- (-)		Whole Fruit	< 0.01 mg/kg +	< 0.01 mg/kg +	3	08 Sep 2008/ -	Field SP (max days): 493
T009553-07-REG SRF08-009-37FR France (Europe North) (71570)	Melon / Nogaro	1.10 Jul 2008 2 – 3 -	-	-	-	(-)	- (-)		Fruit Pulp	< 0.01 mg/kg	< 0.01 mg/kg	3	08 Sep 2008/ -	Field SP (max days): 493

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
T009553-07-REG SRF08-009-37FR France (Europe North) (71570)	Melon / Nogaro	1.10 Jul 2008 2 – 3 -	-	-	-	(-)	- (-)		Fruit Peel	< 0.01 mg/kg	< 0.01 mg/kg	3	08 Sep 2008/ -	Field SP (max days): 493
T009553-07-REG SRF08-009-37FR France (Europe North) (71570)	Melon / Nogaro	1.10 Jul 2008 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 441 L/ha 2. 423 L/ha 3. 406 L/ha	1. 215 g ai/ha 2. 206 g ai/ha 3. 198 g ai/ha A13703G (-)	1. 20 Aug 2008 2. 28 Aug 2008 3. 05 Sep 2008 (8, 8)	1. BBCH 66-67 2. BBCH 71-74 3. BBCH 77-78	Whole Fruit	0.11 mg/kg +	< 0.01 mg/kg +	0	05 Sep 2008/ -	Field SP (max days): 496
T009553-07-REG SRF08-009-37FR France (Europe North) (71570)	Melon / Nogaro	1.10 Jul 2008 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 441 L/ha 2. 423 L/ha 3. 406 L/ha	1. 215 g ai/ha 2. 206 g ai/ha 3. 198 g ai/ha A13703G (-)	1. 20 Aug 2008 2. 28 Aug 2008 3. 05 Sep 2008 (8, 8)	1. BBCH 66-67 2. BBCH 71-74 3. BBCH 77-78	Fruit Pulp	0.02 mg/kg	< 0.01 mg/kg	0	05 Sep 2008/ -	Field SP (max days): 496

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
T009553-07-REG SRF08-009-37FR France (Europe North) (71570)	Melon / Nogaro	1.10 Jul 2008 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 441 L/ha 2. 423 L/ha 3. 406 L/ha	1. 215 g ai/ha 2. 206 g ai/ha 3. 198 g ai/ha A13703G (-)	1. 20 Aug 2008 2. 28 Aug 2008 3. 05 Sep 2008 (8, 8)	1. BBCH 66-67 2. BBCH 71-74 3. BBCH 77-78	Fruit Peel	0.36 mg/kg	< 0.01 mg/kg	0	05 Sep 2008/ -	Field SP (max days): 496
T009553-07-REG SRF08-009-37FR France (Europe North) (71570)	Melon / Nogaro	1.10 Jul 2008 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 441 L/ha 2. 423 L/ha 3. 406 L/ha	1. 215 g ai/ha 2. 206 g ai/ha 3. 198 g ai/ha A13703G (-)	1. 20 Aug 2008 2. 28 Aug 2008 3. 05 Sep 2008 (8, 8)	1. BBCH 66-67 2. BBCH 71-74 3. BBCH 77-78	Whole Fruit	0.01 mg/kg +	< 0.01 mg/kg +	1	06 Sep 2008/ -	Field SP (max days): 496
T009553-07-REG SRF08-009-37FR France (Europe North) (71570)	Melon / Nogaro	1.10 Jul 2008 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 441 L/ha 2. 423 L/ha 3. 406 L/ha	1. 215 g ai/ha 2. 206 g ai/ha 3. 198 g ai/ha A13703G (-)	1. 20 Aug 2008 2. 28 Aug 2008 3. 05 Sep 2008 (8, 8)	1. BBCH 66-67 2. BBCH 71-74 3. BBCH 77-78	Fruit Pulp	< 0.01 mg/kg	< 0.01 mg/kg	1	06 Sep 2008/ -	Field SP (max days): 496

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
T009553-07-REG SRF08-009-37FR France (Europe North) (71570)	Melon / Nogaro	1.10 Jul 2008 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 441 L/ha 2. 423 L/ha 3. 406 L/ha	1. 215 g ai/ha 2. 206 g ai/ha 3. 198 g ai/ha A13703G (-)	1. 20 Aug 2008 2. 28 Aug 2008 3. 05 Sep 2008 (8, 8)	1. BBCH 66-67 2. BBCH 71-74 3. BBCH 77-78	Fruit Peel	0.03 mg/kg	< 0.01 mg/kg	1	06 Sep 2008/ -	Field SP (max days): 496
T009553-07-REG SRF08-009-37FR France (Europe North) (71570)	Melon / Nogaro	1.10 Jul 2008 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 441 L/ha 2. 423 L/ha 3. 406 L/ha	1. 215 g ai/ha 2. 206 g ai/ha 3. 198 g ai/ha A13703G (-)	1. 20 Aug 2008 2. 28 Aug 2008 3. 05 Sep 2008 (8, 8)	1. BBCH 66-67 2. BBCH 71-74 3. BBCH 77-78	Whole Fruit	0.02 mg/kg +	< 0.01 mg/kg +	3	08 Sep 2008/ -	Field SP (max days): 496
T009553-07-REG SRF08-009-37FR France (Europe North) (71570)	Melon / Nogaro	1.10 Jul 2008 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 441 L/ha 2. 423 L/ha 3. 406 L/ha	1. 215 g ai/ha 2. 206 g ai/ha 3. 198 g ai/ha A13703G (-)	1. 20 Aug 2008 2. 28 Aug 2008 3. 05 Sep 2008 (8, 8)	1. BBCH 66-67 2. BBCH 71-74 3. BBCH 77-78	Fruit Peel	0.03 mg/kg	< 0.01 mg/kg	3	08 Sep 2008/ -	Field SP (max days): 496

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
T009553-07-REG SRF08-009-37FR France (Europe North) (71570)	Melon / Nogaro	1.10 Jul 2008 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 441 L/ha 2. 423 L/ha 3. 406 L/ha	1. 215 g ai/ha 2. 206 g ai/ha 3. 198 g ai/ha A13703G (-)	1. 20 Aug 2008 2. 28 Aug 2008 3. 05 Sep 2008 (8, 8)	1. BBCH 66-67 2. BBCH 71-74 3. BBCH 77-78	Fruit Pulp	< 0.01 mg/kg	< 0.01 mg/kg	3	08 Sep 2008/ -	Field SP (max days): 496
T009553-07-REG SRF09-020-37FR France (Europe North) (71960)	Melon / Hugo	1.26 May 2009 2 – 3 -	-	-	-	(-)	- (-)		Whole Fruit	< 0.01 mg/kg +	< 0.01 mg/kg +	3	03 Aug 2009/ -	Field SP (max days): 164
T009553-07-REG SRF09-020-37FR France (Europe North) (71960)	Melon / Hugo	1.26 May 2009 2 – 3 -	-	-	-	(-)	- (-)		Fruit Pulp	< 0.01 mg/kg	< 0.01 mg/kg	3	03 Aug 2009/ -	Field SP (max days): 164
T009553-07-REG SRF09-020-37FR France (Europe North) (71960)	Melon / Hugo	1.26 May 2009 2 – 3 -	-	-	-	(-)	- (-)		Fruit Peel	< 0.01 mg/kg	< 0.01 mg/kg	3	03 Aug 2009/ -	Field SP (max days): 164

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
T009553-07-REG SRF09-020-37FR France (Europe North) (71960)	Melon / Hugo	1.26 May 2009 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 517 L/ha 2. 507 L/ha 3. 526 L/ha	1. 206 g ai/ha 2. 202 g ai/ha 3. 210 g ai/ha A13703G (-)	1. 16 Jul 2009 2. 24 Jul 2009 3. 31 Jul 2009 (8, 7)	1. BBCH 69-70 2. BBCH 71 3. BBCH 71-73	Fruit Pulp	< 0.01 mg/kg	< 0.01 mg/kg	0	31 Jul 2009/ -	Field SP (max days): 167
T009553-07-REG SRF09-020-37FR France (Europe North) (71960)	Melon / Hugo	1.26 May 2009 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 517 L/ha 2. 507 L/ha 3. 526 L/ha	1. 206 g ai/ha 2. 202 g ai/ha 3. 210 g ai/ha A13703G (-)	1. 16 Jul 2009 2. 24 Jul 2009 3. 31 Jul 2009 (8, 7)	1. BBCH 69-70 2. BBCH 71 3. BBCH 71-73	Fruit Peel	0.21 mg/kg	< 0.01 mg/kg	0	31 Jul 2009/ -	Field SP (max days): 167
T009553-07-REG SRF09-020-37FR France (Europe North) (71960)	Melon / Hugo	1.26 May 2009 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 517 L/ha 2. 507 L/ha 3. 526 L/ha	1. 206 g ai/ha 2. 202 g ai/ha 3. 210 g ai/ha A13703G (-)	1. 16 Jul 2009 2. 24 Jul 2009 3. 31 Jul 2009 (8, 7)	1. BBCH 69-70 2. BBCH 71 3. BBCH 71-73	Whole Fruit	0.04 mg/kg +	< 0.01 mg/kg +	0	31 Jul 2009/ -	Field SP (max days): 167

(1) **Report No.** **Trial No.** **Location** **(Region)** **(Postcode)**	**(2)** **Commodity** **/** **Variety** **(a)**	**(3)** **Date of** **1. Sowing or Planting** **2. Flowering** **3. Harvest** **(b)**	**(4)** **Method of Treatment**	**(5)** **Application rate per treatment**			**(6)** **Date of treatment(s) or no of treatment(s) and last date** **Application Interval (days)** **(c)**	**(7)** **Growth Stage at Treatment**	**(8)** **Portion Analyzed**	**(9)** **Residue found** **(Uncorrected)**		**(10)** **PHI** **(d)**	**(11)** **Sample Date** **/** **Cut Date**	**(12)** **Trial Details** **(e)**
				Concentration	**Water**	**Rate Formulation (Additive Type, Rate)**				**Azoxystrobin (mg/kg)**	**R230310 (mg/kg)**			
T009553-07-REG SRF09-020-37FR France (Europe North) (71960)	Melon / Hugo	1.26 May 2009 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 517 L/ha 2. 507 L/ha 3. 526 L/ha	1. 206 g ai/ha 2. 202 g ai/ha 3. 210 g ai/ha A13703G (-)	1. 16 Jul 2009 2. 24 Jul 2009 3. 31 Jul 2009 (8, 7)	1. BBCH 69-70 2. BBCH 71 3. BBCH 71-73	Whole Fruit	0.02 mg/kg +	< 0.01 mg/kg +	1	01 Aug 2009/ -	Field SP (max days): 167
T009553-07-REG SRF09-020-37FR France (Europe North) (71960)	Melon / Hugo	1.26 May 2009 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 517 L/ha 2. 507 L/ha 3. 526 L/ha	1. 206 g ai/ha 2. 202 g ai/ha 3. 210 g ai/ha A13703G (-)	1. 16 Jul 2009 2. 24 Jul 2009 3. 31 Jul 2009 (8, 7)	1. BBCH 69-70 2. BBCH 71 3. BBCH 71-73	Fruit Pulp	< 0.01 mg/kg	< 0.01 mg/kg	1	01 Aug 2009/ -	Field SP (max days): 167
T009553-07-REG SRF09-020-37FR France (Europe North) (71960)	Melon / Hugo	1.26 May 2009 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 517 L/ha 2. 507 L/ha 3. 526 L/ha	1. 206 g ai/ha 2. 202 g ai/ha 3. 210 g ai/ha A13703G (-)	1. 16 Jul 2009 2. 24 Jul 2009 3. 31 Jul 2009 (8, 7)	1. BBCH 69-70 2. BBCH 71 3. BBCH 71-73	Fruit Peel	0.13 mg/kg	< 0.01 mg/kg	1	01 Aug 2009/ -	Field SP (max days): 167

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
T009553-07-REG SRF09-020-37FR France (Europe North) (71960)	Melon / Hugo	1.26 May 2009 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 517 L/ha 2. 507 L/ha 3. 526 L/ha	1. 206 g ai/ha 2. 202 g ai/ha 3. 210 g ai/ha A13703G (-)	1. 16 Jul 2009 2. 24 Jul 2009 3. 31 Jul 2009 (8, 7)	1. BBCH 69-70 2. BBCH 71 3. BBCH 71-73	Whole Fruit	0.05 mg/kg +	< 0.01 mg/kg +	3	03 Aug 2009/ -	Field SP (max days): 167
T009553-07-REG SRF09-020-37FR France (Europe North) (71960)	Melon / Hugo	1.26 May 2009 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 517 L/ha 2. 507 L/ha 3. 526 L/ha	1. 206 g ai/ha 2. 202 g ai/ha 3. 210 g ai/ha A13703G (-)	1. 16 Jul 2009 2. 24 Jul 2009 3. 31 Jul 2009 (8, 7)	1. BBCH 69-70 2. BBCH 71 3. BBCH 71-73	Fruit Pulp	0.01 mg/kg	< 0.01 mg/kg	3	03 Aug 2009/ -	Field SP (max days): 167
T009553-07-REG SRF09-020-37FR France (Europe North) (71960)	Melon / Hugo	1.26 May 2009 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 517 L/ha 2. 507 L/ha 3. 526 L/ha	1. 206 g ai/ha 2. 202 g ai/ha 3. 210 g ai/ha A13703G (-)	1. 16 Jul 2009 2. 24 Jul 2009 3. 31 Jul 2009 (8, 7)	1. BBCH 69-70 2. BBCH 71 3. BBCH 71-73	Fruit Peel	0.32 mg/kg	< 0.01 mg/kg	3	03 Aug 2009/ -	Field SP (max days): 167

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values

(c) Year must be indicated

(d) Minimum number of 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.

(^) PHI calculated using cut date

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period

A 2.1.3.4.2 Study 2 (Report No. 684125) (New data)

<table>
<tr><td>Comments of zRMS:</td><td>Eight residue field trials on melons were conducted in Northern Europe during 2020. Azoxystrobin and oxathiapiprolin were applied to melons as A22773A, a suspension concentrate (SC) formulation containing nominally 250 g of azoxystrobin per litre and 12 g of oxathiapiprolin per litre. To treated plot P2, two applications, separated by a 7-8 day interval, were made at a nominal rate of 250 g ai/ha for azoxystrobin and 12 g ai/ha for oxathiapiprolin.
For the harvest trials, following the applications, treated melon samples were collected at normal commerical harvest (NCH), 3 days after last application (DALA). Untreated melon samples were collected at 3 DALA (NCH).
For the decline trials, following the applications, treated melon samples were collected at 0, 1, 3 (NCH) and 6-8 DALA. Untreated melon samples were collected at 3 DALA (NCH).
Samples were analysed for azoxystrobin and it's z-isomer R230310 using method RAM 305/03, and oxathiapiprolin using method Dupont-30422, Supplement No. 1.
Samples were stored frozen for a maximum period of ca 5 months (141 days) from sampling to analysis for azoxystrobin and R230310 and oxathipiprolin.

Residues of azoxystrobin, its z-isomer R230310, and oxathiapiprolin are summarised in the table below:

<table>
<tr><th>Actual Sampling Interval (days)</th><th>Azoxystrobin Residues in the range (mg/kg)</th><th>R230310 Residues in the range (mg/kg)</th><th>Oxathiapiprolin Residues in the range (mg/kg)</th></tr>
<tr><td colspan="4">Treated Plot (P2): at a rate of 2 x 250 g ai/ha for azoxystrobin and 2 x 12 g ai/ha for oxathiapiprolin</td></tr>
<tr><td colspan="4">Melon peel</td></tr>
<tr><td>0 DALA</td><td>0.05 – 0.39</td><td><0.01</td><td><0.01 – 0.03</td></tr>
<tr><td>1 DALA</td><td>0.04 – 0.48</td><td><0.01 – 0.01</td><td><0.01 – 0.04</td></tr>
<tr><td>3 DALA (NCH)</td><td>0.02 – 0.42</td><td><0.01 – 0.04</td><td><0.01 – 0.04</td></tr>
<tr><td>6-8 DALA</td><td>0.01 – 0.24</td><td><0.01 – 0.03</td><td><0.01 – 0.03</td></tr>
<tr><td colspan="4">Melon pulp</td></tr>
<tr><td>0 DALA</td><td><0.01 – 0.07</td><td><0.01</td><td><0.01</td></tr>
<tr><td>1 DALA</td><td><0.01 – 0.01</td><td><0.01</td><td><0.01</td></tr>
<tr><td>3 DALA (NCH)</td><td><0.01</td><td><0.01</td><td><0.01</td></tr>
<tr><td>6-8 DALA</td><td><0.01</td><td><0.01</td><td><0.01</td></tr>
<tr><td colspan="4">Control plot (C1)
No residues of azoxystrobin and its z-isomer R230310 or oxathiapiprolin at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in any of the untreated melon peel or pulp samples.</td></tr>
</table>
DALA = days after last application to the treated plot; NCH = normal commercial harvest

The trials 2 and 5 conducted in Poland can be considered independent.
The trials 6 and 7 conducted in Germany can be considered independent.

The study is acceptable.</td></tr>
</table>

Reference: KCA1 6.3

Report: Giles, A. (2021)
Azoxystrobin/Oxathiapiprolin – Residue Study on Melons North France, Belgium, Poland, Germany, Czech Republic and The Netherlands, Initiated in 2020
Syngenta Report No. 684125
Syngenta File No. VV-896705
Unpublished

Guideline(s): Commission of the European Communities, General Recommendations for the Design, Preparation and Realisation of Residue Trials; 7029/VI/95 (rev. 5, working document)
Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances

	in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50 OECD Guidance Document on Overview of Residue Chemistry Studies (as revised 2009), Series on Testing and Assessment (No. 64) and Series on Pesticides (No. 32), ENV/JM/MONO(2009)31 OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, adopted 7-Sep-2009 European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000) Guideline on Pesticide Residue Analytical Methods, SANCO/825/00 revision 8.1 (Nov 2010) The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9 Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32) OECD (2011) Guidance Document on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66).
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 24: Summary of the study 2 trials

Field Trials, Crop Residue (Summary) : Azoxystrobin/Oxathiapiprolin – Residue Study on Melons North France, Belgium, Poland, Germany, Czech Republic and The Netherlands, Initiated in 2020			
Active Substance (common name):	Azoxystrobin	**Commercial Product (name):**	
Crop/Crop Group:	Melon	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	Netherlands, France, Poland, Czechia, Belgium, Germany	**Other active substance in the formulation (common name and content):**	A22773A: oxathiapiprolin (12 g/L)
Content of active substance (g/kg or g/L):	A22773A: 250 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A22773A SC		
Analytical Method:	Azoxystrobin (Fruit) RAM 305/03; 0.01 mg/kg R230310 (Fruit) RAM 305/03; 0.01 mg/kg		
Recovery data:	Azoxystrobin Peel Fruit Mean = 78% RSD = 9% (n = 17 in 0.01 - 0.5 spiking range) Azoxystrobin Pulp Fruit Mean = 79% RSD = 5% (n = 12 in 0.01 - 0.1 spiking range) R230310 Peel Fruit Mean = 82% RSD = 7% (n = 17 in 0.01 - 0.5 spiking range) R230310 Pulp Fruit Mean = 85% RSD = 6% (n = 12 in 0.01 - 0.1 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
684125 684125 Trial 1 FRANCE (Europe North) (37120)	Melon / Tilouka	1.04 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Whole Fruit	<0.01	<0.01	3	17 Aug 2020/ -	Field SP (max days): 157
									Peel	0.10	<0.01			
									Pulp	<0.01	<0.01			
	Melon / Tilouka	1.04 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 571.0 L/ha 2. 604.0 L/ha	1. 237.3 g ai/ha 2. 251.1 g ai/ha A22773A (-)	1. 07 Aug 2020 2. 14 Aug 2020 (7)	1. BBCH 65-71 2. BBCH 87-88	Whole Fruit	0.05	<0.01	3	17 Aug 2020/ -	Field SP (max days): 157
									Peel	0.10	<0.01			
									Pulp	<0.01	<0.01			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
684125 684125 Trial 2 POLAND (Europe North) (62-001)	Melon / Anasta	1.20 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Whole Fruit	<0.01	< 0.01	3	04 Sep 2020/ -	Field SP (max days): 139
									Peel	<0.01	<0.01			
									Pulp	<0.01	<0.01			
684125 684125 Trial 2 POLAND (Europe North) (62-001)	Melon / Anasta	1.20 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 586.0 L/ha 2. 607.0 L/ha	1. 243.8 g ai/ha 2. 252.7 g ai/ha A22773A (-)	1. 24 Aug 2020 2. 01 Sep 2020 (8)	1. BBCH 81 2. BBCH 86	Whole Fruit	0.06	<0.01	3	04 Sep 2020/ -	Field SP (max days): 139
									Peel	0.11	<0.01			
									Pulp	<0.01	<0.01			
684125 684125 Trial 3 CZECHIA (Europe North) (68724)	Melon / Wrangler	1.22 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Whole Fruit	<0.01	<0.01	3	22 Aug 2020/ -	Field SP (max days): 152
									Peel	<0.01	<0.01			
									Pulp	<0.01	<0.01			
	Melon / Wrangler	1.22 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 589.0 L/ha 2. 581.0 L/ha	1. 245.2 g ai/ha 2. 241.7 g ai/ha A22773A (-)	1. 12 Aug 2020 2. 19 Aug 2020 (7)	1. BBCH 73 2. BBCH 81	Whole Fruit	0.17	0.02	3	22 Aug 2020/ -	Field SP (max days): 152
									Peel	0.42	0.04			
									Pulp	<0.01	<0.01			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
684125 684125 Trial 4 BELGIUM (Europe North) (3470)	Melon / Cezanne	1.08 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Whole Fruit	<0.01	<0.01	3	31 Aug 2020/ -	Field SP (max days): 143
									Peel	<0.01	<0.01			
									Pulp	<0.01	<0.01			
	Melon / Cezanne	1.08 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 522.0 L/ha 2. 493.0 L/ha	1. 260.6 g ai/ha 2. 246.0 g ai/ha A22773A (-)	1. 21 Aug 2020 2. 28 Aug 2020 (7)	1. BBCH 87 2. BBCH 87-89	Whole Fruit	<u>0.05</u>	<0.01	3	31 Aug 2020/ -	Field SP (max days): 143
									Peel	0.11	<0.01			
									Pulp	<0.01	<0.01			
684125 684125 Trial 5 POLAND (Europe North) (47-270)	Melon / Charentaise	1.18 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Whole Fruit	<0.01	<0.01	3	14 Sep 2020/ -	Field SP (max days): 129
									Peel	<0.01	<0.01			
									Pulp	<0.01	<0.01			
	Melon / Charentaise	1.18 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 606.0 L/ha 2. 572.0 L/ha	1. 252.2 g ai/ha 2. 238.0 g ai/ha A22773A (-)	1. 04 Sep 2020 2. 11 Sep 2020 (7)	1. BBCH 85- 2. BBCH 86-	Whole Fruit	0.16	<0.01	0	11 Sep 2020/ -	Field SP (max days): 132
									Peel	0.27	<0.01			
									Pulp	0.07	<0.01			
									Whole Fruit	0.06	<0.01	1	12 Sep 2020/ -	
									Peel	0.12	<0.01			
									Pulp	<0.01	<0.01			
									Whole Fruit	<u>0.03</u>	<0.01	3	14 Sep 2020/ -	

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
									Peel	0.06	<0.01			
									Pulp	<0.01	<0.01			
									Whole Fruit	0.02	<0.01	7	18 Sep 2020/ -	
									Peel	0.03	<0.01			
									Pulp	<0.01	<0.01			
684125 684125 Trial 6 GERMANY (Europe North) (04827)	Melon / Anasta	1.20 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Whole Fruit	<0.01	<0.01	3	04 Sep 2020/ -	Field SP (max days): 139
									Peel	<0.01	<0.01			
									Pulp	<0.01	<0.01			
	Melon / Anasta	1.20 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 602.0 L/ha 2. 599.0 L/ha	1. 250.3 g ai/ha 2. 249.2 g ai/ha A22773A (-)	1. 24 Aug 2020 2. 01 Sep 2020 (8)	1. BBCH 81 2. BBCH 86	Whole Fruit	0.04	<0.01	0	01 Sep 2020/ -	Field SP (max days): 142
									Peel	0.07	<0.01			
									Pulp	0.01	<0.01			
									Whole Fruit	0.07	<0.01	1	02 Sep 2020/ -	
									Peel	0.16	<0.01			
									Pulp	<0.01	<0.01			
									Whole Fruit	0.06	<0.01	3	04 Sep 2020/ -	
									Peel	0.12	<0.01			
									Pulp	<0.01	<0.01			
									Whole Fruit	0.04	<0.01	7	07 Sep 2020/ -	
									Peel	0.07	<0.01			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
									Pulp	<0.01	<0.01			
684125 684125 Trial 7 GERMANY (Europe North) (46342)	Melon / Anasta F1	1.10 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Whole Fruit	<0.01	<0.01	3	11 Sep 2020/ -	Field SP (max days): 132
									Peel	<0.01	<0.01			
									Pulp	<0.01	<0.01			
	Melon / Anasta F1	1.10 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 485.0 L/ha 2. 487.0 L/ha	1. 242.1 g ai/ha 2. 242.8 g ai/ha A22773A (-)	1. 01 Sep 2020 2. 08 Sep 2020 (7)	1. BBCH 77 2. BBCH 83	Whole Fruit	0.02	<0.01	0	08 Sep 2020/ -	Field SP (max days): 135
									Peel	0.05	<0.01			
									Pulp	<0.01	<0.01			
									Whole Fruit	0.02	<0.01	1	09 Sep 2020/ -	
									Peel	0.04	<0.01			
									Pulp	<0.01	<0.01			
									Whole Fruit	<0.01	<0.01	3	11 Sep 2020/ -	
									Peel	0.02	<0.01			
									Pulp	<0.01	<0.01			
									Whole Fruit	<0.01	<0.01	7	16 Sep 2020/ -	
									Peel	0.01	<0.01			
									Pulp	<0.01	<0.01			
684125 684125 Trial 8 NETHERLANDS	Melon / Stellio F1	1.10 Jun 2020 2 –	-	-	-		- (-)		Whole Fruit	<0.01	<0.01	3	03 Sep 2020/ -	Field
									Peel	<0.01	<0.01			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
(Europe North) (6599 AV)		3 -				(-)			Pulp	<0.01	<0.01			SP (max days): 140
	Melon / Stellio F1	1.10 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 508.0 L/ha 2. 511.0 L/ha	1. 254.3 g ai/ha 2. 254.8 g ai/ha A22773A (-)	1. 24 Aug 2020 2. 31 Aug 2020 (7)	1. BBCH 87 2. BBCH 87-88	Whole Fruit	0.18	<0.01	0	31 Aug 2020/ -	Field SP (max days): 143
									Peel	0.39	<0.01			
									Pulp	0.02	<0.01			
									Whole Fruit	0.18	<0.01	1	01 Sep 2020/ -	
									Peel	0.48	0.01			
									Pulp	0.01	<0.01			
									Whole Fruit	0.07	<0.01	3	03 Sep 2020/ -	
									Peel	0.15	<0.01			
									Pulp	<0.01	<0.01			
									Whole Fruit	0.09	0.02	7	07 Sep 2020/ -	
									Peel	0.24	0.03			
									Pulp	<0.01	<0.01			

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of 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.

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value
(DBA) Days Before Application
SP (max days): Maximum storage period

A 2.1.3.5 Lettuce

A 2.1.3.6 (extrapolated to salad plants, sweet basil and spinach)

Table A 25: 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)
cGAP N-EU (Art. 12, EFSA, 2013)	4	250 g a.s./ha	-	-	14
Proposed N-EU (EFSA, 2020)	2	250 g a.s./ha	7	-	14
cGAP S-EU (Art. 12, EFSA, 2013)	3	250 g a.s./ha	7	BBCH 49	7
Proposed S-EU (EFSA, 2020)	2	250 g a.s./ha	7	-	7
Intended cGAP A22773A - AT-6, BE-2, CZ-9, DE-16, DE-6, IE-6, NL-6, PL-20, PL-21, SK-10, SI-12 Extrapolated to salad plants, spinach, sweet basil: CZ-31, PL-18, PL-19, PL-38, PL-39, PL-40, SK-37, SK-39, RO-34*	2	250 g a.s./ha	7	BBCH 11-49	14

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
** Timing of applications determined primarily by growth stage
*** Minimum PHI

A 2.1.3.6.1 Study 1 (Report No. RJ3145B) (EU reviewed)

Comments of zRMS:	The study has been reviewed at EU level.

Reference:	KCA1 6.3
Report:	Richards S., Hansen A., Atkinson D. (2001) Azoxystrobin - Residue Levels in Outdoor Lettuces from Trials conducted in the UK during 2000 Syngenta Report No. RJ3145B Syngenta File No. VV-377726 Unpublished
Guideline(s):	Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2), 1996
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 26: Summary of the study 1 trials

Field Trials, Crop Residue (Summary): Azoxystrobin - Residue Levels in Outdoor Lettuces from Trials conducted in the UK during 2000.			
Active Substance (common name):	Azoxystrobin	**Commercial Product (name):**	-
Crop/Crop Group:	Lettuce (Salad), Lettuce (Little Gem),Lettuce (Iceberg)	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	UNITED KINGDOM	**Other active substance in the formulation (common name and content):**	None
Content of active substance (g/kg or g/L):	A12705B: 250 g AI/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A12705B SC		
Analytical Method: Azoxystrobin (Head) SOP RAM 305/02; 0.01 mg/kg			
Recovery data: Azoxystrobin Head Mean = 93% RSD = 4% (n = 10 in 0.05 - 5 mg/kg spiking range)			

(1) Report No. Trial No. Location (Region) (Postcode)	**(2) Commodity/ Variety (a)**	**(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)**	**(4) Method of Treatment**	**(5) Application rate per treatment**			**(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)**	**(7) Growth Stage at Treatment**	**(8) Portion Analyzed**	**(9) Residue found (Uncorrected)**	**(10) PHI (d)**	**(11) Sample Date (Cut Date) (d)**	**(12) Trial Details (e)**
				Conc'n	**Water**	**Rate (Additive Type, Rate)**				**Azoxystrobin (mg/kg)**			
RJ3145B GB01-00-S051 UNITED KINGDOM (Europe North)	Lettuce (Salad) (Romaine)	1.07 Jun 2000 2 – 3 -	Foliar Foliar Foliar		400 L/ha 400 L/ha 400 L/ha	250.00 g ai/ha 250.00 g ai/ha 250.00 g ai/ha (-)	12 Jul 2000 19 Jul 2000 26 Jul 2000 (7, 7)	BBCH 47 BBCH 49 BBCH 49	Head	7.60	0	26 Jul 2000	Field SP (max days): 218
									Head	2.70	2	28 Jul 2000	
									Head	1.20	7	02 Aug 2000	
									Head	0.76	9	04 Aug 2000	
									Head	0.19, 0.18, 0.19, 0.19 (Mean=0.1875)	14	09 Aug 2000	
									Head	0.50, 0.42, 0.45, 0.45 (Mean=0.455)	21	16 Aug 2000	
	Lettuce (Salad) (Romaine)	1.07 Jun 2000 2 – 3 -	Foliar Foliar		400 L/ha 400 L/ha	250.00 g ai/ha 250.00 g ai/ha (-)	19 Jul 2000 26 Jul 2000 (7)	BBCH 49 BBCH 49	Head	5.50	0	26 Jul 2000	Field SP (max
									Head	2.40	2	28 Jul 2000	

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date (Cut Date) (d)	(12) Trial Details (e)
				Conc'n	Water	Rate (Additive Type, Rate)				Azoxystrobin (mg/kg)			
									Head	0.79	7	02 Aug 2000	days):: 211
									Head	0.45	9	04 Aug 2000	
									Head	0.49	14	09 Aug 2000	
									Head	0.28	21	16 Aug 2000	
RJ3145B GB02-00-S052 UNITED KINGDOM (Europe North)	Lettuce (Little Gem) (Tozeas)	1.07 Jun 2000 2 – 3 -	Foliar Foliar Foliar		400 L/ha 400 L/ha 400 L/ha	250.00 g ai/ha 250.00 g ai/ha 250.00 g ai/ha (-)	30 Jun 2000 07 Jul 2000 14 Jul 2000 (7, 7)	BBCH 43 - 44 BBCH 45 BBCH 47 - 48	Head	3.00	0	14 Jul 2000	Field SP (max days): 223
									Head	0.99	3	17 Jul 2000	
									Head	0.20	7	21 Jul 2000	
									Head	0.06	10	24 Jul 2000	
									Head	< 0.01	14	28 Jul 2000	
									Head	< 0.01	21	04 Aug 2000	
	Lettuce (Little Gem) (Tozeas)	1.07 Jun 2000 2 – 3 -	Foliar Foliar		400 L/ha 400 L/ha	250.00 g ai/ha 250.00 g ai/ha (-)	07 Jul 2000 14 Jul 2000 (7)	BBCH 45 BBCH 47 - 48	Head	2.80	0	14 Jul 2000	Field SP (max days): 223
									Head	1.40	3	17 Jul 2000	
									Head	0.14	7	21 Jul 2000	
									Head	0.03	10	24 Jul 2000	
									Head	< 0.01	14	28 Jul 2000	
									Head	< 0.01	21	04 Aug 2000	
RJ3145B GB02-00-S053		1.07 Jun 2000				250.00 g ai/ha 250.00 g ai/ha	04 Jul 2000 11 Jul 2000	BBCH 42 BBCH 45 -	Head	0.50	0	18 Jul 2000	Field

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date (Cut Date) (d)	(12) Trial Details (e)
				Conc'n	Water	Rate (Additive Type, Rate)				Azoxystrobin (mg/kg)			
UNITED KINGDOM (Europe North)	Lettuce (Iceberg) (Robinson)	2 – 3 -	Foliar Foliar Foliar		400 L/ha 400 L/ha 400 L/ha	250.00 g ai/ha (-)	18 Jul 2000 (7, 7)	46 BBCH 46 - 48	Head	0.08	3	21 Jul 2000	SP (max days): 220
									Head	< 0.01	7	25 Jul 2000	
									Head	< 0.01	10	28 Jul 2000	
									Head	< 0.01	13	31 Jul 2000	
									Head	< 0.01	21	08 Aug 2000	
	Lettuce (Iceberg) (Robinson)	1.07 Jun 2000 2 – 3 -	Foliar Foliar		400 L/ha 400 L/ha	250.00 g ai/ha 250.00 g ai/ha (-)	11 Jul 2000 18 Jul 2000 (7)	BBCH 45 - 46 BBCH 46 - 48	Head	0.31	0	18 Jul 2000	Field SP (max days): 220
									Head	0.02	3	21 Jul 2000	
									Head	< 0.01	7	25 Jul 2000	
									Head	< 0.01	10	28 Jul 2000	
									Head	<u>< 0.01</u>	13	31 Jul 2000	
									Head	< 0.01	21	08 Aug 2000	

Residues in control samples were always below the LOQ (<0.01 mg/kg).

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of 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.

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value
(DBA) Days Before Application
SP (max days): Maximum storage period

A 2.1.3.6.2 Study 2 (Report No. S09-01457) (EU reviewed)

Comments of zRMS:	The study has been reviewed at EU level.

Reference:	KCA1 6.3
Report:	Yozgatli H.P. (2011) Azoxystrobin/Difenoconazole - Residue Study on Lettuce in Northern France, the UK and Germany in 2009 Syngenta Report No. S09-01457 Syngenta File No. VV-397331 Unpublished
Guideline(s):	FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials (Rome, 1990) Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document) Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2), 1996
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 27: Summary of the study 2 trials

Field Trials, Crop Residue (Summary): Azoxystrobin/Difenoconazole - Residue study on lettuce in northern France, the UK and Germany in 2009			
Active Substance (common name):	Azoxystrobin	**Commercial Product (name):**	-
Crop/Crop Group:	Lettuce	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	GERMANY, FRANCE, UNITED KINGDOM	**Other active substance in the formulation (common name and content):**	A13703G: Difenoconazole (125 g AI/L)
Content of active substance (g/kg or g/L):	A12705B: 250 g AI/L, A13703G: 200 g AI/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A12705B SC, A13703G SC		
Analytical Method: Azoxystrobin (Head) RAM 305/03; 0.01 mg/kg			
Recovery data: Azoxystrobin Head Mean = 101% RSD = 13% (n = 8 in 0.01 - 80 mg/kg spiking range)			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date (Cut Date) (d)	(12) Trial Details (e)
				Conc'n	Water	Rate (Additive Type, Rate)				Azoxystrobin (mg/kg)			
S09-01457 S09-01457-01 FRANCE (Europe North) (-)	Lettuce (Lirice)	1.17 Jun 2009 2 – 3 -	Foliar Foliar		187 L/ha 223 L/ha	232.00 g ai/ha 278.00 g ai/ha (-)	01 Jul 2009 08 Jul 2009 (7)	BBCH 42 - 43 BBCH 45 - 46	Head	3.70	0	08 Jul 2009	Field SP (max days): 467
									Head	2.50	3	11 Jul 2009	
									Head	0.92	7	15 Jul 2009	
									Head	<u>0.22</u>	14	22 Jul 2009	
									Head	0.11	21	29 Jul 2009	
	Lettuce (Lirice)	1.17 Jun 2009 2 – 3 -	Foliar Foliar		207 L/ha 210 L/ha	206.00 g ai/ha 209.00 g ai/ha (-)	01 Jul 2009 08 Jul 2009 (7)	BBCH 42 - 43 BBCH 45 - 46	Head	3.90	0	08 Jul 2009	Field SP (max days): 467
									Head	2.00	3	11 Jul 2009	
									Head	0.42	7	15 Jul 2009	
									Head	0.14	14	22 Jul 2009	

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date (Cut Date) (d)	(12) Trial Details (e)
				Conc'n	Water	Rate (Additive Type, Rate)				Azoxystrobin (mg/kg)			
									Head	0.02	21	29 Jul 2009	
S09-01457 S09-01457-02 UNITED KINGDOM (Europe North)	Lettuce (Bastile)	1.16 Jun 2009 2 – 3 -	Foliar Foliar		403 L/ha 406 L/ha	251.00 g ai/ha 252.00 g ai/ha (-)	30 Jun 2009 08 Jul 2009 (8)	BBCH 19 - 33 BBCH 33 - 35	Head	14.00	0	08 Jul 2009	Field SP (max days): 467
									Head	2.40	3	11 Jul 2009	
									Head	0.24	7	15 Jul 2009	
									Head	0.03	14	22 Jul 2009	
									Head	0.02	21	29 Jul 2009	
	Lettuce (Bastile)	1.16 Jun 2009 2 – 3 -	Foliar Foliar		402 L/ha 406 L/ha	200.00 g ai/ha 202.00 g ai/ha (-)	30 Jun 2009 08 Jul 2009 (8)	BBCH 19 - 33 BBCH 33 - 35	Head	10.00	0	08 Jul 2009	Field SP (max days): 467
									Head	1.20	3	11 Jul 2009	
									Head	0.18	7	15 Jul 2009	
									Head	0.03	14	22 Jul 2009	
									Head	0.02	21	29 Jul 2009	
S09-01457 S09-01457-03 GERMANY (Europe North)	Lettuce (Santora)	1.05 May 2009 2 – 3 -	Foliar Foliar		325 L/ha 313 L/ha	270.00 g ai/ha 260.00 g ai/ha (-)	10 Jun 2009 17 Jun 2009 (7)	BBCH 47 - 48 BBCH 48	Head	6.90	0	17 Jun 2009	Field SP (max days): 488
									Head	2.90	3	20 Jun 2009	
									Head	1.30	7	24 Jun 2009	
									Head	0.46	14	01 Jul 2009	
									Head	0.23	21	08 Jul 2009	
	Lettuce (Santora)	1.05 May 2009	Foliar Foliar		325 L/ha 292 L/ha	216.00 g ai/ha 194.00 g ai/ha	10 Jun 2009 17 Jun 2009		Head	1.60	0	17 Jun 2009	Field

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date (Cut Date) (d)	(12) Trial Details (e)
				Conc'n	Water	Rate (Additive Type, Rate)				Azoxystrobin (mg/kg)			
		2 – 3 -				(-)	(7)	BBCH 47 - 48 BBCH 48	Head	1.50	3	20 Jun 2009	SP (max days): 488
									Head	0.70	7	24 Jun 2009	
									Head	0.24	14	01 Jul 2009	
									Head	< 0.01	21	08 Jul 2009	
S09-01457 S09-01457-04 GERMANY (Europe North)	Lettuce (Forlina NAS)	1.28 May 2009 2 – 3 -	Foliar Foliar		191 L/ha 306 L/ha	238.00 g ai/ha 254.00 g ai/ha (-)	19 Jun 2009 26 Jun 2009 (7)	BBCH 19 BBCH 42	Head	12.00	0	26 Jun 2009	Field A12705B SP (max days): 479
									Head	4.30	3	29 Jun 2009	
									Head	0.83	7	03 Jul 2009	
									Head	<u>0.17</u>	14	10 Jul 2009	
									Head	< 0.01	21	17 Jul 2009	
	Lettuce (Forlina NAS)	1.28 May 2009 2 – 3 -	Foliar Foliar		201 L/ha 325 L/ha	200.00 g ai/ha 216.00 g ai/ha (-)	19 Jun 2009 26 Jun 2009 (7)	BBCH 19 BBCH 42	Head	13.00	0	26 Jun 2009	Field SP (max days): 479
									Head	3.30	3	29 Jun 2009	
									Head	0.75	7	03 Jul 2009	
									Head	0.15	14	10 Jul 2009	
									Head	< 0.01	21	17 Jul 2009	

Residues in control samples were always below the LOQ (<0.01 mg/kg).

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of 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.

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value
(DBA) Days Before Application

A 2.1.3.6.3 Study 3 (Report No. RJ3182B) (EU reviewed)

Comments of zRMS:	The study has been reviewed at EU level.

