REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: A23109A

Product name: ORONDIS VIP

Chemical active substances:

Metalaxyl-M, 174.4 g/L
Oxathiapiprolin, 30 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(New authorisation)

Applicant: Syngenta

Submission date: June 2022, updated April 2023, July 2023

MS Finalisation date: July 2023 (initial Core Assessment)
November 2023 (final Core Assessment)

Version history

When	What
June 2022	Part B - Section 7 - Core Assessment - Central Zone
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.
July 2023	Table 7.2-9: has been updated with additional open leaf lettuce data 7.2.3.2: lettuce residues summary text updated Appendix 1: updated with three additional open leaf lettuce residue trials A.2.1.3.5 Lettuce (open leaf): additional study data added
July 2023	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.
November 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. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.

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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 A23109A are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central Zone for indended crops.
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.

Metalaxyl-M
An exceedance of the current MRLs for metalaxyl-M as laid down in Reg. (EU) 396/2005 (Reg. (EU) 2017/1164) is not expected for garlic, onion, shallots, spring onion, green onion, welsh onion, broccoli, brussels sprout, head cabbage, savoy cabbage, kale and curly kale, lamb's lettuce, lettuce (open leaf), iceberg lettuce, escarole, cress, rocket, red mustard, baby leaf, spinach, common purslane, chards and beet leaves, chicory / endive, herbs and edible flowers (0256000), parsley, chives, leek.
Considering the intended use on Chinese cabbage/pet-tsai and watercress, an exceedance of the MRLs for metalaxyl-M, as established in Reg. (EU) 2017/1164 is expected. The proposed uses on Chinese cabbage/pet-tsai and watercress are not considered acceptable.

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

Oxathiapiprolin
An exceedance of the current MRLs for oxathiapiprolin as laid down in Reg. (EU) 396/2005 (Reg. (EU) 2023/163) is not expected for garlic, onion, shallots, spring onion, green onion, welsh onion, broccoli, brussels sprout, head cabbage, savoy cabbage, Chinese cabbage/pet-tsai, lamb's lettuce, lettuce (open leaf), iceberg lettuce, escarole, cress, rocket, red mustard, baby leaf, spinach, common purslane, chards and beet leaves, chicory / endive, leek, basil and edible flowers (0256080). These uses are considered acceptable.
Considering the intended uses on kale and curly kale, herbs and edible flowers (0256000) except basil and edible flowers (0256080), chives, parsley and watercress, an exceedance of the MRLs for oxathiapiprolin, as established in Reg. (EU) 2023/163 is expected. The proposed uses on kale and curly kale, herbs and edible flowers (0256000) except basil and edible flowers (0256080), chives, parsley and watercress are not considered acceptable.

The chronic intakes of 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 following uses: garlic, onion, shallots, spring onion, green onion, welsh onion, broccoli, brussels sprout, head cabbage, savoy cabbage, lamb's lettuce, lettuce (open leaf), iceberg lettuce, escarole, cress, rocket, red mustard, baby leaf, spinach, common purslane, chards and beet leaves, chicory / endive, leek, basil and edible flowers (0256080).

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)]~~	~~**Conclusion**~~
					~~**Method / Kind**~~	~~**Timing / Growth stage of crop & season**~~	~~**Max. number a) per use b) per crop/ season**~~	~~**Min. interval between applications (days)**~~	~~**L product / ha a) max. rate per appl. b) max. total rate per crop/season**~~	~~**g MFX/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**~~	~~**Water L/ha min / max**~~			
~~AT-1~~	~~Austria~~	~~Baby leaves~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~AT-3~~	~~Austria~~	~~Broccoli [BRSOK]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		
~~AT-5~~	~~Austria~~	~~Brussels sprouts [BRSOF]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		
~~AT-7~~	~~Austria~~	~~Cauliflower [BRSOB]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		
~~AT-8~~	~~Austria~~	~~Chards and beet leaves [BEAVD]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-600~~	~~10~~		
~~AT-9~~	~~Austria~~	~~Chicory [CICIN]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~AT-10~~	~~Austria~~	~~Chives [ALLSC]~~	~~F~~	~~*Phytophthora porri* [PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~AT-11~~	~~Austria~~	~~Common purslane [POROL]~~	~~F~~	~~*Peronospora farinosa f. sp. spinaciae* [PEROFS]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-600~~	~~10~~	~~-~~	
~~AT-12~~	~~Austria~~	~~Cress [CRESS]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~AT-14~~	~~Austria~~	~~Curly kale [BRSOC]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		

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~~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 product / ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g MFX/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~~	~~Water L/ha min / max~~			
~~AT-15~~	~~Austria~~	~~Endive [CICEN]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~AT-16~~	~~Austria~~	~~Escarole [CICEL]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~AT-17~~	~~Austria~~	~~Garlic [ALLSA]~~	~~F~~	~~*Phytophthora porri* [PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~		
~~AT-18~~	~~Austria~~	~~Garlic [ALLSA]~~	~~F~~	~~*Peronospora destructor* [PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~		
~~AT-20~~	~~Austria~~	~~Head cabbage [BRSOL]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		
~~AT-21~~	~~Austria~~	~~Herbs and edible flowers [NNNEF]~~	~~F~~	~~*Phytophthora/Downy mildew* [SCLPST]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~AT-23~~	~~Austria~~	~~Kale [BRSOA]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		
~~AT-24~~	~~Austria~~	~~Lamb's lettuce [VLLLO]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~AT-26~~	~~Austria~~	~~Leafy brassica [3LFBC]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		
~~AT-27~~	~~Austria~~	~~Leek [ALLPO]~~	~~F~~	~~*Peronospora destructor* [PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~		
~~AT-28~~	~~Austria~~	~~Leek [ALLPO]~~	~~F~~	~~*Phytophthora porri* [PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	-	

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~~**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 product / ha a) max. rate per appl. b) max. total rate per crop/season**~~	~~**g MFX/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**~~	~~**Water L/ha min / max**~~			
~~AT-29~~	~~Austria~~	~~Lettuce [LACSA]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~AT-30~~	~~Austria~~	~~Mustard, red [BRSJU]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		
~~AT-31~~	~~Austria~~	~~Onion [ALLCE]~~	~~F~~	~~*Phytophthora porri* [PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	~~-~~	
~~AT-32~~	~~Austria~~	~~Onion [ALLCE]~~	~~F~~	~~*Peronospora destructor* [PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~		
~~AT-33~~	~~Austria~~	~~Parsley [PARCR]~~	~~F~~	~~*Downy Mildew - Plasmopara umbelliferarum* [PLASCR]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~AT-37~~	~~Austria~~	~~Pe-tsai [BRSPK]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	~~-~~	
~~AT-38~~	~~Austria~~	~~Purple-vein rocket [ERUVE]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~AT-40~~	~~Austria~~	~~Savoy cabbage [BRSOS]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		
~~AT-41~~	~~Austria~~	~~Shallot [ALLAS]~~	~~F~~	~~*Phytophthora porri* [PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	~~-~~	
~~AT-42~~	~~Austria~~	~~Shallot [ALLAS]~~	~~F~~	~~*Peronospora destructor* [PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	~~-~~	

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~~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 product / ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g MFX/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~~	~~Water L/ha min / max~~			
~~AT-43~~	~~Austria~~	~~Spinach [SPQOL]~~	~~F~~	~~*Peronospora farinosa f. sp. spinaciae* [PEROFS]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-600~~	~~10~~	-	
~~AT-44~~	~~Austria~~	~~Spring, welsh and green onion [ALLFI]~~	~~F~~	~~*Peronospora destructor* [PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~		
~~AT-45~~	~~Austria~~	~~Spring, welsh and green onion [ALLFI]~~	~~F~~	~~*Phytophthora porri* [PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	-	
~~AT-46~~	~~Austria~~	~~Watercress [NAAOF]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~BE-1~~	~~Belgium~~	~~Baby leaves~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~BE-3~~	~~Belgium~~	~~Broccoli [BRSOK]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		
~~BE-5~~	~~Belgium~~	~~Brussels sprouts [BRSOF]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		
~~BE-7~~	~~Belgium~~	~~Cauliflower [BRSOB]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		
~~BE-9~~	~~Belgium~~	~~Cress [CRESS]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~BE-11~~	~~Belgium~~	~~Curly kale [BRSOC]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		

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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 product / ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g MFX/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~~	~~Water L/ha min / max~~			
~~BE-12~~	~~Belgium~~	~~Endive [CICEN]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~BE-13~~	~~Belgium~~	~~Escarole [CICEL]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~BE-14~~	~~Belgium~~	~~Garlic [ALLSA]~~	~~F~~	~~*Phytophthora porri* [PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~		
~~BE-15~~	~~Belgium~~	~~Garlic [ALLSA]~~	~~F~~	~~*Peronospora destructor* [PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~		
~~BE-17~~	~~Belgium~~	~~Head cabbage [BRSOL]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		
~~BE-18~~	~~Belgium~~	~~Herbs and edible flowers [NNNEF]~~	~~F~~	~~*Phytophthora/Downy mildew* [SCLPST]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~BE-19~~	~~Belgium~~	~~Lamb's lettuce [VLLLO]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~BE-21~~	~~Belgium~~	~~Leafy brassica [3LFBC]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		
~~BE-22~~	~~Belgium~~	~~Leek [ALLPO]~~	~~F~~	~~*Peronospora destructor* [PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~		
~~BE-23~~	~~Belgium~~	~~Leek [ALLPO]~~	~~F~~	~~*Phytophthora porri* [PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~		
~~BE-24~~	~~Belgium~~	~~Lettuce [LACSA]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	

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~~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 product / ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g MFX/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~~	~~Water L/ha min / max~~			
~~BE-25~~	~~Belgium~~	~~Onion [ALLCE]~~	~~F~~	~~*Phytophthora porri*~~ ~~[PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	~~-~~	
~~BE-26~~	~~Belgium~~	~~Onion [ALLCE]~~	~~F~~	~~*Peronospora destructor*~~ ~~[PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	~~-~~	
~~BE-28~~	~~Belgium~~	~~Pe-tsai [BRSPK]~~	~~F~~	~~*Hyaloperonospora parasitica*~~ ~~[PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	~~-~~	
~~BE-29~~	~~Belgium~~	~~Purple-vein rocket [ERUVE]~~	~~F~~	~~*Bremia lactucae*~~ ~~[BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~BE-30~~	~~Belgium~~	~~Shallot [ALLAS]~~	~~F~~	~~*Phytophthora porri*~~ ~~[PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	~~-~~	
~~BE-31~~	~~Belgium~~	~~Shallot [ALLAS]~~	~~F~~	~~*Peronospora destructor*~~ ~~[PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	~~-~~	
~~BE-32~~	~~Belgium~~	~~Spinach [SPQOL]~~	~~F~~	~~*Peronospora farinosa f. sp. spinaciae*~~ ~~[PEROFS]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-600~~	~~10~~	~~-~~	
~~BE-33~~	~~Belgium~~	~~Spring, welsh and green onion [ALLFI]~~	~~F~~	~~*Peronospora destructor*~~ ~~[PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~		
~~BE-34~~	~~Belgium~~	~~Spring, welsh and green onion [ALLFI]~~	~~F~~	~~*Phytophthora porri*~~ ~~[PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~		
~~BE-35~~	~~Belgium~~	~~Watercress [NAAOF]~~	~~F~~	~~*Bremia lactucae*~~ ~~[BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	

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~~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 product / ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g MFX/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~~	~~Water L/ha min / max~~			
~~CZ-1~~	~~Czech Republic~~	~~Baby leaves~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field Minor use~~	
~~CZ-3~~	~~Czech Republic~~	~~Broccoli [BRSOK]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	~~Minor use~~	
~~CZ-5~~	~~Czech Republic~~	~~Brussels sprouts [BRSOF]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	~~Minor use~~	
~~CZ-7~~	~~Czech Republic~~	~~Cauliflower [BRSOB]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	~~Minor use~~	
~~CZ-8~~	~~Czech Republic~~	~~Chards and beet leaves [BEAVD]~~	~~F~~	~~*Peronospora farinosa f. sp. spinaciae* [PEROFS]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-600~~	~~10~~	~~Minor use~~	
~~CZ-9~~	~~Czech Republic~~	~~Chicory [CICIN]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field Minor use~~	
~~CZ-10~~	~~Czech Republic~~	~~Chives [ALLSC]~~	~~F~~	~~*Phytophthora porri* [PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field Minor use~~	
~~CZ-11~~	~~Czech Republic~~	~~Common purslane [POROL]~~	~~F~~	~~*Peronospora farinosa f. sp. spinaciae* [PEROFS]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-600~~	~~10~~	~~Minor use~~	
~~CZ-12~~	~~Czech Republic~~	~~Cress [CRESS]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field Minor use~~	

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~~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 product / ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g MFX/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~~	~~Water L/ha min / max~~			
~~CZ-14~~	~~Czech Republic~~	~~Curly kale [BRSOC]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	~~Minor use~~	
~~CZ-15~~	~~Czech Republic~~	~~Endive [CICEN]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field Minor use~~	
~~CZ-16~~	~~Czech Republic~~	~~Escarole [CICEL]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field Minor use~~	
~~CZ-17~~	~~Czech Republic~~	~~Garlic [ALLSA]~~	~~F~~	~~*Phytophthora porri* [PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	~~Minor use~~	
~~CZ-18~~	~~Czech Republic~~	~~Garlic [ALLSA]~~	~~F~~	~~*Peronospora destructor* [PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	~~Minor use~~	
~~CZ-20~~	~~Czech Republic~~	~~Head cabbage [BRSOL]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	~~Minor use~~	
~~CZ-21~~	~~Czech Republic~~	~~Herbs and edible flowers [NNNEF]~~	~~F~~	~~*Phytophthora/Downy mildew* [SCLPST]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field Minor use~~	
~~CZ-22~~	~~Czech Republic~~	~~Iceberg lettuce~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field Minor use~~	
~~CZ-24~~	~~Czech Republic~~	~~Kale [BRSOA]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	~~Minor use~~	
~~CZ-27~~	~~Czech Republic~~	~~Lamb's lettuce [VLLLO]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field Minor use~~	

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~~**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 product / ha a) max. rate per appl. b) max. total rate per crop/season**~~	~~**g MFX/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**~~	~~**Water L/ha min / max**~~			
~~CZ-29~~	~~Czech Republic~~	~~Leafy brassica [3LFBC]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	~~Minor use~~	
~~CZ-30~~	~~Czech Republic~~	~~Leek [ALLPO]~~	~~F~~	~~*Peronospora destructor* [PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	~~Minor use~~	
~~CZ-31~~	~~Czech Republic~~	~~Leek [ALLPO]~~	~~F~~	~~*Phytophthora porri* [PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	~~Minor use~~	
~~CZ-32~~	~~Czech Republic~~	~~Lettuce [LACSA]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field Minor use~~	
~~CZ-33~~	~~Czech Republic~~	~~Mustard, red~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	~~Minor use~~	
~~CZ-34~~	~~Czech Republic~~	~~Onion [ALLCE]~~	~~F~~	~~*Phytophthora porri* [PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	~~Minor use~~	
~~CZ-35~~	~~Czech Republic~~	~~Onion [ALLCE]~~	~~F~~	~~*Peronospora destructor* [PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	~~Minor use~~	
~~CZ-36~~	~~Czech Republic~~	~~Parsley [PARCR]~~	~~F~~	~~*Downy Mildew - Plasmopara umbelliferarum* [PLASCR]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field Minor use~~	
~~CZ-40~~	~~Czech Republic~~	~~Pe-tsai [BRSPK]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	~~Minor use~~	
~~CZ-41~~	~~Czech Republic~~	~~Purple-vein rocket [ERUVE]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field Minor use~~	