Reference:	KCA1 6.3
Report:	Gill J.P., Barnaud C., Burke S. (2001) Azoxystrobin - Residue Levels in Outdoor Lettuces from Trials Conducted in Northern and Southern France during 2000 Syngenta Report No. RJ3182B Syngenta File No. VV-376946 Unpublished
Guideline(s):	Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2), 1996
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 28: Summary of the study 3 trials

Field Trials, Crop Residue (Summary): Azoxystrobin - Residue Levels in Outdoor Lettuces from Trials Conducted in Northern and Southern France during 2000.			
Active Substance (common name):	Azoxystrobin	**Commercial Product (name):**	
Crop/Crop Group:	Lettuce	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	France	**Other active substance in the formulation (common name and content):**	None
Content of active substance (g/kg or g/L):	A12705B: 250 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A12705B SC		
Analytical Method:	Azoxystrobin (Head, Heads) SOP RAM 305/02; 0.01 mg/kg R230310 (Head, Heads) SOP RAM 305/02; 0.01 mg/kg		
Recovery data:	Azoxystrobin Head Mean = 95% RSD = 5% (n = 12 in 0.01 - 5 spiking range) R230310 Head Mean = 94% RSD = 4% (n = 12 in 0.01 - 5 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
RJ3182B FR75-00-S755 France (Europe North) (37510)	Lettuce / Nadege	1.29 Aug 2000 2 – 3 -	-	-	-	(-)	- (-)		Head	< 0.01 mg/kg, < 0.01 mg/kg (Mean=0.01 mg/kg)	< 0.01 mg/kg, < 0.01 mg/kg (Mean=0.01 mg/kg)	0	02 Oct 2000/ -	Field SP (max days): 245
RJ3182B FR75-00-S755 France (Europe North) (37510)	Lettuce / Nadege	1.29 Aug 2000 2 – 3 -	-	-	-	(-)	- (-)		Head	< 0.01 mg/kg	< 0.01 mg/kg	10	12 Oct 2000/ -	Field SP (max days): 245

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
RJ3182B FR75-00-S755 France (Europe North) (37510)	Lettuce / Nadege	1.29 Aug 2000 2 – 3 -	-	-	-	(-)	- (-)		Head	< 0.01 mg/kg	< 0.01 mg/kg	21	23 Oct 2000/ -	Field SP (max days): 245
RJ3182B FR75-00-S755 France (Europe North) (37510)	Lettuce / Nadege	1.29 Aug 2000 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 300 L/ha 2. 300 L/ha 3. 300 L/ha	1. 250 g ai/ha 2. 250 g ai/ha 3. 250 g ai/ha A12705B (-)	1. 18 Sep 2000 2. 25 Sep 2000 3. 02 Oct 2000 (7, 7)	1. BBCH 14 2. BBCH 16 3. BBCH 45	Head	6.2 mg/kg	0.02 mg/kg	0	02 Oct 2000/ -	Field SP (max days): 244
RJ3182B FR75-00-S755 France (Europe North) (37510)	Lettuce / Nadege	1.29 Aug 2000 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 300 L/ha 2. 300 L/ha 3. 300 L/ha	1. 250 g ai/ha 2. 250 g ai/ha 3. 250 g ai/ha A12705B (-)	1. 18 Sep 2000 2. 25 Sep 2000 3. 02 Oct 2000 (7, 7)	1. BBCH 14 2. BBCH 16 3. BBCH 45	Head	2 mg/kg	0.02 mg/kg	3	05 Oct 2000/ -	Field SP (max days): 244

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
RJ3182B FR75-00-S755 France (Europe North) (37510)	Lettuce / Nadege	1.29 Aug 2000 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 300 L/ha 2. 300 L/ha 3. 300 L/ha	1. 250 g ai/ha 2. 250 g ai/ha 3. 250 g ai/ha A12705B (-)	1. 18 Sep 2000 2. 25 Sep 2000 3. 02 Oct 2000 (7, 7)	1. BBCH 14 2. BBCH 16 3. BBCH 45	Head	0.58 mg/kg	< 0.01 mg/kg	7	09 Oct 2000/ -	Field SP (max days): 244
RJ3182B FR75-00-S755 France (Europe North) (37510)	Lettuce / Nadege	1.29 Aug 2000 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 300 L/ha 2. 300 L/ha 3. 300 L/ha	1. 250 g ai/ha 2. 250 g ai/ha 3. 250 g ai/ha A12705B (-)	1. 18 Sep 2000 2. 25 Sep 2000 3. 02 Oct 2000 (7, 7)	1. BBCH 14 2. BBCH 16 3. BBCH 45	Head	0.52 mg/kg	< 0.01 mg/kg	10	12 Oct 2000/ -	Field SP (max days): 244
RJ3182B FR75-00-S755 France (Europe North) (37510)	Lettuce / Nadege	1.29 Aug 2000 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 300 L/ha 2. 300 L/ha 3. 300 L/ha	1. 250 g ai/ha 2. 250 g ai/ha 3. 250 g ai/ha A12705B (-)	1. 18 Sep 2000 2. 25 Sep 2000 3. 02 Oct 2000 (7, 7)	1. BBCH 14 2. BBCH 16 3. BBCH 45	Head	0.21 mg/kg	< 0.01 mg/kg	14	16 Oct 2000/ -	Field SP (max days): 244

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
RJ3182B FR75-00-S755 France (Europe North) (37510)	Lettuce / Nadege	1.29 Aug 2000 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 300 L/ha 2. 300 L/ha 3. 300 L/ha	1. 250 g ai/ha 2. 250 g ai/ha 3. 250 g ai/ha A12705B (-)	1. 18 Sep 2000 2. 25 Sep 2000 3. 02 Oct 2000 (7, 7)	1. BBCH 14 2. BBCH 16 3. BBCH 45	Head	0.07 mg/kg	< 0.01 mg/kg	21	23 Oct 2000/ -	Field SP (max days): 244
RJ3182B FR75-00-S755 France (Europe North) (37510)	Lettuce / Nadege	1.29 Aug 2000 2 – 3 -	1. Foliar 2. Foliar	-	1. 300 L/ha 2. 300 L/ha	1. 250 g ai/ha 2. 250 g ai/ha A12705B (-)	1. 25 Sep 2000 2. 02 Oct 2000 (7)	1. BBCH 16 2. BBCH 45	Head	4.3 mg/kg	< 0.01 mg/kg	0	02 Oct 2000/ -	Field SP (max days): 244
RJ3182B FR75-00-S755 France (Europe North) (37510)	Lettuce / Nadege	1.29 Aug 2000 2 – 3 -	1. Foliar 2. Foliar	-	1. 300 L/ha 2. 300 L/ha	1. 250 g ai/ha 2. 250 g ai/ha A12705B (-)	1. 25 Sep 2000 2. 02 Oct 2000 (7)	1. BBCH 16 2. BBCH 45	Head	1.6 mg/kg	0.02 mg/kg	3	05 Oct 2000/ -	Field SP (max days): 244
RJ3182B FR75-00-S755 France (Europe North) (37510)	Lettuce / Nadege	1.29 Aug 2000 2 – 3 -	1. Foliar 2. Foliar	-	1. 300 L/ha 2. 300 L/ha	1. 250 g ai/ha 2. 250 g ai/ha A12705B (-)	1. 25 Sep 2000 2. 02 Oct 2000 (7)	1. BBCH 16 2. BBCH 45	Head	0.85 mg/kg	0.01 mg/kg	7	09 Oct 2000/ -	Field SP (max days): 244

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
RJ3182B FR75-00-S755 France (Europe North) (37510)	Lettuce / Nadege	1.29 Aug 2000 2 – 3 -	1. Foliar 2. Foliar	-	1. 300 L/ha 2. 300 L/ha	1. 250 g ai/ha 2. 250 g ai/ha A12705B (-)	1. 25 Sep 2000 2. 02 Oct 2000 (7)	1. BBCH 16 2. BBCH 45	Head	0.23 mg/kg	< 0.01 mg/kg	10	12 Oct 2000/ -	Field SP (max days): 244
RJ3182B FR75-00-S755 France (Europe North) (37510)	Lettuce / Nadege	1.29 Aug 2000 2 – 3 -	1. Foliar 2. Foliar	-	1. 300 L/ha 2. 300 L/ha	1. 250 g ai/ha 2. 250 g ai/ha A12705B (-)	1. 25 Sep 2000 2. 02 Oct 2000 (7)	1. BBCH 16 2. BBCH 45	Head	0.24 mg/kg	< 0.01 mg/kg	14	16 Oct 2000/ -	Field SP (max days): 244
RJ3182B FR75-00-S755 France (Europe North) (37510)	Lettuce / Nadege	1.29 Aug 2000 2 – 3 -	1. Foliar 2. Foliar	-	1. 300 L/ha 2. 300 L/ha	1. 250 g ai/ha 2. 250 g ai/ha A12705B (-)	1. 25 Sep 2000 2. 02 Oct 2000 (7)	1. BBCH 16 2. BBCH 45	Head	0.02 mg/kg	< 0.01 mg/kg	21	23 Oct 2000/ -	Field SP (max days): 244
RJ3182B FR75-00-S755 France (Europe North) (37510)	Lettuce / Nadege	1.29 Aug 2000 2 – 3 -	1. Foliar	-	1. 300 L/ha	1. 250 g ai/ha A12705B (-)	1. 02 Oct 2000 (-)	1. BBCH 45	Head	6.2 mg/kg	< 0.01 mg/kg	0	02 Oct 2000/ -	Field SP (max days): 244

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
RJ3182B FR75-00-S755 France (Europe North) (37510)	Lettuce / Nadege	1.29 Aug 2000 2 – 3 -	1. Foliar	-	1. 300 L/ha	1. 250 g ai/ha A12705B (-)	1. 02 Oct 2000 (-)	1. BBCH 45	Head	1.1 mg/kg	< 0.01 mg/kg	3	05 Oct 2000/ -	Field SP (max days): 244
RJ3182B FR75-00-S755 France (Europe North) (37510)	Lettuce / Nadege	1.29 Aug 2000 2 – 3 -	1. Foliar	-	1. 300 L/ha	1. 250 g ai/ha A12705B (-)	1. 02 Oct 2000 (-)	1. BBCH 45	Head	0.44 mg/kg	< 0.01 mg/kg	7	09 Oct 2000/ -	Field SP (max days): 244
RJ3182B FR75-00-S755 France (Europe North) (37510)	Lettuce / Nadege	1.29 Aug 2000 2 – 3 -	1. Foliar	-	1. 300 L/ha	1. 250 g ai/ha A12705B (-)	1. 02 Oct 2000 (-)	1. BBCH 45	Head	0.32 mg/kg	< 0.01 mg/kg	10	12 Oct 2000/ -	Field SP (max days): 244
RJ3182B FR75-00-S755 France (Europe North) (37510)	Lettuce / Nadege	1.29 Aug 2000 2 – 3 -	1. Foliar	-	1. 300 L/ha	1. 250 g ai/ha A12705B (-)	1. 02 Oct 2000 (-)	1. BBCH 45	Head	0.13 mg/kg	< 0.01 mg/kg	14	16 Oct 2000/ -	Field SP (max days): 244

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
RJ3182B FR75-00-S755 France (Europe North) (37510)	Lettuce / Nadege	1.29 Aug 2000 2 – 3 -	1. Foliar	-	1. 300 L/ha	1. 250 g ai/ha A12705B (-)	1. 02 Oct 2000 (-)	1. BBCH 45	Head	0.08 mg/kg	< 0.01 mg/kg	21	23 Oct 2000/ -	Field SP (max days): 244

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(c) Year must be indicated

(d) Minimum number of 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.

(*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^) PHI calculated using cut date

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period

A 2.1.3.6.4 Study 4 (Report No. S12-01269) (EU reviewed)

Comments of zRMS:	The study has been reviewed at EU level.

Reference:	KCA1 6.3
Report:	Yozgatli H.P., Winkler K. (2013) Azoxystrobin - Residue Study on Open Leaf Varieties of Lettuce in the United Kingdom in 2012 Syngenta Report No. S12-01269 Syngenta File No. VV-404294 Unpublished
Guideline(s):	EU 1999: 1607/VI/97 FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials (Rome, 1990) Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document) Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2), 1996
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 29: Summary of the study 4 trials

Field Trials, Crop Residue (Summary): Azoxystrobin - Residue study on open leaf varieties of Lettuce in the United Kingdom in 2012			
Active Substance (common name):	Azoxystrobin	**Commercial Product (name):**	
Crop/Crop Group:	Lettuce	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	United Kingdom	**Other active substance in the formulation (common name and content):**	None
Content of active substance (g/kg or g/L):	A12705B: 250 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A12705B SC		
Analytical Method:	Azoxystrobin (Head) RAM 305/03; 0.01 mg/kg R230310 (Head) RAM 305/03; 0.01 mg/kg		
Recovery data:	Azoxystrobin Head Mean = 91% RSD = 10% (n = 4 in 0.01 - 4 spiking range) R230310 Head Mean = 95% RSD = N/A (n = 2 in 0.01 - 0.1 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
S12-01269 S12-01269-01 United Kingdom (Europe North) (WR10 3AG)	Lettuce / Frisee	1.23 Jul 2012 2 – 3 -	-	-	-	(-)	- (-)		Head	< 0.01 mg/kg	< 0.01 mg/kg	7	05 Sep 2012/ -	Field SP (max days): 87
S12-01269 S12-01269-01 United Kingdom (Europe North) (WR10 3AG)	Lettuce / Frisee	1.23 Jul 2012 2 – 3 -	1. Foliar 2. Foliar	-	1. 207 L/ha 2. 213 L/ha	1. 258 g ai/ha 2. 267 g ai/ha A12705B (-)	1. 22 Aug 2012 2. 29 Aug 2012 (7)	1. BBCH 16-41 2. BBCH 43-45	Head	2.6 mg/kg	0.1 mg/kg	7	05 Sep 2012/ -	Field SP (max days): 87

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
S12-01269 S12-01269-01 United Kingdom (Europe North) (WR10 3AG)	Lettuce / Frisee	1.23 Jul 2012 2 – 3 -	1. Foliar 2. Foliar	-	1. 207 L/ha 2. 213 L/ha	1. 258 g ai/ha 2. 267 g ai/ha A12705B (-)	1. 22 Aug 2012 2. 29 Aug 2012 (7)	1. BBCH 16-41 2. BBCH 43-45	Head	<u>0.13 mg/kg</u>	< 0.01 mg/kg	14	12 Sep 2012/ -	Field SP (max days): 87

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of 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.

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value
(DBA) Days Before Application
SP (max days): Maximum storage period

A 2.1.3.7 Leek (extrapolated to spring onion)

Table A 30: 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)
cGAP N-EU (Art. 12, EFSA, 2013)	4	250 g a.s./ha	-	-	21
cGAP S-EU (Art. 12, EFSA, 2013)	4	250 g a.s./ha	-	-	14
Intended cGAP A22773A - AT-2, AT-3, AT-4, AT-5, BE-3, BE-4, BE-5, BE-6, CZ-5, CZ-6, CZ-7, CZ-8, DE-2, DE-3, DE-4, DE-5, IE-2, IE-3, IE-4, IE-5, NL-2, NL-3, NL-4, NL-5, PL-30, PL-31, PL-32, PL-33, SK-6, SK-7, SK-8, SK-9, SI-8, SI-9, SI-10, SI-11, RO-35, RO-36, RO-37, RO-38 Extrapolated to spring onion: BE-7, CZ-30, NL-8, PL-71, SK-36, RO-39*	2	250 g a.s./ha	12-14	BBCH 11-49	7

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
** Timing of applications determined primarily by growth stage
*** Minimum PHI

A 2.1.3.7.1 Study 1 (Report No. 684141) (New data)

Comments of zRMS:	Eight residue field trials on leeks were conducted in Northern Europe during 2020. Azoxystrobin and oxathiapiprolin were applied to leeks as A22773A, a suspension concentrate (SC) formulation containing nominally 250 g of azoxystrobin per litre and 12 g of oxathiapiprolin per litre. To treated plot P2, two applications, separated by a 10-13 day interval, were made at a nominal rate of 250 g ai/ha for azoxystrobin and 12 g ai/ha for oxathiapiprolin. For the harvest trials, following the applications, treated samples of leek whole plant were collected at 7-8 days after last application (DALA), normal commercial harvest (NCH). Untreated leek whole plant samples were collected at 7-8 DALA (NCH). For the decline trials, following the applications, treated samples of leek whole plant were collected at 0, 1, 3, 7 (NCH) and 9-10 days after last application (DALA). Untreated leek whole plant samples were collected at 7 DALA (NCH). Samples were analysed for azoxystrobin and it's z-isomer R230310 using method RAM 305/03, and oxathiapiprolin using method Dupont-30422, Supplement No. 1. Samples were stored frozen for a maximum period of ca 6 months (175 days) from sampling to analysis for azoxystrobin and R230310 and oxathipiprolin. Residues of azoxystrobin, its z-isomer R230310, and oxathiapiprolin are summarised in the table below:

Actual Sampling Interval (days)	Azoxystrobin Residues in the range (mg/kg)	R230310 Residues in the range (mg/kg)	Oxathiapiprolin Residues in the range (mg/kg)
Treated Plot (P2): at a rate of 2 x 250 g ai/ha for azoxystrobin and 2 x 12 g ai/ha for oxathiapiprolin			
Leek Whole Plant			
0 DALA	0.66 – 1.40	<0.01	0.04 – 0.11
1 DALA	0.47 – 1.54	<0.01	0.02 – 0.09
3 DALA	0.18 – 1.01	<0.01 – 0.01	0.02 – 0.10
7-8 DALA (NCH)	0.09 – 1.16	<0.01 – 0.03	<0.01 – 0.05
9-10 DALA	0.07 – 0.34	<0.01	<0.01 – 0.03
Control plot (C1) No residues of azoxystrobin and its metabolite R230310 or oxathiapiprolin at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in any of the untreated leek samples.			

DALA = days after last application to the treated plot; NCH = normal commercial harvest

All trials can be considered independent.
The study is acceptable.

Reference:	KCA1 6.3
Report:	Giles A. (2021) Azoxystrobin/Oxathiapiprolin – Residue Study on Leeks in the United Kingdom, North France, Belgium, Germany and The Netherlands, Initiated in 2020 Syngenta Report No. 684141 Syngenta File No. VV-900599 Unpublished
Guideline(s):	Commission of the European Communities, General Recommendations for the Design, Preparation and Realisation of Residue Trials; 7029/VI/95 (rev. 5, working document) Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50

	OECD Guidance Document on Overview of Residue Chemistry Studies (as revised 2009), Series on Testing and Assessment (No. 64) and Series on Pesticides (No. 32), ENV/JM/MONO(2009)31 OECD Guidelines for the Testing of Chemicals – Crop Field Trials, No. 509, adopted 7-Sep2009 European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000) Guideline on Pesticide Residue Analytical Methods, SANCO/825/00 revision 8.1 (Nov 2010) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32) OECD (2011) Guidance Document on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66)
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 31: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) : Azoxystrobin/Oxathiapiprolin – Residue Study on Leeks in the United Kingdom, North France, Belgium, Germany and The Netherlands, Initiated in 2020			
Active Substance (common name):	azoxystrobin	**Commercial Product (name):**	
Crop/Crop Group:	Leek	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	UNITED KINGDOM, FRANCE, NETHERLANDS, BELGIUM, GERMANY	**Other active substance in the formulation (common name and content):**	A22773A: oxathiapiprolin (12 g/L)
Content of active substance (g/kg or g/L):	A22773A: 250 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A22773A SC		
Analytical Method:	Azoxystrobin (Whole plant) RAM 305/03; 0.01 mg/kg R230310 (Whole plant) RAM 305/03; 0.01 mg/kg		
Recovery data:	Azoxystrobin Whole plant Mean = 83% RSD = 11% (n = 17 in 0.01 - 1.6 spiking range) R230310 Whole plant Mean = 87% RSD = 10% (n = 12 in 0.01 - 0.1 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	**(2) Commodity / Variety (a)**	**(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)**	**(4) Method of Treatment**	**(5) Application rate per treatment**			**(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)**	**(7) Growth Stage at Treatment**	**(8) Portion Analyzed**	**(9) Residue found (Uncorrected)**		**(10) PHI (d)**	**(11) Sample Date / Cut Date**	**(12) Trial Details (e)**
				Concentration	**Water**	**Rate Formulation (Additive Type, Rate)**				**Azoxystrobin (mg/kg)**	**R230310 (mg/kg)**			
684141 684141 Trial 1 BELGIUM (Europe North) (8890)	Leek / Krypton	1.15 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Whole plant	< 0.01 mg/kg	< 0.01 mg/kg	8	02 Oct 2020/ -	Field SP (max days): 133
684141 684141 Trial 1 BELGIUM (Europe North) (8890)	Leek / Krypton	1.15 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 595.075 L/ha 2. 610.06 L/ha	1. 247.3941 g ai/ha 2. 253.6239 g ai/ha A22773A (-)	1. 14 Sep 2020 2. 24 Sep 2020 (10)	1. BBCH 48- 2. BBCH 48-	Whole plant	0.1 mg/kg	< 0.01 mg/kg	8	02 Oct 2020/ -	Field SP (max days): 133

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
684141 684141 Trial 2 FRANCE (Europe North) (80290)	Leek / Pluston	1.24 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Whole plant	< 0.01 mg/kg	< 0.01 mg/kg	7	19 Oct 2020/ -	Field SP (max days): 116
684141 684141 Trial 2 FRANCE (Europe North) (80290)	Leek / Pluston	1.24 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 602.4917 L/ha 2. 590.182 L/ha	1. 250.4775 g ai/ha 2. 245.3599 g ai/ha A22773A (-)	1. 01 Oct 2020 2. 12 Oct 2020 (11)	1. BBCH 48- 2. BBCH 48-	Whole plant	0.45 mg/kg	< 0.01 mg/kg	7	19 Oct 2020/ -	Field SP (max days): 116
684141 684141 Trial 3 GERMANY (Europe North) (04827)	Leek / Bulgaarse Reuzen	1.04 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Whole plant	< 0.01 mg/kg	< 0.01 mg/kg	7	12 Oct 2020/ -	Field SP (max days): 123
684141 684141 Trial 3 GERMANY (Europe North) (04827)	Leek / Bulgaarse Reuzen	1.04 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 411 L/ha 2. 435 L/ha	1. 256.2344 g ai/ha 2. 271.197 g ai/ha A22773A (-)	1. 22 Sep 2020 2. 05 Oct 2020 (13)	1. BBCH 45-47 2. BBCH 45-47	Whole plant	0.51 mg/kg	< 0.01 mg/kg	7	12 Oct 2020/ -	Field SP (max days): 123

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
684141 684141 Trial 4 GERMANY (Europe North) (46342)	Leek / Krypton	1.13 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Whole plant	< 0.01 mg/kg	< 0.01 mg/kg	7	21 Sep 2020/ -	Field SP (max days): 144
684141 684141 Trial 4 GERMANY (Europe North) (46342)	Leek / Krypton	1.13 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 378.5 L/ha 2. 388.5 L/ha	1. 235.9726 g ai/ha 2. 242.207 g ai/ha A22773A (-)	1. 02 Sep 2020 2. 14 Sep 2020 (12)	1. BBCH 47- 2. BBCH 47-	Whole plant	1.16 mg/kg	0.03 mg/kg	7	21 Sep 2020/ -	Field SP (max days): 144
684141 684141 Trial 5 UNITED KINGDOM (Europe North) (YO62 4NH)	Leek / Atlantic	1.06 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Whole plant	< 0.01 mg/kg	< 0.01 mg/kg	7	04 Nov 2020/ -	Field SP (max days): 100
684141 684141 Trial 5 UNITED KINGDOM (Europe North) (YO62 4NH)	Leek / Atlantic	1.06 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 304.2 L/ha 2. 302.6107 L/ha	1. 252.5897 g ai/ha 2. 251.2701 g ai/ha A22773A (-)	1. 16 Oct 2020 2. 28 Oct 2020 (12)	1. BBCH 47- 2. BBCH 48-	Whole plant	1.35 mg/kg	< 0.01 mg/kg	0	28 Oct 2020/ -	Field SP (max days): 107

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
684141 684141 Trial 5 UNITED KINGDOM (Europe North) (YO62 4NH)	Leek / Atlantic	1.06 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 304.2 L/ha 2. 302.6107 L/ha	1. 252.5897 g ai/ha 2. 251.2701 g ai/ha A22773A (-)	1. 16 Oct 2020 2. 28 Oct 2020 (12)	1. BBCH 47- 2. BBCH 48-	Whole plant	1.45 mg/kg	< 0.01 mg/kg	1	29 Oct 2020/ -	Field SP (max days): 107
684141 684141 Trial 5 UNITED KINGDOM (Europe North) (YO62 4NH)	Leek / Atlantic	1.06 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 304.2 L/ha 2. 302.6107 L/ha	1. 252.5897 g ai/ha 2. 251.2701 g ai/ha A22773A (-)	1. 16 Oct 2020 2. 28 Oct 2020 (12)	1. BBCH 47- 2. BBCH 48-	Whole plant	0.45 mg/kg	< 0.01 mg/kg	3	31 Oct 2020/ -	Field SP (max days): 107
684141 684141 Trial 5 UNITED KINGDOM (Europe North) (YO62 4NH)	Leek / Atlantic	1.06 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 304.2 L/ha 2. 302.6107 L/ha	1. 252.5897 g ai/ha 2. 251.2701 g ai/ha A22773A (-)	1. 16 Oct 2020 2. 28 Oct 2020 (12)	1. BBCH 47- 2. BBCH 48-	Whole plant	0.1 mg/kg	< 0.01 mg/kg	7	04 Nov 2020/ -	Field SP (max days): 107
684141 684141 Trial 5 UNITED KINGDOM (Europe North) (YO62 4NH)	Leek / Atlantic	1.06 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 304.2 L/ha 2. 302.6107 L/ha	1. 252.5897 g ai/ha 2. 251.2701 g ai/ha A22773A (-)	1. 16 Oct 2020 2. 28 Oct 2020 (12)	1. BBCH 47- 2. BBCH 48-	Whole plant	0.08 mg/kg	< 0.01 mg/kg	9	06 Nov 2020/ -	Field SP (max days): 107

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
684141 684141 Trial 6 UNITED KINGDOM (Europe North) (NR)	Leek / Lancaster	1.28 Apr 2020 2 – 3 -	-	-	-	(-)	- (-)		Whole plant	< 0.01 mg/kg	< 0.01 mg/kg	7	08 Dec 2020/ -	Field SP (max days): 66
684141 684141 Trial 6 UNITED KINGDOM (Europe North) (NR)	Leek / Lancaster	1.28 Apr 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 399.608 L/ha 2. 409.646 L/ha	1. 249.1322 g ai/ha 2. 255.3903 g ai/ha A22773A (-)	1. 19 Nov 2020 2. 01 Dec 2020 (12)	1. BBCH 49- 2. BBCH 49-	Whole plant	0.66 mg/kg	< 0.01 mg/kg	0	01 Dec 2020/ -	Field SP (max days): 73
684141 684141 Trial 6 UNITED KINGDOM (Europe North) (NR)	Leek / Lancaster	1.28 Apr 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 399.608 L/ha 2. 409.646 L/ha	1. 249.1322 g ai/ha 2. 255.3903 g ai/ha A22773A (-)	1. 19 Nov 2020 2. 01 Dec 2020 (12)	1. BBCH 49- 2. BBCH 49-	Whole plant	1.54 mg/kg	< 0.01 mg/kg	1	02 Dec 2020/ -	Field SP (max days): 73
684141 684141 Trial 6 UNITED KINGDOM (Europe North) (NR)	Leek / Lancaster	1.28 Apr 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 399.608 L/ha 2. 409.646 L/ha	1. 249.1322 g ai/ha 2. 255.3903 g ai/ha A22773A (-)	1. 19 Nov 2020 2. 01 Dec 2020 (12)	1. BBCH 49- 2. BBCH 49-	Whole plant	0.18 mg/kg	< 0.01 mg/kg	3	04 Dec 2020/ -	Field SP (max days): 73

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
684141 684141 Trial 6 UNITED KINGDOM (Europe North) (NR)	Leek / Lancaster	1.28 Apr 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 399.608 L/ha 2. 409.646 L/ha	1. 249.1322 g ai/ha 2. 255.3903 g ai/ha A22773A (-)	1. 19 Nov 2020 2. 01 Dec 2020 (12)	1. BBCH 49- 2. BBCH 49-	Whole plant	0.09 mg/kg	< 0.01 mg/kg	7	08 Dec 2020/ -	Field SP (max days): 73
684141 684141 Trial 6 UNITED KINGDOM (Europe North) (NR)	Leek / Lancaster	1.28 Apr 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 399.608 L/ha 2. 409.646 L/ha	1. 249.1322 g ai/ha 2. 255.3903 g ai/ha A22773A (-)	1. 19 Nov 2020 2. 01 Dec 2020 (12)	1. BBCH 49- 2. BBCH 49-	Whole plant	0.1 mg/kg	< 0.01 mg/kg	10	11 Dec 2020/ -	Field SP (max days): 73
684141 684141 Trial 7 FRANCE (Europe North) (62138)	Leek / Nunton	1.01 Jul 2020 2 – 3 -	-	-	-	(-)	- (-)		Whole plant	< 0.01 mg/kg	< 0.01 mg/kg	7	17 Nov 2020/ -	Field SP (max days): 87
684141 684141 Trial 7 FRANCE (Europe North) (62138)	Leek / Nunton	1.01 Jul 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 556.3932 L/ha 2. 610.5553 L/ha	1. 231.4447 g ai/ha 2. 253.9748 g ai/ha A22773A (-)	1. 30 Oct 2020 2. 10 Nov 2020 (11)	1. BBCH 48- 2. BBCH 48-49	Whole plant	1.4 mg/kg	< 0.01 mg/kg	0	10 Nov 2020/ -	Field SP (max days): 94

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
684141 684141 Trial 7 FRANCE (Europe North) (62138)	Leek / Nunton	1.01 Jul 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 556.3932 L/ha 2. 610.5553 L/ha	1. 231.4447 g ai/ha 2. 253.9748 g ai/ha A22773A (-)	1. 30 Oct 2020 2. 10 Nov 2020 (11)	1. BBCH 48- 2. BBCH 48-49	Whole plant	1.31 mg/kg	< 0.01 mg/kg	1	11 Nov 2020/ -	Field SP (max days): 94
684141 684141 Trial 7 FRANCE (Europe North) (62138)	Leek / Nunton	1.01 Jul 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 556.3932 L/ha 2. 610.5553 L/ha	1. 231.4447 g ai/ha 2. 253.9748 g ai/ha A22773A (-)	1. 30 Oct 2020 2. 10 Nov 2020 (11)	1. BBCH 48- 2. BBCH 48-49	Whole plant	1.01 mg/kg	< 0.01 mg/kg	3	13 Nov 2020/ -	Field SP (max days): 94
684141 684141 Trial 7 FRANCE (Europe North) (62138)	Leek / Nunton	1.01 Jul 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 556.3932 L/ha 2. 610.5553 L/ha	1. 231.4447 g ai/ha 2. 253.9748 g ai/ha A22773A (-)	1. 30 Oct 2020 2. 10 Nov 2020 (11)	1. BBCH 48- 2. BBCH 48-49	Whole plant	0.51 mg/kg	< 0.01 mg/kg	7	17 Nov 2020/ -	Field SP (max days): 94
684141 684141 Trial 7 FRANCE (Europe North) (62138)	Leek / Nunton	1.01 Jul 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 556.3932 L/ha 2. 610.5553 L/ha	1. 231.4447 g ai/ha 2. 253.9748 g ai/ha A22773A (-)	1. 30 Oct 2020 2. 10 Nov 2020 (11)	1. BBCH 48- 2. BBCH 48-49	Whole plant	0.34 mg/kg	< 0.01 mg/kg	10	20 Nov 2020/ -	Field SP (max days): 94

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
684141 684141 Trial 8 NETHERLANDS (Europe North) (6599 AV)	Leek / Krypton	1.18 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Whole plant	< 0.01 mg/kg	< 0.01 mg/kg	7	28 Aug 2020/ -	Field SP (max days): 168
684141 684141 Trial 8 NETHERLANDS (Europe North) (6599 AV)	Leek / Krypton	1.18 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 412.25 L/ha 2. 392.25 L/ha	1. 257.01372 g ai/ha 2. 244.5449 g ai/ha A22773A (-)	1. 10 Aug 2020 2. 21 Aug 2020 (11)	1. BBCH 45- 2. BBCH 47-	Whole plant	0.68 mg/kg	< 0.01 mg/kg	0	21 Aug 2020/ -	Field SP (max days): 175
684141 684141 Trial 8 NETHERLANDS (Europe North) (6599 AV)	Leek / Krypton	1.18 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 412.25 L/ha 2. 392.25 L/ha	1. 257.01372 g ai/ha 2. 244.5449 g ai/ha A22773A (-)	1. 10 Aug 2020 2. 21 Aug 2020 (11)	1. BBCH 45- 2. BBCH 47-	Whole plant	0.47 mg/kg	< 0.01 mg/kg	1	22 Aug 2020/ -	Field SP (max days): 175
684141 684141 Trial 8 NETHERLANDS (Europe North) (6599 AV)	Leek / Krypton	1.18 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 412.25 L/ha 2. 392.25 L/ha	1. 257.01372 g ai/ha 2. 244.5449 g ai/ha A22773A (-)	1. 10 Aug 2020 2. 21 Aug 2020 (11)	1. BBCH 45- 2. BBCH 47-	Whole plant	0.55 mg/kg	0.01 mg/kg	3	24 Aug 2020/ -	Field SP (max days): 175

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)		(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin (mg/kg)	R230310 (mg/kg)			
684141 684141 Trial 8 NETHERLANDS (Europe North) (6599 AV)	Leek / Krypton	1.18 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 412.25 L/ha 2. 392.25 L/ha	1. 257.01372 g ai/ha 2. 244.5449 g ai/ha A22773A (-)	1. 10 Aug 2020 2. 21 Aug 2020 (11)	1. BBCH 45- 2. BBCH 47-	Whole plant	<u>0.31 mg/kg</u>	< 0.01 mg/kg	7	28 Aug 2020/ -	Field SP (max days): 175
684141 684141 Trial 8 NETHERLANDS (Europe North) (6599 AV)	Leek / Krypton	1.18 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 412.25 L/ha 2. 392.25 L/ha	1. 257.01372 g ai/ha 2. 244.5449 g ai/ha A22773A (-)	1. 10 Aug 2020 2. 21 Aug 2020 (11)	1. BBCH 45- 2. BBCH 47-	Whole plant	0.07 mg/kg	< 0.01 mg/kg	10	31 Aug 2020/ -	Field SP (max days): 175

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(c) Year must be indicated

(d) Minimum number of 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.

(*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^) PHI calculated using cut date

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period

A 2.1.3.8 Hops

Table A 32: 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)
cGAP N-EU (Art. 12; EFSA, 2013)	2	400 g a.s./ha	14-28	BBCH 31-89	28
cGAP S-EU (Art. 12; EFSA, 2013)	-	-	-	-	-
Intended cGAP A22773A - AT-1, BE-1, CZ-4, DE-1, DE-15, HU-7, IE-1, NL-1, PL-17, RO-7, SI-7*	2	250 g a.s./ha	12-16	BBCH 21-89	28

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
** Timing of applications determined primarily by growth stage
*** Minimum PHI

A 2.1.3.8.1 Study 1 (Report No. T009307-07-REG) (New data)

Comments of zRMS:	Two residue trials on hops were conducted in Germany during 2008. Azoxystrobin (ICI5504) was applied as A12705B, an aqueous suspension concentrate (SC) formulation containing 250 g/L azoxystrobin. Two applications, each separated by a 8 day interval were made at 400 g ai/ha for azoxystrobin. Following the final application samples were collected at 0, 7, 14, 21 and 28 days with untreated hops being collected at 28 days. Treated and untreated dried samples from additional 28 days after last application (DALA) samples were prepared by drying the samples in a kiln. Samples were analysed for azoxystrobin (as the analytes azoxystrobin and R230310). For trial S08-00665-01, **no residues of azoxystrobin** or R230310 were found at or above the limit of quantification **in the untreated** fresh and dried hops samples. For trial S08-00665-02, residues of azoxystrobin were found at **0.04 mg/kg in the untreated** fresh and dried hops samples. No residues of R230310 was found at or above the limit of quantification in the untreated hops samples. Treated dried samples produced from 28 DALA hops samples gave residues of azoxystrobin in the range 1.13 to 7.03 mg/kg. Specimens were stored frozen for a maximum period of 50 weeks from sampling to analysis. This study can only be considered as informative.

Reference:	KCA1 6.3
Report:	Wormald S. (2011) Azoxystrobin - Residue Study on Hops in Germany in 2008 Syngenta Report No. T009307-07-REG Syngenta File No. VV-395720 Unpublished
Guideline(s):	FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials (Rome, 1990) Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document) Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2), 1996
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 33: Summary of the study 1 trials

Active Substance (common name):	Azoxystrobin	**Commercial Product (name):**	-
Crop/Crop Group:	Hops	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	Germany	**Other active substance in the formulation (common name and content):**	A12705B: Azoxystrobin
Content of active substance (g/kg or g/L):	A12705B	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A12705B SC		
Analytical Method:	Azoxystrobin (Cone, Dried, Cone, Fresh) RAM 305/03; 0.01 mg/kg		
Recovery data:	Azoxystrobin Mean = 95% RSD = 17% (n = 6 in 0.01 - 5 spiking range) Azoxystrobin Cone, Dried Mean = 87% RSD = 9% (n = 10 in 0.01 - 20 spiking range)		

(1) Report No.Trial No.Location (Region) (Postcode)	(2) Commodity/Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date/Cut Date (d)	(12) Trial Details (e)
				Conc'n	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin			
T009307-07-REG S08-00665-02 Germany (Europe North) (88069)	Hops (Spalter)	1.15 Jun 1950 2 – 3 -	-	-	-	- (-)	- (-)	-	Cone, Fresh	0.04 mg/kg	28	03 Sep 2008	Field SP (max days): 358
									Cone, Dried	0.04 mg/kg	28	03 Sep 2008	
			foliar	-	3297.45 L/ha 3006.86 L/ha	439.7 g ai/ha 401 g ai/ha A12705B (-)	29 Jul 2008 06 Aug 2008 (8)	BBCH 75 BBCH 78	Cone, Fresh	8.84 mg/kg	0	06 Aug 2008	Field SP (max days): 386
									Cone, Fresh	2.8 mg/kg	7	13 Aug 2008	
									Cone, Fresh	0.07 mg/kg	14	20 Aug 2008	
									Cone, Fresh	4.67 mg/kg	21	27 Aug 2008	
									Cone, Dried	7.03 mg/kg	28	03 Sep 2008	
									Cone, Fresh	3.22 mg/kg	28	03 Sep 2008	
T009307-07-REG	Hops	1.15 Jun 1991	-	-	-	-	-	-	Cone, Fresh	< 0.01 mg/kg	27	28 Aug 2008	Field

(1) Report No.Trial No.Location (Region) (Postcode)	(2) Commodity/Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date/Cut Date (d)	(12) Trial Details (e)
				Conc'n	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin			
S08-00665-01 Germany (Europe North) (85283)	(Hallertauer Tradition)	2 – 3 -							Cone, Dried	< 0.01 mg/kg	27	28 Aug 2008	SP (max days): 364
			foliar	-	3208.58 L/ha 2937.17 L/ha	391.7 g ai/ha 427.9 g ai/ha A12705B (-)	01 Aug 2008 24 Jul 2008 (8)	BBCH 71 BBCH 69	Cone, Fresh	7.03 mg/kg	0	01 Aug 2008	Field SP (max days): 391
									Cone, Fresh	2.81 mg/kg	6	07 Aug 2008	
									Cone, Fresh	1.33 mg/kg	13	14 Aug 2008	
									Cone, Fresh	1.35 mg/kg	20	21 Aug 2008	
									Cone, Dried	1.13 mg/kg	27	28 Aug 2008	
									Cone, Fresh	1.11 mg/kg	27	28 Aug 2008	

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of 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.

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value
(DBA) Days Before Application
SP (max days): Maximum storage period

A 2.1.3.8.2 Study 2 (Report No. FSGD-063-REG) (New data)

Comments of zRMS:	Six residue field trials on hops were conducted in Northern France, the United Kingdom and Germany during 2009. Azoxystrobin was applied as A12705B, a suspension concentrate (SC) formulation containing 250 g azoxystrobin per litre. Two applications, separated by 6-8 day intervals were made at a target application rate of 400 g ai/ha for azoxystrobin. For trials S09-01444-01, S09-01444-02, S09-01444-03 and S09-01444-04, following the final application, both treated and untreated samples were collected at normal commercial harvest (28 days after the last application (DALA)). Treated and untreated dried samples, from additional 28 DALA samples, were prepared by drying the samples in a kiln. For trials S09-01444-05 and S09-01444-06, following the final application, samples were collected at 0, 7, 14, 21 and 28 DALA with untreated hops being collected at 28 DALA. Treated and untreated dried samples from additional 28 DALA samples were prepared by drying the samples in a kiln. Samples were shipped frozen to the analytical facility where they were then analysed for azoxystrobin and R230310. **Results:** Residues of azoxystrobin in fresh hops samples collected immediately after the last application were in the range 0.46 to 6.24 mg/kg and by 28 DALA were in the range 1.48 to 2.75 mg/kg. Treated dried samples produced from 28 DALA hops samples gave residues of azoxystrobin in the range 5.25 to 29.2 mg/kg. Residues of R230310 in fresh hops samples collected immediately after the last application were in the range 0.02 to 0.04 mg/kg and by 28 DALA were in the range 0.02 to 0.04 mg/kg. Treated dried samples produced from 28 DALA hops samples gave residues of R230310 in the range 0.07 to 0.32 mg/kg. For trials S09-01444-01 and S09-01444-06, no residues of azoxystrobin or R230310 were found at or above the limit of quantification in the untreated fresh and dried hops samples. For trial S09-01444-02, no residue of azoxystrobin was found at or above the limit of quantification in the untreated fresh hops sample. A residue of azoxystrobin was found at 0.011 mg/kg in the untreated dried hops sample. No residue of R230310 was found at or above the limit of quantification in the untreated fresh or dried hops sample. For trial S09-01444-03, residues of azoxystrobin were found at 0.02 mg/kg and 0.04 mg/kg in the untreated fresh and dried hops samples respectively. No residues of R230310 were found at or above the limit of quantification in the untreated fresh or dried hops sample. For trial S09-01444-04, residues of azoxystrobin were found at 0.06 mg/kg and 0.23 mg/kg in the untreated fresh and dried hops samples respectively. A residue of 0.01 mg/kg was found in the untreated fresh hops sample. No residue of R230310 was found at or above the limit of quantification in the untreated dried hops sample. For trial S09-01444-05, residues of azoxystrobin were found at 0.04 mg/kg and 0.14 mg/kg in the untreated fresh and dried hops samples respectively. No residue of R230310 was found at or above the limit of quantification in the untreated fresh or dried hops sample. This study can only be considered as informative.