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~~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 product / ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g MFX/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~~	~~Water L/ha min / max~~			
~~CZ-43~~	~~Czech Republic~~	~~Savoy cabbage [BRSOS]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	~~Minor use~~	
~~CZ-44~~	~~Czech Republic~~	~~Shallot [ALLAS]~~	~~F~~	~~*Phytophthora porri* [PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	~~Minor use~~	
~~CZ-45~~	~~Czech Republic~~	~~Shallot [ALLAS]~~	~~F~~	~~*Peronospora destructor* [PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	~~Minor use~~	
~~CZ-46~~	~~Czech Republic~~	~~Spinach [SPQOL]~~	~~F~~	~~*Peronospora farinosa f. sp. spinaciae* [PEROFS]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-600~~	~~10~~	~~Minor use~~	
~~CZ-47~~	~~Czech Republic~~	~~Spring, welsh and green onion [ALLFI]~~	~~F~~	~~*Peronospora destructor* [PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	~~Minor use~~	
~~CZ-48~~	~~Czech Republic~~	~~Spring, welsh and green onion [ALLFI]~~	~~F~~	~~*Phytophthora porri* [PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	~~Minor use~~	
~~CZ-49~~	~~Czech Republic~~	~~Watercress [NAAOF]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field Minor use~~	
~~DE-1~~	~~Germany~~	~~Baby leaves~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~DE-3~~	~~Germany~~	~~Broccoli [BRSOK]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		
~~DE-5~~	~~Germany~~	~~Brussels sprouts [BRSOF]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		

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~~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 product / ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g MFX/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~~	~~Water L/ha min / max~~			
~~DE-7~~	~~Germany~~	~~Cauliflower [BRSOB]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		
~~DE-8~~	~~Germany~~	~~Chards and beet leaves [BEAVD]~~	~~F~~	~~*Peronospora farinosa f. sp. spinaciae* [PEROFS]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-600~~	~~10~~		
~~DE-9~~	~~Germany~~	~~Chicory [CICIN]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~DE-10~~	~~Germany~~	~~Chives [ALLSC]~~	~~F~~	~~*Phytophthora porri* [PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~DE-11~~	~~Germany~~	~~Common purslane [POROL]~~	~~F~~	~~*Peronospora farinosa f. sp. spinaciae* [PEROFS]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-600~~	~~10~~		
~~DE-12~~	~~Germany~~	~~Cress [CRESS]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~DE-14~~	~~Germany~~	~~Curly kale [BRSOC]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		
~~DE-15~~	~~Germany~~	~~Endive [CICEN]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~DE-16~~	~~Germany~~	~~Escarole [CICEL]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~DE-17~~	~~Germany~~	~~Garlic [ALLSA]~~	~~F~~	~~*Phytophthora porri* [PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~		
~~DE-18~~	~~Germany~~	~~Garlic [ALLSA]~~	~~F~~	~~*Peronospora destructor*~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~		

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~~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 product / ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g MFX/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~~	~~Water L/ha min / max~~			
~~DE-20~~	~~Germany~~	~~Head cabbage [BRSOL]~~	~~F~~	~~[PERODE]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		
~~DE-21~~	~~Germany~~	~~Herbs and edible flowers [NNNEF]~~	~~F~~	~~*Phytophthora/Downy mildew* [SCLPST]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~DE-23~~	~~Germany~~	~~Kale [BRSOA]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		
~~DE-24~~	~~Germany~~	~~Lamb's lettuce [VLLLO]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~DE-26~~	~~Germany~~	~~Leafy brassica [3LFBC]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		
~~DE-27~~	~~Germany~~	~~Leek [ALLPO]~~	~~F~~	~~*Peronospora destructor* [PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~		
~~DE-28~~	~~Germany~~	~~Leek [ALLPO]~~	~~F~~	~~*Phytophthora porri* [PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	-	
~~DE-29~~	~~Germany~~	~~Lettuce [LACSA]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~DE-30~~	~~Germany~~	~~Mustard, red~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		
~~DE-31~~	~~Germany~~	~~Onion [ALLCE]~~	~~F~~	~~*Phytophthora porri* [PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~		
~~DE-32~~	~~Germany~~	~~Onion [ALLCE]~~	~~F~~	~~*Peronospora destructor* [PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~		

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~~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 product / ha a) max. rate per appl. b) max. total rate per crop/season~~**	**~~g MFX/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~~**	**~~Water L/ha~~** **~~min / max~~**			
~~DE-33~~	~~Germany~~	~~Parsley [PARCR]~~	~~F~~	*~~Downy Mildew - Plasmopara umbelliferarum~~* ~~[PLASCR]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~DE-37~~	~~Germany~~	~~Pe-tsai [BRSPK]~~	~~F~~	*~~Hyaloperonospora parasitica~~* ~~[PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	~~-~~	
~~DE-38~~	~~Germany~~	~~Purple-vein rocket [ERUVE]~~	~~F~~	*~~Bremia lactucae~~* ~~[BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~DE-40~~	~~Germany~~	~~Savoy cabbage [BRSOS]~~	~~F~~	*~~Hyaloperonospora parasitica~~* ~~[PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		
~~DE-41~~	~~Germany~~	~~Shallot [ALLAS]~~	~~F~~	*~~Phytophthora porri~~* ~~[PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~		
~~DE-42~~	~~Germany~~	~~Shallot [ALLAS]~~	~~F~~	*~~Peronospora destructor~~* ~~[PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~		
~~DE-43~~	~~Germany~~	~~Spinach [SPQOL]~~	~~F~~	*~~Peronospora farinosa f. sp. spinaciae~~* ~~[PEROFS]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-600~~	~~10~~		
~~DE-44~~	~~Germany~~	~~Spring, welsh and green onion [ALLFI]~~	~~F~~	*~~Peronospora destructor~~* ~~[PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~		
~~DE-45~~	~~Germany~~	~~Spring, welsh and green onion [ALLFI]~~	~~F~~	*~~Phytophthora porri~~* ~~[PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~		
~~DE-46~~	~~Germany~~	~~Watercress [NAAOF]~~	~~F~~	*~~Bremia lactucae~~* ~~[BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	

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~~**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 product / ha a) max. rate per appl. b) max. total rate per crop/season**~~	~~**g MFX/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**~~	~~**Water L/ha**~~ ~~**min / max**~~			
~~NL-1~~	~~Netherlands~~	~~Baby leaves~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~NL-3~~	~~Netherlands~~	~~Broccoli [BRSOK]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		
~~NL-5~~	~~Netherlands~~	~~Brussels sprouts [BRSOF]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		
~~NL-7~~	~~Netherlands~~	~~Cauliflower [BRSOB]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		
~~NL-10~~	~~Netherlands~~	~~Curly kale [BRSOC]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		
~~NL-11~~	~~Netherlands~~	~~Endive [CICEN]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~NL-12~~	~~Netherlands~~	~~Escarole [CICEL]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~NL-13~~	~~Netherlands~~	~~Garlic [ALLSA]~~	~~F~~	~~*Phytophthora porri* [PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~		
~~NL-14~~	~~Netherlands~~	~~Garlic [ALLSA]~~	~~F~~	~~*Peronospora destructor* [PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~		
~~NL-16~~	~~Netherlands~~	~~Head cabbage [BRSOL]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		

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~~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 product / ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g MFX/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~~	~~Water L/ha min / max~~			
~~NL-17~~	~~Netherlands~~	~~Herbs and edible flowers [NNNEF]~~	~~F~~	~~*Phytophthora/Downy mildew*~~ ~~[SCLPST]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2~~ ~~b) 2~~	~~7~~	~~a) 0.5~~ ~~b) 1~~	~~a) 87.2~~ ~~b) 174.4~~	~~a) 15~~ ~~b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~NL-18~~	~~Netherlands~~	~~Lamb's lettuce~~ ~~[VLLLO]~~	~~F~~	~~*Bremia lactucae*~~ ~~[BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2~~ ~~b) 2~~	~~7~~	~~a) 0.5~~ ~~b) 1~~	~~a) 87.2~~ ~~b) 174.4~~	~~a) 15~~ ~~b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~NL-20~~	~~Netherlands~~	~~Leafy brassica~~ ~~[3LFBC]~~	~~F~~	~~*Hyaloperonospora parasitica*~~ ~~[PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2~~ ~~b) 2~~	~~7-10~~	~~a) 0.5~~ ~~b) 1~~	~~a) 87.2~~ ~~b) 174.4~~	~~a) 15~~ ~~b) 30~~	~~200-800~~	~~20~~		
~~NL-21~~	~~Netherlands~~	~~Leek~~ ~~[ALLPO]~~	~~F~~	~~*Peronospora destructor*~~ ~~[PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2~~ ~~b) 2~~	~~12-14~~	~~a) 0.5~~ ~~b) 1~~	~~a) 87.2~~ ~~b) 174.4~~	~~a) 15~~ ~~b) 30~~	~~200-800~~	~~14~~		
~~NL-22~~	~~Netherlands~~	~~Leek~~ ~~[ALLPO]~~	~~F~~	~~*Phytophthora porri*~~ ~~[PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2~~ ~~b) 2~~	~~12-14~~	~~a) 0.5~~ ~~b) 1~~	~~a) 87.2~~ ~~b) 174.4~~	~~a) 15~~ ~~b) 30~~	~~200-800~~	~~14~~		
~~NL-23~~	~~Netherlands~~	~~Lettuce~~ ~~[LACSA]~~	~~F~~	~~*Bremia lactucae*~~ ~~[BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2~~ ~~b) 2~~	~~7~~	~~a) 0.5~~ ~~b) 1~~	~~a) 87.2~~ ~~b) 174.4~~	~~a) 15~~ ~~b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~NL-24~~	~~Netherlands~~	~~Onion~~ ~~[ALLCE]~~	~~F~~	~~*Phytophthora porri*~~ ~~[PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2~~ ~~b) 2~~	~~7~~	~~a) 0.5~~ ~~b) 1~~	~~a) 87.2~~ ~~b) 174.4~~	~~a) 15~~ ~~b) 30~~	~~200-800~~	~~14~~		
~~NL-25~~	~~Netherlands~~	~~Onion~~ ~~[ALLCE]~~	~~F~~	~~*Peronospora destructor*~~ ~~[PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2~~ ~~b) 2~~	~~7~~	~~a) 0.5~~ ~~b) 1~~	~~a) 87.2~~ ~~b) 174.4~~	~~a) 15~~ ~~b) 30~~	~~200-800~~	~~14~~		
~~NL-27~~	~~Netherlands~~	~~Pe-tsai~~ ~~[BRSPK]~~	~~F~~	~~*Hyaloperonospora parasitica*~~ ~~[PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2~~ ~~b) 2~~	~~7-10~~	~~a) 0.5~~ ~~b) 1~~	~~a) 87.2~~ ~~b) 174.4~~	~~a) 15~~ ~~b) 30~~	~~200-800~~	~~20~~		
~~NL-28~~	~~Netherlands~~	~~Purple-vein rocket~~ ~~[ERUVE]~~	~~F~~	~~*Bremia lactucae*~~ ~~[BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2~~ ~~b) 2~~	~~7~~	~~a) 0.5~~ ~~b) 1~~	~~a) 87.2~~ ~~b) 174.4~~	~~a) 15~~ ~~b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~NL-29~~	~~Netherlands~~	~~Shallot~~ ~~[ALLAS]~~	~~F~~	~~*Phytophthora porri*~~ ~~[PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2~~ ~~b) 2~~	~~7~~	~~a) 0.5~~ ~~b) 1~~	~~a) 87.2~~ ~~b) 174.4~~	~~a) 15~~ ~~b) 30~~	~~200-800~~	~~14~~		

~~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 product / ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g MFX/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~~	~~Water L/ha min / max~~			
~~NL-30~~	~~Netherlands~~	~~Shallot~~ ~~[ALLAS]~~	~~F~~	~~*Peronospora destructor*~~ ~~[PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2~~ ~~b) 2~~	~~7~~	~~a) 0.5~~ ~~b) 1~~	~~a) 87.2~~ ~~b) 174.4~~	~~a) 15~~ ~~b) 30~~	~~200-800~~	~~14~~		
~~NL-31~~	~~Netherlands~~	~~Spinach~~ ~~[SPQOL]~~	~~F~~	~~*Peronospora farinosa f. sp. spinaciae*~~ ~~[PEROFS]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2~~ ~~b) 2~~	~~7~~	~~a) 0.5~~ ~~b) 1~~	~~a) 87.2~~ ~~b) 174.4~~	~~a) 15~~ ~~b) 30~~	~~200-600~~	~~10~~		
~~NL-32~~	~~Netherlands~~	~~Spring, welsh and green onion~~ ~~[ALLFI]~~	~~F~~	~~*Peronospora destructor*~~ ~~[PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2~~ ~~b) 2~~	~~12-14~~	~~a) 0.5~~ ~~b) 1~~	~~a) 87.2~~ ~~b) 174.4~~	~~a) 15~~ ~~b) 30~~	~~200-800~~	~~14~~		
~~NL-33~~	~~Netherlands~~	~~Spring, welsh and green onion~~ ~~[ALLFI]~~	~~F~~	~~*Phytophthora porri*~~ ~~[PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2~~ ~~b) 2~~	~~12-14~~	~~a) 0.5~~ ~~b) 1~~	~~a) 87.2~~ ~~b) 174.4~~	~~a) 15~~ ~~b) 30~~	~~200-800~~	~~14~~		
~~PL-1~~	~~Poland~~	~~Baby leaves~~	~~F~~	~~*Bremia lactucae*~~ ~~[BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2~~ ~~b) 2~~	~~7~~	~~a) 0.5~~ ~~b) 1~~	~~a) 87.2~~ ~~b) 174.4~~	~~a) 15~~ ~~b) 30~~	~~200-800~~	~~10~~	~~Minor Use – Art 51~~ ~~Max 2 app per year in same field~~	
~~PL-3~~	~~Poland~~	~~Broccoli~~ ~~[BRSOK]~~	~~F~~	~~*Hyaloperonospora parasitica*~~ ~~[PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2~~ ~~b) 2~~	~~7-10~~	~~a) 0.5~~ ~~b) 1~~	~~a) 87.2~~ ~~b) 174.4~~	~~a) 15~~ ~~b) 30~~	~~200-800~~	~~20~~	~~Minor Use – Art 51~~	
~~PL-3a~~	~~Poland~~	~~Broccoli~~ ~~[BRSOK]~~	~~F~~	~~*Albugo sp.*~~ ~~[ALBUSP]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2~~ ~~b) 2~~	~~7-10~~	~~a) 0.5~~ ~~b) 1~~	~~a) 87.2~~ ~~b) 174.4~~	~~a) 15~~ ~~b) 30~~	~~200-800~~	~~20~~	~~Minor Use – Art 51~~	
~~PL-5~~	~~Poland~~	~~Brussels sprouts~~ ~~[BRSOF]~~	~~F~~	~~*Hyaloperonospora parasitica*~~ ~~[PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2~~ ~~b) 2~~	~~7-10~~	~~a) 0.5~~ ~~b) 1~~	~~a) 87.2~~ ~~b) 174.4~~	~~a) 15~~ ~~b) 30~~	~~200-800~~	~~20~~	~~Minor Use – Art 51~~	
~~PL-5a~~	~~Poland~~	~~Brussels sprouts~~ ~~[BRSOF]~~	~~F~~	~~*Albugo* sp.~~ ~~[ALBUSP]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2~~ ~~b) 2~~	~~7-10~~	~~a) 0.5~~ ~~b) 1~~	~~a) 87.2~~ ~~b) 174.4~~	~~a) 15~~ ~~b) 30~~	~~200-800~~	~~20~~	~~Minor Use – Art 51~~	