Reference:	KCA1 6.3
Report:	Wormald S. (2011) Azoxystrobin - Residue Study on Hops in Northern France, the United Kingdom and Germany in 2009 Syngenta Report No. FSGD-063-REG Syngenta File No. VV-396812 Unpublished

Guideline(s):	Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2), 1996
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 34: Summary of the study 2 trials

Field Trials, Crop Residue (Summary) :Azoxystrobin - Residue study on hops in northern France, the United Kingdom and Germany in 2009			
Active Substance (common name):	Azoxystrobin	**Commercial Product (name):**	-
Crop/Crop Group:	Hops	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	United Kingdom, Germany, France	**Other active substance in the formulation (common name and content):**	A12705B: Azoxystrobin
Content of active substance (g/kg or g/L):	A12705B	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A12705B SC		
Analytical Method:	Azoxystrobin (Cone, Cone, Dried) RAM 305/03; 0.01 mg/kg		
Recovery data:	Azoxystrobin Mean = 88% RSD = 15% (n = 12 in 0.01 - 5 spiking range)		

(1) Report No.Trial No.Location (Region) (Postcode)	(2) Commodity/Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date/Cut Date(d)	(12) Trial Details(e)
				Conc'n	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin			
FSGD-063-REG S09-01444-04 Germany (Europe North) (85283)	Hops (Tradition)	1.31 Dec 1990 2 – 3 -	-	-	-	- (-)	- (-)	-	Cone	0.06 mg/kg	28	01 Sep 2009	Field SP (max days): 568
									Cone, Dried	0.23 mg/kg	28	01 Sep 2009	
			foliar	-	4419 L/ha 4499 L/ha	428.5 g ai/ha 420.9 g ai/ha A12705B	29 Jul 2009 04 Aug 2009 (6)	BBCH 65 BBCH 68	Cone, Dried	5.86 mg/kg	28	01 Sep 2009	Field

(1) Report No.Trial No.Location (Region) (Postcode)	(2) Commodity/Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date/Cut Date(d)	(12) Trial Details(e)
				Conc'n	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin			
						(-)			Cone	1.66 mg/kg	28	01 Sep 2009	SP (max days): 568
FSGD-063-REG S09-01444-06 France (Europe North) (67160)	Hops (Strisselspalt)	1.- 2 – 3 -	-	-	-	- (-)	- (-)	-	Cone	< 0.01 mg/kg	28	16 Sep 2009	Field SP (max days): 553
									Cone, Dried	< 0.01 mg/kg	28	16 Sep 2009	
			foliar	-	2103 L/ha 2128 L/ha	382 g ai/ha 386.5 g ai/ha A12705B (-)	11 Aug 2009 19 Aug 2009 (8)	BBCH 71 BBCH 75-79	Cone	0.46 mg/kg	0	19 Aug 2009	Field SP (max days): 581
									Cone	2.64 mg/kg	7	26 Aug 2009	
									Cone	3.15 mg/kg	14	02 Sep 2009	
									Cone	2.03 mg/kg	21	09 Sep 2009	
									Cone	2.26 mg/kg	28	16 Sep 2009	
									Cone, Dried	8.37 mg/kg	28	16 Sep 2009	
FSGD-063-REG S09-01444-02 United Kingdom (Europe North) (WR6 5BT)	Hops (Pioneer)	1.19 May 2000 2 – 3 -	-	-	-	- (-)	- (-)	-	Cone, Dried	0.01 mg/kg	28	29 Sep 2009	Field SP (max days): 540
									Cone	< 0.01 mg/kg	28	29 Sep 2009	
			foliar	-			25 Aug 200901 Sep	BBCH 67 BBCH 67	Cone, Dried	12.4 mg/kg	28	29 Sep 2009	Field

(1) Report No.Trial No.Location (Region) (Postcode)	(2) Commodity/Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date/Cut Date(d)	(12) Trial Details(e)
				Conc'n	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin			
					1492 L/ha 1484 L/ha	395.4 g ai/ha 391.7 g ai/ha A12705B (-)	2009 (7)		Cone	2.75 mg/kg	28	29 Sep 2009	SP (max days): 540
FSGD-063-REG S09-01444-05 Germany (Europe North) (85283)	Hops (Perle)	1.31 Dec 1990 2 – 3 -	-	-	-	- (-)	- (-)	-	Cone	0.04 mg/kg	28	03 Sep 2009	Field SP (max days): 566
									Cone, Dried	0.14 mg/kg	28	03 Sep 2009	
			foliar	-	4291 L/ha 4349 L/ha	414.3 g ai/ha 408.7 g ai/ha A12705B (-)	31 Jul 2009 06 Aug 2009 (6)	BBCH 68 BBCH 72	Cone	6.24 mg/kg	0	06 Aug 2009	Field SP (max days): 594
									Cone	2.74 mg/kg	7	13 Aug 2009	
									Cone	2.08 mg/kg	14	20 Aug 2009	
									Cone	1.26 mg/kg	21	27 Aug 2009	
									Cone	1.48 mg/kg	28	03 Sep 2009	
									Cone, Dried	<ins>5.25 mg/kg</ins>	28	03 Sep 2009	
	Hops		-	-	-	-	-	-	Cone	< 0.01 mg/kg	28	29 Sep 2009	

(1) Report No.Trial No.Location (Region) (Postcode)	(2) Commodity/Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date/Cut Date(d)	(12) Trial Details(e)
				Conc'n	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin			
FSGD-063-REG S09-01444-01 United Kingdom (Europe North) (WR6 5BT)	(Target)	1.16 May 2001 2 – 3 -				(-)	(-)		Cone, Dried	< 0.01 mg/kg	28	29 Sep 2009	Field SP (max days): 539
			foliar	-	1490 L/ha 1471 L/ha	394.1 g ai/ha 391 g ai/ha A12705B (-)	25 Aug 2009 01 Sep 2009 (7)	BBCH 67 BBCH 67	Cone	1.65 mg/kg	28	29 Sep 2009	Field SP (max days): 539
									Cone, Dried	31 mg/kg, 29.6 mg/kg, 27.5 mg/kg, 28.5 mg/kg (Mean = 29.2 mg/kg)	28	29 Sep 2009	
FSGD-063-REG S09-01444-03 Germany (Europe North) (88068)	Hops (Hallertaurer Mittelfruh)	1. - 2 – 3 -	-	-	-	- (-)	- (-)	-	Cone	0.02 mg/kg	28	02 Sep 2009	Field SP (max days): 567
									Cone, Dried	0.04 mg/kg	28	02 Sep 2009	
			foliar	-	4613 L/ha 4559 L/ha	434.2 g ai/ha 439.4 g ai/ha A12705B (-)	30 Jul 2009 05 Aug 2009 (6)	BBCH 68 BBCH 75	Cone	1.85 mg/kg	28	02 Sep 2009	Field SP (max days): 567
									Cone, Dried	17.3 mg/kg	28	02 Sep 2009	

(a) According to Codex (or other e.g. EU) classification

(*) Indicates sample taken prior to application

(1) Report No.Trial No.Location (Region) (Postcode)	(2) Commodity/Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date/Cut Date(d)	(12) Trial Details(e)
				Conc'n	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin			

(b) Only if relevant

(c) Year must be indicated

(d) Minimum number of 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.

(#) Indicates corrected Residue values

(^) PHI calculated using cut date

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period

A 2.1.3.8.3 Study 3 (Report No. RJ2841B) (EU reviewed)

Comments of zRMS:	The study has been reviewed at EU level.

Reference:	KCA1 6.3
Report:	Gill J. P., Kappes E., Renner G. (1999) Azoxystrobin: Residue Levels in Hops, Beer and Process Fractions from Studies carried out in Germany during 1998 Syngenta Report No. RJ2841B Syngenta File No. VV-326273 Unpublished
Guideline(s):	Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2), 1996
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 35: Summary of the study 3 trials

Field Trials, Crop Residue (Summary): Azoxystrobin - Residue Levels in Hops, Beer and Process Fractions from Studies carried out in Germany during 1998.			
Active Substance (common name):	Azoxystrobin	**Commercial Product (name):**	-
Crop/Crop Group:	Hops	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	Germany	**Other active substance in the formulation (common name and content):**	A12705B: Azoxystrobin
Content of active substance (g/kg or g/L):	A12705B	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A12705B SC		
Analytical Method:	Azoxystrobin (Beer, Spent Yeast, Trub, Wort, Young Beer) RAM 243/05; 0.01 mg/kg Azoxystrobin (Cone, Fresh, Dried cone) RAM 305/01; 0.01 mg/kg Azoxystrobin (Malt, Spent Grain) RAM 260/03; 0.01 mg/kg		
Recovery data:	Azoxystrobin Cone, Dried Mean = 94% RSD = 2% (n = 4 in 0.5 - 10 spiking range) Azoxystrobin Cone, Fresh Mean = 93% RSD = 3% (n = 2 in 1 - 5 spiking range) Azoxystrobin Beer Cone, Dried Mean = 100% RSD = 0% (n = 3 in 0.01 - 0.02 spiking range) Azoxystrobin Malt Cone, Dried Mean = 110% RSD = 9% (n = 3 in 0.01 - 0.01 spiking range) Azoxystrobin Spent Grain Cone, Dried Mean = 104% RSD = 5% (n = 2 in 0.02 - 0.05 spiking range) Azoxystrobin Spent Yeast Cone, Dried Mean = 110% RSD = 9% (n = 3 in 0.01 - 0.05 spiking range) Azoxystrobin Trub Cone, Dried Mean = 102% RSD = 0% (n = 2 in 0.2 - 0.5 spiking range) Azoxystrobin Wort Cone, Dried Mean = 100% RSD = 0% (n = 3 in 0.01 - 0.02 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date/ Cut Date (d)	(12) Remarks (e)
				Conc'n	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin			
RJ2841B RS-9801-G2 Germany (Europe North) (D-85283)	Hops (Hallertauer Magnum)	1. 15 Jun 1997 2. - 3. 2 Sep 1998	-	-	-	- (-)	-	-	Dried cone Malt	< 0.01 mg/kg	-	01 Sep 1998	Field SP (max days): 241
									Dried cone Trub	< 0.01 mg/kg	-	01 Sep 1998	
									Dried cone Spent Grain	< 0.01 mg/kg	-	01 Sep 1998	
									Dried cone Beer	< 0.01 mg/kg	-	01 Sep 1998	
									Dried cone Spent Yeast	< 0.01 mg/kg	-	01 Sep 1998	
									Dried cone Young Beer	< 0.01 mg/kg	-	01 Sep 1998	
									Dried cone Wort	< 0.01 mg/kg	-	01 Sep 1998	
									Dried cone	0.02 mg/kg	26	01 Sep 1998	
									Dried cone	0.02 mg/kg	26	01 Sep 1998	
									Cone, Fresh	< 0.01 mg/kg	26	01 Sep 1998	
									Dried cone	0.03 mg/kg	26	01 Sep 1998	
			foliar	-	1500 L/ha 1500 L/ha 2200 L/ha 2200 L/ha 2700 L/ha 2700 L/ha	225 g ai/ha 225 g ai/ha 300 g ai/ha 300 g ai/ha 405 g ai/ha 405 g ai/ha A12705B (-)	01 Jul 1998 10 Jul 1998 15 Jul 1998 22 Jul 1998 30 Jul 1998 06 Aug 1998 (5, 9, 8, 7, 7)	BBCH 38 BBCH 61 BBCH 61-65 BBCH 65 BBCH 65 BBCH 69	Dried cone Beer	0.02 mg/kg	-	01 Sep 1998	Field SP (max days): 241
									Dried cone Wort	0.03 mg/kg	-	01 Sep 1998	
									Dried cone Trub	0.26 mg/kg	-	01 Sep 1998	
									Dried cone Spent Grain	< 0.01 mg/kg	-	01 Sep 1998	
									Dried cone Spent Yeast	0.15 mg/kg	-	01 Sep 1998	
									Dried cone Young Beer	0.02 mg/kg	-	01 Sep 1998	
									Dried cone	8.5 mg/kg	26	01 Sep 1998	
									Dried cone	<u>11 mg/kg</u>	26	01 Sep 1998	
									Dried cone	9.1 mg/kg	26	01 Sep 1998	
									Cone, Fresh	3.2 mg/kg	26	01 Sep 1998	
RJ2841B RS-9801-G1	Hops (Perle)	1. 15 Jun 1990	-	-	-	-	-	-	Cone, Fresh	< 0.01 mg/kg	28	27 Aug 1998	Field
									Dried cone	< 0.01 mg/kg	28	27 Aug 1998	

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date/ Cut Date (d)	(12) Remarks (e)
				Conc'n	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin			
Germany (Europe North) (D-85283)		2. - 3. 28 Aug 1998				(-)			Dried cone	0.01 mg/kg	28	27 Aug 1998	SP (max days): 246
			foliar	-	1500 L/ha 1500 L/ha 2200 L/ha 2200 L/ha 2700 L/ha 2700 L/ha	225 g ai/ha 225 g ai/ha 300 g ai/ha 300 g ai/ha 405 g ai/ha 405 g ai/ha A12705B (-)	25 Jun 1998 02 Jul 1998 10 Jul 1998 15 Jul 1998 22 Jul 1998 30 Jul 1998 (8, 5, 7, 8, 7)	BBCH 38 BBCH 51 BBCH 61 BBCH 65 BBH 65 BBCH 65-69	Cone, Fresh	1.8 mg/kg	28	27 Aug 1998	Field SP (max days): 246
									Dried cone	4.8 mg/kg	28	27 Aug 1998	
									Dried cone	<u>5.7 mg/kg</u>	28	27 Aug 1998	

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of 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.

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value
(DBA) Days Before Application
SP (max days): Maximum storage period

A 2.1.3.8.4 Study 4 (Report No. RJ2981B) (EU reviewed)

Comments of zRMS:	The study has been reviewed at EU level.

Reference:	KCA1 6.3
Report:	Gill J.P., Hughes A. (2000) Azoxystrobin - Residue Levels in Hops from Trials Carried out in the UK During 1999 Syngenta Report No. RJ2981B Syngenta File No. VV-328581 Unpublished
Guideline(s):	Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2), 1996
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 36: Summary of the study 4 trials

Field Trials, Crop Residue (Summary) :Azoxystrobin - Residue Levels in Hops from Trials Carried out in the UK During 1999.			
Active Substance (common name):	Azoxystrobin	**Commercial Product (name):**	-
Crop/Crop Group:	Hops	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	United Kingdom	**Other active substance in the formulation (common name and content):**	A12705B: Azoxystrobin
Content of active substance (g/kg or g/L):	A12705B	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A12705B SC		
Analytical Method:	Azoxystrobin (Cone, Dried, Cone, Fresh) RAM 305/02; 0.01 mg/kg		
Recovery data:	Azoxystrobin Cone, Dried Mean = 90% RSD = 2% (n = 4 in 0.02 - 5 spiking range) Azoxystrobin Cone, Fresh Mean = 85% RSD = 9% (n = 8 in 0.02 - 2 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date/ Cut Date (d)	(12) Remarks (e)
				Conc'n	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin			
RJ2981B GB07-99-S252 United Kingdom (Europe North) (-)	Hops (Whitbread Golding)	1. 15 Jun 1991 2. - 3. 13 Aug – 9 Sep 1999	-	-	-	- (-)	-	-	Cone, Fresh	< 0.01 mg/kg	0	13 Aug 1999	Field SP (max days): 194
									Cone, Dried	< 0.01 mg/kg	27	09 Sep 1999	
									Cone, Fresh	< 0.01 mg/kg	27	09 Sep 1999	
									Cone, Dried	< 0.01 mg/kg	27	09 Sep 1999	
									Cone, Fresh	< 0.01 mg/kg	27	09 Sep 1999	
			foliar	-	1405 L/ha 1430 L/ha 2204 L/ha 2204 L/ha 2666 L/ha 2666 L/ha	210 g ai/ha 210 g ai/ha 330 g ai/ha 330 g ai/ha 405 g ai/ha 405 g ai/ha A12705B (-)	07 Jul 1999 15 Jul 1999 22 Jul 1999 29 Jul 1999 06 Aug 1999 13 Aug 1999 (8, 7, 7, 8, 7)	Bine at top of wire Early Flowering Flowering End of flowering/cones developing Cones developing Early Ripe	Cone, Fresh	2.6 mg/kg	0	13 Aug 1999	Field SP (max days): 194
									Cone, Fresh	2.1 mg/kg	3	16 Aug 1999	
									Cone, Fresh	1.9 mg/kg	6	19 Aug 1999	
									Cone, Fresh	1.6 mg/kg	13	26 Aug 1999	
									Cone, Fresh	0.17 mg/kg	27	09 Sep 1999	
									Cone, Fresh	0.05 mg/kg	27	09 Sep 1999	
									Cone, Dried	0.45 mg/kg	27	09 Sep 1999	
									Cone, Dried	<u>1.2 mg/kg</u>	27	09 Sep 1999	

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date/ Cut Date (d)	(12) Remarks (e)
				Conc'n	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin			
RJ2981B GB07-99-S253 United Kingdom (Europe North) (-)	Hops (Target)	1. 15 Jun 1976 2. - 3. 20 Aug – 17 Sep 1999	-	-	-	- (-)	-	-	Cone, Fresh	< 0.01 mg/kg	0	20 Aug 1999	Field SP (max days): 187
									Cone, Dried	< 0.01 mg/kg	28	17 Sep 1999	
									Cone, Fresh	< 0.01 mg/kg	28	17 Sep 1999	
									Cone, Dried	< 0.01 mg/kg	28	17 Sep 1999	
									Cone, Fresh	< 0.01 mg/kg	28	17 Sep 1999	
			foliar	-	1449 L/ha 1449 L/ha 2087 L/ha 2087 L/ha 2612 L/ha 2612 L/ha	210 g ai/ha 210 g ai/ha 330 g ai/ha 330 g ai/ha 405 g ai/ha 405 g ai/ha A12705B (-)	15 Jul 1999 22 Jul 1999 29 Jul 1999 06 Aug 1999 13 Aug 1999 20 Aug 1999 (7, 7, 8, 7, 7)	Early flowering Flowering Cone development Cones developing Early ripe Mid-ripe	Cone, Fresh	2.9 mg/kg	0	20 Aug 1999	Field SP (max days): 187
									Cone, Fresh	2.6 mg/kg	3	23 Aug 1999	
									Cone, Fresh	3.2 mg/kg	6	26 Aug 1999	
									Cone, Fresh	2.4 mg/kg	14	03 Sep 1999	
									Cone, Fresh	0.19 mg/kg	28	17 Sep 1999	
									Cone, Dried	1.8 mg/kg	28	17 Sep 1999	
									Cone, Dried	2.5 mg/kg	28	17 Sep 1999	
									Cone, Fresh	0.29 mg/kg	28	17 Sep 1999	

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of 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.

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value
(DBA) Days Before Application
SP (max days): Maximum storage period

A 2.1.3.8.5 Study 5 (Report No. RJ3015B) (EU reviewed)

Comments of zRMS:	The study has been reviewed at EU level.

Reference:	KCA1 6.3
Report:	Gill J.P., Kappes E., Griehl T. (2000) Residue Levels in Hops, Beer & Processed Fractions from stuidies Carried out in Germany during 1999 Syngenta Report No. RJ3015B Syngenta File No. VV-377467 Unpublished
Guideline(s):	Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2), 1996
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 37: Summary of the study 5 trials

Field Trials, Crop Residue (Summary): Residue Levels in Hops, Beer and Process Fractions from Studies carried out in Germany during 1999			
Active Substance (common name):	Azoxystrobin	**Commercial Product (name):**	-
Crop/Crop Group:	Hops	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	Germany	**Other active substance in the formulation (common name and content):**	A12705B: Azoxystrobin
Content of active substance (g/kg or g/L):	A12705B	**Residues calculated as:**	mg/L, mg/kg
Formulation (e.g. WP):	A12705B SC		
Analytical Method:	Azoxystrobin (Beer, Cone, Dried, Cone, Fresh, Malt, Spent Grain, Spent Yeast, Trub, Wort, Young Beer) RAM 305/02; 0.01 mg/kg		
Recovery data:	Azoxystrobin Cone, Dried Mean = 79% RSD = 11% (n = 14 in 0.02 - 10 spiking range) Azoxystrobin Cone, Fresh Mean = 88% RSD = 8% (n = 8 in 0.02 - 2 spiking range) Azoxystrobin Beer Cone, Dried Mean = 90% RSD = 3% (n = 10 in 0.01 - 1 spiking range) Azoxystrobin Malt Cone, Dried Mean = 95% RSD = 4% (n = 2 in 0.02 - 0.02 spiking range) Azoxystrobin Spent Grain Cone, Dried Mean = 88% RSD = 5% (n = 12 in 0.01 - 1 spiking range) Azoxystrobin Spent Yeast Cone, Dried Mean = 91% RSD = 7% (n = 10 in 0.01 - 1 spiking range) Azoxystrobin Trub Cone, Dried Mean = 87% RSD = 8% (n = 10 in 0.01 - 1 spiking range) Azoxystrobin Wort Cone, Dried Mean = 93% RSD = 4% (n = 8 in 0.01 - 1 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date/ Cut Date (d)	(12) Remarks (e)
				Conc'n	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin			
RJ3015B RS-9906-G2 Germany (Europe North) (D-85283)	Hops (Spalter Select)	1. 15 Jun 1991 2. - 3. 5 Aug - 25 Nov 1999	-	-	-	- (-)	-	-	Cone, Fresh	< 0.01 mg/kg	0	05 Aug 1999	Field SP (max days): 216
									Cone, Fresh	< 0.01 mg/kg	15	20 Aug 1999	
									Cone, Dried	0.23 mg/kg, 0.21 mg/kg, 0.22 mg/kg (Mean = 0.22 mg/kg)	26	31 Aug 1999	
									Cone, Dried	0.15 mg/kg	26	31 Aug 1999	
									Cone, Dried Spent Grain	< 0.01 mg/kg, < 0.01 mg/kg (Mean = 0.01 mg/kg)	26	31 Aug 1999	
									Cone, Dried Malt	< 0.01 mg/kg	26	31 Aug 1999	
									Cone, Dried Beer	< 0.01 mg/L	26	31 Aug 1999	
									Cone, Dried Spent Yeast	< 0.01 mg/kg	26	31 Aug 1999	
									Cone, Dried Young Beer	< 0.01 mg/L	26	31 Aug 1999	
									Cone, Fresh	0.05 mg/kg, 0.04 mg/kg, 0.05 mg/kg (Mean = 0.05 mg/kg)	26	31 Aug 1999	
									Cone, Fresh	0.05 mg/kg, 0.05 mg/kg, 0.05 mg/kg (Mean = 0.05 mg/kg)	26	31 Aug 1999	
									Cone, Dried Trub	0.01 mg/kg	26	31 Aug 1999	
									Cone, Dried Wort	< 0.01 mg/kg	26	31 Aug 1999	
									Cone, Dried	0.2 mg/kg, 0.21 mg/kg, 0.21 mg/kg (Mean = 0.2067 mg/kg)	26	31 Aug 1999	
			foliar	-	1500 L/ha 1500 L/ha 2200 L/ha	247.5 g ai/ha 247.5 g ai/ha 363 g ai/ha	02 Jul 1999 16 Jul 1999	BBCH 51 BBCH 61	Cone, Fresh	12 mg/kg	0	05 Aug 1999	Field
									Cone, Fresh	4.9 mg/kg	7	12 Aug 1999	
									Cone, Fresh	5.3 mg/kg	15	20 Aug 1999	

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date/ Cut Date (d)	(12) Remarks (e)
				Conc'n	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin			
					2200 L/ha 2700 L/ha 2700 L/ha	363 g ai/ha 445.5 g ai/ha 445.5 g ai/ha A12705B (-)	21 Jul 1999 26 Jul 1999 31 Jul 1999 05 Aug 1999 (14, 5, 5, 5, 5)	BBCH 65 BBCH 65 BBCH 69 BBCH 71	Cone, Dried Spent Grain	< 0.01 mg/kg	26	31 Aug 1999	SP (max days): 216
									Cone, Dried Young Beer	0.03 mg/L	26	31 Aug 1999	
									Cone, Fresh	2.9 mg/kg	26	31 Aug 1999	
									Cone, Fresh	3.3 mg/kg	26	31 Aug 1999	
									Cone, Dried	12 mg/kg	26	31 Aug 1999	
									Cone, Dried	12 mg/kg	26	31 Aug 1999	
									Cone, Dried Wort	0.05 mg/kg	26	31 Aug 1999	
									Cone, Dried Trub	0.5 mg/kg	26	31 Aug 1999	
									Cone, Dried	7.1 mg/kg, 6.9 mg/kg, 6.9 mg/kg, 6.5 mg/kg (Mean = 6.85 mg/kg)	26	31 Aug 1999	
									Cone, Dried Beer	0.03 mg/L	26	31 Aug 1999	
									Cone, Dried Spent Yeast	0.11 mg/kg	26	31 Aug 1999	
RJ3015B RS-9906-G1 Germany (Europe North) (D-85283)	Hops (Perle)	1. 15 Jun 1992 2. - 3. 2 Aug – 25 Nov 1999	-	-	-	- (-)	-	-	Cone, Fresh	< 0.01 mg/kg, < 0.01 mg/kg, < 0.01 mg/kg, < 0.01 mg/kg (Mean = < 0.01 mg/kg)	0	02 Aug 1999	Field SP (max days): 219
									Cone, Fresh	< 0.01 mg/kg	12	14 Aug 1999	

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date/ Cut Date (d)	(12) Remarks (e)
				Conc'n	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin			
									Cone, Fresh	< 0.01 mg/kg	28	30 Aug 1999	
									Cone, Fresh	< 0.01 mg/kg	28	30 Aug 1999	
									Cone, Dried Wort	< 0.01 mg/kg	28	30 Aug 1999	
									Cone, Dried Malt	< 0.01 mg/kg	28	30 Aug 1999	
									Cone, Dried	< 0.01 mg/kg, < 0.01 mg/kg (Mean = < 0.01 mg/kg)	28	30 Aug 1999	
									Cone, Dried	< 0.01 mg/kg, < 0.01 mg/kg, < 0.01 mg/kg (Mean = < 0.01 mg/kg)	28	30 Aug 1999	
									Cone, Dried Trub	< 0.01 mg/kg	28	30 Aug 1999	
									Cone, Dried	< 0.01 mg/kg	28	30 Aug 1999	
									Cone, Dried Spent Grain	< 0.01 mg/kg	28	30 Aug 1999	
									Cone, Dried Beer	< 0.01 mg/L	28	30 Aug 1999	
									Cone, Dried Spent Yeast	< 0.01 mg/kg	28	30 Aug 1999	
									Cone, Dried Young Beer	< 0.01 mg/L	28	30 Aug 1999	
			foliar	-	1500 L/ha 1500 L/ha 2200 L/ha 2200 L/ha 2700 L/ha 2700 L/ha	247.5 g ai/ha 247.5 g ai/ha 363 g ai/ha 363 g ai/ha 445.5 g ai/ha 445.5 g ai/ha	25 Jun 1999 02 Jul 1999 16 Jul 1999 21 Jul 1999 26 Jul 1999 02 Aug 1999	BBCH 37 BBCH 51 BBCH 65 BBCH 61 BBCH 65 BBCH 71	Cone, Fresh	8.2 mg/kg	0	02 Aug 1999	Field SP (max days): 219
									Cone, Fresh	4.4 mg/kg	7	09 Aug 1999	
									Cone, Fresh	3.0 mg/kg	12	14 Aug 1999	
									Cone, Dried	10 mg/kg	28	30 Aug 1999	
									Cone, Fresh	2.9 mg/kg	28	30 Aug 1999	
									Cone, Dried Spent Grain	< 0.01 mg/kg	28	30 Aug 1999	

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date/ Cut Date (d)	(12) Remarks (e)
				Conc'n	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin			
						A12705B (-)	(14, 5, 7, 7, 5)		Cone, Dried Spent Yeast	0.12 mg/kg	28	30 Aug 1999	
									Cone, Dried Young Beer	0.03 mg/L	28	30 Aug 1999	
									Cone, Fresh	2.9 mg/kg	28	30 Aug 1999	
									Cone, Dried	7.7 mg/kg, 7.2 mg/kg, 7.7 mg/kg, 7.1 mg/kg (Mean =7.4 mg/kg)	28	30 Aug 1999	
									Cone, Dried	11 mg/kg	28	30 Aug 1999	
									Cone, Dried Wort	0.03 mg/kg	28	30 Aug 1999	
									Cone, Dried Trub	0.49 mg/kg	28	30 Aug 1999	
									Cone, Dried Beer	0.02 mg/L	28	30 Aug 1999	

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of 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.

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value
(DBA) Days Before Application
SP (max days): Maximum storage period

A 2.1.3.8.6 Study 6 (Report No. RJ2801B) (EU reviewed)

Comments of zRMS:	The study has been reviewed at EU level.

Reference:	KCA1 6.3
Report:	Lister N. (1998) Azoxystrobin: Residue Levels in Hops from Trials Carried out in the UK during 1998 Syngenta Report No. RJ2801B Syngenta File No. VV-377468 Unpublished
Guideline(s):	Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2), 1996
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 38: Summary of the study 6 trials

Field Trials, Crop Residue (Summary) :Azoxystrobin: Residue Levels in Hops from Trials Carried out in the UK during 1998			
Active Substance (common name):	Azoxystrobin	**Commercial Product (name):**	-
Crop/Crop Group:	Hops	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	United Kingdom	**Other active substance in the formulation (common name and content):**	A12705B: Azoxystrobin
Content of active substance (g/kg or g/L):	A12705B	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A12705B SC		
Analytical Method:	Azoxystrobin (Cone, Cone, Dried) RAM 305/01; 0.01 mg/kg		
Recovery data:	Azoxystrobin Cone, Dried Mean = 83% RSD = 6% (n = 10 in 0.01 - 1 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date/ Cut Date (d)	(12) Remarks (e)
				Conc'n	Water	Rate Formulation (Additive Type, Rate)				Azoxystrobin			
RJ2801B GB52-98-S042 United Kingdom (Europe North) (-)	Hops (Target)	1. - 2. - 3. 15 Sep 1998	-	-	-	- (-)	-	-	Cone Cone, Dried	< 0.01 mg/kg < 0.01 mg/kg	28 28	15 Sep 1998 15 Sep 1998	Field SP (max days): 197
			foliar	-	1020 L/ha 1480 L/ha 1020 L/ha 1760 L/ha 1980 L/ha 1980 L/ha	400 g ai/ha 400 g ai/ha 400 g ai/ha 480 g ai/ha 400 g ai/ha 400 g ai/ha A12705B (-)	14 Jul 1998 20 Jul 1998 28 Jul 1998 04 Aug 1998 11 Aug 1998 18 Aug 1998 (7, 8, 7, 6, 7)	Bine at top of wire Bine at top of wire Flowering Flowering Flowering Cones developing	Cone, Dried Cone	1.3 mg/kg 0.31 mg/kg	28 28	15 Sep 1998 15 Sep 1998	
RJ2801B	Hops	1. - 2. -	-	-	-	-	-	-	Cone, Dried	< 0.01 mg/kg	-	-	

(1) Report No. Trial No. Location (Region) (Postcode)	**(2) Commodity/ Variety (a)**	**(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)**	**(4) Method of Treatment**	**(5) Application rate per treatment**			**(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)**	**(7) Growth Stage at Treatment**	**(8) Portion Analyzed**	**(9) Residue found (Uncorrected)**	**(10) PHI (d)**	**(11) Sample Date/ Cut Date (d)**	**(12) Remarks (e)**
				Conc'n	**Water**	**Rate Formulation (Additive Type, Rate)**				**Azoxystrobin**			
GB52-98-S041 United Kingdom (Europe North) (-)	(Whitbread Golding)	3. 15 Sep 1998				(-)			Cone	< 0.01 mg/kg	28	15 Sep 1998/	
									Cone, Dried	0.05 mg/kg	28	15 Sep 1998/	
			foliar	-	1080 L/ha 1080 L/ha 1480 L/ha 1480 L/ha 2160 L/ha 2160 L/ha	400 g ai/ha 400 g ai/ha 830 g ai/ha 400 g ai/ha 400 g ai/ha 400 g ai/ha A12705B (-)	04 Aug 1998 21 Jul 1998 28 Jul 1998 14 Jul 1998 18 Aug 1998 11 Aug 1998 (7, 7, 7, 7, 7)	Bine at top of wire Flower Bud Flowering Flowering End of flowering Cones developing	Cone, Dried	1.1 mg/kg	28	15 Sep 1998/	
									Cone	0.29 mg/kg	28	15 Sep 1998/	

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of 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.

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value
(DBA) Days Before Application
SP (max days): Maximum storage period

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

No new or additional studies have been submitted.

A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

A 2.1.5.1 Distribution of the residue in peel/pulp

No new or additional studies have been submitted.

A 2.1.5.2 Processing studies on a core set of representative processes

A 2.1.5.2.1 Study 1 (Report No. RJ2488B) (~~New data~~ EU reviewed)

Comments of zRMS:	The study has been reviewed at EU level.

Reference:	KCA1 6.5.3/01
Report	Azoxystrobin - Residue Levels in Tomatoes and Process Fractions from Trials carried out in Italy during 1997 Clark D M, Bonfanti F (1998) Report No. RJ2488B, Syngenta File No. VV-380583
Guideline(s):	EC Guideline 7035/VI/95, rev. 5 Council Directive 91/414/EEC EPA OPPTS 860.1520
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Executive Summary

In southern Europe, two outdoor residue trials (IT33-97-P317; IT33-97-P318) were conducted with azoxystrobin 250 SC (250 g/L azoxystrobin, nominal concentration) on tomatoes in Italy during 1997. Six or seven applications were made with spray concentrations of 25 g as/hL with intervals of 7-9 days. The water volumes used ranged from 800-1200 L/ha, giving calculated application rates of 200-300 g as/ha. Samples of ripe fruit were taken for processing at harvest, three days after the final spray.

All processing samples from tomatoes (puree, ketchup, juice and canned fruit) were prepared according to BBA guideline IV, 3-4. Samples of tomato fruit were peeled, processed to puree, ketchup, juice and conserved tomatoes. All samples were analysed using the residue analytical method RAM 243/05.

Residues of azoxystrobin in the fruits prior to processing were 0.07 and 0.11 mg/kg, which decreased to 0.05-0.07 mg/kg on washing and further to non-quantifiable (<0.01 mg/kg) after removal of the peel. When the washed tomato fruits were crushed, heated and concentrated, the resulting puree contained residue of 0.06 and 0.10 mg/kg. Low residues were found in in ketchup and juice, i.e. lower than in the raw commodity. Conserved tomatoes produced from peeled fruit contained non-quantifiable (<0.01 mg/kg) residues.

Materials and Methods
A. MATERIALS
A1. Test Materials

Description:	SC 250 (suspension concentrate)
Code:	YF9246
Batch No:	J0802/134; G530-1
Content:	Azoxystrobin: 250 g/L (nominal)

A2. Test Commodities

Crop:	Tomato (*Lycopersicon esculentum*)
Variety:	IT33-97-P317: Ideal peel IT33-97-P318: Snob
Processed Commodity:	Puree, ketchup, juice, canned fruit

A3. Test Facilities

Field Phase:	IT33-97-P317: 29017-Fiorenzuola d'Arda, Emilia Romagna, Italy. IT33-97-P318: 04010-Borgno Sabotino, Lazio, Italy.
Processing Phase:	AGROPLAN, Berlinder Str, 75, D-47574 Goch-Nierswalde.
Analytical Phase:	Zeneca Agrochemicals, Jealott's Hill International Research Centre, Bracknell, Berkshire. RG42 6ET, UK.

B. Study Design and Methods
B1. Field Phase
In southern Europe, two outdoor residue trials (IT33-97-P317; IT33-97-P318) were conducted with azoxystrobin 250 SC (250 g/L azoxystrobin, nominal concentration) on tomatoes in Italy during 1997. Seven or eight applications were made with spray concentrations of 25 g as/hL with intervals of 7-9 days. The water volumes used ranged from 800-1200 L/ha, giving calculated application rates of 200-300 g as/ha. Samples of ripe fruit were taken for processing at harvest, three days after the final spray.

B2. Processing Phase
All processing samples from grapes (must and wine) were prepared according to BBA guideline IV, 3-4.
Peeling: Tomatoe fruits were cleaned under water, dipped for approx. 20 sec. into boiling water and peeled using a kitchen knive.
Puree: After cleaning under running water, tomatoe fruits were cut in a combined cutter/mixer and warmed up to approx. 70°C for 20 minutes. The resulting tomato mush was pressed through a sieve (0.8-1.0 mm). The puree was concentrated at approx. 90°C.
Ketchup: After cleaning under running water, tomatoe fruits were cut in a combined cutter/mixer and warmed up to approx. 70°C for 20 minutes. The resulting tomato mush was pressed through a sieve (0.8-1.0 mm). For preparation of ketchup, water, vinegar, NaCl, sugar and starch were added, and the mixture was concentrated at approx. 90°C.
Juice: After cleaning under running water, tomatoe fruits were quartered and extracted usind a juice extractor. The juice was warmed up in glasses at a water bath temperature of approx. 80°C for a period of 10 minutes.

B3. Analytical Phase
All samples were analysed using the residue analytical method RAM 243. The results for residues of R230310 (z-isomer) are not summarised in this document.
RAM 243/05: Samples were extracted with acetonitrile/water. Aliquots were diluted with sodium chloride solution and partitioned with dichloromethane. The aliquots were cleaned up by adsorption chromatography on silica and final quantitative determination was by GC-NPD. The limit of quantification of the method was 0.01 mg/kg for each analyte. The results of the fortification experiments are summarised in
Table A 39.

Table A 39: Procedural recovery results for the determination of azoxystrobin residues in processed tomato products

Matrix	Fortification Level (mg/kg)	Recovery (%)	Mean Recovery (%)	RSD (%)	n
Fruit	0.05	100	100	-	1
	0.1	95, 97, 96, 99, 98	97	1.6	5
	0.2	98, 101	100	-	2
	0.5	96, 93, 99, 97, 99, 99, 103	98	3.2	7
	Overall	-	*98*	*2.5*	*15*
Juice	0.1	104	104	-	1
	0.2	102	102	-	1
	Overall	-	*103*	-	*2*
Conserve	0.1	101	101	-	1
	0.2	100	100	-	1
	Overall	-	*101*	-	*2*
Puree	0.1	93	93	-	1
	0.5	98	98	-	1
	Overall	-	*96*	-	*2*
Peel	0.5	101, 103	102	-	2
Ketchup	0.5	94	94	-	1

Results and Discussion

Tomato fruit samples taken from the two outdoor trials 3 days after the last application contained 0.07 and 0.11 mg/kg residues of azoxystrobin pior to processing. These residues decreased to 0.05-0.07 mg/kg on washing and further to non-quantifiable (<0.01 mg/kg) after removal of the peel. Low residues of azoxystrobin were found in the ketchup and juice with non-quantifyable residues in the tomato conserve. The azoxystrobin residues and calculated transfer factors for the processed samples are presented Table A 40. All residues of azoxystrobin in untreated samples were below the limit of quantification (LOQ).

Table A 40: Azoxystrobin residues in tomatoes and tomato by-products with corresponding transfer factors

Country Year Trial	Commodity	Azoxystrobin Residue (uncorrected, mg/kg)	Azoxystrobin Transfer Factor[1]
Italy 1997 IT33-97-P317	Pre-process fruit	0.07	-
	Washed fruit	0.05 (0.05, 0.05, 0.04)	0.71
	Peeled fruit	<0.01	<0.14
	Peel	0.13 (0.10, 0.15)	1.86
	Puree	0.10	1.43
	Ketchup	0.04	0.57
	Juice	0.02	0.29
	Conserve	<0.01	<0.14
Italy 1997 IT33-97-P318	Pre-process fruit	0.11	-
	Washed fruit	0.07	0.64
	Peeled fruit	<0.01	<0.09
	Peel	0.14 (0.13, 0.15)	1.27
	Puree	0.06	0.55
	Ketchup	0.04	0.36
	Juice	0.04	0.36
	Conserve	<0.01	<0.09

[1] – Transfer factor = residue in processed commodity (mg/kg)/ residue in RAC (mg/kg)

The transfer factors for azoxystrobin residues in processed tomato commodities are summarised in Table A 41.

Table A 41: Azoxystrobin transfer factors for processed tomato commodities

Commodity	Transfer factor	
	Individual values	**Mean**
Washed fruit	0.71, 0.64	0.68
Peeled fruit	<0.14, <0.09	<0.12
Peel	1.86, 1.27	1.56
Puree	1.43, 0.55	0.99
Ketchup	0.57, 0.36	0.47
Juice	0.29, 0.36	0.32
Conserve	<0.14, <0.09	<0.12

Conclusion

The processing of tomatoes resulted in an increase of azoxystrobin residue in tomato peel. Residues of azoxystrobin decreased in ketchup, juice and canned fruit. Results for puree were mixed, with an increase in one trial and a decrease in the other. Transfer factors for azoxystrobin from tomatoes were: 1.3/1.9 in peel, 0.55/1.4 in puree, 0.36/0.57 in ketchup, 0.29/0.36 in juice and <0.09/<0.14 in canned fruit (conserves).

A 2.1.5.2.2 Study 2 (Report No. RJ2841B) (EU reviewed)

Comments of zRMS:	The study has been reviewed at EU level.

Reference:	KCA1 6.5.3/02
Report	Azoxystrobin: Residue Levels in Hops, Beer and Process Fractions carried out in Germany during 1998 Gill J P, Kappes E, Renner G (1999) Report No. RJ2841B, Syngenta File No. VV-326273
Guideline(s):	Commission of the European Communities. Processing Studies (SANCO 7035/VI/95 rev.5, 22/07/1997) BBA Guideline IV, 3-4 (1990) IVA Guideline I-III (1992)
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Executive Summary

Two residue field trials (RS-9801-G1, RS-9801-G2) were conducted in Germany during 1998 in which azoxystrobin formulated as YF10537, a suspension concentrate (SC) containing 250 g azoxystrobin per litre, was applied to hops. Six applications were made at a rate of 15 g as/hL, separated by intervals of 5-9 days. Samples of hops were collected 26-28 days after the final application, and sub-samples of the hops were dried overnight.

Hops from one trial (RS-9801-G2) were used for the production of beer. The processing phase included one mass balance study. Common commercial practices were simulated in the process and quality assessment of the finished beer was included. Residues of azoxystrobin were measured in the starting (dried) hops, malt, spent malt, spent hops, spent yeast, wort, young beer and beer using analytical methods RAM 305/01, RAM 260/03 and RAM 243/05.

Acceptable mass balances were obtained for azoxystrobin during the processing of hops. The transfer factor for azoxystrobin residues from raw agricultural commodity to beer was 0.002.

Materials and Methods

A. Materials

A1. Test Materials

Description:	SC 250 (suspension concentrate)
Code:	YF10537
Batch No:	Not provided
Content:	Azoxystrobin: 23.3% (w/w; density 1.10 mg/mL)

A2. Test Commodities

Crop:	Hops (*Humulus lupulus*)
Variety:	Hallertauer Magnum
Processed Commodity:	Malt, spent malt, spent hops, spent yeast, wort, young beer, beer.

A3. Test Facilities

Field Phase:	Wolznach-Larsbach, Bayern (D-85283), Germany.
Processing Phase:	Fachhochschule Anhalt, Fachbereich Lebensmittel- und Biotechnologie, D-06366 Köthen, Sachsen-Anhalt, Germany.
Analytical Phase:	Zeneca Agrochemicals, Jealott's Hill International Research Centre, Bracknell, Berkshire. RG42 6ET, UK.

B. Study Design and Methods

B1. Field Phase

Two residue field trials (RS-9801-G1, RS-9801-G2) were conducted in Germany during 1998 in which azoxystrobin formulated as YF10537, a suspension concentrate (SC) containing 250 g azoxystrobin per litre, was applied to hops. Six applications were made at a rate of 15 g as/hL, separated by intervals of 5-9 days. The application volume ranged from 1500 L/ha (225 g as/ha) at the first two applications, 2200 L/ha (330 g as/ha) at the intermediate applications, to 2700 L/ha (405 g as/ha) at the last two applications. Samples of hops were collected 26-28 days after the final application, and sub-samples of the hops were dried overnight.

B2. Processing Phase

Hops from one trial (RS-9801-G2) were used for the production of beer. The processing phase included one mass balance study. Common commercial practices were simulated in the process and quality assessment of the finished beer was included.

Fresh cones harvested 26 days after the final application were dried at temperatures ≥ 70°C. Beer brewing included mashing of the malt, separation of the wort from insoluble malt components, boiling of the wort after addition of milled dried cones, conditioning of the wort by separation of the trub, fermentation after addition of pure culture yeast, and maturation of the young beer.