~~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 product / ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g MFX/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~~	~~Water L/ha min / max~~			
~~PL-7~~	~~Poland~~	~~Cauliflower [BRSOB]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	~~Minor Use – Art 51~~	
~~PL-7a~~	~~Poland~~	~~Cauliflower [BRSOB]~~	~~F~~	~~*Albugo* sp. [ALBUSP]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	~~Minor Use – Art 51~~	
~~PL-8~~	~~Poland~~	~~Chards and beet leaves [BEAVD]~~	~~F~~	~~*Peronospora farinosa f. sp. spinaciae* [PEROFS]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-600~~	~~10~~	~~Minor Use – Art 51~~	
~~PL-9~~	~~Poland~~	~~Chicory [CICIN]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Minor Use – Art 51 Max 2 app per year in same field~~	
~~PL-10~~	~~Poland~~	~~Chives [ALLSC]~~	~~F~~	~~*Phytophthora porri* [PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Minor Use – Art 51 Max 2 app per year in same field~~	
~~PL-11~~	~~Poland~~	~~Common purslane [POROL]~~	~~F~~	~~*Peronospora farinosa f. sp. spinaciae* [PEROFS]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-600~~	~~10~~	~~Minor Use – Art 51~~	
~~PL-12~~	~~Poland~~	~~Cress [CRESS]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Minor Use – Art 51Max 2 app per year in same field~~	
~~PL-14~~	~~Poland~~	~~Curly kale [BRSOC]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	~~Minor Use – Art 51~~	
~~PL-14a~~	~~Poland~~	~~Curly kale [BRSOC]~~	~~F~~	~~*Albugo* sp. [ALBUSP]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	~~Minor Use – Art 51~~	

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 product / ha a) max. rate per appl. b) max. total rate per crop/season	g MFX/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	Water L/ha min / max			
PL-15	Poland	Endive [CICEN]	F	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 – 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	
PL-16	Poland	Escarole [CICEL]	F	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 – 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	
PL-17	Poland	Garlic [ALLSA]	F	*Phytophthora porri* [PHYTPO]	Foliar	BBCH 12 – 48	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	14	Minor Use – Art 51	
PL-18	Poland	Garlic [ALLSA]	F	*Peronospora destructor* [PERODE]	Foliar	BBCH 12 – 48	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	14	Minor Use – Art 51	
PL-20	Poland	Head cabbage [BRSOL]	F	*Hyaloperonospora parasitica* [PEROPA]	Foliar	BBCH 12 – 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	20		
PL-20a	Poland	Head cabbage [BRSOL]	F	*Albugo* sp. [ALBUSP]	Foliar	BBCH 12 – 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	20	Minor Use – Art 51	
PL-21	Poland	Herbs and edible flowers [NNNEF]	F	*Phytophthora/Downy mildew* [SCLPST]	Foliar	BBCH 12 – 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	
PL-23	Poland	Kale [BRSOA]	F	*Hyaloperonospora parasitica* [PEROPA]	Foliar	BBCH 12 – 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	20	Minor Use – Art 51	
PL-23a	Poland	Kale [BRSOA]	F	*Albugo* sp. [ALBUSP]	Foliar	BBCH 12 – 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	20	Minor Use – Art 51	

~~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 product / ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g MFX/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~~	~~Water L/ha min / max~~			
~~PL-24~~	~~Poland~~	~~Lamb's lettuce [VLLLO]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Minor Use – Art 51 Max 2 app per year in same field~~	
~~PL-26~~	~~Poland~~	~~Leafy brassica [3LFBC]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	~~Minor Use – Art 51~~	
~~PL-26a~~	~~Poland~~	~~Leafy brassica [3LFBC]~~	~~F~~	~~*Albugo* sp. [ALBUSP]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	~~Minor Use – Art 51~~	
~~PL-27~~	~~Poland~~	~~Leek [ALLPO]~~	~~F~~	~~*Peronospora destructor* [PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	~~Minor Use – Art 51~~	
~~PL-28~~	~~Poland~~	~~Leek [ALLPO]~~	~~F~~	~~*Phytophthora porri* [PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	~~-~~	
~~PL-29~~	~~Poland~~	~~Lettuce [LACSA]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Minor Use – Art 51 Max 2 app per year in same field~~	
~~PL-30~~	~~Poland~~	~~Mustard, red~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	~~Minor Use – Art 51~~	
~~PL-31~~	~~Poland~~	~~Onion [ALLCE]~~	~~F~~	~~*Phytophthora porri* [PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	~~Minor Use – Art 51~~	
~~PL-32~~	~~Poland~~	~~Onion [ALLCE]~~	~~F~~	~~*Peronospora destructor* [PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~		

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~~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 product / ha a) max. rate per appl. b) max. total rate per crop/season~~**	**~~g MFX/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~~**	**~~Water L/ha min / max~~**			
~~PL-33~~	~~Poland~~	~~Parsley [PARCR]~~	~~F~~	~~*Downy Mildew - Plasmopara umbelliferarum*~~ ~~[PLASCR]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Minor Use – Art 51~~ ~~Max 2 app per year in same field~~	
~~PL-37~~	~~Poland~~	~~Pe-tsai [BRSPK]~~	~~F~~	~~*Hyaloperonospora parasitica*~~ ~~[PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	~~Minor Use – Art 51~~	
~~PL-37a~~	~~Poland~~	~~Pe-tsai [BRSPK]~~	~~F~~	~~*Albugo* sp.~~ ~~[ALBUSP]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	~~Minor Use – Art 51~~	
~~PL-38~~	~~Poland~~	~~Purple-vein rocket [ERUVE]~~	~~F~~	~~*Bremia lactucae*~~ ~~[BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Minor Use – Art 51~~ ~~Max 2 app per year in same field~~	
~~PL-40~~	~~Poland~~	~~Savoy cabbage [BRSOS]~~	~~F~~	~~*Hyaloperonospora parasitica*~~ ~~[PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	~~Minor Use – Art 51~~	
~~PL-40a~~	~~Poland~~	~~Savoy cabbage [BRSOS]~~	~~F~~	~~*Albugo* sp.~~ ~~[ALBUSP]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	~~Minor Use – Art 51~~	
~~PL-41~~	~~Poland~~	~~Shallot [ALLAS]~~	~~F~~	~~*Phytophthora porri*~~ ~~[PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	~~Minor Use – Art 51~~	
~~PL-42~~	~~Poland~~	~~Shallot [ALLAS]~~	~~F~~	~~*Peronospora destructor*~~ ~~[PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	~~Minor Use – Art 51~~	
~~PL-43~~	~~Poland~~	~~Spinach [SPQOL]~~	~~F~~	~~*Peronospora farinosa f. sp. spinaciae*~~ ~~[PEROFS]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-600~~	~~10~~	~~Minor Use – Art 51~~	

~~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 product / ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g MFX/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~~	~~Water L/ha min / max~~			
~~PL-44~~	~~Poland~~	~~Spring, welsh and green onion [ALLFI]~~	~~F~~	~~*Peronospora destructor* [PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	~~Minor Use – Art 51~~	
~~PL-45~~	~~Poland~~	~~Spring, welsh and green onion [ALLFI]~~	~~F~~	~~*Phytophthora porri* [PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	~~-Minor Use – Art 51~~	
~~PL-46~~	~~Poland~~	~~Watercress [NAAOF]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Minor Use – Art 51 Max 2 app per year in same field~~	
~~SK-1~~	~~Slovakia~~	~~Baby leaves~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~SK-3~~	~~Slovakia~~	~~Broccoli [BRSOK]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	-	
~~SK-5~~	~~Slovakia~~	~~Brussels sprouts [BRSOF]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	-	
~~SK-7~~	~~Slovakia~~	~~Cauliflower [BRSOB]~~	~~F~~	~~*Hyaloperonospora parasitica* [PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	-	
~~SK-8~~	~~Slovakia~~	~~Chards and beet leaves [BEAVD]~~	~~F~~	~~*Peronospora farinosa f. sp. spinaciae* [PEROFS]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-600~~	~~10~~	-	
~~SK-9~~	~~Slovakia~~	~~Chives [ALLSC]~~	~~F~~	~~*Phytophthora porri* [PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	

~~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 product / ha a) max. rate per appl. b) max. total rate per crop/season~~	~~g MFX/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~~	~~Water L/ha~~ ~~min / max~~			
~~SK-10~~	~~Slovakia~~	~~Common purslane [POROL]~~	~~F~~	~~*Peronospora farinosa f. sp. spinaciae*~~ ~~[PEROFS]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-600~~	~~10~~	-	
~~SK-11~~	~~Slovakia~~	~~Cress [CRESS]~~	~~F~~	~~*Bremia lactucae*~~ ~~[BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~SK-13~~	~~Slovakia~~	~~Curly kale [BRSOC]~~	~~F~~	~~*Hyaloperonospora parasitica*~~ ~~[PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	-	
~~SK-14~~	~~Slovakia~~	~~Garlic [ALLSA]~~	~~F~~	~~*Phytophthora porri*~~ ~~[PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	-	
~~SK-15~~	~~Slovakia~~	~~Garlic [ALLSA]~~	~~F~~	~~*Peronospora destructor*~~ ~~[PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	-	
~~SK-17~~	~~Slovakia~~	~~Head cabbage [BRSOL]~~	~~F~~	~~*Hyaloperonospora parasitica*~~ ~~[PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	-	
~~SK-18~~	~~Slovakia~~	~~Herbs and edible flowers [NNNEF]~~	~~F~~	~~*Phytophthora/Downy mildew*~~ ~~[SCLPST]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	
~~SK-20~~	~~Slovakia~~	~~Kale [BRSOA]~~	~~F~~	~~*Hyaloperonospora parasitica*~~ ~~[PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~	-	
~~SK-22~~	~~Slovakia~~	~~Kale [BRSOA]~~	~~F~~	~~*Hyaloperonospora parasitica*~~ ~~[PEROPA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7-10~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~20~~		
~~SK-23~~	~~Slovakia~~	~~Leek [ALLPO]~~	~~F~~	~~*Peronospora destructor*~~ ~~[PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~		

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 product / ha a) max. rate per appl. b) max. total rate per crop/season	g MFX/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	Water L/ha min / max			
SK-24	Slovakia	Leek [ALLPO]	F	*Phytophthora porri* [PHYTPO]	Foliar	BBCH 12 – 48	a) 2 b) 2	12-14	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	14	-	
SK-25	Slovakia	Lettuce [LACSA]	F	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 – 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	
SK-26	Slovakia	Mustard, red	F	*Hyaloperonospora parasitica* [PEROPA]	Foliar	BBCH 12 – 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	20		
SK-27	Slovakia	Onion [ALLCE]	F	*Phytophthora porri* [PHYTPO]	Foliar	BBCH 12 – 48	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	14	-	
SK-28	Slovakia	Onion [ALLCE]	F	*Peronospora destructor* [PERODE]	Foliar	BBCH 12 – 48	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	14		
SK-29	Slovakia	Parsley [PARCR]	F	*Downy Mildew – Plasmopara umbelliferarum* [PLASCR]	Foliar	BBCH 12 – 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	
SK-33	Slovakia	Pe-tsai [BRSPK]	F	*Hyaloperonospora parasitica* [PEROPA]	Foliar	BBCH 12 – 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	20	-	
SK-35	Slovakia	Savoy cabbage [BRSOS]	F	*Hyaloperonospora parasitica* [PEROPA]	Foliar	BBCH 12 – 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	20		
SK-36	Slovakia	Shallot [ALLAS]	F	*Phytophthora porri* [PHYTPO]	Foliar	BBCH 12 – 48	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	14	-	
SK-37	Slovakia	Shallot [ALLAS]	F	*Peronospora destructor* [PERODE]	Foliar	BBCH 12 – 48	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	14	-	

~~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 product / ha a) max. rate per appl. b) max. total rate per crop/season**~~	~~**g MFX/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**~~	~~**Water L/ha min / max**~~			
~~SK-38~~	~~Slovakia~~	~~Spinach [SPQOL]~~	~~F~~	~~*Peronospora farinosa f. sp. spinaciae* [PEROFS]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-600~~	~~10~~	~~-~~	
~~SK-39~~	~~Slovakia~~	~~Spring, welsh and green onion [ALLFI]~~	~~F~~	~~*Peronospora destructor* [PERODE]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~		
~~SK-40~~	~~Slovakia~~	~~Spring, welsh and green onion [ALLFI]~~	~~F~~	~~*Phytophthora porri* [PHYTPO]~~	~~Foliar~~	~~BBCH 12 – 48~~	~~a) 2 b) 2~~	~~12-14~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~14~~	~~-~~	
~~SK-41~~	~~Slovakia~~	~~Watercress [NAAOF]~~	~~F~~	~~*Bremia lactucae* [BREMLA]~~	~~Foliar~~	~~BBCH 12 – 49~~	~~a) 2 b) 2~~	~~7~~	~~a) 0.5 b) 1~~	~~a) 87.2 b) 174.4~~	~~a) 15 b) 30~~	~~200-800~~	~~10~~	~~Max 2 app per year in same field~~	

Table 7.1-2: 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)]	**Conclusion**
					Method / Kind	**Timing / Growth stage of crop & season**	**Max. number a) per use b) per crop/ season**	**Min. interval between applications (days)**	**L product / ha a) max. rate per appl. b) max. total rate per crop/season**	**g MFX/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**	**Water L/ha** **min / max**			
AT-1	Austria	Baby leaves [251080]	F	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field.	A
AT-3	Austria	Broccoli [241010]	F	*Hyaloperonospora parasitica* [PEROPA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	21~~0~~		A
AT-5	Austria	Brussels sprouts [242010]	F	*Hyaloperonospora parasitica* [PEROPA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	21~~0~~		A
AT-7	Austria	Cauliflower [241020]	F	*Hyaloperonospora parasitica* [PEROPA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	21~~0~~		A
AT-8	Austria	Chards and beet leaves [252030]	F	*Hyaloperonospora parasitica* [PEROPA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-600	10		A
AT-9/ AT-15	Austria	Chicory / Endive [255000]	F	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field.	A
AT-10	Austria	Chives [0256020]	F	*Phytophthora porri* [PHYTPO]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field.	N
AT-11	Austria	Common purslane [252020]	F	*Peronospora farinosa f. sp. spinaciae* [PEROFS]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-600	10		A
AT-12	Austria	Cress [251040]	F	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in 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]	**Conclusion**
					Method / Kind	**Timing / Growth stage of crop & season**	**Max. number a) per use b) per crop/ season**	**Min. interval between applications (days)**	**L product / ha a) max. rate per appl. b) max. total rate per crop/season**	**g MFX/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**	**Water L/ha min / max**			
AT-16	Austria	Escarole [251030]	F	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field.	A
AT-17	Austria	Garlic [220010]	F	*Phytophthora porri* [PHYTPO]	Foliar	BBCH 12 - 48	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	14		A
AT-20	Austria	Head cabbage [242020]	F	*Hyaloperonospora parasitica* [PEROPA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	21		A
AT-21	Austria	Herbs and edible flowers [256000]	F	*Phytophthora/Downy mildew* [SCLPST]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field.	N except basil and edible flowers (0256080)
AT-23	Austria	Kale [243020]	F	*Hyaloperonospora parasitica* [PEROPA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	21		N
AT-24	Austria	Lamb's lettuce [251010]	F	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field.	A
AT-26	Austria	Leafy brassica [0243000]	F	*Hyaloperonospora parasitica* [PEROPA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	21		N
AT-27	Austria	Leek [270060]	F	*Peronospora destructor* [PERODE]	Foliar	BBCH 12 - 48	a) 2 b) 2	12-14	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	14		A
AT-29	Austria	Lettuce [251020]	F	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field.	A
AT-30	Austria	Mustard, red [251070]	F	*Hyaloperonospora parasitica* [PEROPA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	21		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 product / ha a) max. rate per appl. b) max. total rate per crop/season**	**g MFX/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**	**Water L/ha** **min / max**			
AT-31	Austria	Onion [220020]	F	*Phytophthora porri* [PHYTPO]	Foliar	BBCH 12 - 48	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	14		A
AT-33	Austria	Parsley [0256040]	F	*Downy Mildew - Plasmopara umbelliferarum* [PLASCR]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field.	N
AT-37	Austria	Pe-tsai [0243010]	F	*Hyaloperonospora parasitica* [PEROPA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	21~~0~~		N
AT-38	Austria	Purple-vein rocket [251060]	F	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field.	A
AT-40	Austria	Savoy cabbage [242020]	F	*Hyaloperonospora parasitica* [PEROPA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	21~~0~~		A
AT-41	Austria	Shallot [220030]	F	*Phytophthora porri* [PHYTPO]	Foliar	BBCH 12 - 48	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	14		A
AT-43	Austria	Spinach [252010]	F	*Peronospora farinosa f. sp. spinaciae* [PEROFS]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-600	10		A
AT-44	Austria	Spring, welsh and green onion [220040]	F	*Peronospora destructor* [PERODE]	Foliar	BBCH 12 - 48	a) 2 b) 2	12-14	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	14		A
AT-46	Austria	Watercress [254000]	F	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field.	N

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

Explanation for Column 15 "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 A23109A is composed of metalaxyl-M and oxathiapiprolin.

Table 7.1-3: Toxicological reference values for the dietary risk assessment of Metalaxyl-M, oxathiapiprolin,

Reference value	Source	Year	Value	Study relied upon	Safety factor
Metalaxyl-M					
ADI	EFSA	2015a	0.08 mg/kg bw/day	Overall NOAEL from dog studies	100
ARfD	EFSA	2015a	0.5 mg/kg bw	Rat developmental study	100
Oxathiapiprolin					
ADI	EFSA	2016	0.14 mg/kg bw/day	1 year dog study	100
ARfD	EFSA	2016	Not considered necessary	-	-

7.1.2.1 Summary for metalaxyl-M

Table 7.1-4: Summary for metalaxyl-M

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-17, AT-18, BE-14, BE-15, CZ-17, CZ-18, DE-17, DE-18, NL-13, NL-14, PL-17, PL-18, SK-14, SK-15*	Garlic [220010]	Yes	Yes (extrapolation from onion; 14 trials)	Yes	Yes	Yes	No	No
AT-31, AT-32, BE-25, BE-26, CZ-34, CZ-35, DE-31, DE-32, NL-24, NL-25, PL-31, PL-32, SK-27, SK-28*	Onion [220020]	Yes	Yes (14 trials)	Yes	Yes	Yes		No
AT-41, AT-42, BE-30, BE-31,	Shallots [220030]	Yes	Yes (extrapolation from onion; 14 trials)	Yes	Yes	Yes		No

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-44, CZ-45, DE-41, DE-42, NL-29, NL30, PL-41, PL-42, SK-36, SK-37*								
AT-44, AT-45, BE-33, BE-34, CZ-47, CZ-48, DE-44, DE-45, NL-32, NL-33, PL-44, PL-45, SK-39, SK-40*	Spring onion, Green onion, Welsh onion [220040]	Yes	Yes (extrapolation from leek; 8 trials)	Yes	Yes	Yes		No
AT-3, BE-3, CZ-3, DE-3, NL-3 PL-3, PL-3a SK-3*	Broccoli [241010]	Yes	Yes (4 trials on broccoli and 4 trials on cauliflower)	Yes	Yes	Yes		No
AT-7, BE-7, CZ-7, DE-7, NL-7, PL-7, PL-7a, SK7*	Broccoli [241010]	Yes	Yes (4 trials on broccoli and 4 trials on cauliflower)	Yes	Yes	Yes		No
AT-5, BE-5, CZ-5, DE-5, NL-5, PL-5, PL-5a, SK-5*	Brussels sprout [242010]	Yes	Yes (4 trials)	Yes	Yes	Yes		No
AT-20, BE-17, CZ-20, DE-20, NL-16, PL-20, PL-20a, SK-17*	Head cabbage [242020]	Yes	Yes (8 trials)	Yes	Yes	Yes		No
AT-40, CZ-43, DE-40, PL-40,	Savoy cabbage [242020]	Yes	Yes (extrapolation from head	Yes	Yes	Yes		No

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-40a, SK-35*			cabbage; 8 trials)					
~~AT-26, BE-21, CZ-29, DE-26, NL-20, PL-26, PL-26a*~~	~~Leafy brassicas [0243000]~~	~~Yes~~	~~Yes (extrapolation from lettuce; 8 trials)~~	~~Yes~~	~~Yes~~	~~Yes~~		
AT-37, BE-28, CZ-40, DE-37, NL-27, PL-37, PL-37a, SK-33	Pe-tsai [0243010]	Yes	Yes (extrapolation from kales; 4 trials)	Yes	Yes	No		No
AT-23, CZ-24, DE-23, PL-23, PL-23a, SK-20, SK-22 AT-14, BE-11, CZ-14, DE-14, NL-10, PL-14, PL-14a, SK-13*	Kale and curly kale [243020]	Yes	Yes (4 trials)	Yes	Yes	Yes		No
AT-24, BE-19, CZ-27, DE-24, NL-18, PL-24*	Lamb's lettuce [251010]	Yes	Yes (extrapolation from lettuce; 16 trials)	Yes	Yes	Yes		No
AT-29, BE-24, CZ-32, DE-29, NL-23, PL-29, SK-25 CZ-22*	Lettuce (open leaf) Iceberg lettuce [251020]	Yes	Yes (16 trials)	Yes	Yes	Yes		No
AT-16, BE-13, CZ-16, DE-16, NL-12, PL-16*	Escarole [251030]	Yes	Yes (extrapolation from lettuce; 16 trials)	Yes	Yes	Yes		No
AT-12, BE-9, CZ-12, DE-12,	Cress [251040]	Yes	Yes (extrapolation from lettuce; 16 trials)	Yes	Yes	Yes		No

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-12, SK-11*								
AT-38, BE-29, CZ-41, DE-38, NL-28, PL-38*	Rocket [251060]	Yes	Yes (extrapolation from lettuce; 16 trials)	Yes	Yes	Yes		No
AT-30, CZ-33, DE-30, PL-30, SK-26*	Red mustard [251070]	Yes	Yes (extrapolation from lettuce; 16 trials)	Yes	Yes	Yes		No
AT-1, BE-1, CZ-1, DE-1, NL-1, PL-1, SK-1	Baby leaf [251080]	Yes	Yes (extrapolation from lettuce; 16 trials)	Yes	Yes	Yes		No
AT-43, BE-32, CZ-46, DE-43, NL-31, PL-43, SK-38*	Spinach [252010]	Yes	Yes (extrapolation from lettuce; 16 trials)	Yes	Yes	Yes		No
AT-11, CZ-11, DE-11, PL-11, SK-10*	Common purslane [252020]	Yes	Yes (extrapolation from lettuce; 16 trials)	Yes	Yes	Yes		No
AT-8, CZ-8, DE-8, PL-8, SK-8*	Chards and beet leaves [252030]	Yes	Yes (extrapolation from lettuce; 16 trials)	Yes	Yes	Yes		No
AT-46, BE-35, CZ-49, DE-46, PL-46, SK-41*	Water cress [254000]	Yes	Yes (extrapolation from lettuce; 16 trials)	Yes	Yes	No		No
AT-9, CZ-9, DE-9, PL-9 AT-15, BE-12, CZ-15, DE-15, NL-11, PL-15*	Chicory / Endive [255000]	Yes	Yes (extrapolation from lettuce; 16 trials)	Yes	Yes	Yes		No

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-21, BE-18, CZ-21, DE-21, NL-17, PL-21, SK-18*	Herbs and edible flowers [256000]	Yes	Yes (extrapolation from lettuce; 16 trials)	Yes	Yes	Yes		No
AT-33, CZ-36, DE-33, PL-33, SK-29*	Parsley [0256040]	Yes	Yes (extrapolation from lettuce; 8 trials)	Yes	Yes	Yes		No
AT-10, CZ-10, DE-10, PL-10, SK-9*	Chives [0256020]	Yes	Yes (extrapolation from lettuce; 8 trials)	Yes	Yes	Yes		No
AT-27, AT-28, BE-22, BE-23, CZ-30, CZ-31, DE-27, DE-28, NL-21, NL-22, PL-27, PL-28, SK-23, SK-24*	Leek [270060]	Yes	Yes (8 trials)	Yes	Yes	Yes		No

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

Explanation for Column “MRL compliance”

A	Yes
N	No

The residues arising from the proposed uses: garlic, onion, shallots, spring onion, green onion, welsh onion, broccoli, brussels sprout, head cabbage, savoy cabbage, kale and curly kale, lamb’s lettuce, lettuce (open leaf), iceberg lettuce, escarole, cress, rocket, red mustard, baby leaf, spinach, common purslane, chards and beet leaves, chicory / endive, herbs and edible flowers, parsley, chives, leek except pe-tsai and watercress will not exceed the MRLs established for metalaxyl-M in Reg. (EU) 2017/1164. These uses are considered acceptable.

Considering the intended use on Chinese cabbage/pet-tsai and watercress, an exceedance of the MRLs for metalaxyl-M, as established in Reg. (EU) 2017/1164 is expected. Therefore until the new MRLs for Chinese cabbage/pet-tsai and watercress come into force, authorization of the GAP will not be possible.
The proposed uses on Chinese cabbage/pet-tsai and watercress are not considered acceptable.

The effects of processing on the nature of metalaxyl-M residues have been investigated. Data on effects of processing on the amount of residue have been submitted. Metalaxyl-M is hydrolytically stable under the representative processing conditions and the same residue definitions as for raw agricultural commodities apply.

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.

Considering 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.

No chronic and acute risk for the consumer is identified.

7.1.2.2 Summary for oxathiapiprolin

Table 7.1-5: 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?
AT-17, AT-18, BE-14, BE-15, CZ-17, CZ-18, DE-17, DE-18, NL-13, NL-14, PL-17, PL-18, SK-14, SK-15*	Garlic [220010]	Yes	Yes (extrapolation from onion; 8 trials)	Yes	Yes	Yes	No	Not relevant
AT-31, AT-32, BE-25, BE-26, CZ-34, CZ-35, DE-31, DE-32, NL-24, NL-25, PL-31, PL-32, SK-27, SK-28*	Onion [220020]	Yes	Yes (8 trials)	Yes	Yes	Yes		Not relevant
AT-41, AT-42, BE-30, BE-31, CZ-44, CZ-45, DE-41, DE-42, NL-29, NL30, PL-41, PL-42, SK-36, SK-37*	Shallots [220030]	Yes	Yes (extrapolation from onion; 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?
AT-44, AT-45, BE-33, BE-34, CZ-47, CZ-48, DE-44, DE-45, NL-32, NL-33, PL-44, PL-45, SK-39, SK-40*	Spring onion, Green onion, Welsh onion [220040]	Yes	Yes (extrapolation from leek; 8 trials)	Yes	Yes	Yes		Not relevant
AT-3, BE-3, CZ-3, DE-3, NL-3 PL-3, PL-3a SK-3*	Broccoli [241010]	Yes	Yes (4 trials on broccoli and 4 trials on cauliflower)	Yes	Yes	Yes		Not relevant
AT-7, BE-7, CZ-7, DE-7, NL-7, PL-7, PL-7a, SK7*	Cauliflower [241020]	Yes	Yes (4 trials on broccoli and 4 trials on cauliflower)	Yes	Yes	Yes		Not relevant
AT-5, BE-5, CZ-5, DE-5, NL-5, PL-5, PL-5a, SK-5*	Brussels sprout [242010]	Yes	Yes (4 trials)	Yes	Yes	Yes		Not relevant
AT-20, BE-17, CZ-20, DE-20, NL-16, PL-20, PL-20a, SK-17*	Head cabbage [242020]	Yes	Yes (8 trials)	Yes	Yes	Yes		Not relevant
AT-40, CZ-43, DE-40, PL-40, PL-40a, SK-35*	Savoy cabbage [242020]	Yes	Yes (extrapolation from head cabbage; 8 trials)	Yes	Yes	Yes		Not relevant
~~AT-26, BE-21, CZ-29, DE-26, NL-20, PL-26, PL-26a*~~	~~Leafy brassicas [0243000]~~	~~Yes/No~~	~~Yes/No (number of trials)~~	~~Yes/No~~	~~Yes/No~~	~~Yes/No~~		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-37, BE-28, CZ-40, DE-37, NL-27, PL-37, PL-37a, SK-33	Pe-tsai [0243010]	Yes	Yes (extrapolation from kales; 4 trials)	Yes	Yes	Yes		Not relevant
AT-23, CZ-24, DE-23, PL-23, PL-23a, SK-20, SK-22 AT-14, BE-11, CZ-14, DE-14, NL-10, PL-14, PL-14a, SK-13*	Kale and curly kale [243020]	Yes	Yes (4 trials)	Yes	Yes	No		Not relevant
AT-24, BE-19, CZ-27, DE-24, NL-18, PL-24*	Lamb's lettuce [251010]	Yes	Yes (extrapolation from lettuce; 8 trials)	Yes	Yes	Yes		Not relevant
AT-29, BE-24, CZ-32, DE-29, NL-23, PL-29, SK-25 CZ-22*	Lettuce (open leaf) Iceberg lettuce [251020]	Yes	Yes (8 trials)	Yes	Yes	Yes		Not relevant
AT-16, BE-13, CZ-16, DE-16, NL-12, PL-16*	Escarole [251030]	Yes	Yes (extrapolation from lettuce; 8 trials)	Yes	Yes	Yes		Not relevant
AT-12, BE-9, CZ-12, DE-12, PL-12, SK-11*	Cress [251040]	Yes	Yes (extrapolation from lettuce; 8 trials)	Yes	Yes	Yes		Not relevant
AT-38, BE-29, CZ-41, DE-38, NL-28, PL-38*	Rocket [251060]	Yes	Yes (extrapolation from lettuce; 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?
AT-30, CZ-33, DE-30, PL-30, SK-26*	Red mustard [251070]	Yes	Yes (extrapolation from lettuce; 8 trials)	Yes	Yes	Yes		Not relevant
AT-1, BE-1, CZ-1, DE-1, NL-1, PL-1, SK-1	Baby leaf [251080]	Yes	Yes (extrapolation from lettuce; 8 trials)	Yes	Yes	Yes		Not relevant
AT-43, BE-32, CZ-46, DE-43, NL-31, PL-43, SK-38*	Spinach [252010]	Yes	Yes (extrapolation from lettuce; 8 trials)	Yes	Yes	Yes		Not relevant
AT-11, CZ-11, DE-11, PL-11, SK-10*	Common purslane [252020]	Yes	Yes (extrapolation from lettuce; 8 trials)	Yes	Yes	Yes		Not relevant
AT-8, CZ-8, DE-8, PL-8, SK-8*	Chards and beet leaves [252030]	Yes	Yes (extrapolation from lettuce; 8 trials)	Yes	Yes	Yes		Not relevant
AT-46, BE-35, CZ-49, DE-46, PL-46, SK-41*	Water cress [254000]	Yes	Yes (extrapolation from lettuce; 8 trials)	Yes	Yes	No		Not relevant
AT-9, CZ-9, DE-9, PL-9 AT-15, BE-12, CZ-15, DE-15, NL-11, PL-15*	Chicory / Endive [255000]	Yes	Yes (extrapolation from lettuce; 8 trials)	Yes	Yes	Yes		Not relevant
AT-21, BE-18, CZ-21, DE-21, NL-17, PL-21, SK-18*	Herbs and edible flowers [256000]	Yes	Yes (extrapolation from lettuce; 8 trials)	Yes	Yes	No for herbs and edible flowers [256000] Yes for basil and edible flowers [0256080]		Not relevant
AT-33, CZ-36,	Parsley [0256040]	Yes	Yes (extrapolation	Yes	Yes	No		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?
DE-33, PL-33, SK-29*			from lettuce; 8 trials)					
AT-10, CZ-10, DE-10, PL-10, SK-9*	Chives [0256020]	Yes	Yes (extrapolation from lettuce; 8 trials)	Yes	Yes	No		Not relevant
AT-27, AT-28, BE-22, BE-23, CZ-30, CZ-31, DE-27, DE-28, NL-21, NL-22, PL-27, PL-28, SK-23, SK-24*	Leek [270060]	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

Explanation for Column "MRL compliance"

A	Yes
N	No

The residues arising from the following proposed uses: garlic, onion, shallots, spring onion, green onion, welsh onion, broccoli, brussels sprout, head cabbage, savoy cabbage, Chinese cabbage/pet-tsai, lamb's lettuce, lettuce (open leaf), iceberg lettuce, escarole, cress, rocket, red mustard, baby leaf, spinach, common purslane, chards and beet leaves, chicory / endive, leek, basil and edible flowers (0256080) will not exceed the MRLs established for oxathiapiprolin in Reg. (EU) 2023/163. These uses are considered acceptable.