The following samples were collected for analysis for azoxystrobin residues: dried cones, trub (spent hops), wort, young beer, spent yeast, beer.

B3. Analytical Phase

Samples from starting (dried) hops, beer and processed fractions were analysed for residues of azoxystrobin (and R230310) using analytical methods RAM 305/01 (hops), RAM 260/03 (malt, spent grain) and RAM 243/05 (wort, yeast, beer, trub). The results for R230310 are not summarised in this document.

RAM 305/01: Samples of hops were extracted with acetonitrile/water and clean-up was by solid-phase extraction (C18 and silica phases). Azoxystrobin (and R230310) were determined by HPLC-MS/MS. The limit of quantification of the method was 0.01 mg/kg for each analyte. The results of the fortification experiments are summarised in Table A 42.

Table A 42: Recovery results from method validation of RAM 305/01 for azoxystrobin in hops

Matrix	Fortification Level (mg/kg)	Recovery (%)	Mean Recovery (%)	RSD (CV) (%)	n
Fresh hops	1.0	95	94	2.4	6
	5.0	91			
Dried hops	0.5	93			
	5.0	95, 92			
	10	97			

RAM 260/03: Samples of malt and spent grain were extracted with acetonitrile/water (9/1). Extracts were partitioned into dichloromethane, evaporated to dryness and re-dissolved in ethyl acetate/methanol (75/25) for gel permeation chromatography (GPC). After cleaning-up on solid phase cartridges (alumina-N, Florisil), residues of azoxystrobin were determined by GC-NPD. The limit of quantification of the method was 0.01 mg/kg for each analyte. The results of the fortification experiments are summarised in Table A 43.
RAM 243/05: Samples of wort, yeast, beer and trub were extracted with acetonitrile/water (9/1). Extracts were partitioned into dichloromethane and cleaned up by silica adsorption chromatography. The eluate was evaporated to dryness and re-dissolved in acetone for analysis by GC-NPD. The limit of quantification of the method was 0.01 mg/kg (or 0.01 mg/L) for each analyte. The results of the fortification experiments are summarised in Table A 43.

Table A 43: Recovery results from method validation of RAM 260/03 and RAM 243/05 for azoxystrobin in processed hops products

Matrix	Fortification level (mg/kg)	Recovery (%)	Mean Recovery (%)	RSD (CV) (%)	n
Wort	0.02	100	102	2.9	7
Yeast	0.05	100			
Beer	0.02	100			
Grain	0.02	100			
	0.05	108			
Trub	0.2	102			
	0.5	102			

Results and Discussion

Residues of azoxystrobin in the dried hops cones at the commencement of beer making were 9.8 mg/kg, compared to 12 mg/kg on completion of drying. After brewing, residues of azoxystrobin remaining in the hops were 0.26 mg/kg and in spent yeast were 0.15 mg/kg. Residues of azoxystrobin in other fractions (wort, young beer and finished beer) were low (0.02 or 0.03 mg/L). Residues from the untreated hops and processed fractions were all less than the limit of quantification (<0.01 mg/kg or mg/L). The results are summarised in
Table A 44.
All the azoxystrobin added to the beer-making process was accounted for in the measured fractions, with the greatest proportion (4.7 mg of the 5.6 mg added) remaining in the spent hops (trub). The amount of azoxystrobin recovered from the process can be estimated by summing the azoxystrobin found in the trub, spent yeast and finished beer, since these are the fractions which are removed from the process. The other analysed materials are from intermediate products. Summing these three fractions gives a total of 7.15 mg azoxystrobin recovered. Because of the relatively high uncertainty of measurement at the low levels found (especially in beer), the nominal total of azoxystrobin recovered from the process was 128% of the added quantity.

Table A 44: Azoxystrobin residues in hops, beer and process fractions with corresponding transfer factors

Country Year Trial	Commodity	Azoxystrobin Residue (corrected, mg/kg)[1]	Azoxystrobin Transfer Factor[2]	Author Year Report No.
Germany 1998 RS-9801-G2	Dried hops cones[3]	9.8	-	Gill JP, Kappes E, Renner G 1999 RJ2841B
	Trub (spent hops)	0.26	0.03	
	Wort	0.03	0.00	
	Young beer	0.02	0.00	
	Spent yeast	0.15	0.02	
	Beer	0.02	0.00	
	Dried hops cones[4]	9.2	-	

[1] – Units are mg/kg for dried hops cones, units for trub, wort, young beer, spent yeast and beer are in mg/L
[2] - Transfer factor = residue in processed commodity (mg/kg)/residue in RAC (mg/kg)
[3] – At commencement of beer-making process
[4] – After storage under ambient conditions for 5 months

Conclusions

A mass balance processing study was conducted where dried hops cones treated with azoxystrobin were used for beer brewing. Acceptable mass balances of azoxystrobin were obtained. The transfer factor for azoxystrobin from raw agricultural produce to beer was 0.002.

A 2.1.5.2.3 Study 3 (Report No. RJ3015B) (EU reviewed)

Comments of zRMS:	The study has been reviewed at EU level.

Reference:	KCA1 6.5.3/03
Report	Azoxystrobin: Residue Levels in Hops, Beer and Process Fractions from Studies carried out in Germany during 1999 Gill J P, Kappes E, Griehl T (2000) Report No. RJ3015B, Syngenta File No. VV-377467
Guideline(s):	Commission of the European Communities. Processing Studies (SANCO 7035/VI/95 rev.5, 22/07/1997) BBA Guideline IV, 3-4 (1990) IVA Guideline I-III (1992)
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Executive Summary
Two residue field trials (RS-9906-G1, RS-9906-G2) were conducted in Germany during 1999 in which azoxystrobin formulated as YF10537, a suspension concentrate (SC) containing 250 g azoxystrobin per litre, was applied to hops. Six applications were made at a rate of 15 g as/hL, separated by intervals of 5-14 days. Samples of hops were collected 28 (RS-9906-G1) or 26 (RS-9906-G2) days after the final application, and sub-samples of the hops were dried overnight.
Dried hops from both field trials were used for the production of beer. Both processing phases included mass balance studies. Common commercial practices were simulated in the process and quality assessment of the finished beer was included. Residues of azoxystrobin were measured in the starting (dried) hops, malt, spent malt, spent hops, spent yeast, wort, young beer and beer using analytical methods RAM 305/02. Acceptable mass balances were obtained for azoxystrobin during the processing of hops. The transfer factor for azoxystrobin residues from raw agricultural commodity to beer was 0.003 in both studies.

Materials and Methods

A. Materials

A1. Test Materials

Description:	SC 250 (suspension concentrate)
Code:	YF10537
Batch No:	H668C
Content:	Azoxystrobin: 23.3% (w/w; density 1.10 mg/mL)

A2. Test Commodities

Crop:	Hops (*Humulus lupulus*)
Variety:	Trial RS-9906-G1: Perle Trial RS-9906-G2: Spaller-Select
Processed Commodity:	Malt, spent malt, spent hops, spent yeast, wort, young beer, beer.

A3. Test Facilities

Field Phase:	Trial RS-9906-G1: Gebrontshausen, Bayern (D-85283), Germany. Trial RS-9906-G2: Gebrontshausen, Bayern (D-85283), Germany
Processing Phase:	Fachhochschule Anhalt, Fachbereich Lebensmittel- und Biotechnologie, D-06366 Köthen, Sachsen-Anhalt, Germany.
Analytical Phase:	Zeneca Agrochemicals, Jealott's Hill International Research Centre, Bracknell, Berkshire. RG42 6ET, UK.

B. Study Design and Methods

B1. Field Phase

Two residue field trials (RS-9906-G1, RS-9906-G2) were conducted in Germany during 1999 in which azoxystrobin formulated as YF10537, a suspension concentrate (SC) containing 250 g azoxystrobin per litre, was applied to hops. Six applications were made at a rate of 15 g as/hL, separated by intervals of 5-14 days. The application volume ranged from 1500 L/ha (225 g as/ha) at the first two applications, 2200 L/ha (330 g as/ha) at the intermediate applications, to 2700 L/ha (405 g as/ha) at the last two applications. Samples of hops were collected 28 (RS-9906-G1) or 26 (RS-9906-G2) days after the final application, and sub-samples of the hops were dried under controlled conditions (4h, average 54°C).

B2. Processing Phase

Dried hops from both field trials were used for the production of beer. Both processing phases included mass balance studies. Common commercial practices were simulated in the process and quality assessment of the finished beer was included.

Beer brewing included mashing of the malt, separation of the wort from insoluble malt components, boiling of the wort after addition of milled dried cones, conditioning of the wort by separation of the trub, fermentation after addition of pure culture yeast, and maturation of the young beer.

Residues of azoxystrobin were determined in the starting (dried) hops, trub (spent hops), wort, young beer, spent yeast and beer using analytical method RAM 305/02.

B3. Analytical Phase

Samples from starting (dried) hops, beer and processed fractions were analysed for residues of azoxystrobin (and R230310) using analytical method RAM 305/02. The results for R230310 are not summarised in this document.

RAM 305/02: Aliquots of the samples were extracted with acetonitrile/water and clean-up was by adsorption chromatography on a C18 Isolute cartridge. Azoxystrobin (and R230310) were determined by HPLC-MS/MS. The limit of quantification of the method was 0.01 mg/kg for each analyte. The results of the fortification experiments are summarised in Table A 45 and Table A 46.

Table A 45: Recovery results from method validation of RAM 305/01 for azoxystrobin in hops

Matrix	Fortification Level (mg/kg)	Recovery (%)	Mean Recovery (%)	RSD (CV) (%)	n
Fresh hops	0.02	83, 80, 85	83	11	22
	0.05	81			
	0.5	91, 96			
	2.0	92, 98			

Matrix	Fortification Level (mg/kg)	Recovery (%)	Mean Recovery (%)	RSD (CV) (%)	n
Dried hops	0.02	85			
	0.05	74, 71, 88			
	0.5	73, 68			
	1.0	93, 78			
	5.0	77, 85, 76, 76			
	10.0	96, 69			

Table A 46: Recovery results from method validation of RAM 305/01 for azoxystrobin in processed hops products

Matrix	Fortification Level (mg/kg)	Recovery (%)	Mean Recovery (%)	RSD (CV) (%)	n
Malt	0.02	98, 92	88	7.4	12
Spent grain	0.02	94, 97, 89, 87			
Trub (spent hops)	0.1	77			
	0.2	84			
Spent yeast	0.1	90			
	0.2	79			
Beer	0.02	88, 85			

Results and Discussion

Residues of azoxystrobin in the dried hops cones at the commencement of beer making were 10 and 9.3 mg/kg, compared to 12 and 15 mg/kg on completion of drying. After brewing, residues of azoxystrobin remaining in the spent hops were 0.61 and 0.62 mg/kg. Residues in spent yeast were 0.15 mg/L and 0.13 mg/L. Residues of azoxystrobin in finished beer and the other fractions (wort and young beer) were low (0.03 to 0.05 mg/L). Residues from the untreated hops and processed fractions were less than the limit of quantification (<0.01 mg/kg or mg/L) in the first trial. In the second trial, a mean azoxystrobin residue of 0.06 mg/kg was found in the untreated samples taken 26 days after the final application, although no residues had been found in samples collected earlier. On drying, this residue increased to a mean of 0.28 mg/kg. The results are summarised in
Table A 47.

The amount of recovered from the process can be estimated by summing the azoxystrobin found in the trub, spent yeast and finished beer, since these are the three fractions which are removed from the process – the other analysed materials are from intermediate products. Summing these three fractions gives totals of 4.72 mg and 5.03 mg azoxystrobin recovered in the two trials, compared to added amounts of 5.0 mg and 4.7 mg respectively. Thus, the nominal totals of azoxystrobin recovered from the process were 94% and 107% of the added quantities. The greatest proportion of the azoxystrobin was recovered in the beer itself 3.3 mg/L in each trial (66% and 70% of the starting azoxystrobin).

Table A 47: Azoxystrobin residues in hops, beer and process fractions with corresponding transfer factors

Country Year Trial	Commodity	Azoxystrobin Residue (corrected, mg/kg)[1]	Azoxystrobin Transfer Factor[2]	Author Year Report No.
Germany 1999 RS-9906-G1	Dried hops cones[3]	10[4]	-	Gill JP, Kappes E, Griehl T 2000 RJ3015B
	Trub (spent hops)	0.61	0.061	
	Wort	0.04	0.004	
	Young beer	0.3	0.030	
	Spent yeast	0.15	0.015	
	Beer	0.03	0.003	
Germany 1999 RS-9906-G2	Dried hops cones[3]	9.3[4]	-	Gill JP, Kappes E, Griehl T 2000 RJ3015B
	Trub (spent hops)	0.62	0.067	
	Wort	0.05	0.005	
	Young beer	0.04	0.004	
	Spent yeast	0.13	0.014	
	Beer	0.03	0.003	

[1] – Units are mg/kg for dried hops cones, units for trub, wort, young beer, spent yeast and beer are in mg/L

[2] - Transfer factor = residue in processed commodity (mg/kg)/residue in RAC (mg/kg)
[3] – At commencement of beer-making process
[4] – Mean of four determinations

Conclusions

Two mass balance processing studies were conducted where dried hops cones treated with azoxystrobin were used for beer brewing. Acceptable mass balances of azoxystrobin were obtained. The transfer factor for azoxystrobin from raw agricultural produce to beer was 0.003 in both studies.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new or additional studies have been submitted.

A 2.1.7 Other/Special Studies

A 2.1.7.1.1 Study 1 (Report No. T011298-06-REG) (~~New data~~ EU reviewed)

Comments of zRMS:	The study has been reviewed at EU level.

Reference:	KCA 6.10/01
Report	Azoxystrobin (ICI5504) and Cyproconazole (SAN619) - Residues in Honey following Exposure of Bees to Treated Winter Oil-seed Rape in Germany during 2007 Bocksch, S (2008) Report No. T011298-06-REG, Syngenta File No. VV-382035
Guideline(s):	Guidance Document for Residue Trials on Honey of the Federal Office for Consumer Protection and Food Safety, version 2, 03/10/2003. IVA (1992), EU 91/414/EEC (1997)
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Executive summary

This study contained three trials during 2007 in Northern and Southern Germany. In each trial tunnels were placed in oil seed rape fields to maximise the exposure of the bee colonies to the treated rape plants. Each trial consisted of four tunnels (one control and three treated). To each of the three treated tunnels a single foliar application of azoxystrobin (ICl5504, A 12750B, 250 SC) and cyproconazole (SAN619, A9898A, 100 SL) as a tank mixture was made to oil-seed rape at the onset of flowering. Honey was then collected for analysis of azoxystrobin and cyproconazole.
The health effects on the bee colonies were also monitored.
Samples were analysed for azoxystrobin, its metabolite R230310 and cyproconazole; due to low amounts of honey in trial G07N013B both ship and retain samples were sent for analysis. Only data for azoxystrobin is presented and discussed here.
The method was validated in compliance with European guidelines for residue analytical methods SANCO/825/00 Rev.7 (17/03/2004) and SANCO/3029/99 Rev.4 (11/07/2000).
At each fortification level, the mean recoveries for each analyte were in the range 71-103% and the relative standard deviation less than 20%. The specificity of the method was demonstrated with the two transitions described in the methods, with no significant interference being detected in any of the blank and unfortified specimens. The linearity of the detector was checked using calibration solutions. The calibration curves obtained were linear with correlation coefficients above 0.990.
In two tunnels from one of the trials (G07N011B), residues of azoxystrobin were found to be at the limit of quantification (0.01 mg/kg), all other residues were below LOQ.

I. MATERIAL AND METHODS

A. MATERIALS

A1. Test Materials

Common Name:	Azoxystrobin
Code Name:	A12705B
Description	SC 250
Content	252 g/L
Source:	Syngenta
Standard Reference:	ASJ10008-03 (Batch)
Purity:	99.7%
Storage Conditions:	Stored at ADME Bioanalyses at 0-9 °C
Expiration Date:	Jan 2011

A2. Test System

Crop:	Oilseed rape (Brassica napus)
Pollenator:	Honey bee (Apis mellifera)
Processed Commodities:	Honey

A3. Test Facilities

Field Phase (Trial G07N011B):	Eurofins-GAB GmbH, Eutinger Str. 24, 75223 Niefern Oschelbronn, Germany
Field Phase (Trial G07N012B):	BioChem agrar GmbH, Kupferstr. 6, D-04827 Gerichshain, Germany
Field Phase (Trial G07N013B):	LAVES lnstitut tor Bienenkunde Celle, Herzogin-Eleonore-Allee 5, 29221 Celle, Germany
Analytical Phase:	Eurofins/ADME BIOANALYSES, 75 chemin de Sommières, 30310 Vergèze, France.

B. STUDY DESIGN AND METHODS

B1. Field phase

Three residue trials (G07N011B, G07N012B, G07N013B) were conducted with A12705B SC 250 (250 g/L, azoxystrobin nominal concentration) and A9898A SL 100 (100 g/L cyproconazole, nominal concentration) on oilseed rape in Germany in 2007. One application, at growth stages BBCH 63, was made at 250 g ai/ha for azoxystrobin and at 100 g a.s./ha for cyproconazole. The health of the colonies was assessed prior to introduction into the tunnels and at the end of the trial when the honey had been collected. No differences were seen between the treatment and control for any parameters measured. Considering the restricted conditions in the tunnel tents and beekeeper activities, the health status of all colonies was good throughout the trial, all colonies were free of visible symptoms of diseases.

Honey was then collected at maturity, with the exception of deviations documented (water content >20%) for trials G07N011B in the samples of plot T3, and in the trial G07N013B in all samples except the samples of T3 at DAA+8

B2. Analytical phase

Samples were stored under deep-frozen conditions for a period of about 2 months prior to analysis. Azoxystrobin has been shown to be stable in a range of crops for at least 12 months under these storage conditions.

Samples were extracted with acetonitrile/water (90/10 v/v) for azoxystrobin. Final quantitation was by HPLC-MS/MS with external standardisation.

The methods RAM 305/03 was successfully validated for azoxystrobin in honey during the course of this study.

The limit of quantification (LOQ) was 0.01 mg/kg for azoxystrobin in honey. Method validation procedural recoveries are summarised in

Table A 48. Procedural recoveries from the analyses of honey samples are summarised in Table A 49.

During the validation experiments, the matrix effects of honey were also checked by comparing, for each analyte, the peak area of an analytical standard in the mobile phase and in a matrix-matched analytical standard. Matrix effect for azoxystrobin is above 10%, and therefore considered as significant. It is recommended to use matrix matched calibration standards for the quantification of azoxystrobin in honey.

Table A 48: Method validation recovery data – primary and confirmatory transitions

Azoxystrobin (Primary Transition 404.2 → 372.4 m/z)					
Matrix	**Fortification Level (mg/kg)**	**Recovery (%)**	**Mean (%)**	**RSD (%)**	**Range (%)**
Honey	0.01	78, 77, 75, 81, 71	76	4.8	71-81
	0.10	83, 82, 83, 89, 82	84	3.4	82-89
	Overall		80	6.3	71-89
Azoxystrobin (Secondary Transition 404.2 → 343.8 m/z)					
Matrix	**Fortification Level (mg/kg)**	**Recovery (%)**	**Mean (%)**	**RSD (%)**	**Range (%)**
Honey	0.01	98, 93, 95, 103, 90	96	5.2	90-103
	0.10	83, 80, 81, 90, 85	84	4.5	80-90
	Overall		90	8.4	80-103

Table A 49: Procedural recovery (sample analysis)

Substrate (Control)	**Fortification Levels (mg/kg)**	**Azoxystrobin (%)**
Honey	0.01	91
	0.1	91
Mean		91

II. RESULTS AND DISCUSSION

Azoxystrobin residues in honey are presented in Table A 50.

Table A 50: Azoxystrobin residues in honey

Trial	Tunnel	Sampling Interval (Days After Application)	Matrix	Azoxystrobin Residue (mg/kg)
G07N011B	1	13 DAA	Honey	0.01
	2	13 DAA	Honey	0.01
	3	13 DAA	Honey	<0.01
G07N012B	1	14 DAA	Honey	<0.01
	2	14 DAA	Honey	<0.01
	3	14 DAA	Honey	<0.01
G07N013B	1	14 DAA	Honey	<0.01
	2	14 DAA	Honey	<0.01
	3	14 DAA	Honey	<0.01

III. CONCLUSION

Residues of azoxystrobin in the honey specimens from trial G07N011B were at 0.01 mg/kg in Tunnel 1 and Tunnel 2 at 13 DAA, and were below the limit of quantification of 0.01 mg/kg in Tunnel 3 at 13 DAA. No residues of azoxystrobin were detected at or above the limit of quantification of 0.01 mg/kg in any of the honey specimens from trials G07N012B and G07N013B at 14 DAA.
No residues of azoxystrobin were detected at or above the limit of quantification (0.01 mg/kg) in the control honey specimens.
The method RAM 305/03 was successfully validated for azoxystrobin in honey during the course of this study.

A 2.1.7.1.2 Study 2 (Report No. S21-01128) (New data)

Comments of zRMS:	The study contained five field trials (four were performed successfully) on winter oilseed rape was conducted in northern/southern Europe. Azoxystrobin was applied to winter oilseed rape as A12705B, an SC formulation containing nominally 250 g azoxystrobin per litre. Two applications, (applied at growth stage 62-65 BBCH), separated by a 5-7 day interval were made at a nominal rate of 250 g ai/ha for A1 and A2. Treated samples were collected once at maturity (trials -01 and -04) of honey or at the end of flowering (trials -02 and -05) at 2-18 days after the last application (DALA). Untreated samples were collected once at maturity (trials -01 and -04) of honey or at the end of flowering (trials -02 and -05) at 2-18 days after the last application (DALA). In trial -03 no samples could be collected. The samples of trials -02 and -05 were dried in the laboratory to reach the requested sugar content of at least 80%. The sugar content of the honey samples was assessed by performing BRIX analysis. The ranges of residues of azoxystrobin were <0.01 – 0.02 mg/kg and R230310 were <0.01 mg/kg. No residues of azoxystrobin and its metabolite R230310 at or above the limit of quantification of 0.01 mg/kg were found in any of the untreated honey samples. Samples were stored frozen for a maximum period of 76 days from sampling to extraction. Field samples for residue analysis were analysed for azoxystrobin and its metabolite R230310 in honey using method RAM 305/03 as described in Syngenta Report Number: T011298-06-REG. The analytical method has been validated for beer, wheat flour and various crop matrices and honey. Limit of Quantification: 0.01 mg/kg The study is acceptable.

Reference:	KCA 6.10
Report:	Azoxystrobin - Determination of Residues of Azoxystrobin and R230310 (z-isomer) in Honey after Two Applications of A12705B to Winter Oilseedrape at 5 Sites in Northern and Southern Europe in 2021 Appeltauer, A (2022) Report No. S21-01128, Syngenta File No. VV-931501
Guideline(s):	OECD 509 (September 2009) SANTE/2020/12830, Rev. 1 (2021): Guidance document on pesticide analytical methods for risk assessment and post-approval control and monitoring purposes (February 2021) EC (2018) Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey (SANTE/11956/2016 rev. 9)
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Executive Summary

A semi-field study was conducted on four trials in Germany, Austria and Spain on winter oilseed rape in 2021. A fifth residue trial on winter oilseed rape in Romania was not successfully conducted because no honey could be sampled. One untreated plot and one treated plot (each 200m²) were established in separate tunnels at each field site and one bee colony (honey bee, *Apis mellifera* L.) was introduced into each tunnel one day before treatment (trial -01, -02, -04 and -05) and in the morning before treatment for trial -03.

Azoxystrobin was applied twice by foliar spraying with a calibrated boom sprayer at a rate of 250 g a.i./ha to the treated plot. During first application the crop was at BBCH 62 and during the second application at BBCH 63-65. The bee colonies were protected from direct spray with plastic foil during application.

Samples of mature, capped honey (4.72 – 62.35g) were taken 2-18 days after the last application (DALA) for residue analysis. All samples were maintained frozen at the testing facility, during shipping to the laboratory, and were stored frozen for a maximum of 76 days until analysis for azoxystrobin and its metabolite R230310 residues. Adequate storage stability data are available to support the storage conditions and intervals for samples in the current trials.

The bee colonies remained in good health throughout the trial, free of visible symptoms of diseases.

Samples were analysed using method RAM 305/03, an LC-MS/MS method to determine residues of azoxystrobin and its metabolite R230310. Acceptable concurrent recoveries were reported for honey at fortification levels of 0.01 and 0.1 mg/kg, thus validating the method. The limit of quantification (LOQ) was 0.01 mg/kg.

No residues of azoxystrobin or R230310 were found at or above the LOQ in honey from the untreated control plot. Individual sample residues in the collected honey from the treated plot ranged from < 0.01mg/kg to 0.02 mg/kg (azoxystrobin) and were below LOQ (0.01 mg/kg) for R230310 (Z-isomer).

I. MATERIAL AND METHODS

A. MATERIALS

A1. Test Materials

Common Name:	Azoxystrobin
Code Name:	A12705B
Description	SC 250
Content	250 g/L
Source:	Syngenta
Standard Reference:	ASJ10008-05 (Batch)
Purity:	99.8%
Expiration Date:	Feb 2025

A2. Test System

Crop:	Oilseed rape (*Brassica napus*)
Pollinator:	Honeybee (*Apis mellifera* L.)
Processed Commodities:	Honey

A3. Test Facilities

Field Phase (Trial S12-01128-01):	Eurofins-GAB GmbH, Eutinger Str. 24, D-75223 Niefern-Öschelbronn, Germany
Field Phase (Trial S12-01128-02):	Am Tieberhof 21, A-8200 Gleisdorf, Austria
Field Phase (Trial S12-01128-03):	Muntele Mic Street, No 20, RO-307210 Giarmata, Timis Counbty, Romania
Field Phase (Trial S12-01128-04):	Avda. Antic Regne de Valencia 25, E-46290, Alcasser – Valencia, Spain
Field Phase (Trial S12-01128-05):	Avda. Antic Regne de Valencia 25, E-46290, Alcasser – Valencia, Spain
Analytical Phase:	Neulaendar Gewerbepark 2, D-21079 Hamburg, Germany

B. STUDY DESIGN AND METHODS

B1. Field phase

A semi-field study was conducted on four trials in Germany, Austria and Spain on winter oilseed rape in 2021. A fifth residue trial on winter oilseed rape in Romania was not successfully conducted because no honey could be sampled. One untreated plot and one treated plot (each 200m²) were established in separate tunnels at each field site and one bee colony (honey bee, *Apis mellifera* L.) was introduced into each tunnel one day before treatment (trial -01, -02, -04 and -05) and in the morning before treatment for trial -03.
Azoxystrobin (A12705B, 250 SC) was applied twice by foliar spraying with a calibrated boom sprayer at a rate of 250 g a.i./ha to the treated plot During first application the crop was at BBCH 62 and during the second application at BBCH 63-65. The bee colonies were protected from direct spray with plastic foil during application.
The health of the colonies was assessed before introduction to the tunnels and at the end of the trial, by assessing the strength of the colony (number of frames covered with bees), the presence of a healthy queen (i.e., presence of eggs or presence of queen cells), and visual assessment of the percentage of frames containing pollen, nectar, and brood (eggs, larvae and capped cells).
Samples of mature, capped honey (4.72 – 62.35g) were taken 2-18 days after the last application (DALA) for residue analysis.

B2. Analytical phase

All samples were maintained frozen at the testing facility, during shipping to the laboratory, and were stored frozen for a maximum of 76 days until analysis for azoxystrobin and its metabolite R230310 residues. The stability of the storage of azoxystrobin and R230310 in honey was assessed for 81 days within this study. Adequate storage stability data are available to support the storage conditions and intervals for samples in the current trials.
Samples were analysed using method RAM 305/03, an LC-MS/MS method to determine residues of azoxystrobin and its metabolite R230310. Acceptable concurrent recoveries were reported for honey at fortification levels of 0.01 and 0.1 mg/kg, thus validating the method. These are reported in the table below. The limit of quantification (LOQ) was 0.01 mg/kg.

Table A 51: Procedural recovery

Analyte	Fortification level (mg/kg)	Sample size (n)	Recoveries (%)	Mean recovery (%)	RSD (%)
Azoxystrobin	0.01	5	100, 118, 103, 104, 100	103	5.2
	0.10	5	100, 100, 102, 100, 100		
R230310	0.01	5	100, 102, 101. 103, 100	100	1.5
	0.10	5	99, 100, 100, 99, 99, 100		

II. RESULTS AND DISCUSSION

Azoxystrobin residues in honey are presented in Table A 52

Table A 52: Azoxystrobin residues in honey

Trial	Number and Nominal Rate of Application (g ai/ha)	Sampling Interval (Days After Last Application)	Matrix	Azoxystrobin Residue (mg/kg)
S12-01128-01	2 x 250	2	Mature honey	0.02
S12-01128-02	2 x 250	14	Mature honey	<0.01
S12-01128-04	2 x 250	12	Mature honey	<0.01
S12-01128-05	2 x 250	18	Mature honey	<0.01

III. CONCLUSION

Residues of azoxystrobin in the honey specimens from trial S12-1128-01 were at 0.02 mg/kg; residues were below the limit of quantification (LOQ; 0.01 mg/kg) in all other trials.

No residues of azoxystrobin were detected at or above the limit of quantification (0.01 mg/kg) in the control honey specimens.

The stability of residues of azoxystrobin in honey was assessed during this study; azoxystrobin was demonstrated to be stable for up to 81 days when stored in honey.

A 2.2 Oxathiapiprolin

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 or additional studies have been submitted.

A 2.2.1.1.2 Storage stability of residues in animal products

A 2.2.1.1.2.1 Study 1 (Report No. CEMR-9822) (New data)

Comments of zRMS:	The stability was tested in honey following deep frozen storage for 3 and 5 months. The residues of oxathiapiprolin showed no significant decrease (>30% as compared to the fortification level at the zero time value) in the honey matrix studied after deep frozen storage for at least 5 months. The analyses of the control samples showed that no residues of oxathiapiprolin were present above 30% of the limit of quantification. Frozen storage stability of oxathiapiprolin in honey was demonstrated for a period of five months when stored at temperatures of <-18°C. The study meets the criteria of OECD 506 and is acceptable.

Reference	KCA2 6.1
Report	Oxathiapiprolin – Honey Residue Study on ~~Spring~~ Winter Oilseed Rape in Northern and Southern Europe in 2021, Ford, K., 2021, CEMR-9822, VV-924794
Guidelines	OECD 506 (October 2007) EPA OPPTS 860.1380 (August 1996) EC 7032/V1/95 rev.5, Appendix H (July 1997) EC 1107/2009 (October 2009) amending Directives 79/117/EEC and 91/414/EEC
Deviations	None,
GLP	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability	Yes

Executive Summary

The stability of oxathiapiprolin has been tested in honey following deep frozen storage for up to 5 months. Individual samples of honey were fortified with standard solutions containing oxathiapiprolin in acetonitrile/water (70/30) at a fortification rate of 0.10 mg/kg. Samples were left to stand for at least five minutes after fortification to allow the spiking solution to soak into the matrix before being sealed and transferred to the freezer to simulate conditions under which actual field samples are stored prior to their analysis.

Triplicate samples of the honey matrix were analysed at the commencement of the study for oxathiapiprolin. Duplicate samples were removed after 3 and 5 months of frozen storage at a nominal temperature of -18°C, and analysed for oxathiapiprolin using procedures in residue analytical method DuPont-30422 Supplement No. 1.

Control and fortified recovery samples were analysed alongside each batch of stored samples.

There was no significant decrease (>30% as compared to the nominal fortification level) in the observed residue levels of oxathiapiprolin after deep frozen storage for up to 5 months.

Residues of oxathiapiprolin were confirmed to be stable in honey when stored deep frozen at a temperature of ≤-18°C for 5 months.

Materials

Test Material	Oxathiapiprolin
Lot/Batch #:	953157
Purity (%):	96.7%
IUPAC name:	1-(4-(4-((5RS)-5-(2,6-difluorophenyl)-4,5-dihydro-1,2-oxazol-3-yl)-1,3-thiazol-2-yl)-1-piperidyl)-2-(5-methyl-3-(trifluoromethyl)-1H-pyrazol-1-yl)ethanone
CAS number:	1003318-67-9

Test commodities			
Crop	**Commodity**	**Commodity type**	**Source**
Multi-flower	Honey	Bee matrices	Local supplier

Study Design and Methods

Test facility: CEM Analytical Services Ltd (CEMAS), Imperial House, Oaklands Business Centre, Oaklands Park, Wokingham, Berkshire, RG41 2FD, United Kingdom
Study start date: 01 Mar 2021
Study end date: 20 Oct 2021
Sub-samples (5 g) were fortified with standard solutions of oxathiapiprolin in acetonitrile/water (70/30) to give a fortification rate of 0.10 mg/kg. Samples were left to stand for five minutes then transferred to a deep freezer at –18°C after fortification. Untreated samples were stored in the same freezer for use as control and procedural recovery samples.
Three replicate samples were extracted for analysis immediately after fortification. Duplicate stored samples were extracted for analysis at 5 months.
After the scheduled storage period, the required number of fortified samples were removed from frozen storage, along with three untreated control samples. Two untreated samples were fortified with oxathiapiprolin as concurrent recovery samples and then the set of samples (untreated, recovery and stored samples) were analysed using method DuPont-30422 Supplement No. 1, previously validated for honey to a limit of quantification (LOQ) of 0.01 mg/kg.
Residues of oxathiapiprolin were extracted by homogenizing in a genogrinder with acetonitrile/water and formic acid three times. Extracts were combined and mixed and 0.5 mL aliquots were diluted with 2 mL of methanol and 4.5 mL of 1% formic acid in water. Final determination was by high performance liquid chromatography with triple quadrupole mass spectrometric detection (LC-MS/MS).

Results

Residues of oxathiapiprolin found in stored frozen honey tested are shown in Table A 54. There was no significant change in the levels of oxathiapiprolin over a 5-month storage period (any apparent losses were less than 30% of the initial value). These losses are not considered significant according to EU and OECD guidelines (SANCO 7032/VI/95 rev. 5 and OECD Guideline 506).

Table A 53: Summary of procedural/concurrent recoveries of oxathiapiprolin from honey

Storage duration (days/months)	Fortification level (mg/kg)	Number of recoveries (n)	Individual recoveries (%)	Mean (RSD) (%)
Oxathiapiprolin				
0	0.1	2	98, 94	96 (n.a)
96 (3 months)	0.1	2	104, 103	104 (n.a)
153 (5 months)	0.1	2	103, 102	102 (n.a)

Table A 54: Stability of residues of Oxathiapiprolin in honey during storage at ≤-18°C

Commodity	Storage duration (days/months)	Fortification Level (mg/kg)	Recovered residues (mg/kg)	Mean stored recovery (%)	Mean concurrent recovery (%)	Corrected recovery[1] (%)
Oxathiapiprolin						
Honey	0	0.1	92, 98, 97	96	96	100

Commodity	Storage duration (days/months)	Fortification Level (mg/kg)	Recovered residues (mg/kg)	Mean stored recovery (%)	Mean concurrent recovery (%)	Corrected recovery[1] (%)
	96 (3)	0.1	100, 97	98	104	95
	153 (5)	0.1	97, 104	100	102	98

[1] Corrected for concurrent recovery.

Conclusion
Oxathiapiprolin has been shown to be stable in samples of honey for at least 5 months when stored frozen at ≤-18°C.

(Ford K, 2021)

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 or additional studies have been submitted.

A 2.2.2.1.2 Nature of residue in rotational crops
No new or additional studies have been submitted.

A 2.2.2.1.3 Nature of residues in processed commodities
No new or additional studies have been submitted.

A 2.2.2.2 Nature of residues in livestock
No new or additional studies have been submitted.

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 Tomato (extrapolated to support eggplant)

Table A 55: 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)
cGAP N-EU	-	-	-	-	-
cGAP S-EU (DAR, Ireland, 2015; EFSA, 2016)	3	30 g a.s./ha	7	-	3
Intended cGAP A22773A - CZ-13, CZ-14, HU-11, HU-12, PL-28, PL-29, RO-11, RO-12, SK-13, SK-14, SI-16, SI-17 Extrapolated to eggplant: HU-4, HU-5, HU-6, PL-25, PL-26, PL-27, RO-4, RO-5, RO-6, SK-3, SK-4, SK-5, SI-4, SI-5, SI-6*	2	12 g a.s./ha	7	BBCH 11-89	3

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
** Timing of applications determined primarily by growth stage
*** Minimum PHI

A 2.2.3.1.1 Study 1 (Report No. S19-02717) (New data)

<table>
<tr>
<td>Comments of zRMS:</td>
<td>Six residue field trials on tomato were successfully conducted in Northern France, Germany and Hungary during 2019.
Oxathiapiprolin and mandipropamid were applied to tomato as A21591C, a suspension concentrate (SC) formulation containing nominally 30 grams of oxathiapiprolin and 250 grams of mandipropamid per litre.
Three applications, separated by a 7-8 day intervals (applied at 17-18 days before harvest (17-18 DBH), 10-11 days before harvest (10-11 DBH) and 3 days before harvest (3 DBH)) were made at a nominal rate of 12 g ai/ha for oxathiapiprolin at each application.
For decline trials, treated tomato samples were collected immediately after the last application (0 DALA), 1 day after the last application (1 DALA), 3 days after the last application at normal commercial harvest (3 DALA (NCH)), and 7 days after the last application (7 DALA).
For harvest trials, treated tomato samples were collected 3 days after the last application at normal commercial harvest (3 DALA (NCH)).
For all trials, untreated tomato samples were collected 3 days after the last application at normal commercial harvest (3 DALA (NCH)).

Residues of oxathiapiprolin found in are summarised in the table below.

<table>
<tr><th>Actual Sampling Interval (days)</th><th>Oxathiapiprolin Residues in the Range [mg/kg]</th></tr>
<tr><td colspan="2">Treated Plot (P2): at a rate of 3 x 12g oxathiapiprolin/ha</td></tr>
<tr><td colspan="2">Fruit</td></tr>
<tr><td>0 DALA</td><td>0.01 - 0.02</td></tr>
<tr><td>1 DALA</td><td>< 0.01- 0.03</td></tr>
<tr><td>3 DALA (NCH)</td><td>0.01 - 0.03</td></tr>
<tr><td>7 DALA</td><td>< 0.01 - 0.02</td></tr>
<tr><td colspan="2">Control plot (C1)

No residues of oxathiapiprolin at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in any of the untreated tomato fruit samples.</td></tr>
</table>

Analytical method: DuPont-30422 for oxathiapiprolin
Limit of Quantification: 0.01 mg/kg
The analytical method has been validated for analysis of oxathiapiprolin in a wide range of crops (wheat grain, ginseng, wheat straw, canola, grapes, oranges, tomatoes and potatoes) and is therefore considered to be valid for the analysis of tomato (fruit) samples.

Specimens were stored frozen for a maximum period of 169 days from sampling to analysis

The study is acceptable.</td>
</tr>
</table>

Reference: KCA2 6.3

Report: Lakaschus S., Reinhardt R. (2020)
Oxathiapiprolin - Residue study on Tomato in Northern France, Germany, ~~Poland~~ and Hungary in 2019
Syngenta Report No. S19-02717
Syngenta File No. VV-854096
Unpublished

Guideline(s): Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).

	Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009. OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50. OECD Guidance Document on Overview of Residue Chemistry Studies (as revised 2009), Series on Testing and Assessment (No. 64) and Series on Pesticides (No. 32), ENV/JM/MONO(2009)31. OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009. European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000). The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9. OECD Series on Principles of GLP and Compliance Monitoring No. 1 (as revised in 1997) "OECD Principles on Good Laboratory Practice", Paris 1998. ENV/MC/CHEM(98)17 and respective national regulations. The national GLP requirements are based on the OECD Principles of Good Laboratory Practice, which are accepted by regulatory authorities throughout the European Community, the United States of America (FDA and EPA) and Japan (MHW, MAFF and METI) on the basis of intergovernmental agreements.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 56: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) : Oxathiapiprolin - Residue study on Tomato in Northern France, Germany, Poland and Hungary in 2019			
Active Substance (common name):	oxathiapiprolin	**Commercial Product (name):**	
Crop/Crop Group:	Tomato	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	FRANCE, GERMANY, HUNGARY	**Other active substance in the formulation (common name and content):**	A21591C: mandipropamid (250 g/L)
Content of active substance (g/kg or g/L):	A21591C: 30 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A21591C SC		
Analytical Method:	Oxathiapiprolin (Fruit) DuPont-30422; 0.01 mg/kg		
Recovery data:	oxathiapiprolin Fruit Mean = 108% RSD = N/A (n = 0 in 0 - 0 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
S19-02717 S19-02717-01 FRANCE (EU Submissions) (91140)	Tomato / Brillante	1. 2 – 3 -	Foliar Foliar Foliar	-	401 L/ha 399 L/ha 401 L/ha	12 g ai/ha 12 g ai/ha 12 g ai/ha A21591C (-)	20 Aug 2019 27 Aug 2019 03 Sep 2019 (7, 7)	BBCH 65-83 BBCH 65-85 BBCH 67-89	Fruit	0.03 mg/kg	0	03 Sep 2019/	Field SP (max days): 169
S19-02717 S19-02717-01 FRANCE (EU Submissions) (91140)	Tomato / Brillante	1. 2 – 3 -	Foliar Foliar Foliar	-	400.8889 L/ha 398.8148 L/ha 400.5926 L/ha	12.01465 g ai/ha 11.9525 g ai/ha 12.005772 g ai/ha A21591C (-)	20 Aug 2019 27 Aug 2019 03 Sep 2019 (7, 7)	BBCH 65-83 BBCH 65-85 BBCH 67-89	Fruit	0.02 mg/kg	1	04 Sep 2019/	Field SP (max days): 169

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
S19-02717 S19-02717-01 FRANCE (EU Submissions) (91140)	Tomato / Brillante	1. 2 – 3 -	Foliar Foliar Foliar	-	400.8889 L/ha 398.8148 L/ha 400.5926 L/ha	12.01465 g ai/ha 11.9525 g ai/ha 12.005772 g ai/ha A21591C (-)	20 Aug 2019 27 Aug 2019 03 Sep 2019 (7, 7)	BBCH 65-83 BBCH 65-85 BBCH 67-89	Fruit	0.01 mg/kg	3	06 Sep 2019/	Field SP (max days): 169
S19-02717 S19-02717-01 FRANCE (EU Submissions) (91140)	Tomato / Brillante	1. 2 – 3 -	Foliar Foliar Foliar	-	400.8889 L/ha 398.8148 L/ha 400.5926 L/ha	12.01465 g ai/ha 11.9525 g ai/ha 12.005772 g ai/ha A21591C (-)	20 Aug 2019 27 Aug 2019 03 Sep 2019 (7, 7)	BBCH 65-83 BBCH 65-85 BBCH 67-89	Fruit	< 0.01 mg/kg	7	10 Sep 2019/	Field SP (max days): 169
S19-02717 S19-02717-02 GERMANY (EU Submissions) (71706)	Tomato / Pannovy F1	1. 2 – 3 -	Foliar Foliar Foliar	-	594 L/ha 601 L/ha 599 L/ha	12 g ai/ha 12 g ai/ha 12 g ai/ha A21591C (-)	06 Sep 2019 13 Sep 2019 20 Sep 2019 (7, 7)	BBCH 74 BBCH 75 BBCH 76	Fruit	0.02 mg/kg	0	20 Sep 2019/	Field SP (max days): 152

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
S19-02717 S19-02717-02 GERMANY (EU Submissions) (71706)	Tomato / Pannovy F1	1. 2 – 3 -	Foliar Foliar Foliar	-	594.02519 L/ha 600.84 L/ha 599.3585 L/ha	11.8834 g ai/ha 12.0197 g ai/ha 11.9901 g ai/ha A21591C (-)	06 Sep 2019 13 Sep 2019 20 Sep 2019 (7, 7)	BBCH 74-74 BBCH 75-75 BBCH 76-76	Fruit	0.03 mg/kg	1	21 Sep 2019/	Field SP (max days): 152
S19-02717 S19-02717-02 GERMANY (EU Submissions) (71706)	Tomato / Pannovy F1	1. 2 – 3 -	Foliar Foliar Foliar	-	594.02519 L/ha 600.84 L/ha 599.3585 L/ha	11.8834 g ai/ha 12.0197 g ai/ha 11.9901 g ai/ha A21591C (-)	06 Sep 2019 13 Sep 2019 20 Sep 2019 (7, 7)	BBCH 74-74 BBCH 75-75 BBCH 76-76	Fruit	0.01 mg/kg	3	23 Sep 2019/	Field SP (max days): 152
S19-02717 S19-02717-02 GERMANY (EU Submissions) (71706)	Tomato / Pannovy F1	1. 2 – 3 -	Foliar Foliar Foliar	-	594.02519 L/ha 600.84 L/ha 599.3585 L/ha	11.8834 g ai/ha 12.0197 g ai/ha 11.9901 g ai/ha A21591C (-)	06 Sep 2019 13 Sep 2019 20 Sep 2019 (7, 7)	BBCH 74-74 BBCH 75-75 BBCH 76-76	Fruit	0.02 mg/kg	7	27 Sep 2019/	Field SP (max days): 152

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
S19-02717 S19-02717-04 HUNGARY (EU Submissions) (H-5900)	Tomato / UD Red	1. 2 – 3 -	Foliar Foliar Foliar	-	319 L/ha 299 L/ha 307 L/ha	13 g ai/ha 12 g ai/ha 12 g ai/ha A21591C (-)	06 Sep 2019 13 Sep 2019 20 Sep 2019 (7, 7)	BBCH 83 BBCH 85 BBCH 89	Fruit	0.01 mg/kg	0	20 Sep 2019/	Field SP (max days): 152
S19-02717 S19-02717-04 HUNGARY (EU Submissions) (H-5900)	Tomato / UD Red	1. 2 – 3 -	Foliar Foliar Foliar	-	318.9489 L/ha 298.7267 L/ha 306.7267 L/ha	12.7668 g ai/ha 11.9574 g ai/ha 12.2776 g ai/ha A21591C (-)	06 Sep 2019 13 Sep 2019 20 Sep 2019 (7, 7)	BBCH 83-83 BBCH 85-85 BBCH 89-89	Fruit	< 0.01 mg/kg	1	21 Sep 2019/	Field SP (max days): 152
S19-02717 S19-02717-04 HUNGARY (EU Submissions) (H-5900)	Tomato / UD Red	1. 2 – 3 -	Foliar Foliar Foliar	-	318.9489 L/ha 298.7267 L/ha 306.7267 L/ha	12.7668 g ai/ha 11.9574 g ai/ha 12.2776 g ai/ha A21591C (-)	06 Sep 2019 13 Sep 2019 20 Sep 2019 (7, 7)	BBCH 83-83 BBCH 85-85 BBCH 89-89	Fruit	<u>0.01 mg/kg</u>	3	23 Sep 2019/	Field SP (max days): 152

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
S19-02717 S19-02717-04 HUNGARY (EU Submissions) (H-5900)	Tomato / UD Red	1. 2 – 3 -	Foliar Foliar Foliar	-	318.9489 L/ha 298.7267 L/ha 306.7267 L/ha	12.7668 g ai/ha 11.9574 g ai/ha 12.2776 g ai/ha A21591C (-)	06 Sep 2019 13 Sep 2019 20 Sep 2019 (7, 7)	BBCH 83-83 BBCH 85-85 BBCH 89-89	Fruit	< 0.01 mg/kg	7	27 Sep 2019/	Field SP (max days): 152
S19-02717 S19-02717-05 FRANCE (EU Submissions) (67600)	Tomato / Roma VF	1. 2 – 3 -	Foliar Foliar Foliar	-	438 L/ha 426 L/ha 408 L/ha	13 g ai/ha 13 g ai/ha 12 g ai/ha A21591C (-)	19 Aug 2019 26 Aug 2019 03 Sep 2019 (7, 8)	BBCH 69-89 BBCH 74-89 BBCH 75-89	Fruit	<u>0.01 mg/kg</u>	3	06 Sep 2019/	Field SP (max days): 166
S19-02717 S19-02717-06 GERMANY (EU Submissions) (67245)	Tomato / Hamlet	1. 2 – 3 -	Foliar Foliar Foliar	-	371 L/ha 422 L/ha 382 L/ha	11 g ai/ha 13 g ai/ha 12 g ai/ha A21591C (-)	30 Jul 2019 06 Aug 2019 13 Aug 2019 (7, 7)	BBCH 72-89 BBCH 72-89 BBCH 75-89	Fruit	<u>0.03 mg/kg</u>	3	16 Aug 2019/	Field SP (max days): 187
S19-02717 S19-02717-08 HUNGARY (EU Submissions) (H-6762)	Tomato / Torquay F1	1. 2 – 3 -	Foliar Foliar Foliar	-	292 L/ha 296 L/ha 288 L/ha	12 g ai/ha 12 g ai/ha 12 g ai/ha A21591C (-)	04 Sep 2019 11 Sep 2019 18 Sep 2019 (7, 7)	BBCH 85 BBCH 87 BBCH 89	Fruit	<u>0.01 mg/kg</u>	3	21 Sep 2019/	Field SP (max days): 151

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			

(d) Minimum number of 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.

Residues in control samples were always below the LOQ (<0.01 mg/kg).

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period

A 2.2.3.1.2 Study 2 (Report No. S20-03173) (New data)

Comments of zRMS:

Two residue field trials on tomato were successfully conducted in Northern France and Germany during 2020.

Oxathiapiprolin and mandipropamid were applied to tomato as A21591C, a suspension concentrate (SC) formulation containing nominally 30 grams of oxathiapiprolin and 250 grams of mandipropamid per litre.

Three applications separated by 7 day intervals (applied at 17 days before harvest (17 DBH), 10 days before harvest (10 DBH) and 3 days before harvest (3 DBH)), were made at a nominal rate of 12 g ai/ha for oxathiapiprolin at each application.

For the decline trial, treated tomato samples were collected immediately after the last application (0 DALA), 1 day after the last application (1 DALA), 3 days after the last application at normal commercial harvest (3 DALA (NCH)),and 7 days after the last application (7 DALA).

For the harvest trial, treated tomato samples were collected 3 days after the last application at normal commercial harvest (3 DALA (NCH)).

For all trials, untreated tomato samples were collected 3 days after the last application at normal commercial harvest (3 DALA (NCH)).

Residues of oxathiapiprolin are summarised in the table below.

Actual Sampling Interval (days)	oxathiapiprolin Residues in the range (mg/kg)
Treated Plot (P2): at a rate of 3 x (12 g oxathiapiprolin/ha, 100 g mandipropamid/ha)	
Fruit	
0 DALA	0.01
1 DALA	< 0.01
3 DALA (NCH)	< 0.01 – 0.02
7 DALA	< 0.01
Control plot (C1) No residues of oxathiapiprolin at or above the limit of quantification (LOQ, <0.01 mg/kg for oxathiapiprolin) were found in any of the untreated tomato fruit samples.	

Analytical method: DuPont-30422 for oxathiapiprolin
Limit of Quantification: 0.01 mg/kg
The analytical method has been validated for analysis of oxathiapiprolin in a wide range of crops (wheat grain, ginseng, wheat straw, canola, grapes, oranges, tomatoes and potatoes) and is therefore considered to be valid for the analysis of tomato (fruit) samples.

Samples were stored frozen for a maximum period of 27 days from sampling to analysis.
The trials can be considered independent.
The study is acceptable.

Reference:	KCA2 6.3
Report:	Fritzsch S. (2020) Oxathiapiprolin – Residue Study on Tomato in Northern France and Germany in 2020 Syngenta Report No. S20-03173 Syngenta File No. VV-875090 Unpublished
Guideline(s):	Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).

	OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50. OECD Guidance Document on Overview of Residue Chemistry Studies (as revised 2009), Series on Testing and Assessment (No. 64) and Series on Pesticides (No. 32), ENV/JM/MONO(2009)31. Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009. OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009. European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000). The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9. OECD Series on Principles of GLP and Compliance Monitoring No. 1 (as revised in 1997) "OECD Principles on Good Laboratory Practice", Paris 1998. ENV/MC/CHEM(98)17 and respective national regulations.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 57: Summary of the study 2 trials

Field Trials, Crop Residue (Summary) : Oxathiapiprolin - Residue study on Tomato in Northern France and Germany in 2020			
Active Substance (common name):	oxathiapiprolin	**Commercial Product (name):**	
Crop/Crop Group:	Tomato	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	FRANCE, GERMANY	**Other active substance in the formulation (common name and content):**	A21591C: mandipropamid (250 g/L)
Content of active substance (g/kg or g/L):	A21591C: 30 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A21591C SC		
Analytical Method:	Oxathiapiprolin (Fruit) DuPont-30422; 0.01 mg/kg		
Recovery data:	Oxathiapiprolin Fruit Mean = 105% RSD = 3% (n = 10 in 0.01 - 0.1 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	**(2) Commodity / Variety (a)**	**(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)**	**(4) Method of Treatment**	**(5) Application rate per treatment**			**(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)**	**(7) Growth Stage at Treatment**	**(8) Portion Analyzed**	**(9) Residue found (Uncorrected)**	**(10) PHI (d)**	**(11) Sample Date / Cut Date**	**(12) Trial Details (e)**
				Concentration	**Water**	**Rate Formulation (Additive Type, Rate)**				**Oxathiapiprolin (mg/kg)**			
S20-03173 S20-03173-01 FRANCE (Europe North) (91140)	Tomato / Brillante	1.25 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	3	14 Aug 2020/ -	Field SP (max days): 12
S20-03173 S20-03173-01 FRANCE (Europe North) (91140)	Tomato / Brillante	1.25 May 2020 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 402.163 L/ha 2. 402.163 L/ha 3. 402.9037 L/ha	1. 12.05284 g ai/ha 2. 12.05284 g ai/ha 3. 12.07504 g ai/ha A21591C (-)	1. 28 Jul 2020 2. 04 Aug 2020 3. 11 Aug 2020 (7, 7)	1. BBCH 65-83 2. BBCH 69-84 3. BBCH 84-84	Fruit	0.01 mg/kg	0	11 Aug 2020/ -	Field SP (max days): 15

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
S20-03173 S20-03173-01 FRANCE (Europe North) (91140)	Tomato / Brillante	1.25 May 2020 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 402.163 L/ha 2. 402.163 L/ha 3. 402.9037 L/ha	1. 12.05284 g ai/ha 2. 12.05284 g ai/ha 3. 12.07504 g ai/ha A21591C (-)	1. 28 Jul 2020 2. 04 Aug 2020 3. 11 Aug 2020 (7, 7)	1. BBCH 65-83 2. BBCH 69-84 3. BBCH 84-84	Fruit	< 0.01 mg/kg	1	12 Aug 2020/ -	Field SP (max days): 15
S20-03173 S20-03173-01 FRANCE (Europe North) (91140)	Tomato / Brillante	1.25 May 2020 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 402.163 L/ha 2. 402.163 L/ha 3. 402.9037 L/ha	1. 12.05284 g ai/ha 2. 12.05284 g ai/ha 3. 12.07504 g ai/ha A21591C (-)	1. 28 Jul 2020 2. 04 Aug 2020 3. 11 Aug 2020 (7, 7)	1. BBCH 65-83 2. BBCH 69-84 3. BBCH 84-84	Fruit	< 0.01 mg/kg	3	14 Aug 2020/ -	Field SP (max days): 15
S20-03173 S20-03173-01 FRANCE (Europe North) (91140)	Tomato / Brillante	1.25 May 2020 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 402.163 L/ha 2. 402.163 L/ha 3. 402.9037 L/ha	1. 12.05284 g ai/ha 2. 12.05284 g ai/ha 3. 12.07504 g ai/ha A21591C (-)	1. 28 Jul 2020 2. 04 Aug 2020 3. 11 Aug 2020 (7, 7)	1. BBCH 65-83 2. BBCH 69-84 3. BBCH 84-84	Fruit	< 0.01 mg/kg	7	18 Aug 2020/ -	Field SP (max days): 15

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
S20-03173 S20-03173-02 GERMANY (Europe North) (69124)	Tomato / Phantasia	1.07 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	3	30 Jul 2020/ -	Field SP (max days): 27
S20-03173 S20-03173-02 GERMANY (Europe North) (69124)	Tomato / Phantasia	1.07 May 2020 2 – 3 -	1. Foliar 2. Foliar 3. Foliar	-	1. 523.5556 L/ha 2. 506.8889 L/ha 3. 545.7778 L/ha	1. 12.5553 g ai/ha 2. 12.1556 g ai/ha 3. 13.0882 g ai/ha A21591C (-)	1. 13 Jul 2020 2. 20 Jul 2020 3. 27 Jul 2020 (7, 7)	1. BBCH 66-81 2. BBCH 67-82 3. BBCH 68-83	Fruit	<u>0.02 mg/kg</u>	3	30 Jul 2020/ -	Field SP (max days): 27

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(c) Year must be indicated

(d) Minimum number of 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.

(*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^) PHI calculated using cut date

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period

A 2.2.3.1.3 Study 3 (Report No. IF20-05334280) (New data)

Comments of zRMS:

Eight residue field trials on tomato were successfully conducted in Germany, Poland, Northern France and Hungary during 2020. Four decline trials and four harvest trials were conducted.
Oxathiapiprolin was applied to tomato as A22773A, suspension concentrate SC formulation containing nominally 250 g of azoxystrobin per litre and 12 g of oxathiapiprolin per litre.
In plot P2 two applications were made at a nominal rate of 12 g oxathiapiprolin/ha.
The first application in plot P2 was done 9-11 days before harvest (DBH), the second application was done 3 DBH .
In decline trials, treated samples were collected at 0, 1, 3 (normal commercial harvest (NCH)) and 7 days after last application (DALA) with untreated tomato being collected 3 DALA (NCH).
In harvest trials, treated samples were collected at 3 DALA (NCH) with untreated tomato being collected 3 DALA (NCH).

The ranges of residues of Oxathiapiprolin are summarised in the table below.

Actual Sampling Interval (days)	Oxathiapiprolin Residues in the range (mg/kg)
Tomato (fruit)	
Treated Plot (P2)	at a rate of 2 x 12 g ai/ha
0 DALA	< 0.01 - 0.031
1 DALA	< 0.01 - 0.031
3 DALA (NCH)	< 0.01 - 0.021
7 DALA	< 0.01 - 0.010
Control Plot (C1) No residues of oxathiapiprolin at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in any of the untreated tomato specimen.	

DALA: days after last application, NCH: normal commercial harvest

Analytical method: DuPont-30422, Supplement No. 1 for oxathiapiprolin
Limit of Quantification: 0.01 mg/kg

Samples were stored frozen for a maximum period of 109 days from sampling to analysis.
The trials can be considered independent.
The study is acceptable.

Reference:	KCA2 6.3
Report:	Stolze J., Wolfgarten E. (2021) Oxathiapiprolin - Residue Study on Tomato in Germany, Poland, Northern France and Hungary 2020 Syngenta Report No. IF20-05334280 Syngenta File No. VV-896130 Unpublished
Guideline(s):	Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document). OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50. OECD Guidance Document on Overview of Residue Chemistry Studies (as revised 2009), Series on Testing and Assessment (No. 64) and Series on Pesticides (No. 32), ENV/JM/MONO(2009)31. Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances

	in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009. OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009. European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000). The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9. OECD Series on Principles of GLP and Compliance Monitoring No. 1 (as revised in 1997) "OECD Principles on Good Laboratory Practice", Paris 1998. ENV/MC/CHEM(98)17 and respective national regulations.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 58: Summary of the study 3 trials

Field Trials, Crop Residue (Summary) : Oxathiapiprolin - Residue Study on Tomato in Germany, Poland, Northern France and Hungary 2020			
Active Substance (common name):	oxathiapiprolin	**Commercial Product (name):**	
Crop/Crop Group:	Tomato	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	GERMANY, POLAND, FRANCE, HUNGARY	**Other active substance in the formulation (common name and content):**	A22773A: azoxystrobin (250 g/L)
Content of active substance (g/kg or g/L):	A22773A: 12 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A22773A SC		
Analytical Method:	Oxathiapiprolin (Fruit) DuPont-30422; 0.01 mg/kg		
Recovery data:	Oxathiapiprolin Fruit Mean = 107% RSD = 2% (n = 11 in 0.01 - 1.1 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
IF20-05334280 20-00241-01 GERMANY (Europe North) (79367)	Tomato / Feline	1.21 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	3	16 Aug 2020/ -	Field SP (max days): 101
IF20-05334280 20-00241-01 GERMANY (Europe North) (79367)	Tomato / Feline	1.21 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 1001.5333 L/ha 2. 990.8667 L/ha	1. 12.006394 g ai/ha 2. 11.8785 g ai/ha A22773A (-)	1. 07 Aug 2020 2. 13 Aug 2020 (6)	1. BBCH 73-81 2. BBCH 73-87	Fruit	0.031 mg/kg	0	13 Aug 2020/ -	Field SP (max days): 104

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
IF20-05334280 20-00241-01 GERMANY (Europe North) (79367)	Tomato / Feline	1.21 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 1001.5333 L/ha 2. 990.8667 L/ha	1. 12.006394 g ai/ha 2. 11.8785 g ai/ha A22773A (-)	1. 07 Aug 2020 2. 13 Aug 2020 (6)	1. BBCH 73-81 2. BBCH 73-87	Fruit	0.031 mg/kg	1	14 Aug 2020/ -	Field SP (max days): 104
IF20-05334280 20-00241-01 GERMANY (Europe North) (79367)	Tomato / Feline	1.21 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 1001.5333 L/ha 2. 990.8667 L/ha	1. 12.006394 g ai/ha 2. 11.8785 g ai/ha A22773A (-)	1. 07 Aug 2020 2. 13 Aug 2020 (6)	1. BBCH 73-81 2. BBCH 73-87	Fruit	<u>0.021 mg/kg</u>	3	16 Aug 2020/ -	Field SP (max days): 104
IF20-05334280 20-00241-01 GERMANY (Europe North) (79367)	Tomato / Feline	1.21 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 1001.5333 L/ha 2. 990.8667 L/ha	1. 12.006394 g ai/ha 2. 11.8785 g ai/ha A22773A (-)	1. 07 Aug 2020 2. 13 Aug 2020 (6)	1. BBCH 73-81 2. BBCH 73-87	Fruit	0.01 mg/kg	7	20 Aug 2020/ -	Field SP (max days): 104
IF20-05334280 20-00241-02 POLAND (Europe North) (88-400)	Tomato / Dyno	1.05 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	3	11 Sep 2020/ -	Field SP (max days): 75

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
IF20-05334280 20-00241-02 POLAND (Europe North) (88-400)	Tomato / Dyno	1.05 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 308.4444 L/ha 2. 306.4444 L/ha	1. 12.3444 g ai/ha 2. 12.2644 g ai/ha A22773A (-)	1. 01 Sep 2020 2. 08 Sep 2020 (7)	1. BBCH 86-86 2. BBCH 88-88	Fruit	< 0.01 mg/kg	0	08 Sep 2020/ -	Field SP (max days): 78
IF20-05334280 20-00241-02 POLAND (Europe North) (88-400)	Tomato / Dyno	1.05 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 308.4444 L/ha 2. 306.4444 L/ha	1. 12.3444 g ai/ha 2. 12.2644 g ai/ha A22773A (-)	1. 01 Sep 2020 2. 08 Sep 2020 (7)	1. BBCH 86-86 2. BBCH 88-88	Fruit	< 0.01 mg/kg	1	09 Sep 2020/ -	Field SP (max days): 78
IF20-05334280 20-00241-02 POLAND (Europe North) (88-400)	Tomato / Dyno	1.05 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 308.4444 L/ha 2. 306.4444 L/ha	1. 12.3444 g ai/ha 2. 12.2644 g ai/ha A22773A (-)	1. 01 Sep 2020 2. 08 Sep 2020 (7)	1. BBCH 86-86 2. BBCH 88-88	Fruit	< 0.01 mg/kg	3	11 Sep 2020/ -	Field SP (max days): 78
IF20-05334280 20-00241-02 POLAND (Europe North) (88-400)	Tomato / Dyno	1.05 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 308.4444 L/ha 2. 306.4444 L/ha	1. 12.3444 g ai/ha 2. 12.2644 g ai/ha A22773A (-)	1. 01 Sep 2020 2. 08 Sep 2020 (7)	1. BBCH 86-86 2. BBCH 88-88	Fruit	< 0.01 mg/kg	7	15 Sep 2020/ -	Field SP (max days): 78

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
IF20-05334280 20-00241-03 FRANCE (Europe North) (51110)	Tomato / Ananas	1.26 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	3	13 Aug 2020/ -	Field SP (max days): 106
IF20-05334280 20-00241-03 FRANCE (Europe North) (51110)	Tomato / Ananas	1.26 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 398.08333 L/ha 2. 411.4173 L/ha	1. 11.9127 g ai/ha 2. 12.3175 g ai/ha A22773A (-)	1. 03 Aug 2020 2. 10 Aug 2020 (7)	1. BBCH 79-79 2. BBCH 81-81	Fruit	0.014 mg/kg	0	10 Aug 2020/ -	Field SP (max days): 109
IF20-05334280 20-00241-03 FRANCE (Europe North) (51110)	Tomato / Ananas	1.26 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 398.08333 L/ha 2. 411.4173 L/ha	1. 11.9127 g ai/ha 2. 12.3175 g ai/ha A22773A (-)	1. 03 Aug 2020 2. 10 Aug 2020 (7)	1. BBCH 79-79 2. BBCH 81-81	Fruit	0.014 mg/kg	1	11 Aug 2020/ -	Field SP (max days): 109
IF20-05334280 20-00241-03 FRANCE (Europe North) (51110)	Tomato / Ananas	1.26 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 398.08333 L/ha 2. 411.4173 L/ha	1. 11.9127 g ai/ha 2. 12.3175 g ai/ha A22773A (-)	1. 03 Aug 2020 2. 10 Aug 2020 (7)	1. BBCH 79-79 2. BBCH 81-81	Fruit	0.011 mg/kg	3	13 Aug 2020/ -	Field SP (max days): 109

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
IF20-05334280 20-00241-03 FRANCE (Europe North) (51110)	Tomato / Ananas	1.26 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 398.08333 L/ha 2. 411.4173 L/ha	1. 11.9127 g ai/ha 2. 12.3175 g ai/ha A22773A (-)	1. 03 Aug 2020 2. 10 Aug 2020 (7)	1. BBCH 79-79 2. BBCH 81-81	Fruit	< 0.01 mg/kg	7	17 Aug 2020/ -	Field SP (max days): 109
IF20-05334280 20-00241-04 HUNGARY (Europe North) (H-4482)	Tomato / Prestomech	1.10 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	3	31 Aug 2020/ -	Field SP (max days): 88
IF20-05334280 20-00241-04 HUNGARY (Europe North) (H-4482)	Tomato / Prestomech	1.10 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 403.08333 L/ha 2. 408.08333 L/ha	1. 12.06234 g ai/ha 2. 12.212 g ai/ha A22773A (-)	1. 21 Aug 2020 2. 28 Aug 2020 (7)	1. BBCH 81-83 2. BBCH 87-89	Fruit	< 0.01 mg/kg	0	28 Aug 2020/ -	Field SP (max days): 91
IF20-05334280 20-00241-04 HUNGARY (Europe North) (H-4482)	Tomato / Prestomech	1.10 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 403.08333 L/ha 2. 408.08333 L/ha	1. 12.06234 g ai/ha 2. 12.212 g ai/ha A22773A (-)	1. 21 Aug 2020 2. 28 Aug 2020 (7)	1. BBCH 81-83 2. BBCH 87-89	Fruit	< 0.01 mg/kg	1	29 Aug 2020/ -	Field SP (max days): 91

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
IF20-05334280 20-00241-04 HUNGARY (Europe North) (H-4482)	Tomato / Prestomech	1.10 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 403.08333 L/ha 2. 408.08333 L/ha	1. 12.06234 g ai/ha 2. 12.212 g ai/ha A22773A (-)	1. 21 Aug 2020 2. 28 Aug 2020 (7)	1. BBCH 81-83 2. BBCH 87-89	Fruit	< 0.01 mg/kg	3	31 Aug 2020/ -	Field SP (max days): 91
IF20-05334280 20-00241-04 HUNGARY (Europe North) (H-4482)	Tomato / Prestomech	1.10 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 403.08333 L/ha 2. 408.08333 L/ha	1. 12.06234 g ai/ha 2. 12.212 g ai/ha A22773A (-)	1. 21 Aug 2020 2. 28 Aug 2020 (7)	1. BBCH 81-83 2. BBCH 87-89	Fruit	< 0.01 mg/kg	7	04 Sep 2020/ -	Field SP (max days): 91
IF20-05334280 20-00241-05 POLAND (Europe North) (09-142)	Tomato / Dyno	1.16 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	3	14 Sep 2020/ -	Field SP (max days): 74
IF20-05334280 20-00241-05 POLAND (Europe North) (09-142)	Tomato / Dyno	1.16 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 817.619 L/ha 2. 822.381 L/ha	1. 12.2643 g ai/ha 2. 12.3357 g ai/ha A22773A (-)	1. 03 Sep 2020 2. 11 Sep 2020 (8)	1. BBCH 86-86 2. BBCH 88-88	Fruit	< 0.01 mg/kg	3	14 Sep 2020/ -	Field SP (max days): 74

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
IF20-05334280 20-00241-06 POLAND (Europe North) (55-216)	Tomato / Pietrarossa	1.08 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	3	13 Sep 2020/ -	Field SP (max days): 75
IF20-05334280 20-00241-06 POLAND (Europe North) (55-216)	Tomato / Pietrarossa	1.08 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 702.8778 L/ha 2. 706.6566 L/ha	1. 12.03543 g ai/ha 2. 12.1001 g ai/ha A22773A (-)	1. 02 Sep 2020 2. 10 Sep 2020 (8)	1. BBCH 83-83 2. BBCH 83-83	Fruit	< 0.01 mg/kg	3	13 Sep 2020/ -	Field SP (max days): 75
IF20-05334280 20-00241-07 POLAND (Europe North) (89-430)	Tomato / Asterix	1.04 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	3	11 Sep 2020/ -	Field SP (max days): 77
IF20-05334280 20-00241-07 POLAND (Europe North) (89-430)	Tomato / Asterix	1.04 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 513.3147 L/ha 2. 501.5893 L/ha	1. 12.3196 g ai/ha 2. 12.03814 g ai/ha A22773A (-)	1. 01 Sep 2020 2. 08 Sep 2020 (7)	1. BBCH 81-81 2. BBCH 82-82	Fruit	< 0.01 mg/kg	3	11 Sep 2020/ -	Field SP (max days): 77

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
IF20-05334280 20-00241-08 HUNGARY (Europe North) (H-4253)	Tomato / Tyking	1.13 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	3	31 Aug 2020/ -	Field SP (max days): 88
IF20-05334280 20-00241-08 HUNGARY (Europe North) (H-4253)	Tomato / Tyking	1.13 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 405 L/ha 2. 395 L/ha	1. 12.1197 g ai/ha 2. 11.8204 g ai/ha A22773A (-)	1. 21 Aug 2020 2. 28 Aug 2020 (7)	1. BBCH 81-83 2. BBCH 87-89	Fruit	0.012 mg/kg	3	31 Aug 2020/ -	Field SP (max days): 88

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of 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.

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value
(DBA) Days Before Application
SP (max days): Maximum storage period

A 2.2.3.2 Bell pepper

Table A 59: 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)
cGAP N-EU	-	-	-	-	-
cGAP S-EU	-	-	-	-	-
Intended cGAP A22773A - CZ-29, HU-1, PL-23, PL-24, RO-1, SK-35, SI-1*	2	12 g a.s./ha	7	BBCH 11-89	3

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
** Timing of applications determined primarily by growth stage
*** Minimum PHI

A 2.2.3.2.1 Study 1 (Report No. IF20-05334851) (New data)

<table>
<tr><td>Comments of zRMS:</td><td>Nine residue field trials on peppers were successfully conducted in Germany, Poland, Hungary and Northern France during 2020. Five decline trials and four harvest trials were conducted. One trial was conducted as a contingency and was not analysed. Data from this trial is not reported.
Oxathiapiprolin was applied to peppers as A22773A, suspension concentrate SC formulation containing nominally 250 g of azoxystrobin per litre and 12 g of oxathiapiprolin per litre.
In plot P2 two applications were made at a nominal rate of 12 g oxathiapiprolin/ha.
The first application in plot P2 was done at 6-8 days before the second one, the second application was done 3 days before harvest (DBH).
For decline trials following the final application treated samples were collected at 0 days after last application (DALA), 1 DALA, 3 DALA (NCH (normal commercial harvest)) and 7-8 DALA with untreated samples being collected 3 DALA (NCH).
For harvest trials following the final application untreated and treated samples were collected at 3 DALA (NCH (normal commercial harvest)).

The ranges of residues of oxathiapiprolin are summarised in the table below.

<table><tr><th>Actual Sampling Interval (days)</th><th>Oxathiapiprolin Residues in the range (mg/kg)</th></tr><tr><td colspan="2">Pepper (fruit)</td></tr><tr><td>Treated Plot (P2)</td><td>at a rate of 2 x 12 g ai/ha</td></tr><tr><td>0 DALA</td><td>< 0.01 - 0.03</td></tr><tr><td>1 DALA</td><td>< 0.01 - 0.03</td></tr><tr><td>3 DALA (NCH)</td><td>< 0.01 - 0.02</td></tr><tr><td>7 - 8 DALA</td><td>< 0.01 - 0.02</td></tr></table>DALA: days after last application, NCH: normal commercial harvest

Analytical method: DuPont-30422, Supplement No. 1 for oxathiapiprolin
Limit of Quantification: 0.01 mg/kg

Samples were stored frozen for a maximum period of 113 days from sampling to analysis. The study is acceptable.</td></tr>
</table>

Reference:	KCA2 6.3
Report:	Thirkell C., Wofgarten E. (2021) Oxathiapiprolin - Residue Study on Pepper in Germany, Poland, Hungary and Northern France, in 2020 Syngenta Report No. IF20-05334851 Syngenta File No. VV-896488 Unpublished
Guideline(s):	Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document). OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50. OECD Guidance Document on Overview of Residue Chemistry Studies (as revised 2009), Series on Testing and Assessment (No. 64) and Series on Pesticides (No. 32), ENV/JM/MONO(2009)31. Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances

	in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009. OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009. European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000). The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9. OECD Series on Principles of GLP and Compliance Monitoring No. 1 (as revised in 1997) "OECD Principles on Good Laboratory Practice", Paris 1998. ENV/MC/CHEM(98)17 and respective national regulations.
Deviations:	Sample weight for trial 20-00243 was lower than the 2 kg required by the guidelines, this is considered to have no impact on the study as the number of samples taken was representative for the plot.
GLP:	Yes
Acceptability:	Yes

Table A 60: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) : Oxathiapiprolin - Residue Study on Pepper in Germany, Poland, Hungary and Northern France, in 2020			
Active Substance (common name):	oxathiapiprolin	**Commercial Product (name):**	
Crop/Crop Group:	Pepper	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	HUNGARY, POLAND, GERMANY, FRANCE	**Other active substance in the formulation (common name and content):**	A22773A: azoxystrobin (250 g/L)
Content of active substance (g/kg or g/L):	A22773A: 12 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A22773A SC		
Analytical Method:	Oxathiapiprolin (Fruit) DuPont-30422; 0.01 mg/kg		
Recovery data:	Oxathiapiprolin Fruit Mean = 95% RSD = 12% (n = 12 in 0.01 - 0.1 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
IF20-05334851 20-00243-01 GERMANY (Europe North) (79353)	Pepper / Maratos	1.28 Apr 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	3	04 Sep 2020/ -	Field SP (max days): 96
IF20-05334851 20-00243-01 GERMANY (Europe North) (79353)	Pepper / Maratos	1.28 Apr 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 594.6117 L/ha 2. 597.945 L/ha	1. 11.8776 g ai/ha 2. 11.9442 g ai/ha A22773A (-)	1. 24 Aug 2020 2. 01 Sep 2020 (8)	1. BBCH 85 2. BBCH 87	Fruit	< 0.01 mg/kg	0	01 Sep 2020/ -	Field SP (max days): 99

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
IF20-05334851 20-00243-01 GERMANY (Europe North) (79353)	Pepper / Maratos	1.28 Apr 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 594.6117 L/ha 2. 597.945 L/ha	1. 11.8776 g ai/ha 2. 11.9442 g ai/ha A22773A (-)	1. 24 Aug 2020 2. 01 Sep 2020 (8)	1. BBCH 85 2. BBCH 87	Fruit	< 0.01 mg/kg	1	02 Sep 2020/ -	Field SP (max days): 99
IF20-05334851 20-00243-01 GERMANY (Europe North) (79353)	Pepper / Maratos	1.28 Apr 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 594.6117 L/ha 2. 597.945 L/ha	1. 11.8776 g ai/ha 2. 11.9442 g ai/ha A22773A (-)	1. 24 Aug 2020 2. 01 Sep 2020 (8)	1. BBCH 85 2. BBCH 87	Fruit	< 0.01 mg/kg	3	04 Sep 2020/ -	Field SP (max days): 99
IF20-05334851 20-00243-01 GERMANY (Europe North) (79353)	Pepper / Maratos	1.28 Apr 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 594.6117 L/ha 2. 597.945 L/ha	1. 11.8776 g ai/ha 2. 11.9442 g ai/ha A22773A (-)	1. 24 Aug 2020 2. 01 Sep 2020 (8)	1. BBCH 85 2. BBCH 87	Fruit	< 0.01 mg/kg	7	08 Sep 2020/ -	Field SP (max days): 99
IF20-05334851 20-00243-02 POLAND (Europe North) (55-216)	Pepper / Aristotle	1.08 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	3	21 Sep 2020/ -	Field SP (max days): 80

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
IF20-05334851 20-00243-02 POLAND (Europe North) (55-216)	Pepper / Aristotle	1.08 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 605 L/ha 2. 596 L/ha	1. 12.09378 g ai/ha 2. 11.9226 g ai/ha A22773A (-)	1. 11 Sep 2020 2. 18 Sep 2020 (7)	1. BBCH 75-75 2. BBCH 85-85	Fruit	< 0.01 mg/kg	0	18 Sep 2020/ -	Field SP (max days): 83
IF20-05334851 20-00243-02 POLAND (Europe North) (55-216)	Pepper / Aristotle	1.08 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 605 L/ha 2. 596 L/ha	1. 12.09378 g ai/ha 2. 11.9226 g ai/ha A22773A (-)	1. 11 Sep 2020 2. 18 Sep 2020 (7)	1. BBCH 75-75 2. BBCH 85-85	Fruit	< 0.01 mg/kg	1	19 Sep 2020/ -	Field SP (max days): 83
IF20-05334851 20-00243-02 POLAND (Europe North) (55-216)	Pepper / Aristotle	1.08 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 605 L/ha 2. 596 L/ha	1. 12.09378 g ai/ha 2. 11.9226 g ai/ha A22773A (-)	1. 11 Sep 2020 2. 18 Sep 2020 (7)	1. BBCH 75-75 2. BBCH 85-85	Fruit	< 0.01 mg/kg	3	21 Sep 2020/ -	Field SP (max days): 83
IF20-05334851 20-00243-02 POLAND (Europe North) (55-216)	Pepper / Aristotle	1.08 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 605 L/ha 2. 596 L/ha	1. 12.09378 g ai/ha 2. 11.9226 g ai/ha A22773A (-)	1. 11 Sep 2020 2. 18 Sep 2020 (7)	1. BBCH 75-75 2. BBCH 85-85	Fruit	< 0.01 mg/kg	7	25 Sep 2020/ -	Field SP (max days): 83

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
IF20-05334851 20-00243-04. HUNGARY (Europe North) (H-4030)	Pepper / Vazul	1.15 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	3	27 Aug 2020/ -	Field SP (max days): 104
IF20-05334851 20-00243-04. HUNGARY (Europe North) (H-4030)	Pepper / Vazul	1.15 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 417 L/ha 2. 403.6667 L/ha	1. 12 g ai/ha 2. 12.0798 g ai/ha A22773A (-)	1. 17 Aug 2020 2. 24 Aug 2020 (7)	1. BBCH 83 2. BBCH 87	Fruit	< 0.01 mg/kg	3	27 Aug 2020/ -	Field SP (max days): 104
IF20-05334851 20-00243-05 FRANCE (Europe North) (49350)	Pepper / DENVER	1.18 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	3	21 Aug 2020/ -	Field SP (max days): 110
IF20-05334851 20-00243-05 FRANCE (Europe North) (49350)	Pepper / DENVER	1.18 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 468.9161 L/ha 2. 468.9159 L/ha	1. 12.4755 g ai/ha 2. 12.4736 g ai/ha A22773A (-)	1. 10 Aug 2020 2. 18 Aug 2020 (8)	1. BBCH 81 2. BBCH 85	Fruit	0.0307 mg/kg	0	18 Aug 2020/ -	Field SP (max days): 113

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
IF20-05334851 20-00243-05 FRANCE (Europe North) (49350)	Pepper / DENVER	1.18 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 468.9161 L/ha 2. 468.9159 L/ha	1. 12.4755 g ai/ha 2. 12.4736 g ai/ha A22773A (-)	1. 10 Aug 2020 2. 18 Aug 2020 (8)	1. BBCH 81 2. BBCH 85	Fruit	0.0274 mg/kg	1	19 Aug 2020/ -	Field SP (max days): 113
IF20-05334851 20-00243-05 FRANCE (Europe North) (49350)	Pepper / DENVER	1.18 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 468.9161 L/ha 2. 468.9159 L/ha	1. 12.4755 g ai/ha 2. 12.4736 g ai/ha A22773A (-)	1. 10 Aug 2020 2. 18 Aug 2020 (8)	1. BBCH 81 2. BBCH 85	Fruit	0.0166 mg/kg	3	21 Aug 2020/ -	Field SP (max days): 113
IF20-05334851 20-00243-05 FRANCE (Europe North) (49350)	Pepper / DENVER	1.18 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 468.9161 L/ha 2. 468.9159 L/ha	1. 12.4755 g ai/ha 2. 12.4736 g ai/ha A22773A (-)	1. 10 Aug 2020 2. 18 Aug 2020 (8)	1. BBCH 81 2. BBCH 85	Fruit	<u>0.0174 mg/kg</u>	8	26 Aug 2020/ -	Field SP (max days): 113
IF20-05334851 20-00243-06 HUNGARY (Europe North) (H-4432)	Pepper / Vazul	1.16 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	3	27 Aug 2020/ -	Field SP (max days): 104

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
IF20-05334851 20-00243-06 HUNGARY (Europe North) (H-4432)	Pepper / Vazul	1.16 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 385 L/ha 2. 408.3333 L/ha	1. 11.5212 g ai/ha 2. 12.2195 g ai/ha A22773A (-)	1. 18 Aug 2020 2. 24 Aug 2020 (6)	1. BBCH 83 2. BBCH 87	Fruit	< 0.01 mg/kg	3	27 Aug 2020/ -	Field SP (max days): 104
IF20-05334851 20-00243-07. POLAND (Europe North) (26-414)	Pepper / Aristotle F1	1.27 Apr 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	3	18 Sep 2020/ -	Field SP (max days): 82
IF20-05334851 20-00243-07. POLAND (Europe North) (26-414)	Pepper / Aristotle F1	1.27 Apr 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 733.5398 L/ha 2. 735.2064 L/ha	1. 11.7218 g ai/ha 2. 11.7484 g ai/ha A22773A (-)	1. 09 Sep 2020 2. 15 Sep 2020 (6)	1. BBCH 87-87 2. BBCH 88-88	Fruit	< 0.01 mg/kg	0	15 Sep 2020/ -	Field SP (max days): 85
IF20-05334851 20-00243-07. POLAND (Europe North) (26-414)	Pepper / Aristotle F1	1.27 Apr 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 733.5398 L/ha 2. 735.2064 L/ha	1. 11.7218 g ai/ha 2. 11.7484 g ai/ha A22773A (-)	1. 09 Sep 2020 2. 15 Sep 2020 (6)	1. BBCH 87-87 2. BBCH 88-88	Fruit	< 0.01 mg/kg	1	16 Sep 2020/ -	Field SP (max days): 85

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
IF20-05334851 20-00243-07. POLAND (Europe North) (26-414)	Pepper / Aristotle F1	1.27 Apr 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 733.5398 L/ha 2. 735.2064 L/ha	1. 11.7218 g ai/ha 2. 11.7484 g ai/ha A22773A (-)	1. 09 Sep 2020 2. 15 Sep 2020 (6)	1. BBCH 87-87 2. BBCH 88-88	Fruit	< 0.01 mg/kg	3	18 Sep 2020/ -	Field SP (max days): 85
IF20-05334851 20-00243-07. POLAND (Europe North) (26-414)	Pepper / Aristotle F1	1.27 Apr 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 733.5398 L/ha 2. 735.2064 L/ha	1. 11.7218 g ai/ha 2. 11.7484 g ai/ha A22773A (-)	1. 09 Sep 2020 2. 15 Sep 2020 (6)	1. BBCH 87-87 2. BBCH 88-88	Fruit	< 0.01 mg/kg	7	22 Sep 2020/ -	Field SP (max days): 85
IF20-05334851 20-00243-08 POLAND (Europe North) (09-142)	Pepper / Cayanne	1.16 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	3	21 Sep 2020/ -	Field SP (max days): 79
IF20-05334851 20-00243-08 POLAND (Europe North) (09-142)	Pepper / Cayanne	1.16 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 821 L/ha 2. 818 L/ha	1. 12.3184 g ai/ha 2. 12.2755 g ai/ha A22773A (-)	1. 11 Sep 2020 2. 18 Sep 2020 (7)	1. BBCH 87-87 2. BBCH 88-88	Fruit	< 0.01 mg/kg	3	21 Sep 2020/ -	Field SP (max days): 80

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
IF20-05334851 20-00243-09 POLAND (Europe North) (88-400)	Pepper / Basalt	1.05 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	3	21 Sep 2020/ -	Field SP (max days): 79
IF20-05334851 20-00243-09 POLAND (Europe North) (88-400)	Pepper / Basalt	1.05 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 309 L/ha 2. 305 L/ha	1. 12.3787 g ai/ha 2. 12.2103 g ai/ha A22773A (-)	1. 11 Sep 2020 2. 18 Sep 2020 (7)	1. BBCH 79-79 2. BBCH 79-79	Fruit	< 0.01 mg/kg	3	21 Sep 2020/ -	Field SP (max days): 80

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of 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.