Considering the intended uses on kale and curly kale, herbs and edible flowers (0256000) except basil and edible flowers (0256080), chives, parsley and watercress, an exceedance of the MRLs for oxathiapiprolin, as established in Reg. (EU) 2023/163 is expected. Therefore until the new MRLs for these crops come into force, authorization of the GAP will not be possible.
The proposed uses on kale and curly kale, herbs and edible flowers (0256000) except basil and edible flowers (0256080), chives, parsley and watercress are not considered acceptable.

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 A23109A

Table 7.1-6: Information on A23109A (KCA 6.8)

Crop	PHI for A23109A proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for A23109A proposed by zRMS	zRMS Comments (if different PHI proposed)
		Metalaxyl-M	Oxathiapiprolin		
Garlic [220010]	14 days	Yes	Yes	14 days	-
Onion [220020]	14 days	Yes	Yes	14 days	-
Shallots [220030]	14 days	Yes	Yes	14 days	-
Spring onion, Green onion, Welsh onion [220040]	14 days	Yes	Yes	14 days	-
Broccoli [241010]	20 days	Yes	Yes	21~~0~~ days	***
Cauliflower [241020]	20 days	Yes	Yes	21~~0~~ days	***
Brussels sprout - [242010]	20 days	Yes	Yes	21~~0~~ days	***
Head cabbage [242020]	20 days	Yes	Yes	21~~0~~ days	***
Savoy cabbage [242020]	20 days	Yes	Yes	21~~0~~days	***
Leafy brassicas [0243000]	20 days	Yes	Yes	21~~0~~ days	***
Pe-tsai [0243010]	20 days	Yes	Yes	21~~0~~ days	***
Kale and curly kale [243020]	20 days	Yes	Yes	21~~0~~ days	***
Lamb's lettuce [251010]	10 days	Yes	Yes	10 days	-
Lettuce (open leaf) Iceberg lettuce [251020]	10 days	Yes	Yes	10 days	-

Crop	PHI for A23109A proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for A23109A proposed by zRMS	zRMS Comments (if different PHI proposed)
		Metalaxyl-M	Oxathiapiprolin		
Escarole [251030]	10 days	Yes	Yes	10 days	-
Cress [251040]	10 days	Yes	Yes	10 days	-
Rocket [251060]	10 days	Yes	Yes	10 days	-
Red mustard [251070]	~~10~~ 20 days	Yes	Yes	~~10~~ 21 days	***
Baby leaf [251080]	10 days	Yes	Yes	10 days	-
Spinach [252010]	10 days	Yes	Yes	10 days	-
Common purslane [252020]	10 days	Yes	Yes	10 days	-
Chards and beet leaves [252030]	10 days	Yes	Yes	10 days	-
Water cress [254000]	10 days	Yes	Yes	10 days	-
Chicory / Endive [255000]	10 days	Yes	Yes	10 days	-
Herbs and edible flowers [256000]	10 days	Yes	Yes	10 days	-
Parsley [0256040]	10 days	Yes	Yes	10 days	-
Chives [0256020]	10 days	Yes	Yes	10 days	-
Leek [270060]	14 days	Yes	Yes	14 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).
*** PHI of 21 days instead of 20 days is complying with the pre-harvest interval classes defined in the SANCO 7039/VI/95, 22/7/1997

Table 7.1-7: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops			Overall waiting period proposed by zRMS for A23109A
Crop group	**Led by metalaxyl-M**	**Led by oxathiapiprolin**	
All crops	Not required	Not required	There is no required waiting period before planting succeeding crops.

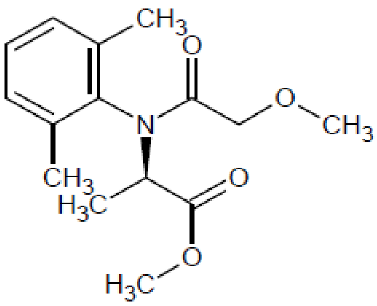
NR: not relevant

Assessment
This submission document provides data to support the review of the registration of the foliar application product A23109A in Europe.
This submission document provides data to support the review of the registration of the foliar application product A23109A in UK.

7.2 Metalaxyl-M

General data on metalaxyl-M are summarized in the table below

Table 7.2-1: General information on metalaxyl-M

Active substance (ISO Common Name)	Metalaxyl-M (ISO-approved); Code CGA329351
IUPAC	Methyl N-(methoxyacetyl)-N-(2,6-xylyl)-D-alaninate or Methyl (R)-2-{[(2,6-dimethylphenyl)methoxyacetyl] amino}-propionate
Chemical structure	
Molecular formula	$C_{15}H_{21}NO_4$
Molar mass	279.3 g/mol
Chemical group	Phenylamide compound
Mode of action (if available)	Selective interference with the synthesis of ribosomal RNA
Systemic	Yes
Company (ies)	Syngenta*
Rapporteur Member State (RMS)	Belgium
Approval status	Approved Date of 01/06/2020 Commission Implementing Regulation (EU) 2020/617
Restriction	N/A
Review Report	SANTE/11112/2019 Rev 5, 24 March 2020
Current MRL regulation	Regulation (EU) No 2017/1164
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes (EFSA, 2015)
Current MRL applications on intended uses	Yes (EFSA, 2011, 2014, 2015a)

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

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

New stability studies have been submitted by the applicant in the framework of this application. Results are summarised in the table below. The detailed assessment of this study is presented in Appendix 2.

Table 7.2-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Commodity category	Commodity	Acceptable maximum storage period	Report Reference	Source
EU reviewed data				
Plant products				
High water content	Tomato fruit	24 months	201/01	Belgium, 2013
	Tomato paste	32 months	119-96	Belgium, 2013
High oil content	Rapeseed	24 months	201/01	Belgium, 2013
	Soybean	32 months	119-96	Belgium, 2013
	Soybean oil	32 months	119-96	Belgium, 2013
High Starch Content	Potato tuber	24 months	201/01	Belgium, 2013
	Wheat grain	24 months	201/01	Belgium, 2013
	Maize grain	32 months	119-96	Belgium, 2013
	Maize meal	32 months	119-96	Belgium, 2013
	Soybean meal	32 months	119-96	Belgium, 2013
	Soybean hulls	32 months	119-96	Belgium, 2013
Animal Products				
Meat	Ruminant	21 months	ABR-98053	Belgium, 2013
Liver	Ruminant	21 months	ABR-98053	Belgium, 2013
Milk	Ruminant	21 months	ABR-98053	Belgium, 2013
Eggs	Poultry	21 months	ABR-98053	Belgium, 2013
New data				
Plant products				
High starch content	Wheat grain	24 months	RNB19-00020	Baumy G., 2022
High water content	Lettuce	24 months	RNB19-00020	Baumy G., 2022
High oil content	Oilseed rape seed	24 months	RNB19-00020	Baumy G., 2022
High acid content	Orange whole fruit	24 months	RNB19-00020	Baumy G., 2022
Animal Products				
Honey	Bee	51 days	S20-03602	Knäbe, 2021

Summary of stability of residues during storage studies reported in the EU

Reference: Belgium, 2013

The potential for degradation of residues during storage has been previously assessed in the framework of the Annex I renewal for metalaxyl-M. Storage stability of metalaxyl-M was demonstrated for the following periods in the plant and animal commodities listed in the table below when frozen (approximately -20°C).

New data

Storage stability of metalaxyl-M was demonstrated for 24 months in high water content, high oil content high acid content and high starch content crop groups when frozen (approximately -20°C). It has also been demonstrated in honey for 51 days when frozen (approximately -20°C).

Conclusion on stability of residues during storage
The storage stability of metalaxyl-M has been investigated in crops from the high water content, high oil content, high acid content and high starch content crop groups, and in animal products (muscle, liver, milk, eggs and honey). 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
Procedural recoveries obtained during residue analysis demonstrate the stability of residues of metalaxyl-M in sample extracts and fully support the residue data presented in the submission.

Conclusion on stability of residues in sample extracts
Sufficient stability has been demonstrated to support the residue data presented in the submission.

zRMS comments:
In EFSA Journal 2015;13(3):3999 it is stated that *Residues of metalaxyl-M are stable during deep frozen storage (-20°C) for at least 24 months in commodities of plant origin from all four crop matrix categories. The ratio of the R- and S-enantiomers was constant over the storage period.*
Total residues (determined as 2,6-dimethylaniline) of metalaxyl-M and CGA62826 appeared stable in muscle, liver, milk and eggs when stored at approximately –20°C for at least 21 months. In accordance with SANCO 7032/VI/95 rev.5 and OECD Technical Guideline 506 (2007), stability under those storage conditions can also be assumed for kidney and fat, although no storage stability testing was performed on these matrices.

Additionally the Applicant submitted a new studies on storage stability of metalaxyl-M in plant products (wheat grain, lettuce, oilseed rape seed and orange whole fruit; Baumy G., 2022) and in honey (Knäbe, 2021).
Storage stability of metalaxyl-M was demonstrated for a period of 24 months at -20°C in commodities with high water, oil, starch and high acid content commodities.
Metalaxyl-M has been shown to be stable in honey for 51 days when stored frozen at -18ºC.

Procedural recoveries obtained during residue analysis demonstrate the stability of residues of metalaxyl-M in sample extracts.

The residue data are valid with regard to storage stability.

The stability of residues during storage of metalaxyl-M in plants and animal products is sufficiently addressed to support the proposed uses of the product A23109A / Orondis VIP. No additional study is 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
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)[(b)]	No	Sampling (DAT)		
EU reviewed data								
Fruits and fruiting vegetables	Tomato	[phenyl-U-^{14}C]-Metalaxyl-M	Foliar, G	160 g a.s./ha	3	Foliage, immature fruit, mature fruit: 3, 14	026135-1	Belgium, 2013

Crop Group	Crop	Label position	Application and sampling details				Report Reference	Source
			Method, F or G[(a)]	**Rate (kg a.s./ha)[(b)]**	**No**	**Sampling (DAT)**		
	Grape	[phenyl-U-^{14}C]-metalaxyl[(c)]	Foliar, G	50 g a.s./hL	7	Fruit: 52	11/78 06/79	Belgium, 1999
Leafy vegetables	Lettuce	[phenyl-U-^{14}C]-Metalaxyl-M [phenyl-U-^{14}C]-metalaxyl[(c)]	Foliar, F	200 g a.s./ha	3	Leaves: 0 (1 hour after application), 14, 21	98JS30	Belgium, 1999
		[phenyl-U-^{14}C]-metalaxyl[(c)]	Foliar, G	250 g a.s./ha	2	Plants: 14	38/79 38/80	Belgium, 1999
	Tobacco	[phenyl-U-^{14}C]-metalaxyl[(c)]	Soil treatment at trans-planting, G	280 g a.s./ha	1	Leaves: at regular intervals 3-20 weeks after transplanting	ABR-78036 ABR-78044 ABR-79008	Belgium, 1999
				560 g a.s./ha	1			
		[phenyl-U-^{14}C]-metalaxyl[(c)]	Pre-planting soil incorporated, G	3530 g a.s./ha	1	Leaves: 5, 9, 13, 16 weeks after transplanting	ABR-79100	Belgium, 1999
Root and tuber vegetables	Potato	[phenyl-U-^{14}C]-metalaxyl[(c)]	Foliar, F	~~62.5~~ 200 g a.s./ha	~~4~~ 5	Leaves, stalks, roots, tubers: ~~47~~ 37	30/77 39/79	Belgium, 1999
		[phenyl-U-^{14}C]-metalaxyl[(c)]	Foliar, F	426 g a.s./ha (total rate)	6	Mature tubers and foliage: 7	ABR-81037	Belgium, 1999
				1280 g a.s./ha (total rate)	6			
Pulses and oilseeds	Sunflower	Formulated metalaxyl and Metalaxyl-M (unlabelled)	Seed treatment, G	-[(d)]	1	Leaves: at 3-10 day intervals from 7 to 85	J. Agric. Food Chem. 2002, 50, 5373-5377[(d)]	Belgium, 1999
Cereals	Spring wheat	[phenyl-U-^{14}C]-Metalaxyl-M	Seed treatment, F	19.3 g a.s./100 kg seed (=32.2 g a.s./ha)	1	Forage: 83 (BBCH 45-49) Grain and straw: 127 (BBCH 99)	02JS38	Belgium, 2013
				157 g a.s./100 kg seed (=268 g a.s./ha)	1			
		[phenyl-U-^{14}C]-metalaxyl[(c)]	Seed treatment, F	17.8 g a.s./100 kg seed (=26.7 g a.s./ha)	1	Forage: 83 (BBCH 45-49) Grain and straw: 127 (BBCH 99)	02JS37	Belgium, 2013
				156 g a.s./100 kg seed (=234 g a.s./ha)	1			

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

(b): Rate for each individual application unless stated.
(c): Supporting studies only.
(d): Zadra C., Marucchini C. and Zazzerini A. 2002. Behaviour of Metalaxyl and its Pure R - Enantiomer in Sunflower Plants (Helianthus Annus), J. Agric. Food Chem. 2002, 50, 5373-5377. Treatment rate not specified.

Summary of plant metabolism studies reported in the EU
Reference: Belgium, 2013
"In plants metalaxyl undergoes an important degradation into more than 8 identifiable metabolites. At harvest the parent compound accounted for 64% of the TRR in grapes, approximately 20% in lettuce, and only 3 % of the TRR in potato leaves. Metabolite CGA94689, free and conjugated, accounted for 20% of the TRR in grapes, and 25% in lettuce. In potato leaves CGA108905 was found at 48% of the TRR. All other metabolites were below the trigger value of 10% of the TRR.
A comparative investigation of the metabolism of metalaxyl-M (R-enantiomer) and metalaxyl (racemic mixture) in lettuce showed a qualitatively similar metabolic pattern. Enantiomeric ratio measurements did not show clear differences in degradation rates for both enantiomers. However, comparative experiments reported in a scientific publication (Zadra et al., 2002) revealed a faster degradation of the S-enantiomer compared to the R-enantiomer in sunflower leaves (enantiomeric ratio R/S varied between 0.49 and 4.80), which indicates an enantioselective preference of biotransformation systems in plants. However, it was confirmed that interconversion between enantiomers does not occur in plants and therefore, this information has no real impact on the risk assessment of metalaxyl-M (i.e. R-enantiomer only).
In tomatoes, parent metalaxyl-M was the principal component of the residue in fruit (>76 % TRR) and foliage (>52% TRR), with a more significant metabolism of metalaxyl-M observed in tomato foliage. A new minor plant metabolite was identified (SYN546555), which however does not seem to be indicative of any particular new degradation pathway. Metabolism in wheat following seed treatment was shown to be very extensive, with parent metalaxyl-M not or barely found (max.1.2% TRR in straw). The major identified metabolites in forage, grain and straw were CGA108906, SYN530281, CGA108905 and CGA94689 (free and conjugated to sugar). However, the new plant metabolite identified (SYN530281) does not seem to be indicative of any particular new degradation pathway. In both studies, parent metalaxyl-M maintained its stereochemical integrity (R), which confirms that racemisation of the parent metalaxyl-M is unlikely to occur in plants".

Conclusion on metabolism in primary crops
The metabolism of metalaxyl-M in plants following foliar, soil and seed treatment applications is sufficiently addressed to support the proposed uses of the product A23109A.