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value
(DBA) Days Before Application
SP (max days): Maximum storage period

A 2.2.3.3 Cucumber and zucchini (courgette)

Table A 61: 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)
cGAP N-EU	-	-	-	-	-
cGAP S-EU (DAR, Ireland, 2015; EFSA, 2016)	3	20 g a.s./ha	7	-	3
Intended cGAP A22773A – CZ-1, CZ-2, CZ-3, HU-2, HU-3, PL-1, PL-2, PL-3, RO-2, RO-3, SK-1, SK-2, SI-2, SI-3 Extrapolated to zucchini: CZ-15, CZ-16, CZ-17, HU-16, HU-17, HU-18, PL-4, PL-5, PL-6, RO-16, RO-17, RO-18, SK-17, SK-18, SI-21, SI-22, SI-23*	2	12 g a.s./ha	7	BBCH 11-89	3

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
** Timing of applications determined primarily by growth stage
*** Minimum PHI

A 2.2.3.3.1 Study 1 (Report No. 684120) (New data)

Comments of zRMS:

Eight residue field trials on cucumbers were conducted in Northern Europe during 2020.

Azoxystrobin and oxathiapiprolin were applied to cucumbers as A22773A, a suspension concentrate (SC) formulation containing nominally 250 g of azoxystrobin per litre and 12 g of oxathiapiprolin per litre. To treated plot P2, two applications, separated by a 6-8 day interval, were made at a nominal rate of 250 g ai/ha for azoxystrobin and 12 g ai/ha for oxathiapiprolin.

For the harvest trials, following the applications, treated samples of cucumber fruit were collected at normal commercial harvest (NCH), 3 days after last application (DALA). Untreated cucumber fruit samples were collected at 3 DALA (NCH).

For the decline trials, following the applications, treated samples of cucumber fruit were collected at 0, 1, 3 (NCH) and 6-8 DALA. Untreated cucumber fruit samples were collected at 3 DALA (NCH).

Samples were analysed for azoxystrobin and it's z-isomer R230310 using method RAM 305/03, and oxathiapiprolin using method Dupont-30422, Supplement No. 1 with LOQ=0.01 mg/kg.

Actual Sampling Interval (days)	Azoxystrobin Residues in the range (mg/kg)	R230310 Residues in the range (mg/kg)	Oxathiapiprolin Residues in the range (mg/kg)
Treated Plot (P2): at a rate of 2 x 250 g ai/ha for azoxystrobin, 2 x 12 g ai/ha for oxathiapiprolin			
Cucumber fruit			
0 DALA	<0.01 – 0.15	<0.01	<0.01 – 0.01
1 DALA	0.01 – 0.25	<0.01	<0.01 – 0.02
3 DALA (NCH)	<0.01 – 0.12	<0.01	<0.01
6-8 DALA	0.01 – 0.06	<0.01	<0.01
Control plot (C1) No residues of azoxystrobin, R230310 or oxathiapiprolin at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in any of the untreated cucumber samples, Except the following; The detected residue of azoxystrobin for sample 005 for Trial 8 was above the LOQ therefore the primary sample (005) and spare sample (006) were re-analysed in duplicate. The three residue values detected in the primary sample (005) were 0.03 mg/kg and the two residue values detected in the spare sample (006) were also 0.03 mg/kg. All detected values from acceptable analysis are detailed in section 4.1.			

DALA = days after last application to the treated plot; NCH = normal commercial harvest

Samples were stored frozen for a maximum period of 140 days from sampling to analysis. The study is acceptable.

Reference: KCA2 6.3

Report: Giles, A.. (2021)
Azoxystrobin/Oxathiapiprolin – Residue Study on Cucumber in North France, The Netherlands, Belgium, Germany, Poland and Czech Republic, Initiated in 2020
Syngenta Report No. 684120
Syngenta File No. VV-896693
Unpublished

Guideline(s): Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).
OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50.

	OECD Guidance Document on Overview of Residue Chemistry Studies (as revised 2009), Series on Testing and Assessment (No. 64) and Series on Pesticides (No. 32), ENV/JM/MONO(2009)31. Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009. OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009. European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000). The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9. OECD Series on Principles of GLP and Compliance Monitoring No. 1 (as revised in 1997) "OECD Principles on Good Laboratory Practice", Paris 1998. ENV/MC/CHEM(98)17 and respective national regulations.
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 62: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) : Azoxystrobin/Oxathiapiprolin – Residue Study on Cucumber in North France, The Netherlands, Belgium, Germany, Poland and Czech Republic, Initiated in 2020			
Active Substance (common name):	oxathiapiprolin	**Commercial Product (name):**	
Crop/Crop Group:	Cucumber	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	GERMANY, POLAND, FRANCE, BELGIUM, CZECHIA, NETHERLANDS	**Other active substance in the formulation (common name and content):**	A22773A: azoxystrobin (250 g/L)
Content of active substance (g/kg or g/L):	A22773A: 12 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A22773A SC		
Analytical Method:	Oxathiapiprolin (Fruit) DuPont-30422; 0.01 mg/kg		
Recovery data:	Oxathiapiprolin Fruit Mean = 95% RSD = 5% (n = 10 in 0.01 - 0.1 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
684120 684120 Trial 1 FRANCE (Europe North) (59450)	Cucumber / Gynial	1.03 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	3	17 Aug 2020/ -	Field SP (max days): 116
684120 684120 Trial 1 FRANCE (Europe North) (59450)	Cucumber / Gynial	1.03 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 606.6043 L/ha 2. 586.3357 L/ha	1. 12.1179 g ai/ha 2. 11.713 g ai/ha A22773A (-)	1. 06 Aug 2020 2. 14 Aug 2020 (8)	1. BBCH 65-71 2. BBCH 72-76	Fruit	< 0.01 mg/kg	3	17 Aug 2020/ -	Field SP (max days): 116

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
684120 684120 Trial 2 BELGIUM (Europe North) (3470)	Cucumber / Delikateß	1.12 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	3	13 Aug 2020/ -	Field SP (max days): 120
684120 684120 Trial 2 BELGIUM (Europe North) (3470)	Cucumber / Delikateß	1.12 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 474.7556 L/ha 2. 492.5333 L/ha	1. 11.3714 g ai/ha 2. 11.7972 g ai/ha A22773A (-)	1. 03 Aug 2020 2. 10 Aug 2020 (7)	1. BBCH 74- 2. BBCH 78-	Fruit	< 0.01 mg/kg	3	13 Aug 2020/ -	Field SP (max days): 120
684120 684120 Trial 3 POLAND (Europe North) (47-270)	Cucumber / Octopus	1.19 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	3	24 Jul 2020/ -	Field SP (max days): 140
684120 684120 Trial 3 POLAND (Europe North) (47-270)	Cucumber / Octopus	1.19 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 548.5787 L/ha 2. 622.4453 L/ha	1. 10.9584 g ai/ha 2. 12.434 g ai/ha A22773A (-)	1. 13 Jul 2020 2. 21 Jul 2020 (8)	1. BBCH 71-72 2. BBCH 73-75	Fruit	< 0.01 mg/kg	3	24 Jul 2020/ -	Field SP (max days): 140

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
684120 684120 Trial 4 CZECHIA (Europe North) (69671)	Cucumber / Othello	1.05 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	3	02 Aug 2020/ -	Field SP (max days): 131
684120 684120 Trial 4 CZECHIA (Europe North) (69671)	Cucumber / Othello	1.05 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 604.312 L/ha 2. 614.712 L/ha	1. 12.07173 g ai/ha 2. 12.2795 g ai/ha A22773A (-)	1. 23 Jul 2020 2. 30 Jul 2020 (7)	1. BBCH 72- 2. BBCH 73-	Fruit	< 0.01 mg/kg	3	02 Aug 2020/ -	Field SP (max days): 131
684120 684120 Trial 5 NETHERLANDS (Europe North) (6599)	Cucumber / Vorgebirgstrauben	1.12 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	3	31 Jul 2020/ -	Field SP (max days): 133
684120 684120 Trial 5 NETHERLANDS (Europe North) (6599)	Cucumber / Vorgebirgstrauben	1.12 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 523.015 L/ha 2. 484.6667 L/ha	1. 12.668 g ai/ha 2. 11.6088 g ai/ha A22773A (-)	1. 20 Jul 2020 2. 28 Jul 2020 (8)	1. BBCH 73- 2. BBCH 77-	Fruit	< 0.01 mg/kg	0	28 Jul 2020/ -	Field SP (max days): 136

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
684120 684120 Trial 5 NETHERLANDS (Europe North) (6599)	Cucumber / Vorgebirgstrauben	1.12 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 523.015 L/ha 2. 484.6667 L/ha	1. 12.668 g ai/ha 2. 11.6088 g ai/ha A22773A (-)	1. 20 Jul 2020 2. 28 Jul 2020 (8)	1. BBCH 73- 2. BBCH 77-	Fruit	< 0.01 mg/kg	1	29 Jul 2020/ -	Field SP (max days): 136
684120 684120 Trial 5 NETHERLANDS (Europe North) (6599)	Cucumber / Vorgebirgstrauben	1.12 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 523.015 L/ha 2. 484.6667 L/ha	1. 12.668 g ai/ha 2. 11.6088 g ai/ha A22773A (-)	1. 20 Jul 2020 2. 28 Jul 2020 (8)	1. BBCH 73- 2. BBCH 77-	Fruit	< 0.01 mg/kg	3	31 Jul 2020/ -	Field SP (max days): 136
684120 684120 Trial 5 NETHERLANDS (Europe North) (6599)	Cucumber / Vorgebirgstrauben	1.12 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 523.015 L/ha 2. 484.6667 L/ha	1. 12.668 g ai/ha 2. 11.6088 g ai/ha A22773A (-)	1. 20 Jul 2020 2. 28 Jul 2020 (8)	1. BBCH 73- 2. BBCH 77-	Fruit	< 0.01 mg/kg	6	03 Aug 2020/ -	Field SP (max days): 136
684120 684120 Trial 6 GERMANY (Europe North) (46342)	Cucumber / Vorgebirgstrauben	1.02 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	3	09 Aug 2020/ -	Field SP (max days): 124

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
684120 684120 Trial 6 GERMANY (Europe North) (46342)	Cucumber / Vorgebirgstrauben	1.02 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 523.015 L/ha 2. 514.6667 L/ha	1. 12.668 g ai/ha 2. 12.3273 g ai/ha A22773A (-)	1. 30 Jul 2020 2. 06 Aug 2020 (7)	1. BBCH 71- 2. BBCH 73-	Fruit	< 0.01 mg/kg	0	06 Aug 2020/ -	Field SP (max days): 127
684120 684120 Trial 6 GERMANY (Europe North) (46342)	Cucumber / Vorgebirgstrauben	1.02 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 523.015 L/ha 2. 514.6667 L/ha	1. 12.668 g ai/ha 2. 12.3273 g ai/ha A22773A (-)	1. 30 Jul 2020 2. 06 Aug 2020 (7)	1. BBCH 71- 2. BBCH 73-	Fruit	< 0.01 mg/kg	1	07 Aug 2020/ -	Field SP (max days): 127
684120 684120 Trial 6 GERMANY (Europe North) (46342)	Cucumber / Vorgebirgstrauben	1.02 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 523.015 L/ha 2. 514.6667 L/ha	1. 12.668 g ai/ha 2. 12.3273 g ai/ha A22773A (-)	1. 30 Jul 2020 2. 06 Aug 2020 (7)	1. BBCH 71- 2. BBCH 73-	Fruit	< 0.01 mg/kg	3	09 Aug 2020/ -	Field SP (max days): 127
684120 684120 Trial 6 GERMANY (Europe North) (46342)	Cucumber / Vorgebirgstrauben	1.02 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 523.015 L/ha 2. 514.6667 L/ha	1. 12.668 g ai/ha 2. 12.3273 g ai/ha A22773A (-)	1. 30 Jul 2020 2. 06 Aug 2020 (7)	1. BBCH 71- 2. BBCH 73-	Fruit	< 0.01 mg/kg	8	14 Aug 2020/ -	Field SP (max days): 127

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
684120 684120 Trial 7 GERMANY (Europe North) (96157)	Cucumber / Diamant F1	1.05 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	3	10 Aug 2020/ -	Field SP (max days): 123
684120 684120 Trial 7 GERMANY (Europe North) (96157)	Cucumber / Diamant F1	1.05 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 602.244 L/ha 2. 578.644 L/ha	1. 12.02114 g ai/ha 2. 11.5501 g ai/ha A22773A (-)	1. 31 Jul 2020 2. 07 Aug 2020 (7)	1. BBCH 69- 2. BBCH 74-	Fruit	0.01 mg/kg	0	07 Aug 2020/ -	Field SP (max days): 126
684120 684120 Trial 7 GERMANY (Europe North) (96157)	Cucumber / Diamant F1	1.05 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 602.244 L/ha 2. 578.644 L/ha	1. 12.02114 g ai/ha 2. 11.5501 g ai/ha A22773A (-)	1. 31 Jul 2020 2. 07 Aug 2020 (7)	1. BBCH 69- 2. BBCH 74-	Fruit	0.02 mg/kg	1	08 Aug 2020/ -	Field SP (max days): 126
684120 684120 Trial 7 GERMANY (Europe North) (96157)	Cucumber / Diamant F1	1.05 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 602.244 L/ha 2. 578.644 L/ha	1. 12.02114 g ai/ha 2. 11.5501 g ai/ha A22773A (-)	1. 31 Jul 2020 2. 07 Aug 2020 (7)	1. BBCH 69- 2. BBCH 74-	Fruit	< 0.01 mg/kg	3	10 Aug 2020/ -	Field SP (max days): 126

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
684120 684120 Trial 7 GERMANY (Europe North) (96157)	Cucumber / Diamant F1	1.05 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 602.244 L/ha 2. 578.644 L/ha	1. 12.02114 g ai/ha 2. 11.5501 g ai/ha A22773A (-)	1. 31 Jul 2020 2. 07 Aug 2020 (7)	1. BBCH 69- 2. BBCH 74-	Fruit	< 0.01 mg/kg	7	14 Aug 2020/ -	Field SP (max days): 126
684120 684120 Trial 8 POLAND (Europe North) (62-001)	Cucumber / Krak	1.12 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Fruit	< 0.01 mg/kg	3	30 Jul 2020/ -	Field SP (max days): 134
684120 684120 Trial 8 POLAND (Europe North) (62-001)	Cucumber / Krak	1.12 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 622.333 L/ha 2. 623.333 L/ha	1. 12.4228 g ai/ha 2. 12.4428 g ai/ha A22773A (-)	1. 21 Jul 2020 2. 27 Jul 2020 (6)	1. BBCH 71- 2. BBCH 73-	Fruit	0.01 mg/kg	0	27 Jul 2020/ -	Field SP (max days): 137
684120 684120 Trial 8 POLAND (Europe North) (62-001)	Cucumber / Krak	1.12 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 622.333 L/ha 2. 623.333 L/ha	1. 12.4228 g ai/ha 2. 12.4428 g ai/ha A22773A (-)	1. 21 Jul 2020 2. 27 Jul 2020 (6)	1. BBCH 71- 2. BBCH 73-	Fruit	< 0.01 mg/kg	1	28 Jul 2020/ -	Field SP (max days): 137

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
684120 684120 Trial 8 POLAND (Europe North) (62-001)	Cucumber / Krak	1.12 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 622.333 L/ha 2. 623.333 L/ha	1. 12.4228 g ai/ha 2. 12.4428 g ai/ha A22773A (-)	1. 21 Jul 2020 2. 27 Jul 2020 (6)	1. BBCH 71- 2. BBCH 73-	Fruit	<u>< 0.01 mg/kg</u>	3	30 Jul 2020/ -	Field SP (max days): 137
684120 684120 Trial 8 POLAND (Europe North) (62-001)	Cucumber / Krak	1.12 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 622.333 L/ha 2. 623.333 L/ha	1. 12.4228 g ai/ha 2. 12.4428 g ai/ha A22773A (-)	1. 21 Jul 2020 2. 27 Jul 2020 (6)	1. BBCH 71- 2. BBCH 73-	Fruit	< 0.01 mg/kg	7	03 Aug 2020/ -	Field SP (max days): 137

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of 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.

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value
(DBA) Days Before Application
SP (max days): Maximum storage period

A 2.2.3.4 Melon (extrapolated to watermelon, pumpkin, squash)

Table A 63: 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)
cGAP N-EU	-	-	-	-	-
cGAP S-EU (DAR, Ireland, 2015; EFSA, 2016)	3	20 g a.s./ha	7	-	3
Intended cGAP A22773A - HU-8, HU-9, HU-10, PL-7, PL-8, PL-9, PL-10, RO-8, RO-9, RO-10, SK-11, SK-12, SI-13, SI-14, SI-15 Extrapolated to watermelon, pumpkin, squash: CZ-10, CZ-11, CZ-12, HU-13, HU-14, HU-15, PL-11, PL-12, PL-13, PL-14, PL-15, PL-16, RO-13, RO-14, RO-15, SK-15, SK-16, SI-18, SI-19, SI-20, RO-40, RO-41, RO-42*	2	12 g a.s./ha	7	BBCH 11-89	3

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
** Timing of applications determined primarily by growth stage
*** Minimum PHI

A 2.2.3.4.1 Study 1 (Report No. 684125) (New data)

Comments of zRMS:

Eight residue field trials on melons were conducted in Northern Europe during 2020. Azoxystrobin and oxathiapiprolin were applied to melons as A22773A, a suspension concentrate (SC) formulation containing nominally 250 g of azoxystrobin per litre and 12 g of oxathiapiprolin per litre. To treated plot P2, two applications, separated by a 7-8 day interval, were made at a nominal rate of 250 g ai/ha for azoxystrobin and 12 g ai/ha for oxathiapiprolin.
For the harvest trials, following the applications, treated melon samples were collected at normal commerical harvest (NCH), 3 days after last application (DALA). Untreated melon samples were collected at 3 DALA (NCH).
For the decline trials, following the applications, treated melon samples were collected at 0, 1, 3 (NCH) and 6-8 DALA. Untreated melon samples were collected at 3 DALA (NCH).
Samples were analysed for azoxystrobin and it's z-isomer R230310 using method RAM 305/03, and oxathiapiprolin using method Dupont-30422, Supplement No. 1.
Samples were stored frozen for a maximum period of ca 5 months (141 days) from sampling to analysis for azoxystrobin and R230310 and oxathipiprolin.

Residues of azoxystrobin, its z-isomer R230310, and oxathiapiprolin are summarised in the table below:

Actual Sampling Interval (days)	Azoxystrobin Residues in the range (mg/kg)	R230310 Residues in the range (mg/kg)	Oxathiapiprolin Residues in the range (mg/kg)
Treated Plot (P2): at a rate of 2 x 250 g ai/ha for azoxystrobin and 2 x 12 g ai/ha for oxathiapiprolin			
Melon peel			
0 DALA	0.05 – 0.39	<0.01	<0.01 – 0.03
1 DALA	0.04 – 0.48	<0.01 – 0.01	<0.01 – 0.04
3 DALA (NCH)	0.02 – 0.42	<0.01 – 0.04	<0.01 – 0.04
6-8 DALA	0.01 – 0.24	<0.01 – 0.03	<0.01 – 0.03
Melon pulp			
0 DALA	<0.01 – 0.07	<0.01	<0.01
1 DALA	<0.01 – 0.01	<0.01	<0.01
3 DALA (NCH)	<0.01	<0.01	<0.01
6-8 DALA	<0.01	<0.01	<0.01
Control plot (C1) No residues of azoxystrobin and its z-isomer R230310 or oxathiapiprolin at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in any of the untreated melon peel or pulp samples.			

DALA = days after last application to the treated plot; NCH = normal commercial harvest

The trials 2 and 5 conducted in Poland can be considered independent.
The trials 6 and 7 conducted in Germany can be considered independent.
Samples were stored frozen for a maximum period of 157 days from sampling to analysis.

The study is acceptable.

Reference: KCA2 6.3

Report: Giles, A. (2021)
Azoxystrobin/Oxathiapiprolin – Residue Study on Melons North France, Belgium, Poland, Germany, Czech Republic and The Netherlands, Initiated in 2020
Syngenta Report No. 684125
Syngenta File No. VV-896705
Unpublished

Guideline(s): Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).

	OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50. OECD Guidance Document on Overview of Residue Chemistry Studies (as revised 2009), Series on Testing and Assessment (No. 64) and Series on Pesticides (No. 32), ENV/JM/MONO(2009)31. Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009. OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009. European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000). The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9. OECD Series on Principles of GLP and Compliance Monitoring No. 1 (as revised in 1997) "OECD Principles on Good Laboratory Practice", Paris 1998. ENV/MC/CHEM(98)17 and respective national regulations.
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 64: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) : Azoxystrobin/Oxathiapiprolin – Residue Study on Melons North France, Belgium, Poland, Germany, Czech Republic and The Netherlands, Initiated in 2020			
Active Substance (common name):	oxathiapiprolin	**Commercial Product (name):**	
Crop/Crop Group:	Melon	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	NETHERLANDS, FRANCE, POLAND, CZECHIA, BELGIUM, GERMANY	**Other active substance in the formulation (common name and content):**	A22773A: azoxystrobin (250 g/L)
Content of active substance (g/kg or g/L):	A22773A: 12 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A22773A SC		
Analytical Method:	Oxathiapiprolin (Fruit) DuPont-30422; 0.01 mg/kg		
Recovery data:	Oxathiapiprolin Peel Fruit Mean = 94% RSD = 8% (n = 12 in 0.01 - 0.1 spiking range) Oxathiapiprolin Pulp Fruit Mean = 89% RSD = 5% (n = 11 in 0.01 - 0.1 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
684125 684125 Trial 1 FRANCE (Europe North) (37120)	Melon / Tilouka	1.04 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Peel	< 0.01	3	17 Aug 2020/ -	Field SP (max days): 157
									Pulp	<0.01			
									Whole fruit	< 0.01			
	Melon / Tilouka	1.04 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 570.575 L/ha 2. 603.694 L/ha	1. 11.3925 g ai/ha 2. 12.05379 g ai/ha A22773A (-)	1. 07 Aug 2020 2. 14 Aug 2020 (7)	1. BBCH 65-71 2. BBCH 87-88	Peel	0.01	3	17 Aug 2020/ -	Field SP (max days): 157
									Pulp	<0.01			
									Whole fruit	< 0.01			
684125 684125 Trial 2 POLAND (Europe North)	Melon / Anasta	1.20 May 2020 2 – 3 -	-	-	-		- (-)		Peel	< 0.01	3	04 Sep 2020/ -	Field
									Pulp	<0.01			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
(62-001)						(-)			Whole fruit	< 0.01			SP (max days): 139
	Melon / Anasta	1.20 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 585.912 L/ha 2. 607.2453 L/ha	1. 11.7042 g ai/ha 2. 12.1303 g ai/ha A22773A (-)	1. 24 Aug 2020 2. 01 Sep 2020 (8)	1. BBCH 81- 2. BBCH 86-	Peel Pulp Whole fruit	<0.01 <0.01 < 0.01	3	04 Sep 2020/ -	Field SP (max days): 139
684125 684125 Trial 3 CZECHIA (Europe North) (68724)	Melon / Wrangler	1.22 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Peel Pulp Whole fruit	<0.01 <0.01 < 0.01	3	22 Aug 2020/ -	Field SP (max days): 152
	Melon / Wrangler	1.22 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 589.112 L/ha 2. 580.8453 L/ha	1. 11.7681 g ai/ha 2. 11.603 g ai/ha A22773A (-)	1. 12 Aug 2020 2. 19 Aug 2020 (7)	1. BBCH 73- 2. BBCH 81-	Peel Pulp Whole fruit	0.04 <0.01 0.02	3	22 Aug 2020/ -	Field SP (max days): 152
684125 684125 Trial 4 BELGIUM (Europe North) (3470)	Melon / Cezanne	1.08 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Peel Pulp Whole fruit	<0.01 <0.01 < 0.01	3	31 Aug 2020/ -	Field SP (max days): 143

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
	Melon / Cezanne	1.08 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 522.1667 L/ha 2. 493 L/ha	1. 12.507 g ai/ha 2. 11.8084 g ai/ha A22773A (-)	1. 21 Aug 2020 2. 28 Aug 2020 (7)	1. BBCH 87- 2. BBCH 87-89	Peel	0.01	3	31 Aug 2020/ -	Field SP (max days): 143
									Pulp	<0.01			
									Whole fruit	< 0.01			
684125 684125 Trial 5 POLAND (Europe North) (47-270)	Melon / Charentaise	1.18 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Peel	<0.01	3	14 Sep 2020/ -	Field SP (max days): 129
									Pulp	<0.01			
									Whole fruit	< 0.01			
	Melon / Charentaise	1.18 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 606.333 L/ha 2. 572.333 L/ha	1. 12.1035 g ai/ha 2. 11.4248 g ai/ha A22773A (-)	1. 04 Sep 2020 2. 11 Sep 2020 (7)	1. BBCH 85- 2. BBCH 86-	Peel	0.02	0	11 Sep 2020/ -	Field SP (max days): 132
									Pulp	<0.01			
									Whole fruit	0.01			
									Peel	0.01	1	12 Sep 2020/ -	
									Pulp	<0.01			
									Whole fruit	< 0.01			
									Peel	<0.01	3	14 Sep 2020/ -	
									Pulp	<0.01			
									Whole fruit	< 0.01			
									Peel	<0.01	7	18 Sep 2020/ -	
									Pulp	<0.01			
									Whole fruit	< 0.01			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
684125 684125 Trial 6 GERMANY (Europe North) (04827)	Melon / Anasta	1.20 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Peel	<0.01	3	04 Sep 2020/ -	Field SP (max days): 139
									Pulp	<0.01			
									Whole fruit	< 0.01			
	Melon / Anasta	1.20 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 601.7773 L/ha 2. 599.1107 L/ha	1. 12.01252 g ai/ha 2. 11.9593 g ai/ha A22773A (-)	1. 24 Aug 2020 2. 01 Sep 2020 (8)	1. BBCH 81- 2. BBCH 86-	Peel	0.01	0	01 Sep 2020/ -	Field SP (max days): 142 Field
									Pulp	<0.01			
									Whole fruit	< 0.01			
									Peel	0.01	1	02 Sep 2020/ -	
									Pulp	<0.01			
									Whole fruit	< 0.01			
									Peel	<0.01	3	04 Sep 2020/ -	
									Pulp	<0.01			
									Whole fruit	< 0.01			
									Peel	<0.01	6	07 Sep 2020/ -	
									Pulp	<0.01			
									Whole fruit	< 0.01			
684125 684125 Trial 7 GERMANY (Europe North) (46342)	Melon / Anasta F1	1.10 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Peel	<0.01	3	11 Sep 2020/ -	Field SP (max days): 132
									Pulp	<0.01			
									Whole fruit	<0.01			
	Melon / Anasta F1	1.10 Jun 2020	1. Foliar 2. Foliar	-	1. 485.2267	1. 11.6222 g ai/ha	1. 01 Sep 2020	1. BBCH 77-	Peel	<0.01	0	08 Sep 2020/ -	Field
									Pulp	<0.01			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
		2 – 3 -			L/ha 2. 486.56 L/ha	2. 11.6541 g ai/ha A22773A (-)	2. 08 Sep 2020 (7)	2. BBCH 83-	Whole fruit	< 0.01			SP (max days): 135
									Peel	<0.01	1	09 Sep 2020/ -	
									Pulp	<0.01			
									Whole fruit	< 0.01			
									Peel	<0.01	3	11 Sep 2020/ -	
									Pulp	<0.01			
									Whole fruit	< 0.01			
									Peel	<0.01	8	16 Sep 2020/ -	
									Pulp	<0.01			
									Whole fruit	< 0.01			
684125 684125 Trial 8 NETHERLANDS (Europe North) (6599 AV)	Melon / Stellio F1	1.10 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Peel	<0.01	3	03 Sep 2020/ -	Field SP (max days): 140
									Pulp	<0.01			
									Whole fruit	<0.01			
	Melon / Stellio F1	1.10 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 507.8973 L/ha 2. 510.56 L/ha	1. 12.2048 g ai/ha 2. 12.229 g ai/ha A22773A (-)	1. 24 Aug 2020 2. 31 Aug 2020 (7)	1. BBCH 87- 2. BBCH 87-88	Peel	0.03	0	31 Aug 2020/ -	Field SP (max days): 143
									Pulp	<0.01			
									Whole fruit	0.02			
									Peel	0.04	1	01 Sep 2020/ -	
									Pulp	<0.01			
									Whole fruit	0.02			
									Peel	0.02	3	03 Sep 2020/ -	
									Pulp	<0.01			
									Whole fruit	0.01			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
									Peel	0.03	7	07 Sep 2020/ -	
									Pulp	<0.01			
									Whole fruit	0.02			

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of 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.

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value
(DBA) Days Before Application
SP (max days): Maximum storage period

A 2.2.3.5 Lettuce (extrapolated to sweet basil, salad plants and spinach)

Table A 65: 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)
cGAP N-EU (DAR, Ireland, 2015; EFSA, 2016)	2	15 g a.s./ha	7	-	7
cGAP S-EU (DAR, Ireland, 2015; EFSA, 2016)	2	15 g a.s./ha	7	-	7
Intended cGAP A22773A - AT-6, BE-2, CZ-9, DE-16, DE-6, IE-6, NL-6, PL-20, PL-21, SK-10, SI-12 Extrapolated to salad plants, spinach, sweet basil: CZ-31, PL-18, PL-19, PL-38, PL-39, PL-40, SK-37, SK-39, RO-34*	2	12 g a.s./ha	7	BBCH 11-49	14

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
** Timing of applications determined primarily by growth stage
*** Minimum PHI

A 2.2.3.5.1 Study 1 (Report No. DuPont- 31734) (EU reviewed)

Comments of zRMS:	The study has been reviewed at EU level.

Reference:	KCA2 6.3
Report:	Spence C. & Brown D. (2011/12) Decline and magnitude of residues of DPX-QGU42 and its metabolites in field lettuce (leafy vegetables) following foliar application of DPX-QGU42 100 g/L OD or DPX-QGU42 100 g/l SE – Europe, 2011-2012 Dupont-31734. Charles river study number 696296 Unpublished
Guideline(s):	OECD Test Guideline 509
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 66: Summary of the study 1 trials

Decline and magnitude of residues of DPX-QGU42 and its metabolites in field lettuce (leafy vegetables) following foliar application of DPX-QGU42 100 g/L OD or DPX-QGU42 100 g/l SE – Europe, 2011-2012			
Active Substance (common name):	DPX-QGU42	**Commercial Product (name):**	
Crop/Crop Group:	Lettuce	**Producer of commercial product:**	DuPont
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	France, Spain, Greece, Italy	**Other active substance in the formulation (common name and content):**	
Content of active substance (g/kg or g/L):	DPX-QGU42 100 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	DPX-QGU42 OD or DPX-QGU42 SE		
Analytical Method:	DPX-QGU42 (Leaves) Charles river analytical method 1846a (Based on DuPont method 30422) (); 0.01 mg/kg		
Recovery data:	DPX-QGU42 Mean = ≤8.0% RSD = 82-94% (n=2-10)		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commo-dity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treat-ment	(5) Application rate per treatment			(6) Date of treatment (s) or no of treatment (s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analysed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sam-ple Date / Cut Date	(12) Trial Details (e)
				Conc.	**Water**	**Rate Formulation (Additive Type, Rate)**				**Oxathiapiprolin (mg/kg)**			
DuPont - 31734 01 North France (Europe north) (-)	Open field Lettuce (Quello)	2011 2 – 3 -	Foliar	0.0015 as/hL 0.0015 as/hL	948 L/ha 1018 L/ha	14 g ai/ha 15 g ai/ha SE	05 Oct 2011 13 Oct 2011	BBCH 46 BBCH 48-49	leaves	0.051	0*	12 Oct 2011	Field SP (max Months): < 10 Months
										0.41	0	13 Oct 2011	
				0.0015 as/hL 0.0015 as/hL	982 L/ha 998 L/ha	15 g ai/ha 15 g ai/ha SE	05 Oct 2011 12 Oct 2011	BBCH 46 BBCH 48		0.24	1	13 Oct 2011	
				0.0015 as/hL 0.0015 as/hL	1045 L/ha 985 L/ha	16 g ai/ha 15 g ai/ha SE	03 Oct 2011 10 Oct 2011	BBCH 45 BBCH 47		0.31	3	13 Oct 2011	
				0.0015 as/hL 0.0015 as/hL	1017 L/ha 1023 L/ha	15 g ai/ha 15 g ai/ha SE	29 Sep 2011 05 Oct 2011	BBCH 19 BBCH 46		0.11	8	13 Oct 2011	

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commo-dity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treat-ment	(5) Application rate per treatment			(6) Date of treatment (s) or no of treatment (s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analysed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sam-ple Date / Cut Date	(12) Trial Details (e)
				Conc.	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
				0.0015 as/hL 0.0015 as/hL	1014 L/ha 990 L/ha	15 g ai/ha 15 g ai/ha SE	27 Sep 2011 03 Oct 2011	BBCH 19 BBCH 45		0.13	10	13 Oct 2011	
DuPont - 31734 02 North France (Europe north) (-)	Open field Lettuce (Maruschka)	2011 2 – 3 -	Foliar	0.0015 as/hL 0.0015 as/hL	952 L/ha 976 L/ha	14 g ai/ha 15 g ai/ha SE	31 May 2011 08 Jun 2011	BBCH 75 BBCH 77	leaves	0.048	7	15 Jun 2011	Field SP (max Months): < 10 Months
				0.0015 as/hL 0.0015 as/hL	1000 L/ha 1014 L/ha	15 g ai/ha 15 g ai/ha OD	31 May 2011 08 Jun 2011	BBCH 74 BBCH 76		0.069	7	15 Jun 2011	
DuPont - 31734 06 Germany (Europe north) (-)	Open field Lettuce (Lollo Bionda)	2011 2 – 3 -	Foliar	0.0016 as/hL 0.0016 as/hL	1020 L/ha 988 L/ha	16 g ai/ha 16 g ai/ha SE	15 Sep 2011 22 Sep 2011	BBCH 47 BBCH 49	leaves	0.033	0*	21 Sep 2011	Field SP (max Months): < 10 Months
										0.85	0	22 Sep 2011	
				0.0016 as/hL 0.0016 as/hL	1028 L/ha 1044 L/ha	17 g ai/ha 17 g ai/ha SE	14 Sep 2011 21 Sep 2011	BBCH 17 BBCH 49		0.59	1	22 Sep 2011	
				0.0016 as/hL 0.0016 as/hL	972 L/ha 972 L/ha	16 g ai/ha 16 g ai/ha SE	12 Sep 2011 19 Sep 2011	BBCH 16 BBCH 48		0.52	3	22 Sep 2011	
				0.0016 as/hL 0.0016 as/hL	980 L/ha 1044 L/ha	16 g ai/ha 17 g ai/ha SE	08 Sep 2011 15 Sep 2011	BBCH 16 BBCH 47		0.044	7	22 Sep 2011	
				0.0016 as/hL 0.0016 as/hL	1044 L/ha 956 L/ha	17 g ai/ha 15 g ai/ha SE	05 Sep 2011 12 Sep 2011	BBCH 16 BBCH 16		0.070	10	22 Sep 2011	

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commo-dity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treat-ment	(5) Application rate per treatment			(6) Date of treatment (s) or no of treatment (s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analysed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sam-ple Date / Cut Date	(12) Trial Details (e)
				Conc.	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
DuPont - 31734 08 Germany (Europe north) (-)	Open field Lettuce (Eichblatt Rot Prunai)	2011 2 – 3 -	Foliar	0.0015 as/hL 0.0015 as/hL	1007 L/ha 1020 L/ha	15 g ai/ha 15 g ai/ha SE	17 Jun 2011 25 Jun 2011	BBCH 47 BBCH 49	leaves	0.019	0*	24 Jun 2011	Field SP (max Months): < 10 Months
										0.25	0	25 Jun 2011	
				0.0015 as/hL 0.0015 as/hL	1000 L/ha 1013 L/ha	15 g ai/ha 15 g ai/ha SE	17 Jun 2011 24 Jun 2011	BBCH 47 BBCH 49		0.12	1	25 Jun 2011	
				0.0015 as/hL 0.0015 as/hL	980 L/ha 1000 L/ha	15 g ai/ha 15 g ai/ha SE	15 Jun 2011 22 Jun 2011	BBCH 45 BBCH 48		0.061	3	25 Jun 2011	
				0.0015 as/hL 0.0015 as/hL	993 L/ha 1013 L/ha	15 g ai/ha 15 g ai/ha SE	11 Jun 2011 17 Jun 2011	BBCH 43 BBCH 47		0.043	8	25 Jun 2011	
				0.0015 as/hL 0.0015 as/hL	993 L/ha 1007 L/ha	15 g ai/ha 15 g ai/ha SE	08 Jun 2011 15 Jun 2011	BBCH 43 BBCH 45		0.027	10	25 Jun 2011	
DuPont - 31734 09 Germany (Europe north) (-)	Open field Lettuce (Kitare)	2011 2 – 3 -	Foliar	0.0015 as/hL 0.0015 as/hL	1013 L/ha 1020 L/ha	15 g ai/ha 15 g ai/ha SE	08 Jun 2011 15 Jun 2011	BBCH 43 BBCH 47	leaves	0.022	7	22 Jun 2011	Field SP (max Months): < 10 Months
				0.0015 as/hL 0.0015 as/hL	1007 L/ha 933 L/ha	15 g ai/ha 15 g ai/ha OD	08 Jun 2011 15 Jun 2011	BBCH 43 BBCH 47		0.015	7	22 Jun 2011	

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commo-dity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treat-ment	(5) Application rate per treatment			(6) Date of treatment (s) or no of treatment (s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatm ent	(8) Portion Analyse d	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sam-ple Date / Cut Date	(12) Trial Details (e)
				Conc.	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
DuPont - 31734 12 South UK (Europe north) (-)	Open field Lettuce (Emocion (Green Batavia))	2012 2 – 3 -	Foliar	0.0015 as/hL 0.0015 as/hL	1017 L/ha 994 L/ha	15 g ai/ha 15 g ai/ha SE	17 May 2012 24 May 2012	BBCH 43 BBCH 47	leaves	0.19	7	31 May 2012	Field SP (max Months): < 10 Months
DuPont - 31734 16 South UK (Europe north) (-)	Open field Lettuce (Madrigon Multi Red Rossa)	2012 2 – 3 -	Foliar	0.0015 as/hL 0.0015 as/hL	1017 L/ha 994 L/ha	15 g ai/ha 15 g ai/ha SE	17 May 2012 24 May 2012	BBCH 46 BBCH 46	leaves	0.046	0*	23 May 2012	Field SP (max Months): < 10 Months
										0.30	0	24 May 2012	
				0.0015 as/hL 0.0015 as/hL	1010 L/ha 1019 L/ha	15 g ai/ha 15 g ai/ha SE	15 Oct 2012 22 Oct 2012	BBCH 47-48 BBCH 49		0.26	1	23 Oct 2012	
				0.0015 as/hL 0.0015 as/hL	1000 L/ha 965 L/ha	15 g ai/ha 15 g ai/ha SE	13 Oct 2012 22 Oct 2012	BBCH 47 BBCH 48-49		0.082	3	25 Oct 2012	
				0.0015 as/hL 0.0015 as/hL	1028 L/ha 1005 L/ha	15 g ai/ha 15 g ai/ha SE	09 Oct 2012 16 Oct 2012	BBCH 46-47 BBCH 47-48		0.15	7	23 Oct 2012	
				0.0015 as/hL 0.0015 as/hL	1063 L/ha 1031 L/ha	16 g ai/ha 16 g ai/ha SE	06 Oct 2012 13 Oct 2012	BBCH 46 BBCH 47		0.12	10	23 Oct 2012	

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commo-dity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treat-ment	(5) Application rate per treatment			(6) Date of treatment (s) or no of treatment (s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatm ent	(8) Portion Analyse d	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sam-ple Date / Cut Date	(12) Trial Details (e)
				Conc.	Water	Rate Formulati on (Additive Type, Rate)				Oxathiapiproli n (mg/kg)			
DuPont - 31734 17 Germany (Europe north) (-)	Open field Lettuce (Lollo rosso)	2012 2 – 3 -	Foliar	0.0015 as/hL 0.0015 as/hL	1013 L/ha 1027 L/ha	15 g ai/ha 15 g ai/ha SE	08 Jun 2012 15 Jun 2012	BBCH 19 BBCH 43	leaves	<u>0.035</u>	7		Field SP (max Months): < 10 Months

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of 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.
Residues in control samples were always below the LOQ (<0.01 mg/kg).

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value
(DBA) Days Before Application
SP (max days): Maximum storage period

A 2.2.3.6 Leek, extrapolated to spring onion

Table A 67: 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)
cGAP N-EU	-	-	-	-	-
cGAP S-EU	-	-	-	-	-
Intended cGAP A22773A - AT-2, AT-3, AT-4, AT-5, BE-3, BE-4, BE-5, BE-6, CZ-5, CZ-6, CZ-7, CZ-8, DE-2, DE-3, DE-4, DE-5, IE-2, IE-3, IE-4, IE-5, NL-2, NL-3, NL-4, NL-5, PL-30, PL-31, PL-32, PL-33, SK-6, SK-7, SK-8, SK-9, SI-8, SI-9, SI-10, SI-11, RO-35, RO-36, RO-37, RO-38 Extrapolated to spring onion: BE-7, CZ-30, NL-8, PL-71, SK-36, RO-39*	2	12 g a.s./ha	12-14	BBCH 11-49	7

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
** Timing of applications determined primarily by growth stage
*** Minimum PHI

A 2.2.3.6.1 Study 1 (Report No. 684141) (New data)

<table>
<tr><td>Comments of zRMS:</td><td>Eight residue field trials on leeks were conducted in Northern Europe during 2020.
Azoxystrobin and oxathiapiprolin were applied to leeks as A22773A, a suspension concentrate (SC) formulation containing nominally 250 g of azoxystrobin per litre and 12 g of oxathiapiprolin per litre. To treated plot P2, two applications, separated by a 10-13 day interval, were made at a nominal rate of 250 g ai/ha for azoxystrobin and 12 g ai/ha for oxathiapiprolin.
For the harvest trials, following the applications, treated samples of leek whole plant were collected at 7-8 days after last application (DALA), normal commercial harvest (NCH). Untreated leek whole plant samples were collected at 7-8 DALA (NCH).
For the decline trials, following the applications, treated samples of leek whole plant were collected at 0, 1, 3, 7 (NCH) and 9-10 days after last application (DALA). Untreated leek whole plant samples were collected at 7 DALA (NCH).
Samples were analysed for azoxystrobin and it's z-isomer R230310 using method RAM 305/03, and oxathiapiprolin using method Dupont-30422, Supplement No. 1.
Samples were stored frozen for a maximum period of ca 6 months (175 days) from sampling to analysis for azoxystrobin and R230310 and oxathipiprolin.
Residues of azoxystrobin, its z-isomer R230310, and oxathiapiprolin are summarised in the table below:
<table>
<tr><th>Actual Sampling Interval (days)</th><th>Azoxystrobin Residues in the range (mg/kg)</th><th>R230310 Residues in the range (mg/kg)</th><th>Oxathiapiprolin Residues in the range (mg/kg)</th></tr>
<tr><td colspan="4">Treated Plot (P2): at a rate of 2 x 250 g ai/ha for azoxystrobin and 2 x 12 g ai/ha for oxathiapiprolin</td></tr>
<tr><td colspan="4">Leek Whole Plant</td></tr>
<tr><td>0 DALA</td><td>0.66 – 1.40</td><td><0.01</td><td>0.04 – 0.11</td></tr>
<tr><td>1 DALA</td><td>0.47 – 1.54</td><td><0.01</td><td>0.02 – 0.09</td></tr>
<tr><td>3 DALA</td><td>0.18 – 1.01</td><td><0.01 – 0.01</td><td>0.02 – 0.10</td></tr>
<tr><td>7-8 DALA (NCH)</td><td>0.09 – 1.16</td><td><0.01 – 0.03</td><td><0.01 – 0.05</td></tr>
<tr><td>9-10 DALA</td><td>0.07 – 0.34</td><td><0.01</td><td><0.01 – 0.03</td></tr>
<tr><td colspan="4">Control plot (C1)
No residues of azoxystrobin and its metabolite R230310 or oxathiapiprolin at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in any of the untreated leek samples.</td></tr>
</table>
DALA = days after last application to the treated plot; NCH = normal commercial harvest

All trials can be considered independent.
The study is acceptable.</td></tr>
</table>

Reference:	KCA2 6.3
Report:	Giles, A. (2021) Azoxystrobin/Oxathiapiprolin – Residue Study on Leeks in the United Kingdom, North France, Belgium, Germany and The Netherlands, Initiated in 2020 Report No. 684141 Syngenta File No. VV-900599 Unpublished
Guideline(s):	Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document). OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50. OECD Guidance Document on Overview of Residue Chemistry Studies (as revised 2009), Series on Testing and Assessment (No. 64) and Series on Pesticides (No. 32), ENV/JM/MONO(2009)31.

	Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009. OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009. European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000). The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9. OECD Series on Principles of GLP and Compliance Monitoring No. 1 (as revised in 1997) "OECD Principles on Good Laboratory Practice", Paris 1998. ENV/MC/CHEM(98)17 and respective national regulations.
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 68: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) : Azoxystrobin/Oxathiapiprolin – Residue Study on Leeks in the United Kingdom, North France, Belgium, Germany and The Netherlands, Initiated in 2020			
Active Substance (common name):	oxathiapiprolin	**Commercial Product (name):**	
Crop/Crop Group:	Leek	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	UNITED KINGDOM, FRANCE, NETHERLANDS, BELGIUM, GERMANY	**Other active substance in the formulation (common name and content):**	A22773A: azoxystrobin (250 g/L)
Content of active substance (g/kg or g/L):	A22773A: 12 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A22773A SC		
Analytical Method:	Oxathiapiprolin (Whole plant) DuPont-30422; 0.01 mg/kg		
Recovery data:	Oxathiapiprolin Whole plant Mean = 93% RSD = 9% (n = 12 in 0.01 - 0.1 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
684141 684141 Trial 1 BELGIUM (Europe North) (8890)	Leek / Krypton	1.15 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Whole plant	< 0.01 mg/kg	8	02 Oct 2020/ -	Field SP (max days): 133
684141 684141 Trial 1 BELGIUM (Europe North) (8890)	Leek / Krypton	1.15 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 595.075 L/ha 2. 610.06 L/ha	1. 11.8749 g ai/ha 2. 12.1739 g ai/ha A22773A (-)	1. 14 Sep 2020 2. 24 Sep 2020 (10)	1. BBCH 48- 2. BBCH 48-	Whole plant	< 0.01 mg/kg	8	02 Oct 2020/ -	Field SP (max days): 133
684141 684141 Trial 2 FRANCE (Europe North) (80290)	Leek / Pluston	1.24 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Whole plant	< 0.01 mg/kg	7	19 Oct 2020/ -	Field SP (max days): 116

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
684141 684141 Trial 2 FRANCE (Europe North) (80290)	Leek / Pluston	1.24 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 602.4917 L/ha 2. 590.182 L/ha	1. 12.02292 g ai/ha 2. 11.7773 g ai/ha A22773A (-)	1. 01 Oct 2020 2. 12 Oct 2020 (11)	1. BBCH 48- 2. BBCH 48-	Whole plant	0.05 mg/kg	7	19 Oct 2020/ -	Field SP (max days): 116
684141 684141 Trial 3 GERMANY (Europe North) (04827)	Leek / Bulgaarse Reuzen	1.04 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Whole plant	< 0.01 mg/kg	7	12 Oct 2020/ -	Field SP (max days): 123
684141 684141 Trial 3 GERMANY (Europe North) (04827)	Leek / Bulgaarse Reuzen	1.04 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 411 L/ha 2. 435 L/ha	1. 12.2993 g ai/ha 2. 13.01746 g ai/ha A22773A (-)	1. 22 Sep 2020 2. 05 Oct 2020 (13)	1. BBCH 45-47 2. BBCH 45-47	Whole plant	0.04 mg/kg	7	12 Oct 2020/ -	Field SP (max days): 123
684141 684141 Trial 4 GERMANY (Europe North) (46342)	Leek / Krypton	1.13 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Whole plant	< 0.01 mg/kg	7	21 Sep 2020/ -	Field SP (max days): 144

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
684141 684141 Trial 4 GERMANY (Europe North) (46342)	Leek / Krypton	1.13 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 378.5 L/ha 2. 388.5 L/ha	1. 11.3267 g ai/ha 2. 11.6259 g ai/ha A22773A (-)	1. 02 Sep 2020 2. 14 Sep 2020 (12)	1. BBCH 47- 2. BBCH 47-	Whole plant	0.05 mg/kg	7	21 Sep 2020/ -	Field SP (max days): 144
684141 684141 Trial 5 UNITED KINGDOM (Europe North) (YO62 4NH)	Leek / Atlantic	1.06 Jun 2020 2 – 3 -	-	-	-	(-)	- (-)		Whole plant	< 0.01 mg/kg	7	04 Nov 2020/ -	Field SP (max days): 100
684141 684141 Trial 5 UNITED KINGDOM (Europe North) (YO62 4NH)	Leek / Atlantic	1.06 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 304.2 L/ha 2. 302.6107 L/ha	1. 12.1243 g ai/ha 2. 12.06096 g ai/ha A22773A (-)	1. 16 Oct 2020 2. 28 Oct 2020 (12)	1. BBCH 47- 2. BBCH 48-	Whole plant	0.09 mg/kg	0	28 Oct 2020/ -	Field SP (max days): 107
684141 684141 Trial 5 UNITED KINGDOM (Europe North) (YO62 4NH)	Leek / Atlantic	1.06 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 304.2 L/ha 2. 302.6107 L/ha	1. 12.1243 g ai/ha 2. 12.06096 g ai/ha A22773A (-)	1. 16 Oct 2020 2. 28 Oct 2020 (12)	1. BBCH 47- 2. BBCH 48-	Whole plant	0.09 mg/kg	1	29 Oct 2020/ -	Field SP (max days): 107

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
684141 684141 Trial 5 UNITED KINGDOM (Europe North) (YO62 4NH)	Leek / Atlantic	1.06 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 304.2 L/ha 2. 302.6107 L/ha	1. 12.1243 g ai/ha 2. 12.06096 g ai/ha A22773A (-)	1. 16 Oct 2020 2. 28 Oct 2020 (12)	1. BBCH 47- 2. BBCH 48-	Whole plant	0.04 mg/kg	3	31 Oct 2020/ -	Field SP (max days): 107
684141 684141 Trial 5 UNITED KINGDOM (Europe North) (YO62 4NH)	Leek / Atlantic	1.06 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 304.2 L/ha 2. 302.6107 L/ha	1. 12.1243 g ai/ha 2. 12.06096 g ai/ha A22773A (-)	1. 16 Oct 2020 2. 28 Oct 2020 (12)	1. BBCH 47- 2. BBCH 48-	Whole plant	< 0.01 mg/kg	7	04 Nov 2020/ -	Field SP (max days): 107
684141 684141 Trial 5 UNITED KINGDOM (Europe North) (YO62 4NH)	Leek / Atlantic	1.06 Jun 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 304.2 L/ha 2. 302.6107 L/ha	1. 12.1243 g ai/ha 2. 12.06096 g ai/ha A22773A (-)	1. 16 Oct 2020 2. 28 Oct 2020 (12)	1. BBCH 47- 2. BBCH 48-	Whole plant	< 0.01 mg/kg	9	06 Nov 2020/ -	Field SP (max days): 107
684141 684141 Trial 6 UNITED KINGDOM (Europe North) (NR)	Leek / Lancaster	1.28 Apr 2020 2 – 3 -	-	-	-	(-)	- (-)		Whole plant	< 0.01 mg/kg	7	08 Dec 2020/ -	Field SP (max days): 66

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
684141 684141 Trial 6 UNITED KINGDOM (Europe North) (NR)	Leek / Lancaster	1.28 Apr 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 399.608 L/ha 2. 409.646 L/ha	1. 11.9583 g ai/ha 2. 12.2587 g ai/ha A22773A (-)	1. 19 Nov 2020 2. 01 Dec 2020 (12)	1. BBCH 49- 2. BBCH 49-	Whole plant	0.04 mg/kg	0	01 Dec 2020/ -	Field SP (max days): 73
684141 684141 Trial 6 UNITED KINGDOM (Europe North) (NR)	Leek / Lancaster	1.28 Apr 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 399.608 L/ha 2. 409.646 L/ha	1. 11.9583 g ai/ha 2. 12.2587 g ai/ha A22773A (-)	1. 19 Nov 2020 2. 01 Dec 2020 (12)	1. BBCH 49- 2. BBCH 49-	Whole plant	0.08 mg/kg	1	02 Dec 2020/ -	Field SP (max days): 73
684141 684141 Trial 6 UNITED KINGDOM (Europe North) (NR)	Leek / Lancaster	1.28 Apr 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 399.608 L/ha 2. 409.646 L/ha	1. 11.9583 g ai/ha 2. 12.2587 g ai/ha A22773A (-)	1. 19 Nov 2020 2. 01 Dec 2020 (12)	1. BBCH 49- 2. BBCH 49-	Whole plant	0.02 mg/kg	3	04 Dec 2020/ -	Field SP (max days): 73
684141 684141 Trial 6 UNITED KINGDOM (Europe North) (NR)	Leek / Lancaster	1.28 Apr 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 399.608 L/ha 2. 409.646 L/ha	1. 11.9583 g ai/ha 2. 12.2587 g ai/ha A22773A (-)	1. 19 Nov 2020 2. 01 Dec 2020 (12)	1. BBCH 49- 2. BBCH 49-	Whole plant	0.01 mg/kg	7	08 Dec 2020/ -	Field SP (max days): 73

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
684141 684141 Trial 6 UNITED KINGDOM (Europe North) (NR)	Leek / Lancaster	1.28 Apr 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 399.608 L/ha 2. 409.646 L/ha	1. 11.9583 g ai/ha 2. 12.2587 g ai/ha A22773A (-)	1. 19 Nov 2020 2. 01 Dec 2020 (12)	1. BBCH 49- 2. BBCH 49-	Whole plant	0.02 mg/kg	10	11 Dec 2020/ -	Field SP (max days): 73
684141 684141 Trial 7 FRANCE (Europe North) (62138)	Leek / Nunton	1.01 Jul 2020 2 – 3 -	-	-	-	(-)	- (-)		Whole plant	< 0.01 mg/kg	7	17 Nov 2020/ -	Field SP (max days): 87
684141 684141 Trial 7 FRANCE (Europe North) (62138)	Leek / Nunton	1.01 Jul 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 556.3932 L/ha 2. 610.5553 L/ha	1. 11.1093 g ai/ha 2. 12.1908 g ai/ha A22773A (-)	1. 30 Oct 2020 2. 10 Nov 2020 (11)	1. BBCH 48- 2. BBCH 48-49	Whole plant	0.11 mg/kg	0	10 Nov 2020/ -	Field SP (max days): 94
684141 684141 Trial 7 FRANCE (Europe North) (62138)	Leek / Nunton	1.01 Jul 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 556.3932 L/ha 2. 610.5553 L/ha	1. 11.1093 g ai/ha 2. 12.1908 g ai/ha A22773A (-)	1. 30 Oct 2020 2. 10 Nov 2020 (11)	1. BBCH 48- 2. BBCH 48-49	Whole plant	0.08 mg/kg	1	11 Nov 2020/ -	Field SP (max days): 94

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
684141 684141 Trial 7 FRANCE (Europe North) (62138)	Leek / Nunton	1.01 Jul 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 556.3932 L/ha 2. 610.5553 L/ha	1. 11.1093 g ai/ha 2. 12.1908 g ai/ha A22773A (-)	1. 30 Oct 2020 2. 10 Nov 2020 (11)	1. BBCH 48- 2. BBCH 48-49	Whole plant	0.1 mg/kg	3	13 Nov 2020/ -	Field SP (max days): 94
684141 684141 Trial 7 FRANCE (Europe North) (62138)	Leek / Nunton	1.01 Jul 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 556.3932 L/ha 2. 610.5553 L/ha	1. 11.1093 g ai/ha 2. 12.1908 g ai/ha A22773A (-)	1. 30 Oct 2020 2. 10 Nov 2020 (11)	1. BBCH 48- 2. BBCH 48-49	Whole plant	0.05 mg/kg	7	17 Nov 2020/ -	Field SP (max days): 94
684141 684141 Trial 7 FRANCE (Europe North) (62138)	Leek / Nunton	1.01 Jul 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 556.3932 L/ha 2. 610.5553 L/ha	1. 11.1093 g ai/ha 2. 12.1908 g ai/ha A22773A (-)	1. 30 Oct 2020 2. 10 Nov 2020 (11)	1. BBCH 48- 2. BBCH 48-49	Whole plant	0.03 mg/kg	10	20 Nov 2020/ -	Field SP (max days): 94
684141 684141 Trial 8 NETHERLANDS (Europe North) (6599 AV)	Leek / Krypton	1.18 May 2020 2 – 3 -	-	-	-	(-)	- (-)		Whole plant	< 0.01 mg/kg	7	28 Aug 2020/ -	Field SP (max days): 168

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
684141 684141 Trial 8 NETHERLANDS (Europe North) (6599 AV)	Leek / Krypton	1.18 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 412.25 L/ha 2. 392.25 L/ha	1. 12.3367 g ai/ha 2. 11.7382 g ai/ha A22773A (-)	1. 10 Aug 2020 2. 21 Aug 2020 (11)	1. BBCH 45- 2. BBCH 47-	Whole plant	0.04 mg/kg	0	21 Aug 2020/ -	Field SP (max days): 175
684141 684141 Trial 8 NETHERLANDS (Europe North) (6599 AV)	Leek / Krypton	1.18 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 412.25 L/ha 2. 392.25 L/ha	1. 12.3367 g ai/ha 2. 11.7382 g ai/ha A22773A (-)	1. 10 Aug 2020 2. 21 Aug 2020 (11)	1. BBCH 45- 2. BBCH 47-	Whole plant	0.02 mg/kg	1	22 Aug 2020/ -	Field SP (max days): 175
684141 684141 Trial 8 NETHERLANDS (Europe North) (6599 AV)	Leek / Krypton	1.18 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 412.25 L/ha 2. 392.25 L/ha	1. 12.3367 g ai/ha 2. 11.7382 g ai/ha A22773A (-)	1. 10 Aug 2020 2. 21 Aug 2020 (11)	1. BBCH 45- 2. BBCH 47-	Whole plant	0.03 mg/kg	3	24 Aug 2020/ -	Field SP (max days): 175
684141 684141 Trial 8 NETHERLANDS (Europe North) (6599 AV)	Leek / Krypton	1.18 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 412.25 L/ha 2. 392.25 L/ha	1. 12.3367 g ai/ha 2. 11.7382 g ai/ha A22773A (-)	1. 10 Aug 2020 2. 21 Aug 2020 (11)	1. BBCH 45- 2. BBCH 47-	Whole plant	<u>0.02 mg/kg</u>	7	28 Aug 2020/ -	Field SP (max days): 175

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
684141 684141 Trial 8 NETHERLANDS (Europe North) (6599 AV)	Leek / Krypton	1.18 May 2020 2 – 3 -	1. Foliar 2. Foliar	-	1. 412.25 L/ha 2. 392.25 L/ha	1. 12.3367 g ai/ha 2. 11.7382 g ai/ha A22773A (-)	1. 10 Aug 2020 2. 21 Aug 2020 (11)	1. BBCH 45- 2. BBCH 47-	Whole plant	< 0.01 mg/kg	10	31 Aug 2020/ -	Field SP (max days): 175

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of 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.

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value
(DBA) Days Before Application
SP (max days): Maximum storage period

A 2.2.3.7 Hops

Table A 69: 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)
cGAP N-EU (EFSA, 2019)	2	50 g a.s./ha	10	-	14
cGAP S-EU	-	-	-	-	-
Intended cGAP A22773A - AT-1, BE-1, CZ-4, DE-1, DE-15, HU-7, IE-1, NL-1, PL-17, RO-7, SI-7*	2	12 g a.s./ha	12-16	BBCH 21-89	28

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
** Timing of applications determined primarily by growth stage
*** Minimum PHI

A 2.2.3.7.1 Study 1 (Report No. DuPont - 31990) (EU reviewed)

Comments of zRMS:	The study has been reviewed at EU level.

Reference:	KCA2 6.3
Report:	Spence, C. and Brown, D. (2015) Decline and Magnitude of Residues of DPX-QGU42 and its Metabolites in Hops Following Foliar Application of DPX-QGU42 100 g/L OD – Northern Europe - 2012-2013; Report No. DuPont-31990 Unpublished
Guideline(s):	OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009.
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Table A 70: Summary of the study 1 trials

Decline and Magnitude of Residues of DPX-QGU42 and its Metabolites in Hops Following Foliar Application of DPX-QGU42 100 g/L OD – Northern Europe - 2012-2013			
Active Substance (common name):	DPX-QGU42	**Commercial Product (name):**	
Crop/Crop Group:	Peppers	**Producer of commercial product:**	DuPont
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	Germany, UK, Czech Republic	**Other active substance in the formulation (common name and content):**	
Content of active substance (g/kg or g/L):	DPX-QGU42 100 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	DPX-QGU42 OD		
Analytical Method:	DPX-QGU42 (Dried cones) Charles river analytical method AP.1846cV2.01 (Based on DuPont method 30422); 0.01 mg/kg		
Recovery data:	Oxathiapiprolin (Dried cones) Mean = 75% RSD = 11% (n = 10 in 0.01 - 5 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment Conc.	Water	Rate Formulation (Additive Type, Rate)	(6) Date of treatment (s) or no of treatment (s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analysed	(9) Residue found (Uncorrected) Oxathiapiprolin (mg/kg)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
DuPont - 31990 01 Germany (North Europe) (-)	Hops (Hallertauer Tradition)	1- Apr 1995 2- NR 3- 27 Aug 12 28 Aug 12	Foliar	2.083 g ai/hL 2.083 g ai/hL	2509 L/ha 2294 L/ha	52.28 g ai/ha 47.79 g ai/ha	21 Aug 12 28 Aug 12	BBCH 83 BBCH 89	Dried cones	1.9	0*	27 Aug 2012	Field SP (max months): < 10 months
										3.4	0	28 Aug 2012	Field SP (max months): < 10 months
				2.083 g ai/hL 2.083 g ai/hL	2494 L/ha 2517 L/ha	51.95 g ai/ha 52.44 g ai/ha	17 Aug 12 25 Aug 12	BBCH 78 BBCH 87		4.7	3	28 Aug 2012	Field SP (max months): < 10 months

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment (s) or no of treatment (s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analysed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Conc.	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
				2.083 g ai/hL 2.083 g ai/hL	2371 L/ha 2294 L/ha	49.39 g ai/ha 47.79 g ai/ha	14 Aug 12 21 Aug 14	BBCH 78 BBCH 83		3.2	6	27 Aug 2012	Field SP (max months): < 10 months
				2.083 g ai/hL 2.083 g ai/hL	2286 L/ha 2479 L/ha	47.63 g ai/ha 51.63 g ai/ha	07 Aug 12 14 Aug 14	BBCH 76 BBCH 78		<u>3.1</u>	13	27 Aug 2012	Field SP (max months): < 10 months
				2.083 g ai/hL 2.083 g ai/hL	2294 L/ha 2517 L/ha	47.79 g ai/ha 52.44 g ai/ha	31 Aug 12 07 Aug 14	BBCH 68 BBCH 76		3.0	20	06 Mar 2014	Field SP (max months): < 10 months
DuPont - 31990 02 UK (North Europe) **(-)**	Hops (Target)	1- Mar 2002 2- NR 3- 19 Sep 12	Foliar	1.78 g ai/hL 1.79 g ai/hL	2800 L/ha 2769 L/ha	49.80 g ai/ha 49.50 g ai/ha	12 Sep 2012 19 Sep 2012	BBCH 85 BBCH 89	Dried Cones	0.68	0*	18 Sep 2012	Field SP (max months): < 10 months
										1.8	0	19 Sep 2012	Field SP (max months): < 10 months

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment (s) or no of treatment (s) and last date	(7) Growth Stage at Treatment	(8) Portion Analysed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Conc.	Water	Rate Formulation (Additive Type, Rate)	Application Interval (days) (c)			Oxathiapiprolin (mg/kg)			
				1.78 g ai/hL 1.78 g ai/hL	2800 L/ha 2800 L/ha	49.80 g ai/ha 49.80 g ai/ha	09 Sep 2012 16 Sep 2012	BBCH 83 BBCH 87		1.5	3	19 Sep 2012	Field SP (max months): < 10 months
				1.78 g ai/hL 1.78 g ai/hL	2800 L/ha 2800 L/ha	49.80 g ai/ha 49.80 g ai/ha	05 Sep 2012 12 Sep 2012	BBCH 79-81 BBCH 85		1.9	7	19 Sep 2012	Field SP (max months): < 10 months
				1.79 g ai/hL 1.78 g ai/hL	2800 L/ha 2800 L/ha	50.00 g ai/ha 49.80 g ai/ha	29 Aug 2012 05 Sep 2012	BBCH 79-81 BBCH 79-81		<u>1.6</u>	14	19 Sep 2012	Field SP (max months): < 10 months
				1.79 g ai/hL 1.79 g ai/hL	2800 L/ha 2800 L/ha	50.00 g ai/ha 50.00 g ai/ha	22 Aug 2012 29 Aug 2012	BBCH 79-81 BBCH 79-81		1.0	21	19 Sep 2012	Field SP (max months): < 10 months
DuPont - 31990 03 Germany (North Europe) **(-)**	Hops (Nugget)	1- 1994 2- NR 3- 17 Sep 12	Foliar	1.779 g ai/hL 1.779 g ai/hL	2710 L/ha 2835 L/ha	48.19 g ai/ha 50.41 g ai/ha	27 Aug 2012 03 Sep 2012	BBCH 79 BBCH 85		<u>1.3</u>	14	17 Sep 2012	Field SP (max months): < 10 months

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment (s) or no of treatment (s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analysed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Conc.	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
DuPont - 31990 04 Czech Republic (North Europe) **(-)**	Hops (Premiant)	1- 2006 2- NR 3- 30 Aug 13	Foliar	1.92 g ai/hL 1.92 g ai/hL	2685 L/ha 2715 L/ha	51.7 g ai/ha 52.2 g ai/ha	23 Aug 13 30 Aug 13	BBCH 85 BBCH 89	Dried Cones	0.85	0*	29 Aug 2013	Field SP (max months): < 10 months
										2.2	0	30 Aug 2013	Field SP (max months): < 10 months
				1.92 g ai/hL 1.92 g ai/hL	2537 L/ha 2695 L/ha	48.8 g ai/ha 51.8 g ai/ha	19 Aug 13 27 Aug 13	BBCH 79 BBCH 87		0.84	3	30 Aug 2013	Field SP (max months): < 10 months
				1.92 g ai/hL 1.92 g ai/hL	2535 L/ha 2558 L/ha	48.8 g ai/ha 49.2 g ai/ha	15 Aug 13 23 Aug 13	BBCH 79 BBCH 85		0.73	7	30 Aug 2013	Field SP (max months): < 10 months
				1.92 g ai/hL 1.92 g ai/hL	2672 L/ha 2629 L/ha	51.4 g ai/ha 50.6 g ai/ha	08 Aug 13 15 Aug 13	BBCH 75 BBCH 79		0.69	15	30 Aug 2013	Field SP (max months): < 10 months

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment (s) or no of treatment (s) and last date Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analysed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Conc.	Water	Rate Formulation (Additive Type, Rate)				Oxathiapiprolin (mg/kg)			
				1.92 g ai/hL 1.92 g ai/hL	2559 L/ha 2726 L/ha	49.2 g ai/ha 52.4 g ai/ha	02 Aug 13 08 Aug 13	BBCH 71-75 BBCH 75		0.33	22	30 Aug 2013	Field SP (max months): < 10 months
DuPont - 31990 05 Germany (North Europe) **(-)**	Hops (Hallertauer Tradition)	1- 2001 2- NR 3- 02 Sep 13	Foliar	2.083 g ai/hL 2.083 g ai/hL	2332 L/ha 2409 L/ha	48.59 g ai/ha 51.19 g ai/ha	12 Aug 13 19 Aug 13	BBCH 76 BBCH 78	Dried Cones	<u>3.9</u>	14	02 Sep 2013	Field SP (max months): < 10 months

(a) According to Codex (or other e.g. EU) classification
(b) Only if relevant
(c) Year must be indicated
(d) Minimum number of 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.
Residues in control samples were always below the LOQ (<0.01 mg/kg).

(*) Indicates sample taken prior to application
(#) Indicates corrected Residue values
(^) PHI calculated using cut date
(+) Indicates calculated Residue value
(DBA) Days Before Application
SP (max days): Maximum storage period

A 2.2.4 Magnitude of residues in livestock

A 2.2.4.1 Livestock feeding studies

No new or additional studies have been submitted.

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 or additional studies have been submitted.

A 2.2.5.2 Processing studies on a core set of representative processes

No new or additional studies have been submitted.

A 2.2.6 Magnitude of residues in representative succeeding crops

No new or additional studies have been submitted.

A 2.2.7 Other/Special Studies

A 2.2.7.1 Study 1 (Report No. CEMR-9533) (New data)

Comments of zRMS:	The study has been conducted to determine the magnitude of residues of oxathiapiprolin in honey collected from bees following exposure of honeybees to spring oilseed rape plants, treated with two applications of oxathiapiprolin at a rate of 60 g a.i./ha under semi-field conditions. Two residue trials (SRFR20-001-037FC09 and SRFR20-005-037FC09) were successfully conducted in northern France in 2020 and three trials were unsuccessful. Samples of honey were analysed for residues of oxathiapiprolin using analytical method DuPont-30422, Supplement No.1. This analytical method was successfully validated according to the EU guidelines SANCO/3029/99 rev.4 and SANCO/825/00 rev. 8.1 with the LOQ of 0.01 mg/kg. The stability of residues of oxathiapiprolin in honey samples stored frozen was assessed for a period of at least 3 months. No residues of oxathiapiprolin at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in the untreated or treated honey samples. The study is acceptable.

Reference	KCA2 6.10/1
Report	Oxathiapiprolin – Honey Residue Study on Spring Oilseed Rape in Northern and Southern Europe in 2020, Ford, K., 2020, CEMR-9533, VV-885771
Guidelines	Guideline 1607/VI/97 (rev. 2) to Directive 91/414/EEC and Regulations (EU) 283/2013 and 284/2013 Implementing Regulation (EC) 1107/2009, under Consideration of the Provisions of the Afssa Saisine n° 2007-SA-0209-Document Guide de Fixation de LMR Pour le Miel. Federal Office for Consumer Protection and Food Safety, Guidance Document Part C4 – Honey version 0-2a.doc (2003). EC (1997) Guidance Document 7029/VI/95 rev. 5 General Recommendations for the Design, Preparation and Realization of Residue Trials. Commission of the European Communities. Guidance Document on Residue Analytical Methods (SANCO/825/00 rev. 8.1,

	16/11/2010)
Deviations	Yes: samples were <100 g for two trials: SRFR20-001-037FC09 and SRFR20-002-037FC09,
GLP	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability	Yes

Executive Summary

Five residue trials were initiated on spring oilseed rape in France in 2020 where honey was sampled following the exposure of bees to treated crop. In each trial, tunnels were placed over two plots of spring oilseed rape to maximise the exposure of bee colonies to the treated rape plants. Each of the trial locations of the study consisted of test item treatment group T (one replicate) and a control group C (one replicate). Trial SRFR20-003-037FC09 was terminated after the crop became infested with beetles. It was not possible to sample sufficient honey for sample analysis from SRFR20-004-037FC09 due to bees consuming the honey due to heat stress caused by a period of very hot weather and nor from trial SRFR20-002-037FC09 due to a lack of nectar- producing flowers during the trial. Trials SRFR20-001-037FC09 and SRFR20-005-037FC09 are reported here.

Treated plots received two applications of oxathiapiprolin 100 g/L OD (A20941A) at a rate of 60 g a.i./ha during the flowering period of the oilseed rape. A commercial bee hive was placed in each tunnel in the morning of the application of oxathiapiprolin and the bees were allowed to forage freely on the treated crop.

From each of the treatment and control tunnels, mature honey (approx. 100 g) was sampled at the end of the oilseed rape flowering period. Samples were taken from all honey combs by pushing a plastic spoon into the walls of the storage cells, allowing the honey to flow onto the spoon.

The health effects on the bee colonies were also monitored. Bee hives were assessed twice during the study, once before set-up in the tunnel tents and once at sampling. The health status of all colonies was good throughout the trial, all colonies were free of visible symptoms of diseases.

Honey samples were analysed for oxathiapiprolin using method DuPont-30422 Supplement No. 1.

The residues of oxathiapiprolin in all treated honey samples were below the limit of quantification (LOQ, 0.01 mg/kg).

No residues of oxathiapiprolin at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in the untreated honey samples.

Materials

Description:	100 OD (Oil Dispersion)
Code:	A20941A
Batch No:	APR18CE002
Content:	Oxathiapiprolin 100 g/L

Test System

Crop:	Spring Oilseed rape (*Brassica napus*)
Pollinator:	Honey bee (*Apis mellifera*)
Processed Commodities:	Honey

Test Facilities

Field Phase:	Staphyt France, 613 Route du Boise de Loyse, 71570 La Chapelle de Guinchay, France
Analytical Phase:	CEM Analytical Services Ltd, Imperial House, Oaklands Business Centre, Oaklands Park, Wokingham, Berkshire, RG41 2FD, UK

Study Design and Methods

Field Phase

Five residue trials were initiated on spring oilseed rape in France in 2020 where honey was sampled following the exposure of bees to treated crop. In each trial, tunnels were placed over two plots of spring oilseed rape to maximise the exposure of bee colonies to the treated rape plants. Each of the trial locations of the study consisted of test item treatment group T (one replicate) and a control group C (one replicate). Trial SRFR20-003-037FC09 was terminated after the crop became infested with beetles. It was not possible to sample sufficient honey for sample analysis from SRFR20-004-037FC09 due to

bees consuming the honey due to heat stress caused by a period of very hot weather and nor from trial SRFR20-002-037FC09 due to a lack of nectar- producing flowers during the trial. Trials SRFR20-001-037FC09 and SRFR20-005-037FC09 are reported here.
Treated plots received two applications of oxathiapiprolin 100 g/L OD (A20941A) at a rate of 60 g a.i./ha. A commercial bee hive was placed in each tunnel in the morning of the second application and the bees were allowed to forage freely on the treated crop.
From each of the treatment and control tunnels, mature honey (approx. 100 g) was sampled at the end of oilseed rape flowering). In trial SRFR20-001-037FC09 samples were 6.81 g (Control plot) and 59.92 g (Treated plot). Samples were taken from all honey combs, by pushing a plastic spoon into the walls of the storage cells, allowing the honey to flow onto the spoon.
The health effects on the bee colonies were also monitored. Bee hives were assessed twice, before study set-up in the tunnel tents, and at the end of the study, before sampling.

Analytical Phase

Samples were stored frozen for a maximum period of 86 days from sampling to extraction. Residues of oxathiapiprolin have been shown to be stable under these conditions for up to 112 days within this study. Extract solutions were stored for a maximum of 4 days at 2-8°C in the dark from extraction to analysis. The stability of the analytes in the sample extracts was shown by the corresponding procedural recovery samples, which were stored under the same conditions together with the sample extracts.
Honey samples were analysed for residues of oxathiapiprolin using analytical method DuPont-30422 Supplement No. 1 with a limit of quantification of 0.01 mg/kg. The validation of the method for oxathiapiprolin in honey was also carried out within this study.
Residues of oxathiapiprolin are extracted by homogenizing in a genogrinder with acetonitrile/water and formic acid three times. Extracts are combined and mixed and 0.5 mL aliquots are diluted with 2 mL of methanol and 4.5 mL of 1% formic acid in water. Final determination is by high performance liquid chromatography with triple quadrupole mass spectrometric detection (LC-MS/MS).

Table A 71: Procedural recovery (sample analysis) - Oxathiapiprolin

Substrate (Control)	Fortification Level [mg/kg]	Oxathiapiprolin [%]
Honey	0.01	105
	0.10	111
Mean		108
RSD (%)		na

Recoveries in percent (%). The lowest fortification level is at the limit of quantification
na: Only two procedural recoveries therefore RSD is not applicable.

Results and Discussion

Residues of oxathiapiprolin in honey are presented in the tables below. Residues in honey in all treated and untreated samples were below the LOQ (0.01 mg/kg).

Table A 72: Residues of oxathiapiprolin in honey - Trial SRFR20-001-037FC09

Sample No. Trial -001	Number and Nominal Rate of Application (g ai/ha)	Sample type	Oxathiapiprolin Residue (mg/kg)
Treated Plot			
T	2 x 60	Honey	< 0.01
Control Plot			
C	Control	Honey	< 0.01

No correction of results for either control residues or recovery values has been performed.

Table A 73: Residues of oxathiapiprolin in honey - Trial SRFR20-005-037FC09

Sample No. Trial -005	Number and Nominal Rate of Application (g ai/ha)	Sample type	Oxathiapiprolin Residue (mg/kg)
Treated Plot			

T	2 x 60	Honey	< 0.01
Control Plot			
C	Control	Honey	< 0.01

No correction of results for either control residues or recovery values has been performed.

Conclusion

No residues of oxathiapiprolin at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in any of the treated or untreated honey samples.

A 2.2.7.2 Study 2 (Report No. CEMR-9822) (New data)

Comments of zRMS:	This study contained four trials has been conducted under confined semi-field conditions in Northern and Southern Europe to determine the magnitude of residues of oxathiapiprolin in honey following exposure of honeybees to flowering winter oilseed rape treated with two applications of A20941A (100 g/L OD) at a nominal rate of 60 g a.i./ha per application. Samples were stored frozen for a maximum period of 76 days from sampling (08 Apr 2021) to analysis (23 Jun 2021). Samples of honey were analysed for residues of oxathiapiprolin using analytical method DuPont-30422, Supplement No.1 with LOQ of 0.01 mg/kg. No residues of oxathiapiprolin at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in the untreated or treated honey samples. The study is acceptable.

Reference:	K-CA 6.10
Report:	Oxathiapiprolin – Honey Residue Study on Winter Oilseed Rape in Northern and Southern Europe in 2021, Ford K (2021), Report number CEMR-9822 Syngenta File No. VV-924794
Guideline(s):	Yes: SANTE/11956/2016 rev. 9, 14 September 2018 Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey
Deviations:	Yes: samples were <100 g for three trials
GLP:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability:	Yes

Executive Summary

A semi-field study was conducted on four trials in France on winter oilseed rape in 2021. One untreated plot and one treated plot (each ~200 m^2) were established in separate tunnels at each field site and one bee colony (honey bee, *Apis mellifera* L.) was introduced into each tunnel one day or the day of the second treatment.

Oxathiapiprolin was applied twice by foliar spray at a rate of 60 g a.i/ha to the treated plot. The final application was made when crop was at BBCH growth stage 61 – 64. The bee colonies were protected from direct spray with plastic sheeting during application.

Samples of mature, capped honey (43-126g) were taken at maturity (comb-closure and water content <20%) for residue analysis. All samples were maintained frozen at the testing facility, during shipping to the laboratory, and were stored frozen for a maximum of 76 days until analysis. Adequate storage stability data are available to support the storage conditions and intervals for samples in the current trials.

The bee colonies remained in good health throughout the trial, free of visible symptoms of diseases.

Samples were analysed using DuPont-30422 Supplement No. 1, an LC-MS/MS method to determine residues of oxathiapiprolin. Acceptable procedural recoveries were reported for honey at fortification levels of 0.01 mg/kg and 0.10 mg/kg. The limit of quantification (LOQ) was 0.01 mg/kg.

No residues were found at or above the LOQ in honey from the untreated control plots or from the treated plots.

Materials

Test Material	Oxathiapiprolin 100 g/L OD (A20941A)
Lot/Batch #:	APR18CE002
Active substance content (%):	100 g/L,

Study Design and Methods

Test facility: CEM Analytical Services Ltd (CEMAS), Imperial House, Oaklands Business Centre, Oaklands Park, Wokingham, Berkshire, RG41 2FD, United Kingdom

Study start date: 01 Mar 2021

Study end date: 20 Oct 2021

A semi-field study was conducted on four trials in France on winter oilseed rape in 2021. One untreated plot and one treated plot (each 200 m^2) were established in separate tunnels at each field site and one bee colony (honey bee, *Apis mellifera* L.) was introduced into each tunnel on the day of the second treatment.

Oxathiapiprolin was applied twice by foliar spray at a rate of 60 g a.i/ha to the treated plots. The final application was made when crop was at BBCH growth stage 61 – 64. The bee colonies were protected from direct spray with plastic sheeting during application.

Table A 74: Crop information

Trial Location (City, Province or State Country /Year)	Crop/crop group	Variety	Growth stage at application (BBCH code)
SRFR21-001-037FC04 Nîmes, Gard, Languedoc-Rousillon, 3000,France, 2021	Oilseed rape, *Brassica napus*	Amazzonite	55 – 59, 63
SRFR21-002-037FC04 Meigné le Vicomte,Maine-et-Loire, Pays de la Loire, 49490, France, 2021	Oilseed rape, *Brassica napus*	Zakari	61, 62
SRFR21-003-037FC04 Macey, Aube, Champagne-Ardenne, 10300 France, 2021	Oilseed rape, *Brassica napus*	Amplitude	57, 64
SRES21-125-037FC La Roda, Albacete, Castilla-La Mancha, 02630, Spain, 2021	Oilseed rape, *Brassica napus*	Florida	56, 61

Table A 75: Application and use pattern of end-use product A20941A tested at Nîmes, Gard, Languedoc-Rousillon, France in 2021

Method/ Timing	Rate g ai/ha	Vol L/ha	Spray interval days	Total rate g ai/ha	Tank mix adjuvants
Foliar Spray	60.92	305	-	126.1	None
	65.20	326	7		None

Table A 76: Application and use pattern of end-use product A20941A tested at Meigné le Vicomte, Maine-Et-Loire, Pays de la Loire, France in 2021

Method/ Timing	Rate g ai/ha	Vol L/ha	Spray interval days	Total rate g ai/ha	Tank mix adjuvants
Foliar Spray	61.0	254	-	117.0	None
	56.0	233	7		None

Table A 77: Application and use pattern of end-use product A20941A tested at Macey, Aube, Champagne-Ardennes, France in 2021

Method/ Timing	Rate g ai/ha	Vol L/ha	Spray interval days	Total rate g ai/ha	Tank mix adjuvants
Foliar Spray	61.09	255	-	119.9	None
	58.77	245	28		None

Table A 78: Application and use pattern of end-use product A20941A tested at La Roda, Albacete, Castilla-La-Mancha, Spain in 2021

Method/ Timing	Rate g ai/ha	Vol L/ha	Spray interval days	Total rate g ai/ha	Tank mix adjuvants
Foliar Spray	60.08	401	-	117.0	None
	56.90	380	9		None

Table A 79: Climatic conditions

Trial Location (City, Province or State Country /Year)	Study conditions		Long-term average [1973-2020]	
	Overall daily rainfall range (mm)	Overall temperature range (°C)	Overall monthly rainfall range (mm)	Overall temperature range (°C)
SRFR21-001-037FC04 Nîmes, Gard, Languedoc-Rousillon, 3000,France, 2021	0 – 20.0	-4.0 – 32.0	March 0 – 60.2 April 0 – 54.4 Overall 0 - 60.2	March -7.0 – 26.9 April 0.3 – 29.6 Overall -7.0 – 29.6
SRFR21-002-037FC04 Meigné le Vicomte,Maine-et-Loire, Pays de la Loire, 49490, France, 2021	0 – 2..0	2.5 – 22.5	March 0 – 42.3 April 0 – 36.3 Overall 0 – 42.3	March -10.6 – 24.8 April -3.4 – 29.7 Overall -10.6 – 29.7
SRFR21-003-037FC04 Macey, Aube, Champagne-Ardenne, 10300 France, 2021	0 – 16.4	-6.3 – 25.1	March 0 – 28.4 April 0 – 26.2 Overall 0 – 28.4	March -15.6 – 26.1 April -6.2 – 29.2 Overall -15.6 – 29.2
SRES21-125-037FC La Roda, Albacete, Castilla-La Mancha, 02630, Spain, 2021	0 – 10.9	-2.4 – 26.5	March 0 – 97 April 0 – 308 Overall 0-308	March -8.0 – 31.0 April -5.0 – 31.0 Overall -5.0 – 31.0

Samples of mature, capped honey (43-127 g) were taken at maturity (comb-closure and water content <20%) for residue analysis. All samples were maintained frozen at the testing facility, during shipping to the laboratory, and were stored frozen for a maximum of 76 days until analysis. Adequate storage stability data are available to support the storage conditions and intervals for samples in the current trials.

All samples were frozen within 12 hours or placed on dry ice following sampling (except for trial SRFR21-002-037FC04 where transport time was 22 hr 43mins), maintained frozen at the testing facility, during shipment to the laboratory, and were stored frozen at -18°C until analysis. The maximum storage interval for samples between collection and analysis was 76 days. Residues of oxathiapiprolin have been shown to be stable in honey, for up to 153 days under these conditions. Adequate storage stability data are therefore available to support the storage conditions and intervals for samples in the current trials.

Table A 80: Summary of storage conditions

Matrix (RAC or extract)	Storage temp. (°C)	Actual storage duration (days or months)	Interval of demonstrated storage stability (days or months)
Honey	-18°C	76 days	153 days
Extracts	Not reported	1 day	1 day*

*Stability demonstrated by acceptable procedural recoveries.

Samples were analysed using DuPont-30422 Supplement No. 1, an LC-MS/MS method to determine residues of oxathiapiprolin. Acceptable procedural recoveries were reported for honey at fortification levels of 0.01 mg/kg and 0.10 mg/kg mg/kg. The limit of quantification (LOQ) was 0.01 mg/kg.

The health of the colonies was assessed before introduction to the tunnels and at the end of the trial, by assessing the strength of the colony (number of frames covered with bees), the presence of a healthy queen (i.e., presence of eggs or presence of queen cells), and visual assessment of the percentage of frames containing pollen, nectar, and brood (eggs, larvae and capped cells).