Evaluator comments:
In the EFSA Journal 2015;13(3):3999 it is satetd that *Primary crop metabolism of metalaxyl was investigated following foliar application on tomatoes and lettuce or as a seed treatment to cereals, hereby covering three different crop groups. The metabolism data on metalaxyl can also be applied to metalaxyl-M. Metabolic patterns in the different studies were shown to be similar and the relevant residue for enforcement and risk assessment in all plant commodities could be defined as metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers).*
The metabolism of metalaxyl-M in plants following foliar treatment applications is sufficiently addressed to support the proposed uses of the product A23109A / Orondis VIP. No additional study is required.

Plant residue definition for monitoring:
Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers) - EFSA, 2015;
Metalaxyl and metalaxyl-M (metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)) – Reg. (EU) 2017/1164;
Plant residue definition for risk assessment:
Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers) – EFSA, 2015

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

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

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

Crop group	Crop	Label position	Application and sampling details				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	[phenyl-U-^{14}C]-metalaxyl	Foliar, F[(a)]	6 x 450	245	Leaves: 357, 378, 392	ABR-78013 ABR-78078	Belgium, 1999
		[phenyl-U-^{14}C]-metalaxyl	Soil treatment, G[(a)]	1 x 3360	232	Whole plant: 261 (50% maturity), 292 (100% maturity)	ABR-91084	Belgium, 1999
		[phenyl-U-^{14}C]-Metalaxyl-M	Soil treatment, G[(a)]	1 x 616-626	30, 120, 270	Whole plant: BBCH 41-43 and maturity (BBCH 49)	026134-1	Belgium, 2013
Root and tuber vegetables	Sugar beet	[phenyl-U-^{14}C]-metalaxyl	Foliar, F[(a)]	6 x 450	245	Whole plant: 357, 378 Tops and roots: 420, 455	ABR-78013 ABR-79005	Belgium, 1999
		[phenyl-U-^{14}C]-metalaxyl	Soil treatment, G[(a)]	1 x 3360	232	Whole plant: 271 (25% maturity). Tops and roots: 307 (50% maturity), 411 (100% maturity)	ABR-91084	Belgium, 1999
	Radish	[phenyl-U-^{14}C]-Metalaxyl-M	Soil treatment, G[(a)]	1 x 616-626	30, 120, 270	Tops and roots: maturity (BBCH 49)	026134-1	Belgium, 2013
Pulses and oilseeds	Soybean	[phenyl-U-^{14}C]-metalaxyl	Foliar, F[(a)]	6 x 450	266	Whole plant: 378, 406, 427 Leaves, stems, beans: 476	ABR-78013 ABR-79003	Belgium, 1999
		[phenyl-U-^{14}C]-metalaxyl	Soil treatment, G[(a)]	1 x 3360	232	Stalks: 261 (25% maturity), 292 (50% maturity), 432 (100% maturity) Pods and beans: 432 (100% maturity)	ABR-91084	Belgium, 1999
Cereals	Wheat	[phenyl-U-^{14}C]-metalaxyl	Foliar, F[(a)]	6 x 450	14	Whole plant: 119, 329, 357 Grain, straw: 385	ABR-78013 ABR-78077	Belgium, 1999
		[phenyl-U-^{14}C]-metalaxyl	Soil treatment, G[(a)]	1 x 3360	232	Stalks: 254 (25% maturity), 279 (50% maturity), 323 (100% maturity) Grain and hulls: 323 (100% maturity)	ABR-91084 A1	Belgium, 1999
		[phenyl-U-^{14}C]-Metalaxyl-M	Soil treatment, G[(a)]	1 x 624-628 g	30, 120, 270	Whole plant: BBCH 20-30 and BBCH 61-85 Grain and straw: maturity (BBCH 89)	026134-1	Belgium, 2013
	Oat	[phenyl-U-^{14}C]-metalaxyl	Foliar, F[(a)]	6 x 450	245	Whole plant: 343, 364, 392 Grain, straw: 413	ABR-78013 ABR-79002	Belgium, 1999

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)		
	Maize	[phenyl-U-^{14}C]-metalaxyl	Foliar, F[(a)]	6 x 450	259	Whole plant: 364, 392, 427 Grain, cobs, stalks: 427	ABR-78013 ABR-79004	Belgium, 1999

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

Summary of metabolism studies in rotational crops reported in the EU

Reference: Belgium, 2013

"In the initial DAR, a rotational crop metabolism study investigating the residues in crops planted after tobacco grown on treated soil (3.36 kg [^{14}C]-metalaxyl/ha) was evaluated. Residues were detected at harvest, but the application rate was very high and not representative of EU conditions for lettuce, soyabean and sugar beet. On the other hand, only a plant-back interval (PBI) of 232 days was investigated. Metabolites were identified in wheat stalks, immature lettuce and sugar beet root, but were not characterised in soybean and wheat grain. On the basis of the metabolite identification achieved in that study, it was concluded that the metabolic pathway of metalaxyl in rotational crops is similar to that in primary crops, but with a greater proportion of sugar conjugates.

Some metabolites identified in rotational crops were not identified in any primary crop metabolism study, i.e. CGA67868, CGA79353, NOA402794 (=B1/B2=P1/P2) and CGA119857. However, these metabolites do not seem to be indicative of any particular degradation pathway and seem to be produced by a combination of processes already identified in the primary metabolism studies and as consequence of metabolism proceeding further than in primary crops:

CGA67868 is probably an intermediate metabolite, i.e. the methyl ether variant/precursor of alcohol metabolite CGA37734 (i.e. metabolite identified in primary and rotational crops, as well as in rat, goat and hen);

CGA79353: presumably formed by oxidation of CGA67869 (i.e. metabolite identified in rat, goat, and hen); CGA79353 was also identified in rat urine and faeces;

NOA402794: presumably formed by hydrolysis of SYN530281 (i.e. metabolite identified in primary crop as well as in rat and hen); NOA402794 was also identified in hen;

CGA119857: presumably formed by hydrolysis of CGA100255 (i.e. metabolite identified in primary and rotational crops, as well as in rat and goat).

In the RAR (2013), a new confined rotational crop study was evaluated, in which rotational crops (lettuce, radish and wheat) were grown in soil 30, 120 and 270 days after single application of [^{14}C]-Metalaxyl-M to bare soil at 616 – 628 g a.s./ha. The parent compound metalaxyl-M was extensively metabolised and was a minor residue in rotational crops at 30 PBI and more significant at 120 PBI. Significant metabolites observed included CGA94689, CGA62826, CGA37734, SYN546555 and CGA100255, and these metabolites were primarily present as (glucose) conjugates. The results of the new study are consistent with the metabolic pathway that was proposed on the basis of the previous rotational crop metabolism study and support the conclusion that the metabolic profile in rotational crops is qualitatively the same as that in primary crops. Therefore, the same residue definition as for primary crops is deemed appropriate".

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.

Evaluator comments:

In the EFSA Journal 2015;13(3):3999 it is satetd that *Confined rotational crop studies investigating the uptake of residues in lettuce, sugar beet, radish, and wheat were also reported. The metabolic pathway of metalaxyl in rotational crops is similar to that in primary crops but with a greater proportion of sugar conjugates, and it was concluded to apply the same residue definition for rotational crops as for primary crops. Based on the rotational crop studies, significant residues in rotational crops are not expected.*

Metabolism in primary and rotational crops was found to be similar. Therefore, a specific residue definition for rotational crops is not deemed necessary. No additional study is required.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

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

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

Conditions	Identified compound(s) (%)	Report reference	Source
EU reviewed data			
Pasteurisation (20 minutes, 90°C, pH 4)	Metalaxyl-M (98.6)	00DA05	Belgium, 2001; 2014
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Metalaxyl-M (100.6)		
Sterilisation (20 minutes, 120°C, pH 6)	Metalaxyl-M (99.3)		

Summary of high temperature studies reported in the EU
Reference: Belgium, 2001
The effect of processing on the nature of metalaxyl-M 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).

Conclusion on nature of residues in processed commodities
The nature of residues of metalaxyl-M in processed products has been investigated. Metalaxyl-M is hydrolytically stable under the representative processing conditions and the same residue definitions as for raw agricultural commodities apply.

Evaluator comments:
Information given by the Applicant is sufficient.
According to the EFSA Journal 2015;13(3):3999 *In processed commodities, metalaxyl-M was shown to be stable during pasteurisation, baking/boiling/brewing and sterilisation.*

Metalaxyl-M is stable under hydrolytic conditions representative for industrial processing. No further data are required.

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 - EFSA Journal 2015;13(3):3999	
Plant groups covered	~~Fruit crops (tomato, grape), Leafy crops (lettuce), Root & tuber vegetables (potato) – foliar treatment~~ ~~Leafy crops (tobacco) – soil treatment~~ ~~Cereals (wheat), Pulses/oilseeds (sunflower) – seed treatment~~ - foliar treatment: leafy vegetable (lettuce), fruits and fruiting vegetables (tomatoes); - seed treatment: cereal (wheat)
Rotational crops covered	~~Leafy crops (lettuce), Root & tuber vegetables (radish, sugar beet), Pulses/oilseeds (soybean), Cereals (wheat, oat, maize) – application to bare soil or foliar treatment~~ leafy vegetable (lettuce), root crop (radish, sugar beet root), cereal (wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	~~Metalaxyl-M is stable under standard hydrolysis conditions~~ Metalaxyl-M is stable under hydrolytic conditions representative for industrial processing, i.e. - pasteurisation (20 minutes at 90°C, pH 4); - boiling/brewing/baking (60 minutes at 100°C, pH 5); - sterilisation (20 minutes at 120°C, pH 6)
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers) (Regulation (EC) No ~~36/2014~~ 2017/1164; EFSA, 2015a)
Plant residue definition for risk assessment	Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers) (EFSA, 2015a)
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

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	[phenyl-U-^{14}C]-metalaxyl	2	3.9 (76.9 mg/kg diet)	4	Milk	Twice daily	ABR-90078 ABR-91075 BIOL-89010	Belgium, 1999
						Urine and faeces	Daily		
						Tissues	After sacrifice (6 hours after last dose)		
		[phenyl-U-^{14}C]-metalaxyl	1	0.14 (7.0 mg/kg diet)	10	Milk	Daily	ABR-78046 BIOL-78002	Belgium, 2013
						Urine and faeces	Daily		
						Blood	Every two days		

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		
						Tissues	After sacrifice (24 hours after last dose)		
Laying poultry	Hen	[phenyl-U-^{14}C]-metalaxyl	5	6 (100 mg/kg diet)	4	Eggs	Daily	ABR-90077 ABR-91077 BIOL-89005 BIOL-91011	Belgium, 1999

Summary of animal metabolism studies reported in the EU

Reference: Belgium, 2014

"The presence of many metabolites and the low levels of parent metalaxyl indicate extensive metabolism involving the processes of oxidation and demethylation of the parent compound. Further conjugation also occurs to form sulphate conjugates, fatty acid conjugates, amino acid conjugates or glucuronic acid conjugates. In goats, CGA107955 was the only identified compound representing >10% of the TRR in all of the goat tissues (13.5% in liver, 31.5% in kidney, 29.6% in fat, 18.4% in muscle). Other metabolites found at >10% TRR were CGA94689 (34.2%TRR in kidney), CGA67869 (13.3%TRR in fat) and CGA62826 (10.9% in muscle). In milk, conjugates of metabolite CGA67869 (with fatty acids and glucuronic acid) represented the majority (68%) of the total residues and no other major metabolites were found. Also in laying hens, CGA107955 (free and to a great extent conjugated) was a major metabolite (40.3 % TRR in fat, 17.1% in liver, 14.5% in egg yolk, 11% in gizzard), but was not found in hen muscle. Metabolite isomers P1 and P2 (free and/or conjugated with fatty acids) were major in eggs (up to 31% TRR in egg white), muscle (37.3% TRR) and fat (34% TRR) and probably also in other tissues. Furthermore, there were indications of bound or physically entrapped residues (a.o. in liver and milk), requiring a sample treatment with collagenase and/or protease for efficient extraction of the residues.

The metabolic pattern identified for goats and hens is substantially the same, with probably a faster metabolic rate in hen and is consistent with the rat metabolism. Therefore, the findings in ruminants can be extrapolated to pig. No livestock metabolism studies conducted with metalaxyl-M are available. However, comparative metabolism studies in rat showed that metalaxyl (racemic mixture of R and S enantiomers) and metalaxyl-M (R enantiomer) are metabolised at different rates but along the same routes. Moreover, it is reasonable to assume that, if any metalaxyl-M specific metabolites were formed, they would have been apparent in the available livestock studies, which were conducted with metalaxyl at high dose rates (compared to max. dietary burden) and which thus also implied considerable livestock intake of metalaxyl-M (included in the racemic metalaxyl)".

Conclusion on metabolism in livestock

The metabolism of metalaxyl-M in livestock is sufficiently addressed to support the proposed uses of the product A23109A.

Evaluator comments:

The metabolism of metalaxyl-M in livestock is sufficiently addressed to support the proposed uses of the product A23109A / Orondis VIP. No additional study is required.

According to the EFSA Journal 2015;13(3):3999:
Animal residue definition for monitoring: Not required for the representative uses;
Animal residue definition for risk assessment: Not required for the representative uses.
In the EFSA Journal 2015;13(4):4076 it is stated that *The metabolism of metalaxyl in livestock was evaluated and the relevant residue for enforcement and risk assessment in all commodities of animal origin is defined as the sum of metalaxyl (sum of isomers) and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metalaxyl. For enforcement purposes, the residue might be simplified to metabolie CGA 107955 in animal tissues*

and metabolite CGA 67869 in milk, but analytical methods and livestock feeding studies supporting such a simplified residue definition are currently not available. No additional study is required.

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 (EFSA, 2015a)
Time needed to reach a plateau concentration	Milk: plateau reached immediately (feeding study duration 28 days) Eggs: possible that plateau had not been reached (residues continuously increasing along 4 days of dosing) (EFSA, 2015a)
Animal residue definition for monitoring	~~Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers) and its metabolites containing the 2, 6-dimethylaniline moiety expressed as metalaxyl. (EFSA, 2015b)~~ Sum of metalaxyl (sum of isomers) and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metalaxyl (Regulation (EU) 2017/1164; EFSA, 2015b) Not required for the representative uses (EFSA, 2015a)
Animal residue definition for risk assessment	~~Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers) and its metabolites containing the 2, 6-dimethylaniline moiety expressed as metalaxyl. (EFSA, 2015b)~~ Sum of metalaxyl (sum of isomers) and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metalaxyl (EFSA, 2015b) Not required for the representative uses (EFSA 2015a)
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 residue have been submitted by the applicant in the framework of this application. These studies are summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2.