Results

Acceptable concurrent recoveries were reported as in the table below.

Table A 81: Fortification and recovery

Honey	Fortification level (mg/kg)	Sample size (n)	Recoveries (%)	Mean recovery (%)	RSD (%)
Oxathiapiprolin	0.01	5	106, 101, 108, 106, 103	102	3.6
Oxathiapiprolin	0.1	5	98, 99, 100, 99, 98		

Details of the trials, the individual applications and the analytical residue results obtained are summarised in the following table.

Table A 82: Residue trial summary for oxathiapiprolin in honey from bees foraging on oilseed rape

Trial No./ Location/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or number and last date	Growth stage at last treatment	Date colony placed in tunnel	Portion analysed	Residues (mg/kg)	Sampling occasion	Remarks
			g a.i./ha	Water (L/ha)	kg a.i./hl					Oxathiapiprolin		
SRFR21-001-037FC04 Nîmes, Gard, Languedoc-Rousillon, 3000, France, 2021	Oilseed rape/ Amazzonite	1. 05 Oct 2020 2. 28 Mar 2021 3. na	60.92 65.20	305 326	-	25 Mar 2021 01 Apr 2021	BBCH 55 - 59 BBCH 63	31 Mar 2021	Honey	<0.01	Honey maturity	
SRFR21-002-037FC04 Meigné le Vicomte,Maine-et-Loire, Pays de la Loire, 49490, France, 2021	Oilseed rape/ Zakari	1. 03 Aug 2020 2. 25 Mar 2021 3. na	61.00 56.00	254 233	-	24 Mar 2021 31 Mar 2021	BBCH 61 BBCH 62	31 Mar 2021	Honey	<0.01	Honey maturity	
SRFR21-003-037FC04 Macey, Aube, Champagne-Ardenne, 10300 France, 2021	Oilseed rape/ Amplitude	1. 15 Aug 2020 2. 29 Mar 2021 3. na	61.09 58.77	255 245	-	22 Mar 2021 19 Apr 2021	BBCH 57 BBCH 64	18 Apr 2021	Honey	<0.01	Honey maturity	
SRES21-125-037FC La Roda, Albacete, Castilla-La Mancha, 02630, Spain, 2021	Oilseed rape/ Florida	1. 13 Oct 2020 2. 23 Mar 2021 3. na	60.08 56.90	401 380	-	17 Mar 2021 26 Mar 2021	BBCH 56 BBCH 61	25 Mar 2021	Honey	<0.01	Honey maturity	

Conclusion

A semi-field study was conducted on four trials in France on winter oilseed rape in 2021. One untreated plot and one treated plot (each 200 m^2) were established in separate tunnels at each field site and one bee colony (honey bee, *Apis mellifera* L.) was introduced into each tunnel on the evening before or the day of the second treatment.

Oxathiapiprolin was applied twice by foliar spray at a rate of 60 g a.i/ha to the treated plot. The final application was made when crop was at BBCH growth stage 61 – 64. The bee colonies were protected from direct spray with plastic sheeting during application.

Samples were analysed using DuPont-30422 Supplement No. 1, an LC-MS/MS method to determine residues of oxathiapiprolin. Acceptable procedural recoveries were reported for honey at fortification levels of 0.01 mg/kg and 0.10 mg/kg mg/kg. The limit of quantification (LOQ) was 0.01 mg/kg.

No residues were detected at or above the LOQ in honey from the untreated control plots or from the treated plots.

(Ford K, 2021)

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

A 3.1.1 Azoxystrobin – updated TMDI

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Azoxystrobin

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0,2	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2010	Year of evaluation:	2010

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 : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
83%	NL toddler	165,46	17%	Oranges	15%	Potatoes	13%	Sugar beet roots		
69%	DE child	138,29	30%	Oranges	9%	Potatoes	3%	Mandarins		
68%	NL child	135,89	21%	Sugar beet roots	12%	Potatoes	11%	Oranges		
57%	FR child 3 15 yr	113,14	26%	Oranges	9%	Sugar beet roots	5%	Potatoes		
50%	GEMS/Food G06	99,69	7%	Oranges	7%	Potatoes	5%	Tomatoes		
48%	UK toddler	95,97	15%	Oranges	12%	Potatoes	8%	Sugar beet roots		
47%	IE adult	94,02	8%	Potatoes	8%	Oranges	5%	Grapefruits		
46%	GEMS/Food G07	92,39	13%	Potatoes	10%	Oranges	2%	Wine grapes		
45%	GEMS/Food G10	90,60	10%	Potatoes	8%	Oranges	3%	Rice		
44%	FR toddler 2 3 yr	88,23	11%	Oranges	7%	Sugar beet roots	7%	Potatoes		
44%	GEMS/Food G11	87,79	14%	Potatoes	5%	Oranges	3%	Lemons		
44%	DE women 14-50 yr	87,52	14%	Oranges	11%	Sugar beet roots	4%	Potatoes		
43%	SE general	86,92	15%	Potatoes	6%	Oranges	3%	Mandarins		
41%	GEMS/Food G08	82,97	14%	Potatoes	3%	Oranges	3%	Onions		
40%	DE general	79,76	12%	Oranges	11%	Sugar beet roots	4%	Potatoes		
39%	GEMS/Food G15	78,51	12%	Potatoes	5%	Oranges	3%	Onions		
39%	PT general	77,61	19%	Potatoes	5%	Oranges	4%	Wine grapes		
38%	RO general	76,13	13%	Potatoes	4%	Onions	4%	Head cabbages		
37%	ES child	74,30	16%	Oranges	6%	Potatoes	3%	Lettuces		
37%	NL general	73,14	9%	Potatoes	8%	Oranges	7%	Sugar beet roots		
36%	UK infant	71,27	11%	Potatoes	10%	Oranges	4%	Sugar beet roots		
34%	FI 3 yr	67,05	17%	Potatoes	3%	Mandarins	2%	Onions		
27%	FI 6 yr	54,14	14%	Potatoes	2%	Mandarins	1%	Onions		
27%	ES adult	53,88	10%	Oranges	4%	Lettuces	3%	Potatoes		
23%	UK vegetarian	46,88	6%	Oranges	5%	Potatoes	1%	Sugar beet roots		
23%	FR infant	46,41	7%	Potatoes	3%	Sugar beet roots	2%	Spinaches		
23%	DK child	45,73	9%	Potatoes	1%	Rye	1%	Oranges		
22%	IT toddler	44,98	4%	Oranges	3%	Potatoes	2%	Lettuces		
22%	FR adult	43,29	4%	Oranges	3%	Wine grapes	3%	Potatoes		
20%	IT adult	40,81	3%	Lettuces	3%	Oranges	2%	Potatoes		
20%	PL general	39,56	12%	Potatoes	2%	Onions	1%	Tomatoes		
19%	UK adult	38,51	5%	Potatoes	4%	Oranges	2%	Wine grapes		
16%	LT adult	32,82	11%	Potatoes	1,0%	Head cabbages	0,9%	Tomatoes		
15%	FI adult	29,68	4%	Potatoes	3%	Oranges	1%	Lettuces		
14%	DK adult	27,40	4%	Potatoes	1%	Wine grapes	1%	Oranges		
6%	IE child	11,34	2%	Potatoes	0,7%	Rice	0,6%	Oranges		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Azoxystrobin is unlikely to present a public health concern.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Azoxystrobin

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0,2**	ARfD (mg/kg bw):	**not necessary**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2010**	Year of evaluation:	**2010**

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 : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
82%	NL toddler	163,71	17%	Oranges	15%	Potatoes	13%	Sugar beet roots		
69%	DE child	137,69	30%	Oranges	9%	Potatoes	3%	Mandarins		
67%	NL child	134,82	21%	Sugar beet roots	12%	Potatoes	11%	Oranges		
56%	FR child 3 15 yr	112,53	26%	Oranges	9%	Sugar beet roots	5%	Potatoes		
49%	GEMS/Food G06	98,89	7%	Oranges	7%	Potatoes	5%	Tomatoes		
48%	UK toddler	95,87	15%	Oranges	12%	Potatoes	8%	Sugar beet roots		
47%	IE adult	93,60	8%	Potatoes	8%	Oranges	5%	Grapefruits		
45%	GEMS/Food G07	90,77	13%	Potatoes	10%	Oranges	2%	Wine grapes		
44%	GEMS/Food G10	88,40	10%	Potatoes	8%	Oranges	3%	Rice		
44%	FR toddler 2 3 yr	88,03	11%	Oranges	7%	Sugar beet roots	7%	Potatoes		
43%	DE women 14-50 yr	86,81	14%	Oranges	11%	Sugar beet roots	4%	Potatoes		
43%	GEMS/Food G11	86,73	14%	Potatoes	5%	Oranges	3%	Lemons		
42%	SE general	84,90	15%	Potatoes	6%	Oranges	3%	Mandarins		
41%	GEMS/Food G08	81,39	14%	Potatoes	3%	Oranges	3%	Onions		
40%	DE general	79,16	12%	Oranges	11%	Sugar beet roots	4%	Potatoes		
39%	GEMS/Food G15	77,84	12%	Potatoes	5%	Oranges	3%	Onions		
39%	PT general	77,09	19%	Potatoes	5%	Oranges	4%	Wine grapes		
38%	RO general	76,13	13%	Potatoes	4%	Onions	4%	Head cabbages		
36%	ES child	72,21	16%	Oranges	6%	Potatoes	2%	Lettuces		
36%	NL general	72,04	9%	Potatoes	8%	Oranges	7%	Sugar beet roots		
36%	UK infant	71,27	11%	Potatoes	10%	Oranges	4%	Sugar beet roots		
33%	FI 3 yr	66,83	17%	Potatoes	3%	Mandarins	2%	Onions		
27%	FI 6 yr	53,70	14%	Potatoes	2%	Mandarins	1%	Onions		
26%	ES adult	51,20	10%	Oranges	3%	Potatoes	3%	Lettuces		
23%	FR infant	46,40	7%	Potatoes	3%	Sugar beet roots	2%	Spinaches		
23%	UK vegetarian	46,17	6%	Oranges	5%	Potatoes	1%	Sugar beet roots		
23%	DK child	45,02	9%	Potatoes	1%	Rye	1%	Oranges		
21%	IT toddler	42,92	4%	Oranges	3%	Potatoes	2%	Tomatoes		
21%	FR adult	42,40	4%	Oranges	3%	Wine grapes	3%	Potatoes		
20%	PL general	39,50	12%	Potatoes	2%	Onions	1%	Tomatoes		
19%	IT adult	38,02	3%	Oranges	2%	Potatoes	2%	Lettuces		
19%	UK adult	37,92	5%	Potatoes	4%	Oranges	2%	Wine grapes		
16%	LT adult	32,50	11%	Potatoes	1,0%	Head cabbages	0,9%	Tomatoes		
14%	FI adult	28,97	4%	Potatoes	3%	Oranges	1%	Mandarins		
13%	DK adult	26,94	4%	Potatoes	1%	Wine grapes	1%	Oranges		
6%	IE child	11,31	2%	Potatoes	0,7%	Rice	0,6%	Oranges		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Azoxystrobin is unlikely to present a public health concern.

A 3.1.2 Oxathiapiprolin- updated TMDI

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Oxathiapiprolin

LOQs (mg/kg) range from:	0,01	to:	0,05
Toxicological reference values			
ADI (mg/kg bw/day):	0,14	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2016	Year of evaluation:	2016

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI 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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
11%	NL toddler	15,75	8%	Spinaches	0,9%	Escaroles/broad-leaved endives	0,8%	Table grapes		11%
5%	IT adult	6,98	1%	Lettuces	1%	Spinaches	0,7%	Other spinach and similar		5%
5%	DE child	6,52	2%	Spinaches	0,7%	Table grapes	0,3%	Grape leaves and similar species		5%
5%	NL child	6,37	3%	Spinaches	0,5%	Table grapes	0,3%	Escaroles/broad-leaved endives		5%
4%	ES adult	6,07	2%	Lettuces	0,9%	Chards/beet leaves	0,8%	Spinaches		4%
4%	FR infant	5,77	3%	Spinaches	0,4%	Leeks	0,3%	Chards/beet leaves		4%
4%	IT toddler	5,52	1%	Lettuces	0,6%	Chards/beet leaves	0,6%	Spinaches		4%
4%	ES child	5,36	1%	Lettuces	0,9%	Spinaches	0,9%	Chards/beet leaves		4%
4%	GEMS/Food G06	5,05	1%	Tomatoes	0,5%	Table grapes	0,5%	Spinaches		4%
4%	IE adult	4,91	1%	Spinaches	0,6%	Wine grapes	0,3%	Lettuces		4%
3%	NL general	4,89	2%	Spinaches	0,4%	Escaroles/broad-leaved endives	0,3%	Lettuces		3%
3%	GEMS/Food G11	4,82	1,0%	Spinaches	0,5%	Wine grapes	0,4%	Leeks		3%
3%	SE general	4,70	1%	Lettuces	0,7%	Spinaches	0,3%	Head cabbages		3%
3%	GEMS/Food G10	4,59	1%	Lettuces	0,5%	Spinaches	0,4%	Tomatoes		3%
3%	GEMS/Food G07	4,42	0,9%	Lettuces	0,7%	Wine grapes	0,4%	Spinaches		3%
3%	FR adult	4,27	1%	Wine grapes	0,6%	Spinaches	0,5%	Other lettuce and other salad plants		3%
3%	GEMS/Food G08	4,17	0,7%	Lettuces	0,5%	Wine grapes	0,3%	Tomatoes		3%
3%	FR toddler 2 3 yr	4,16	2%	Spinaches	0,4%	Leeks	0,3%	Cauliflowers		3%
3%	FR child 3 15 yr	4,01	1%	Spinaches	0,4%	Other lettuce and other salad plants	0,3%	Leeks		3%
2%	RO general	3,49	0,8%	Wine grapes	0,7%	Head cabbages	0,6%	Tomatoes		2%
2%	GEMS/Food G15	3,36	0,5%	Wine grapes	0,4%	Head cabbages	0,4%	Lettuces		2%
2%	DE women 14-50 yr	3,26	0,5%	Spinaches	0,4%	Wine grapes	0,4%	Lettuces		2%
2%	DE general	3,05	0,5%	Spinaches	0,4%	Wine grapes	0,3%	Lettuces		2%
2%	PT general	2,93	1%	Wine grapes	0,4%	Lettuces	0,3%	Tomatoes		2%
2%	UK vegetarian	2,68	0,5%	Lettuces	0,4%	Wine grapes	0,4%	Spinaches		2%
2%	UK adult	2,24	0,5%	Wine grapes	0,4%	Lettuces	0,2%	Spinaches		2%
2%	FI 3 yr	2,23	0,7%	Spinaches	0,2%	Tomatoes	0,1%	Cucumbers		2%
1%	FI 6 yr	1,98	0,6%	Spinaches	0,3%	Lettuces	0,1%	Tomatoes		1%
1%	DK adult	1,95	0,5%	Wine grapes	0,3%	Lettuces	0,1%	Tomatoes		1%
1%	DK child	1,76	0,5%	Lettuces	0,2%	Cucumbers	0,2%	Tomatoes		1%
1%	FI adult	1,70	0,5%	Lettuces	0,2%	Tomatoes	0,2%	Wine grapes		1%
1,0%	UK toddler	1,35	0,3%	Spinaches	0,2%	Tomatoes	0,1%	Table grapes		1,0%
0,9%	PL general	1,33	0,3%	Tomatoes	0,2%	Head cabbages	0,2%	Table grapes		0,9%
0,7%	LT adult	0,95	0,2%	Lettuces	0,2%	Head cabbages	0,2%	Tomatoes		0,7%
0,6%	UK infant	0,83	0,3%	Cauliflowers	0,1%	Spinaches	0,1%	Tomatoes		0,6%
0,2%	IE child	0,32	0,1%	Broccoli	0,0%	Spinaches	0,0%	Table grapes		0,2%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Oxathiapiprolin is unlikely to present a public health concern.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Oxathiapiprolin

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0,14**	ARfD (mg/kg bw):	**not necessary**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2016**	Year of evaluation:	**2016**

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 : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
12%	NL toddler	17,21	8%	Spinaches	0,9%	Escaroles/broad-leaved endives	0,8%	Table grapes		
5%	DE child	7,56	2%	Spinaches	0,7%	Table grapes	0,3%	Grape leaves and similar species		
5%	NL child	7,23	3%	Spinaches	0,5%	Table grapes	0,3%	Escaroles/broad-leaved endives		
5%	IT adult	7,11	1%	Lettuces	1%	Spinaches	0,7%	Other spinach and similar		
5%	SE general	7,00	1%	Lettuces	1%	Chinese cabbages/pe-tsai	0,7%	Spinaches		
5%	GEMS/Food G10	6,46	1%	Lettuces	1%	Chinese cabbages/pe-tsai	0,5%	Spinaches		
5%	ES adult	6,38	2%	Lettuces	0,9%	Chards/beet leaves	0,8%	Spinaches		
4%	FR infant	6,07	3%	Spinaches	0,4%	Leeks	0,3%	Chards/beet leaves		
4%	IE adult	5,93	1%	Spinaches	0,6%	Wine grapes	0,3%	Lettuces		
4%	ES child	5,86	1%	Lettuces	0,9%	Spinaches	0,9%	Chards/beet leaves		
4%	IT toddler	5,71	1%	Lettuces	0,6%	Chards/beet leaves	0,6%	Spinaches		
4%	GEMS/Food G06	5,70	1%	Tomatoes	0,5%	Table grapes	0,5%	Spinaches		
4%	NL general	5,36	2%	Spinaches	0,4%	Escaroles/broad-leaved endives	0,3%	Lettuces		
4%	GEMS/Food G11	5,34	1,0%	Spinaches	0,5%	Wine grapes	0,4%	Leeks		
4%	GEMS/Food G07	4,95	0,9%	Lettuces	0,7%	Wine grapes	0,4%	Spinaches		
3%	FR toddler 2 3 yr	4,81	2%	Spinaches	0,4%	Leeks	0,3%	Cauliflowers		
3%	FR child 3 15 yr	4,70	1%	Spinaches	0,4%	Other lettuce and other salad plants	0,3%	Leeks		
3%	GEMS/Food G08	4,64	0,7%	Lettuces	0,5%	Wine grapes	0,3%	Tomatoes		
3%	FR adult	4,52	1%	Wine grapes	0,6%	Spinaches	0,5%	Other lettuce and other salad plan		
3%	RO general	3,81	0,8%	Wine grapes	0,7%	Head cabbages	0,6%	Tomatoes		
3%	DE women 14-50 yr	3,80	0,5%	Spinaches	0,4%	Wine grapes	0,4%	Lettuces		
3%	GEMS/Food G15	3,77	0,5%	Wine grapes	0,4%	Head cabbages	0,4%	Lettuces		
3%	DE general	3,59	0,5%	Spinaches	0,4%	Wine grapes	0,3%	Lettuces		
2%	PT general	3,12	1%	Wine grapes	0,4%	Lettuces	0,3%	Tomatoes		
2%	UK vegetarian	2,91	0,5%	Lettuces	0,4%	Wine grapes	0,4%	Spinaches		
2%	FI 3 yr	2,67	0,7%	Spinaches	0,2%	Tomatoes	0,1%	Cucumbers		
2%	FI 6 yr	2,46	0,6%	Spinaches	0,3%	Lettuces	0,2%	Chinese cabbages/pe-tsai		
2%	UK adult	2,41	0,5%	Wine grapes	0,4%	Lettuces	0,2%	Spinaches		
2%	FI adult	2,25	0,5%	Lettuces	0,2%	Coffee beans	0,2%	Tomatoes		
2%	DK child	2,23	0,5%	Lettuces	0,2%	Cucumbers	0,2%	Tomatoes		
2%	DK adult	2,14	0,5%	Wine grapes	0,3%	Lettuces	0,1%	Tomatoes		
1%	UK toddler	1,92	0,3%	Spinaches	0,2%	Tomatoes	0,1%	Milk: Cattle		
1%	PL general	1,59	0,3%	Tomatoes	0,2%	Head cabbages	0,2%	Table grapes		
1%	UK infant	1,49	0,3%	Milk: Cattle	0,3%	Cauliflowers	0,1%	Spinaches		
0,8%	LT adult	1,11	0,2%	Lettuces	0,2%	Head cabbages	0,2%	Tomatoes		
0,3%	IE child	0,40	0,1%	Broccoli	0,0%	Spinaches	0,0%	Table grapes		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Oxathiapiprolin is unlikely to present a public health concern.

A 3.2 IEDI calculations

A 3.2.1 Azoxystrobin - not required

A 3.2.2

European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

Azoxystrobin

LOQs (mg/kg) range from:	**0.01**	to:	**0.05**
Toxicological reference values			
ADI (mg/kg bw/day):	**0.2**	ARfD (mg/kg bw):	**Not necessary**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2010**	Year of evaluation:	**2010**

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 : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
15%	NL toddler	30.95	5%	Potatoes	2%	Oranges	2%	Rice	0.3%	
13%	DE child	26.60	4%	Oranges	3%	Potatoes	0.7%	Rice	0.1%	
12%	GEMS/Food G06	24.70	4%	Rice	2%	Potatoes	0.9%	Oranges	0.0%	
12%	GEMS/Food G10	24.49	3%	Potatoes	3%	Rice	1%	Oranges	0.0%	
12%	PT general	23.07	6%	Potatoes	2%	Rice	0.9%	Wine grapes		
11%	SE general	21.47	5%	Potatoes	1%	Rice	0.8%	Lettuces	0.1%	
11%	GEMS/Food G07	21.46	4%	Potatoes	1%	Oranges	0.9%	Rice	0.1%	
10%	GEMS/Food G08	20.47	4%	Potatoes	0.7%	Rice	0.6%	Onions	0.0%	
10%	GEMS/Food G11	20.38	4%	Potatoes	0.7%	Rice	0.7%	Oranges	0.1%	
10%	IE adult	19.99	3%	Potatoes	0.9%	Oranges	0.6%	Grapefruits	0.0%	
10%	NL child	19.90	4%	Potatoes	1%	Oranges	0.6%	Mandarins	0.1%	
10%	GEMS/Food G15	19.55	4%	Potatoes	0.8%	Rice	0.6%	Oranges	0.1%	
9%	FI 3 yr	18.60	5%	Potatoes	1%	Rice	0.4%	Onions	0.0%	
9%	UK toddler	18.54	4%	Potatoes	2%	Oranges	1%	Rice	0.1%	
9%	FR child 3 15 yr	18.50	3%	Oranges	2%	Potatoes	1%	Rice	0.1%	
9%	RO general	18.32	4%	Potatoes	0.9%	Head cabbages	0.8%	Onions	0.1%	
8%	FR toddler 2 3 yr	16.95	2%	Potatoes	1%	Rice	1%	Oranges	0.2%	
8%	UK infant	16.72	4%	Potatoes	2%	Rice	1%	Oranges	0.2%	
8%	ES child	15.87	2%	Potatoes	2%	Oranges	1%	Rice	0.1%	
8%	FI 6 yr	15.11	4%	Potatoes	1%	Rice	0.3%	Onions	0.0%	
7%	NL general	13.62	3%	Potatoes	0.9%	Oranges	0.3%	Rice	0.1%	
6%	DK child	11.74	3%	Potatoes	0.7%	Rice	0.3%	Onions	0.1%	
6%	DE women 14-50 yr	11.71	2%	Oranges	1%	Potatoes	0.3%	Wine grapes	0.1%	
6%	ES adult	11.39	1%	Oranges	1%	Potatoes	1%	Lettuces	0.0%	
6%	PL general	11.14	4%	Potatoes	0.4%	Onions	0.2%	Head cabbages		
6%	DE general	11.04	1%	Oranges	1%	Potatoes	0.3%	Wine grapes	0.1%	
5%	IT toddler	10.81	1%	Potatoes	0.6%	Lettuces	0.5%	Rice		
5%	UK vegetarian	10.56	2%	Potatoes	1.0%	Rice	0.8%	Oranges	0.0%	
5%	FR infant	10.53	2%	Potatoes	0.5%	Spinaches	0.3%	Leeks	0.1%	
5%	IT adult	10.47	0.7%	Lettuces	0.7%	Potatoes	0.5%	Florence fennels		
5%	LT adult	10.19	4%	Potatoes	0.5%	Rice	0.2%	Head cabbages	0.0%	
5%	UK adult	9.29	2%	Potatoes	0.9%	Rice	0.5%	Oranges	0.0%	
5%	FR adult	9.09	0.8%	Potatoes	0.8%	Wine grapes	0.5%	Oranges	0.0%	
4%	FI adult	7.32	1%	Potatoes	0.4%	Oranges	0.3%	Rice		
3%	DK adult	6.81	1%	Potatoes	0.3%	Wine grapes	0.2%	Rice	0.0%	
2%	IE child	3.94	0.7%	Rice	0.7%	Potatoes	0.1%	Oranges	0.0%	

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Azoxystrobin is unlikely to present a public health concern.

Oxathiapiprolin

Not required.

A 3.3 IESTI calculations - Raw commodities

A 3.3.1 Azoxystrobin

Not applicable; no ARfD set.

A 3.3.2 Oxathiapiprolin

Not applicable; no ARfD set.

A 3.4 IESTI calculations - Processed commodities

A 3.4.1 Azoxystrobin

Not applicable; no ARfD set.

A 3.4.2 Oxathiapiprolin

Not applicable; no ARfD set.

Appendix 4 Additional information provided by the applicant

A 4.1 Assessment of the comparability of residue levels resulting from the application of OD and SC formulations

Comments of zRMS:	1. **Hampton, M. (2015), Report No. TK0221427|81123** Conclusion: Statistical analysis of the full data set from comparative field trials conducted on cucumbers, at six locations, indicate that there are no significant differences in oxathiapiprolin residue levels between the SC and OD formulations at α = 0.05 significance level. Therefore, oxathiapiprolin residue data generated from application of the OD formulation would also support an identical use pattern with an SC formulation. 2. **Hampton, M. (2015), Report No. TK0221426|81122** Conclusion: Statistical analysis of the full data set from comparative field trials conducted on brassica head and stem vegetables, at six locations, indicate (with exception of trial 02 across PHIs) that there are no significant differences in oxathiapiprolin residue levels between the SC and OD formulations at α = 0.05 significance level. Therefore, oxathiapiprolin residue data generated from application of the OD formulation would also support an identical use pattern with an SC formulation. 3. **Hampton, M. (2015), Report No. 81125|TK0221432** Conclusion: For the cured leaves from trial -03 (across all PHIs), the residue levels from resulting from the SC formulation were lower than those from the OD formulation. Otherwise, analysis of all other data indicated there were no significant differences in oxathiapiprolin residue levels between the SC and OD formulations at α = 0.05 significance level. Therefore, oxathiapiprolin residue data generated from application of the OD formulation would also support an identical use pattern with an SC formulation. 4. **Hampton, M. (2015), Report No. 81124|TK0221431** Conclusion: Comparative residue data for oxathiapiprolin and its metabolites on potato from side-by-side plots treated with either two soil applications (Trt 2) or two soil plus four foliar applications (Trt 3) of the SC formulation were generated at sixteen trial locations. At six of the trials, an additional plot was treated with two soil applications of the SC formulation plus four foliar applications of the OD formulation (Trt 4). Statistical analysis of these data indicate that the foliar applications, from either the SC or the OD formulation, do not significantly contribute (at α = 0.05 significance level) to the residue found in the tubers. The studies are acceptable and it can be concluded that the residue data supporting the approved GAP for the OD formulation are considered relevant to support the proposed GAP for this SC formulation. No additional data is required.

Introduction

The proposed EU uses of the new (SC) formulation A22773A are comparable or less critical than currently registered EU GAPs with oil dispersion (OD) formulation A20941A for tomato, pepper, cucumber, melon, lettuce and hops as summarised in Table A 83. The currently registered EU GAPs with the oil dispersion (OD) formulation are fully supported with an acceptable residue data package.

Table A 83: Comparison of the proposed EU GAPs for the SC formulation and currently registered EU GAPs for the OD formulation

Crop	Outdoor/ Protected	Formulation Type	Maximum Number of Applications	Minimum Application Interval (days)	Maximum Rate (g ai/ha)	Minimum PHI (days)
Tomato	Outdoor (SEU)	OD	3	7	30	3
		SC	2	7	12	3
Tomato	Protected	OD	3	7	30	3
		SC	2	7	12	3
Pepper	Protected	OD	3	7	25	3
		SC	2	7	12	3
Cucumber	Outdoor (SEU)	OD	3	7	20	3
		SC	2	7	12	3
Cucumber	Protected	OD	3	7	30	3
		SC	2	7	12	3
Melon	Outdoor (SEU)	OD	3	7	20	3
		SC	2	7	12	3
Melon	Protected	OD	3	7	30	3
		SC	2	7	12	3
Lettuce	Outdoor (NEU, SEU)	OD	2	7	15	7
		SC	2	7	12	14
Hops	Outdoor (NEU)	OD	2	10	50	14
		SC	2	12-16	12	28

According to the EU Guideline SANTE/2019/12752, new residue trials are, in principle, necessary to show comparability in residue levels if there is a significant change in formulation, for the same critical GAP parameters. Data should be generated for three major crop groups which may be treated, selecting a single representative crop for each crop group. The guidance further states that it has proved sufficient to carry out four comparative trials for each representative crop selected.

Comparative residue trials on crops from three different crop goupings have been selected for data generation to demonstrate that magnitude of residues incurred by the use of an SC formulation are comparable or less critical than the magnitude of residues incurred from the use of the existing OD formulation, according to the OD GAP detailed in Table A 83.

Residues trials conducted in the US have been carried out in a wide range of climatic conditions and are therefore relevant for the assessment of formulation comparability. Residue levels were compared following application of A20941A (the OD formulation used in the submitted residue trials) and A21008A (an SC formulation which is comparable to the SC formulation being considered in this submission). The formulation comparability was conducted using side-by-side trials in cucumber, brassica vegetables, potato and tobacco (21 trials in total) from the United States. These crops are representative of the fruiting vegetable, root and leafy crop groups.

In all trials, the active ingredient was applied to side-by-side plots as formulated products. One plot for each formulation was treated at the GAPs listed in Table A 84. Sampling was carried out at intervals between 0 and 8 DALA for each crop. Samples were stored deep frozen after sampling and remained frozen during transport and storage.

Table A 84: GAPs for side-by-side trials of the OD and SC formulations

Crop	Application rate (1x), g ai/ha	No. of applications	Spray interval, days	Sampling, (DALA)
Cucumber	69.83	2	5	0, 3, 7 or 8
Brassica	69.83	2	4 or 5	0, 2 or 3, 6 or 7
Potato	50.44*	4	5	4 or 5
Tobacco	69.83	2	5	0, 3, 6 or 7

*Prior to foliar treatment, both plots received an SC soil treatment @ 140.11 g ai/ha

All samples were analysed for residues of the active ingredient using a validated analytical method, to an LOQ of 0.01 mg/kg.

Results

Cucumber (TK0221427)
In cucumber, six trials were conducted during 2014 in the United States. In all trials, the active ingredient was applied to side-by-side plots as formulated products (one SC and one OD), as discussed in Table A 84. Residue levels were determined as below.

Table A 85: Mean residues in cucumbers following the application of SC and OD formulations on side-by-side plots in the United States

Sampling event	Mean residues in cucumbers from SC and OD formulations (ppm)						Mean ± SD Across all sites
	1	2	3	4	5	6	
SC							
0 DALA	0.059	0.020	0.041	0.031	<LOQ	0.019	0.030 ± 0.019
3 DALA	0.025	0.011	0.024	0.021	<LOQ	0.020	0.018 ± 0.008
7-8 DALA	<LOQ	0.013	<LOQ	0.012	<LOQ	<LOQ	0.011 ± 0.002
OD							
0 DALA	0.107	0.027	0.035	0.043	0.015	0.019	0.041 ± 0.033
3 DALA	0.035	0.011	0.025	0.031	<LOQ	0.014	0.021 ± 0.011
7-8 DALA	<LOQ	<LOQ	<LOQ	0.019	<LOQ	<LOQ	0.011 ± 0.005

Analysis of the comparability of the residue data generated in side-by-side plots indicates that they belong to similar populations (Mann-Whitney U-test, FAO, 2009). Sample distributions were assessed based on grouping data by PHI across trial sites and then by individual trial sites across all PHIs. The results are summarised in Table A 86 and indicate that the residues resulting from SC and OD formulatons are not statistically different.

Table A 86: Summary of Mann-Whitney U Test evaluating the statistical differences between SC and OD formulations

Grouping: PHI or Trial Number	Sample size (n)		Mean residues (ppm)		U_{obs}>$U_{critical}$* (α= 0.05)	Two-taied p-value	Mann-Whitney Result
	SC	OD	SC	OD			
0 DALA	12	12	0.0287	0.0337	56.0 >37	0.3690	Accept null hypothesis: the results are not statistically different
3 DALA	12	12	0.0193	0.0183	60.0 > 37	0.5019	
7 or 8 DALA	12	12	<LOQ	<LOQ	67.0 > 37	>0.999	
1	6	6	0.0255	0.0349	14.0 > 5	0.5628	Accept null hypothesis: the results are not statistically different
2	6	6	0.0124	0.0108	16.0 > 5	0.8052	
3	6	6	0.0236	0.0250	18.0 > 5	>0.9999	
4	6	6	0.0212	0.0315	9.0 > 5	0.1623	
5	6	6	<LOQ	<LOQ	12.5 > 5	0.5455	
6	6	6	0.0146	0.0132	15.0 > 5	0.6710	

*The value of $U_{critical}$ is found using a U test table and is determined by the combination of sample-sizes (n_1 and n_2), the confidence level (α), and whether the test is one or two-tailed.

According to the results presented above, it can be concluded that the use pattern of an SC formulation is not more critical than that of the OD formulation when applied to cucumbers.

Brassica (TK0221426)
In brassica, six trials were conducted during 2014 in the United States. In all trials, the active ingredient was applied to side-by-side plots as formulated products (one SC and one OD), as discussed in Table A 84. Residue levels were determined as below.

Table A 87: Mean residues in brassica following the application of SC and OD formulations on side-by-side plots in the United States

Sampling event	Mean residues in brassica from SC and OD formulations (ppm)						Mean ± SD Across all sites
	1 (broccoli)	2 (broccoli)	3 (cauliflower)	4 (cauliflower)	5 (cabbage)	6 (cabbage)	
SC							
0 DALA	0.268	0.237	0.012	0.089	0.466	0.601	0.279±0.214
2-3 DALA	0.189	0.243	0.018	0.011	0.238	0.509	0.201±0.179
6-7 DALA	0.145	0.104	<LOQ	<LOQ	0.123	0.510	0.150±0.184
OD							
0 DALA	0.231	<LOQ	<LOQ	0.035	0.324	0.484	0.182±0.190
2-3 DALA	0.146	<LOQ	<LOQ	0.013	0.364	0.478	0.170±0.201
6-7 DALA	0.141	ND	<LOQ	<LOQ	0.182	0.406	0.126±0.151

Analysis of the comparability of the residue data generated in side-by-side plots indicates that they belong to similar populations (Mann-Whitney U-test, FAO, 2009). Sample distributions were assessed based on grouping data by PHI across trial sites and then by individual trial sites across all PHIs. The results are summarised in Table A 88 and, with the exception of trial 2, indicate that the residues resulting from SC and OD formulatons are not statistically different.

Table A 88: Summary of Mann-Whitney U Test evaluating the statistical differences between SC and OD formulations

Grouping: PHI or Trial Number	Sample size (n)		Mean residues (ppm)		U_{obs}>$U_{critical}$* (α= 0.05)	Two-taied p-value	Mann-Whitney Result
	SC	OD	SC	OD			
0 DALA	12	12	0.247	0.124	48.0>37	0.1719	Accept null hypothesis: the results are not statistically different
2 or 3 DALA	12	12	0.215	0.0725	55.0>37	0.3450	
6 or 7 DALA	12	12	0.119	0.0565	63.0>37	0.6132	
1	6	6	0.193	0.171	14.0>5	0.5714	Accept null hypothesis: the results are not statistically different
3	6	6	0.0123	<LOQ	6.0>5	0.0606	
4	6	6	0.0105	0.0133	16.5>5	0.8701	
5	6	6	0.238	0.293	16.0>5	0.7879	
6	6	6	0.582	0.428	7.0>5	0.0931	
2	6	6	0.208	<LOQ	0.0<5	0.0022	Reject null hypothesis: results are significantly different

*The value of $U_{critical}$ is found using a U test table and is determined by the combination of sample-sizes (n_1 and n_2), the confidence level (α), and whether the test is one or two-tailed.

According to the results presented above, it can be concluded that the use pattern of an SC formulation is not more critical than that of the OD formulation when applied to brassica vegetables.

Potato (TK0221431)

In potato, six trials were conducted during 2014 in the United States. In all trials, the active ingredient was applied to side-by-side plots as formulated products (one SC and one OD), as discussed in Table A 84. Residue levels were determined as below.

Table A 89: Mean residues in potatoes following the application of SC and OD formulations on side-by-side plots in the United States

Sampling event	Mean residues in potato from SC and OD formulations (ppm)						Mean ± SD Across all sites
	1	**2**	**3**	**4**	**5**	**6**	
4 or 5 DALA (SC)	<LOQ	0.033	0.027	<LOQ	<LOQ	0.013	0.017±0.010
4 or 5 DALA (OD)	0.011	0.028	0.022	0.011	<LOQ	0.013	0.016±0.008

Analysis of the comparability of the residue data generated in side-by-side plots indicates that they belong to similar populations (Mann-Whitney U-test, FAO, 2009). Sample distributions were assessed based on grouping data by PHI across trial sites. The results are summarised in Table A 90 and indicate that the residues resulting from SC and OD formulatons are not statistically different.

Table A 90: Summary of Mann-Whitney U Test evaluating the statistical differences between SC and OD formulations

Grouping: PHI or Trial Number	Sample size (n)		Mean residues (ppm)		$U_{obs}>U_{critical}$* (α= 0.05)	Two-tailed p-value	Mann-Whitney Result
	SC	OD	SC	OD			
4 or 5 DALA	32	32	<LOQ	<LOQ	456.5>366	0.3861	Accept null hypothesis: the results are not statistically different

*The value of $U_{critical}$ is found using a U test table and is determined by the combination of sample-sizes (n_1 and n_2), the confidence level (α), and whether the test is one or two-tailed.

According to the results presented above, it can be concluded that the use pattern of an SC formulation is not more critical than that of the OD formulation when applied to potato.

Tobacco (TK0221432)

In tobacco, three trials were conducted during 2014 in the United States. In all trials, the active ingredient was applied to side-by-side plots as formulated products (one SC and one OD), as discussed in Table A 84. Residue levels were determined as below.

Table A 91: Mean residues in tobacco following the application of SC and OD formulations on side-by-side plots in the United States

Sampling event	Mean residues in potato from SC and OD formulations (ppm)						Mean ± SD Across all sites	
	1 Fresh leaves	**1 Cured leaves**	**2 Fresh leaves**	**2 Cured leaves**	**3 Fresh leaves**	**3 Cured leaves**	**Fresh leaves**	**Cured leaves**
SC								
0 DALA	1.73	15.0	1.77	16.5	5.43	13.5	2.98±1.96	15.0±4.60
3 DALA	1.76	18.7	2.19	18.5	2.00	10.9	1.98±0.32	16.0±4.42
6-7 DALA	3.24	17.2	1.97	17.2	2.09	11.3	2.43±0.65	15.3±3.69
OD								
0 DALA	1.23	14.7	1.99	17.1	5.23	18.4	2.82±1.93	16.7±3.20
3 DALA	1.18	10.1	2.61	12.7	2.73	16.0	2.18±0.84	12.9±3.42
6-7 DALA	2.53	13.9	2.13	15.8	3.33	19.6	2.66±0.56	16.4±2.76

Analysis of the comparability of the residue data generated in side-by-side plots indicates that they belong to similar populations (Mann-Whitney U-test, FAO, 2009). Sample distributions were assessed based on grouping data by PHI across trial sites and then by individual trial sites across all PHIs. The results are summarised in Table A 92 and indicate that the residues resulting from SC and OD formulatons are not statistically different, with the exception of trial 3 where the results from the SC formulation were statistically lower.

Table A 92: Summary of Mann-Whitney U Test evaluating the statistical differences between SC and OD formulations

Grouping: PHI or Trial Number	Sample size (n)		Mean residues (ppm)		$U_{obs}>U_{critical}$* (α= 0.05)	Two-tailed p-value	Mann-Whitney Result
	SC	OD	SC	OD			
Fresh Leaves							
0 DALA	6	6	2.08	1.99	16.0>5	0.7879	Accept null hypothesis: the results are not statistically different
3 DALA	6	6	1.97	2.43	13.5>5	0.5714	
6 or 7 DALA	6	6	2.19	2.53	12.0>5	0.3874	
1	6	6	1.97	1.46	9.5>5	0.1970	
2	6	6	2.02	2.28	12.0>5	0.3874	
3	6	6	2.31	3.33	10.0>5	0.2381	

Grouping: PHI or Trial Number	Sample size (n)		Mean residues (ppm)		U_{obs}>$U_{critical}$* (α= 0.05)	Two-tailed p-value	Mann-Whitney Result
	SC	OD	SC	OD			
Cured leaves							
0 DALA	6	6	16.5	17.9	13.0>5	0.4740	Accept null hypothesis: the results are not statistically different
3 DALA	6	6	16.9	12.3	11.5>5	0.3874	
6 or 7 DALA	6	6	15.6	15.8	14.0>5	0.5714	
1	6	6	18.1	12.5	8.0>5	0.1320	
2	6	6	17.3	14.8	7.0>5	0.0931	
3	6	6	10.9	18.6	2.0>5	0.0087	Reject null hypothesis: the results are statistically different

*The value of $U_{critical}$ is found using a U test table and is determined by the combination of sample-sizes (n_1 and n_2), the confidence level (α), and whether the test is one or two-tailed.

According to the results presented above, it can be concluded that the use pattern of an SC formulation is not more critical than that of the OD formulation when applied to tobacco.

Conclusion

In line with the EU Guideline SANTE/2019/12752, comparative residue trials were conducted for representative crops from three major crop groups (fruiting vegetables, root crops and leafy crops). Four or more comparative trials were conducted for each crop group where residue levels of active ingredient were compared following the application of an SC and OD formulation on side by side plots. Mann-Whitney U-Tests were carried out for each trial and it was demonstrated that the magnitude of residues incurred by the use of the SC formulation are comparable or less critical than the magnitude of residues incurred from the use of the existing OD formulation.

It can therefore be concluded that the residue data supporting the approved EU GAPs for the OD formulation are considered relevant to support the proposed EU GAPs for this SC formulation (Table A 83) and no further residue data generation is required.

References

EC (European Commission), 2019. Technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin. SANTE/2019/12752.

Studies list

Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**
Hampton, M. M.	2015	Oxathiapiprolin OD (A20941A) and Oxathiapiprolin SC (A21008A) – Magnitude of the Residues in or on Cucumber Raw Agricultural Commodities Resulting from Foliar Applications of OD and SC Formulations - USA, 2014 Report Number: TK0221427 Syngenta File Number: VV-511307 GLP Not published
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