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of A23109A and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[(a)]	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) [(b)]	MRL compliance
Flowering brassica (Broccoli, cauliflower)	**Intended GAP**	**N-EU**	2 x 87.2 g as/ha, 7d int, PHI 20d					
	New trials	N-EU	Broccoli Trials GAP: 2 x 90 g as/ha, PHI 20d <0.01, 0.0107, 0.0238, 0.0239					
	New trials	N-EU	Cauliflower Trials GAP: 2 x 77.6 g as/ha, PHI 14d 2 x <0.01, 2x 0.01					
	Overall supporting data for intended cGAP	N-EU	3x <0.01, 2 x 0.01, 0.0107, 0.0238, 0.0239	0.010	0.024	0.039	0.2	Yes
Kale → extrapolated to Chinese cabbage,	**Intended GAP**	**N-EU**	2 x 87.2 g as/ha, 7d int, PHI 20d					
	New trials	N-EU	Trials GAP: 2 x 90 g as/ha, PHI 20d <0.01, 0.03, 0.04, 0.08					

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[(a)]	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) [(b)]	MRL compliance
leafy brassicas and curly kale	Overall supporting data for intended cGAP	N-EU	<0.01, 0.03, 0.04, 0.08	0.035	0.08	0.158	Kale : 0.3 pe-tsai /Chinese cabbage : 0.02*	Yes for curly kale No for pe-tsai /Chinese cabbage An MRL application for pe-tsai/Chinese cabbage has been submitted to France on 31/08/2021 to increase the MRL from 0.02 mg/kg to 0.2 mg/kg.
Head cabbage → extrapolated to Savoy cabbage	**Intended GAP**	**N-EU**	2 x 87.2 g as/ha, 7d int, PHI 20d					
	New trials	N-EU	Trials GAP: 2 x 90 g as/ha, PHI 20d 7 x <0.01, 0.02					
	Overall supporting data for intended cGAP	N-EU	7 x <0.01, 0.02	0.010	0.02	0.025	0.06	Yes
Brussels sprout	**Intended GAP**	**N-EU**	2 x 87.2 g as/ha, 7d int, PHI 20d					
	New trials	N-EU	Trials GAP: 2 x 90 g as/ha, PHI 20d 3 x <0.01, 0.01					

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[(a)]	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) [(b)]	MRL compliance
	Overall supporting data for intended cGAP	N-EU	3 x <0.01, 0.01	0.01	0.01	0.015	0.15	Yes
Lettuce (open leaf) → extrapolated to Baby leaf, chards and beet leaves, chicory, common purslane, cress, endive, escarole, herbs and edible flowers, parsley, chive, iceberg lettuce, lamb's lettuce, red mustard, watercress, rocket, spinach and chives	**Intended GAP**	**N-EU**	2 x 87.2 g as/ha, 7d int, PHI 10d (20d for red mustard)					
	New trials	N-EU	Trials GAP: 2 x 90 g as/ha, PHI 10d <0.01, 0.01, 2 x 0.02, 3 x 0.03, 0.307,					
	New trials	N-EU	Trials GAP: 1 x 140 g a.s./ha, BBCH 43-49, PHI 10d 2 x 0.01, 0.02, 0.03, 2x 0.04, 0.06, 0.19					
	~~New trials~~	~~S-EU~~	~~Trials GAP: 2 x 90 g as/ha, PHI 10d~~ ~~<0.01, 2 x 0.01, 4 x 0.02, 0.03~~					
	Overall supporting data for intended cGAP	N-EU ~~& S-EU~~	~~2 x <0.01, 3 x 0.01, 6 x 0.02, 4 x 0.03, 0.307~~ <0.01, 3x0.01, 3 x 0.02, 4 x 0.03, 2x 0.04, 0.06, 0.19, 0.307	~~0.020~~ 0.03	0.307	~~0.327~~ 0.374	Lettuce and salad plants: 3 Spinaches and similar leaves: 1.5 Watercress: 0.01* Herbs and edible flower, Parsley, Chives: 3	Yes for lettuce and salad plants, spinach and similar leaves No for watercress An MRL application for watercress has been submitted to France on 31/08/2021 to increase the MRL from 0.01 mg/kg to 0.4 mg/kg.

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[(a)]	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) [(b)]	MRL compliance
Leek → extrapolated to Spring onions/green onions, Welsh onions	**Intended GAP**	**N-EU**	2 x 87.2 g as/ha, 12d int, PHI 14d					
	New trials	N-EU	Trials GAP: 2 x 90 g as/ha, PHI 14d 7 x <0.01, 0.0211					
	Overall supporting data for intended cGAP	N-EU	7 x <0.01, 0.0211	0.010	0.021	0.027	Leeks: 0.03 Spring onions/green onions and Welsh onions: 0.3	Yes
Onion → extrapolated to bulb veges including shallots, garlic	**Intended GAP**	**N-EU**	2 x 87.2 g as/ha, 7d int, PHI 14d					
	EFSA, 2015	N-EU	3x150 g as/ha, PHI 14d 9 x <0.02					
	New trials	N-EU	Trials GAP: 3x150 g as/ha, PHI 14d 5 x <0.02					
	Overall supporting data for intended cGAP	N-EU	14 x <0.02	0.02	0.02	0.02*	Onion: 0.5 Garlic and shallots: 0.02*	Yes

(a) Definition of residue for enforcement and risk assessment are the same: Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)
(b) Source of EU MRL: Reg. (EU) 2017/1164
* Denotes MRL at LOQ

7.2.3.2 Conclusion on the magnitude of residues in plants

A23109A is used as a foliar treatment on flowering brassicas, kale, Chinese cabbage, curly kale, head cabbage, Savoy cabbage, Brussels sprout, field and/or indoor lettuce, baby leaf , chards and beet leaves, chicory, common purslane, cress, endive, escarole, herbs and edible flowers, iceberg lettuce, lamb's lettuce, red mustard, watercress, rocket, spinach leek, spring/green onion, Welsh onion, onion, garlic and shallots.

Flowering brassica

Broccoli is a minor crop in northern Europe (SANTE/2019/12752); and therefore, generally requires four trials in the residue region. Cauliflower is a major crop in northern Europe (SANTE/2019/12752); and therefore, generally requires eight trials in the residue region. But according to SANTE/2019/12752, 4 trials on each crop can allow an extrapolation to the whole subgroup flowering brassica.

The intended GAP for A23109A is 2 x 87.2g as/ha, 7d interval, PHI 20d, field. A total of four trials conducted at 2 x 90 g as/ha, 7d interval, PHI 20d are submitted for broccoli and a total of four trials conducted at 2 x 77.6g as/ha, 7d interval, PHI 20d are submitted for cauliflower.

In order to support the use of A23109A (a DC (dispersible concentrate) formulation) on cauliflower, the submitted residue trials on cauliflower have been conducted using an SL (soluble concentrate) formulation (Report No. S13-03434). Technical Guidelines, SANTE/2019/12752 and OECD 509, state that in general residue trials should be performed with formulations equivalent to the formulations related to the GAP. It also states that according to MacLachlan and Hamilton[1], experience shows that formulations diluted in water prior to application, such as emulsifiable concentrates (EC) and suspension concentrates (SC), produce comparable residues, especially when the time between application and harvest is greater than 7 days.

SL and DC formulations are both diluted in water in the spray tank prior to application to the crop; a DC formulation will result in solid particles of metalaxyl-M similar to an SC formulation, an SL formulation will result in solubilised metalaxyl-M in the same way as an EC formulation. The PHI of A23109A in the proposed use on cauliflower is 20 days, so differences in formulations are unlikely to have an impact on residue values at harvest. According to SANTE/2019/12752 and OECD 509, DC and SL formulations can therefore be considered to be equivalent.

In addition to this, residue trials have been conducted on broccoli using the DC formulation (Report No. IF20-05335380). According to SANTE/2019/12752, residue trials on cauliflower and broccoli can be combined to support uses on the whole subgroup of flowering brassica. A statistical comparison of the broccoli trials (DC formulation) and cauliflower trials (SL formulation), when scaled to the same application rate, show they are statistically comparable using Kruskal-Wallis and Mann-Whitney tests.

Considering this, the data provided to support the use of A23109A on cauliflower and broccoli are sufficient. These trials can be used to support the intended GAP. Therefore, sufficient trials are available to support the proposed use on flowering brassicae. The available submitted data show that no exceedance of the MRL will occur. The use is considered acceptable.

zRMS comments:

Information given by the Applicant is sufficient and accepted.

Cauliflower is the major crop in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of eight trials are required. Broccoli is is a minor crop in northern Europe and therefore requires four trials in the residue region

According to SANTE/2019/12752, four residue trials on cauliflower and four residue trials on broccoli can be combined to support uses on the whole subgroup of flowering brassica.

The intended GAP for metalaxyl-M for flowering brassica in Central Europe is 2x87.2 g a.s./ha with interval between applications of 7-10 days at BBCH 12-49 with PHI of 20 days.

New study on the magnitude of residue have been submitted by the Applicant in the framework of this application. A total of 4 new supervised residue trials on broccoli and 4 trials on cauliflower were performed in Northern Europe during 2020.

1. Meyer M., Poperechna N., 2021, report No IF20-05335380 - the tested application rates and timings,

[1] *Maclachlan and Hamilton (2010) A new tool for the evaluation of crop residue trial data (day-zero-plus decline) Food Additives & Contaminants: Part A Volume 27, 2010 – Issue 3*

corresponded to the intended GAP for A23109A. The trials are supported by valid storage stability data and validated analytical methods.
Residues of metalaxyl-M in broccoli samples taken at 20 DALA (NCH) were between <0.01 – 0.0239 mg/kg.

2. Yozgatli H.P., Breyer N. 2014, report No S13-03434 - two applications, separated by a 14 - 17 day interval were made at 77.6 g ai/ha for metalaxyl-M.
The residues of metalaxyl-M in the treated cauliflower (inflorescences) samples taken from all trials at 21 DALA were in the range < 0.01 mg/kg to 0.01 mg/kg.

The trials were supported by valid storage stability data and validated analytical methods.
The residues arising from the proposed uses will not exceed the MRLs established for metalaxyl-M for broccoli and cauliflower of 0.2 mg/kg in Reg. (EU) 2017/1164.
The uses are considered acceptable.

Kale

Kale is a minor crop in northern Europe (SANTE/2019/12752); and therefore, generally requires four trials in the residue region.
The intended GAP for A23109A is 2 x 87.2g as/ha, 7d interval, PHI 20d, field. A total of four trials conducted with a DC formulation at 2 x 90 g as/ha, 7d interval, PHI 20d are submitted for kale. These trials can be used to support the intended GAP, in accordance with the guidance SANTE/2019/12752.
Therefore, sufficient trials are available to support the proposed use on kale. The available submitted data show that no exceedance of the MRL will occur. The use is considered acceptable.

zRMS comments:
Information given by the Applicant is sufficient and accepted.
Kale is a minor crop in northern Europe and therefore requires four trials in the residue region.
The intended GAP for metalaxyl-M for kale in Central Europe is 2x87.2 g a.s./ha with interval between applications of 7 – 10 days at BBCH 12-49 with PHI of 20 days.

New study on the magnitude of residue have been submitted by the Applicant in the framework of this application.
A total of 4 new supervised residue trials on kale were performed in Northern Europe during 2020/2021.
1. Brown S., 2021, report No RES-00256 - the tested application rates and timings, corresponded to the intended GAP for A23109A. The trials are supported by valid storage stability data and validated analytical methods.
Residues of metalaxyl-M in kale samples taken at 20 DALA (NCH) were between <0.01 – 0.08 mg/kg.

The residues arising from the proposed uses will not exceed the MRL established for metalaxyl-M for kale of 0.3 mg/kg in Reg. (EU) 2017/1164.
The useon kale is considered acceptable.

Leafy brassicas, Chinese cabbage/pet-tsai, curly kale

Leafy brassicas including Chinese cabbage/pet-tsai and curly kale are minor crops in northern Europe (SANTE/2019/12752); and therefore, generally requires four trials in the residue region.
The intended GAP for A23109A is 2 x 87.2g as/ha, 7d interval, PHI 20d, field. No specific residue trials on leafy brassicas including Chinese cabbage/pet-tsai and curly kale were conducted, instead residues trials conducted on kale were used to extrapolate to leafy brassicas including Chinese cabbage/pet-tsai and curly kale (SANTE/2019/12752). The available data were from four trials conducted on kale with a DC formulation at a rate of 2 x 90g as/ha, 7d interval, PHI 20d which is equivalent to the rate proposed for Chinese cabbage and curly kale.
Therefore, sufficient trials are available to support the proposed use on leafy brassicas including Chinese cabbage/pe-tsai and curly kale. The available submitted data show that no exceedance of the MRL will occur for kale but show exceedance of the MRL for pe-tsai/Chinese cabbage. An MRL application for pe-tsai/Chinese cabbage has been submitted to France on 31/08/2021 to increase the MRL from 0.02 mg/kg to 0.2 mg/kg. The use is therefore considered acceptable.

zRMS comments:
Leafy brassicas including Chinese cabbage/pet-tsai and curly kale are a minor crops in northern Europe and therefore requires four trials in the residue region.

The intended GAP for metalaxyl-M for Leafy brassicas in Central Europe is 2x87.2 g a.s./ha with interval between applications of 7 – 10 days at BBCH 12-49 with PHI of 20 days.

No new studies on the magnitude of residue have been submitted by the Applicant in the framework of this application. Residue data on kales (0243020) can be extrapolated to Whole subgroup (c) leafy brassica (0243000) before and after forming of the edible part.
Four supervised residue trials on kale were conducted with the same GAP as for leafy brassica.
The trials were supported by valid storage stability data for lettuce and validated analytical methods.
Residues of metalaxyl-M in kale samples taken at 20 DALA (NCH) were between <0.01 – 0.08 mg/kg.

The residues arising from the proposed use will not exceed the MRL established for metalaxyl-M for curly kale of 0.3 mg/kg in Reg. (EU) 2017/1164.
The use on curly kale is considered acceptable.

Considering the intended use on Chinese cabbage/pet-tsai, an exceedance of the MRL for metalaxyl-M, as established in Reg. (EU) 2017/1164 (MRL of 0.02 mg/kg) is expected. Therefore until the new MRL for Chinese cabbage/pet-tsai come into force, authorization of the GAP will not be possible.
The proposed use on Chinese cabbage/pet-tsai is not considered acceptable.

<u>Head cabbage</u>

Head cabbage is a major crop in northern Europe (SANTE/2019/12752); and therefore, generally requires eight trials in the residue region.
The intended GAP for A23109A is 2 x 87.2g as/ha, 7d interval, PHI 20d, field. A total of eight trials conducted with a DC formulation at 2 x 90 g as/ha, 7d interval, PHI 20d are submitted for head cabbage. These trials can be used to support the intended GAP, in accordance with the guidance SANTE/2019/12752. Therefore, sufficient trials are available to support the proposed use on head cabbage including Savoy cabbage. The available submitted data show that no exceedance of the MRL will occur. The use is considered acceptable.

zRMS comments:
Information given by the Applicant is sufficient and accepted.
Head cabbage 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 metalaxyl-M for head cabbage in Central Europe is 2x87.2 g a.s./ha with interval between applications of 7-10 days at BBCH 12-49 with PHI of 20 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 on head cabbage were performed in Northern Europe during 2020:

- Ford K., 2021, report No CEMR-9523, document No VV-901921 - two applications, separated by a 7 day interval were made at 90 g ai/ha for metalaxyl-M. The trials are supported by valid storage stability data and validated analytical methods.

Residues of metalaxyl-M in head cabbage samples taken at 20 DALA (NCH) were between <0.01 – 0.02 mg/kg.

The residues arising from the proposed use will not exceed the MRLs established for metalaxyl-M for head cabbage of 0.06 mg/kg in Reg. (EU) 2017/1164.
The use on head cabbage is considered acceptable.

<u>Savoy cabbage</u>

Savoy cabbage is minor crop in northern Europe (SANTE/2019/12752); and therefore, generally requires four trials in the residue region.
The intended GAP for A23109A is 2 x 87.2g as/ha, 7d interval, PHI 20d, field. No specific residue trials on Savoy cabbage were conducted, instead residues trials conducted on head cabbage were used to extrapolate to Savoy cabbage (SANTE/2019/12752). A total of eight trials conducted with a DC formulation at 2 x 90 g as/ha, 7d interval, PHI 20d are submitted for head cabbage. These trials can be used to support the intended GAP, in accordance with the guidance SANTE/2019/12752.
Therefore, sufficient trials are available to support the proposed use on head cabbage including Savoy cabbage. The available submitted data show that no exceedance of the MRL will occur. The use is considered acceptable.

zRMS comments: Information given by the Applicant is sufficient and accepted. Savoy cabbage is a minor crop in northern Europe and therefore requires four trials in the residue region. The intended GAP for metalaxyl-M for head cabbage and for savoy cabbage in Central Europe is 2x87.2 g a.s./ha with interval between applications of 7-10 days at BBCH 12-49 with PHI of 20 days. No new studies on the magnitude of residue on savoy cabbage have been submitted by the Applicant in the framework of this application. According to SANTE/2019/12752, residue trials on head cabbage can be extrapolated to support use on Savoy cabbage. New study on the magnitude of residue on head cabbage have been submitted by the Applicant in the framework of this application. A total of 8 new supervised residue trials on head cabbage were performed in Northern Europe during 2020: - Ford K., 2021, report No CEMR-9523, document No VV-901921 - two applications, separated by a 7 day interval were made at 90 g ai/ha for metalaxyl-M. The trials are supported by valid storage stability data and validated analytical methods. Residues of metalaxyl-M in head cabbage samples taken at 20 DALA (NCH) were between <0.01 – 0.02 mg/kg. The residues arising from the proposed use will not exceed the MRLs established for metalaxyl-M for savoy cabbage of 0.06 mg/kg in Reg. (EU) 2017/1164. The use on savoy cabbage is considered acceptable.

Brussels sprout

Brussels sprout is a minor crop in northern Europe (SANTE/2019/12752); and therefore, generally requires four trials in the residue region.
The intended GAP for A23109A is 2 x 87.2g as/ha, 7d interval, PHI 20d, field. A total of four trials conducted with a DC formulation at 2 x 90 g as/ha, 7d interval, PHI 20d are submitted for Brussels sprout. These trials can be used to support the intended GAP, in accordance with the guidance SANTE/2019/12752. Therefore, sufficient trials are available to support the proposed use on Brussels sprout. The available submitted data show that no exceedance of the MRL will occur. The use is considered acceptable.

zRMS comments: Information given by the Applicant is sufficient and accepted. Brussels sprout is a minor crop in northern Europe and therefore requires four trials in the residue region. The intended GAP for metalaxyl-M for Brussels sprout in Central Europe is 2x87.2 g a.s./ha with interval between applications of 7-10 days at BBCH 12-49 with PHI of 20 days. New study on the magnitude of residue have been submitted by the Applicant in the framework of this application. A total of 4 new supervised residue trials on Brussels sprout were performed in Northern Europe during 2020: - Brown S., 2021, report No RES-00257, document No VV-901790 - two applications, separated by a 7 day interval were made at 90 g ai/ha for metalaxyl-M. The trials are supported by valid storage stability data and validated analytical methods. Residues of metalaxyl-M in Brussels sprout samples taken at 20 DALA (NCH) were between <0.01 – 0.01 mg/kg. The residues arising from the proposed use will not exceed the MRLs established for metalaxyl-M for Brussels sprout of 0.15 mg/kg in Reg. (EU) 2017/1164. The use on Brussels sprout is considered acceptable.

Lettuce (field)

Lettuce (open leaf) is a major crop in northern Europe (SANTE/2019/12752); and therefore, generally requires eight trials in the residue region.
The intended GAP for A23109A is 2 x 87.2g as/ha, 7d interval, PHI 10d, field on maximum 1 crop cycle or 1 x 87.2g as/ha, PHI 10d on maximum 2 crop cycles. A total of eight trials conducted with a DC formulation at 2 x 90 g as/ha, 7d interval, PHI 10d are submitted for lettuce (open leaf). These trials can be used to support the intended GAP, in accordance with the guidance SANTE/2019/12752.

An additional eight residue trials were conducted in two studies in northern Europe on open leaf varities of lettuce. Each trial was conducted with one application at rates of 140 g a.s./ha. This application rate exceeds the ±25% acceptance range, however, as these trials are overdosed in comparison, they are considered more critical than the intended GAP. The residues in lettuce leaves at a PHI of 10 days were in the range of 0.01-0.19 mg/kg and therefore comparable to studies conducted at 2 x 90 g as/ha. Residues of metalaxyl-M were also measured in control (untreated) samples during these eight trials and were < 0.01 mg/kg.

In summary, there are sufficient and acceptable residue trials available for lettuce in order to support the cGAP for A23109A. This demonstrates that residues of metalaxyl-M will not exceed the MRL.

Therefore, sufficient trials are available to support the proposed use on lettuce (open leaf). The available submitted data show that no exceedance of the MRL will occur. The use 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.
The intended GAP for metalaxyl-M for lettuce in Central Europe is 2x 87.2g a.s./ha with interval between applications of 7 days at BBCH 12-49 with PHI of 10 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 on lettuce were performed in Northern Europe during 2020 and 2021:

- Brown S., 2021, report No RES-00259, document No VV-901318 - two applications, separated by a 7 day interval were made at 90 g ai/ha for metalaxyl-M;
- Brown S., 2022, report No RES-00332, document No VV-946819 - two applications, separated by a 7 day interval were made at 90 g ai/ha for metalaxyl-M.

The trials are supported by valid storage stability data and validated analytical methods.
Residues of metalaxyl-M in lettuce samples taken at 10 DALA (NCH) were between <0.01 – 0.307 mg/kg.

The lettuce varities used in the trials in studies RES-00259 and RES-00332:

Study Report Number	Trial Number	Lettuce Variety	Variety Type
RES-00259	MLI-20-45529 FR01	Ruffian	Semi-open
	MLI-20-45529 AT02	Kisheri	Open
	MLI-20-45529 PL03	Locarno	Open
	MLI-20-45529 FR05	Analotta	Semi-open
	MLI-20-45529 AT06	Lollo Rosso	Open
	MLI-20-45529 PL09	Iska	Unknown
	MLI-20-45529 HU10	Rolina	Open
RES-00332	JBL-21-51683 GB01	Extranet	Open

It should be noted that the variesties of Ruffian, Analotta and Iska are not representative of open leaf varieties.

Applicant submitted 8 additional trials conducted on open leaf lettuce varieties:

- Lakaschus S, and Fritzsch S, 2019, Report No. S18-04345, Syngenta File No. VV-471900 - one application, applied 10 days before harvest (10 DBH), was made at a nominal rate of 140 g ai/ha for metalaxyl-M;
- Fritsch S, 2020, Report No. S19-02726, Syngenta File No. . VV-749044 - one application, applied 10 days before harvest (10 DBH), was made at a nominal rate of 140 g ai/ha for metalaxyl-M.

The trials are supported by valid storage stability data and validated analytical methods.
Residues of metalaxyl-M in lettuce samples taken at 10 DALA (NCH) were between 0.01 – 0.19 mg/kg.

The lettuce varities used in the trials in study S18-04345 and S19-02726:

Study Report Number	Trial Number	Lettuce Variety	Variety Type
S18-04345	S18-04345-01	Exponent	Open
	S18-04345-02	Feuille de Chene rouge Macai	Open
	S18-04345-03	Kirinia	Open
	S18-04345-05	Extender	Open
	S18-04345-06	Kisheri RZ	Open

	S18-04345-07	Kiribati	Open
S19-02726	S19-02726-01	Vizir nas	Open
	S19-02726-02	Crispa	Open

It should be noted that trials from the studies S18-04345 and S19-02726 were conducted with one application at rates of 140 g a.s./ha. This application rate exceeds the ±25% acceptance range, however, as these trials are overdosed in comparison, they are considered more critical than the intended GAP. The residues in lettuce leaves at a PHI of 10 days were in the range of 0.01-0.19 mg/kg and therefore comparable to studies conducted at 2 x 90 g as/ha.

The residues arising from the proposed use will not exceed the MRLs established for metalaxyl-M for lettuce of 3 mg/kg in Reg. (EU) 2017/1164.
The use on lettuce is considered acceptable.

Baby leaf, chards and beet leaves, chicory, common purslane, cress, endive, escarole, herbs and edible flowers, parsley, chives, iceberg lettuce, lamb's lettuce, red mustard, watercress, rocket, spinach (field)

Baby leaf, chards and beet leaves, chicory, common purslane, cress, endive, escarole, herbs and edible flowers, parsley, chives, iceberg lettuce, lamb’s lettuce, red mustard, watercress, rocket, spinach are minor crops in northern Europe (SANTE/2019/12752); and therefore, generally requires four trials in the residue region.
The intended GAP for A23109A is 2 x 87.2g as/ha, 7d interval, PHI 10d, field and 2 x 87.2g as/ha, 7d interval, PHI 20d, field for red mustard. No specific residue trials on baby leaf, chards and beet leaves, chicory, common purslane, cress, endive, escarole, herbs and edible flowers, parsley, chives, iceberg lettuce, lamb’s lettuce, red mustard, watercress, rocket, spinach were conducted, instead residues trials conducted on lettuce open leaf varieties were used to extrapolate to baby leaf, chards and beet leaves, chicory, common purslane, cress, endive, escarole, herbs and edible flowers, parsley chives, iceberg lettuce, lamb’s lettuce, red mustard, watercress, rocket, spinach (SANTE/2019/12752). The available data were from eight trials conducted with a DC formulation on lettuce open leaf varieties at a rate of 2 x 90g as/ha, 7d interval, PHI 10d which is equivalent to the rate proposed for baby leaf, chards and beet leaves, chicory, common purslane, cress, endive, escarole, herbs and edible flowers, parsley, chives, iceberg lettuce, lamb’s lettuce, ~~red mustard,~~ watercress, rocket, spinach and more critical for red mustard with a shorter PHI.

Therefore, sufficient trials are available to support the proposed use on baby leaf, chards and beet leaves, chicory, common purslane, cress, endive, escarole, herbs and edible flowers, parsley, chives, iceberg lettuce, lamb’s lettuce, red mustard, watercress, rocket, spinach. The available submitted data show that no exceedance of the MRL will occur, but show exceedance of the MRL for watercress. An MRL application for watercress has been submitted to France on 31/08/2021 to increase the MRL from 0.01 mg/kg to 0.4 mg/kg. The application the new MRL for watercress was performed using combined data set from N-EU and S-EU trials because data sets are statistically similar according to Mann-whitney U test. For consistency with this MRL application, both data sets have been combined tu support the use in N-EU. The use is therefore considered acceptable.

zRMS comments:
Baby leaf, chards and beet leaves, chicory, common purslane, cress, endive, escarole, herbs and edible flowers, parsley, chives, iceberg lettuce, lamb's lettuce, red mustard, watercress, rocket, spinach are the minor crops in northern Europe and therefore requires four trials in the residue region.

The intended GAP for metalaxyl-M for lettuce and for baby leaf, chards and beet leaves, chicory, common purslane, cress, endive, escarole, herbs and edible flowers, parsley, chives, iceberg lettuce, lamb's lettuce, red mustard, watercress, rocket, spinach in Central Europe is 2x87.2 g a.s./ha with interval between applications of 7 days at BBCH 12-49 with PHI of 10 days.
No new studies on the magnitude of residue have been submitted by the Applicant in the framework of this application. According to SANTE/2019/12752, residue trials on lettuces (0251020) (trials from open leaf varieties) can be extrapolated to Whole subgroup (a) lettuces and salad plants (0251000), Whole subgroup (b) spinaches and similar leaves (0252000) and Whole subgroup (d) watercresses (0254000) before and after forming of the edible part.

New studies on the magnitude of residue on lettuce have been submitted by the Applicant in the framework of this application.
A total of 16 new supervised residue trials on lettuce were performed in Northern Europe between 2018 and 2021:

- Brown S., 2021, report No RES-00259, document No. VV-901318 - two applications, separated by a 7 day interval were made at 90 g ai/ha for metalaxyl-M;
- Brown S., 2022, report No RES-00332, document No. VV-946819 - two applications, separated by a 7 day interval were made at 90 g ai/ha for metalaxyl-M;
- Lakaschus S., and Fritzsch S., 2019, Report No. S18-04345, Syngenta File No. VV-471900 - one application, applied 10 days before harvest (10 DBH), was made at a nominal rate of 140 g ai/ha for metalaxyl-M;
- Fritsch S., 2020, Report No. S19-02726, Syngenta File No. VV-749044 - one application, applied 10 days before harvest (10 DBH), was made at a nominal rate of 140 g ai/ha for metalaxyl-M.

The trials are supported by valid storage stability data and validated analytical methods.

Residues of metalaxyl-M in lettuce samples taken at 10 DALA (NCH) were between <0.01 – 0.307 mg/kg (report No RES-00259 and report No RES-00332).
Residues of metalaxyl-M in lettuce samples taken at 10 DALA (NCH) were between 0.01 – 0.19 mg/kg (report No. S18-04345 and report No. S19-02726).

Three lettuce varieties used in the trials in study RES-00259 and RES-00332 (Ruffian, Analotta and Iska) are not representative of open leaf varieties. Taking this into account Applicant submitted 8 additional trials conducted on open leaf lettuce varieties (Report No. S18-04345 and Report No. S19-02726).
It should be noted that trials from the studies S18-04345 and S19-02726 were conducted with one application at rates of 140 g a.s./ha. This application rate exceeds the ±25% acceptance range, however, as these trials are overdosed in comparison, they are considered more critical than the intended GAP. The residues in lettuce leaves at a PHI of 10 days were in the range of 0.01-0.19 mg/kg and therefore comparable to studies conducted at 2 x 90 g as/ha.

Based on available residue studies on lettuce the extrapolation from residue trials on lettuces (0251020) (trials from open leaf varieties) to Whole subgroup (a) lettuces and salad plants (0251000), Whole subgroup (b) spinaches and similar leaves (0252000) and Whole subgroup (d) watercresses (0254000) before and after forming of the edible part has been accepted.

The residues arising from the proposed use will not exceed the MRLs of 3 mg/kg established for metalaxyl-M in Reg. (EU) 2017/1164 for lettuce, baby leaf, chicory, cress, endive, escarole, herbs and edible flowers, parsley, chives, iceberg lettuce, lamb's lettuce, red mustard, rocket. **The uses on baby leaf, chicory, cress, endive, escarole, herbs and edible flowers, parsley, chives, iceberg lettuce, lamb's lettuce, red mustard, rocket are considered acceptable.**

The residues arising from the proposed use will not exceed the MRLs of 1.5 mg/kg established for metalaxyl-M in Reg. (EU) 2017/1164 for chards and beet leaves, common purslane, spinach. **The uses on chards and beet leaves, common purslane, spinach are considered acceptable.**

Considering the intended use on watercresses an exceedance of the MRL for metalaxyl-M, as established in Reg. (EU) 2017/1164 (MRL of 0.01 mg/kg) is expected. Therefore until the new MRL for watercresses come into force, authorization of the GAP will not be possible.
The proposed use on watercresses is not considered acceptable.

Leek

Leek is a major crop in northern Europe (SANTE/2019/12752); and therefore, generally requires eight trials in the residue region.
The intended GAP for A23109A is 2 x 87.2g as/ha, 12d interval, PHI 14d, field. A total of eight trials conducted with a DC formulation at 2 x 90 g as/ha, 12d interval, PHI 14d are submitted for leek . These trials can be used to support the intended GAP, in accordance with the guidance SANTE/2019/12752.
Therefore, sufficient trials are available to support the proposed use on leek. The available submitted data show that no exceedance of the MRL will occur. The use is considered acceptable.

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

Leek 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 metalaxyl-M for leek in Central Europe is 2x 87.2g a.s./ha with interval between applications of 12-14 days at BBCH 12-48 with PHI of 14 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 on leek were performed in Northern Europe during 2020:

- Ford K., 2021, report No CEMR-9521, document No VV-901936 - two applications, separated by a 11-13 day interval were made at 90 g ai/ha for metalaxyl-M.

The trials are supported by valid storage stability data and validated analytical methods.

Residues of metalaxyl-M in leek samples taken at 14 DALA (NCH) were between <0.01 – 0.021 mg/kg.

The residues arising from the proposed use will not exceed the MRLs established for metalaxyl-M for leek of 0.03 mg/kg in Reg. (EU) 2017/1164.
The use on leek is considered acceptable.

Spring onions/green onions, Welsh onions

Spring onions/green onions, Welsh onions are minor crops in northern Europe (SANTE/2019/12752); and therefore, generally requires four trials in the residue region.
The intended GAP for A23109A is 2 x 87.2g as/ha, 12d interval, PHI 14d, field. No specific residue trials on spring onions/green onions and Welsh onions were conducted, instead residues trials conducted on leek were used to extrapolate to spring onions/green onions, Welsh onions (SANTE/2019/12752). The available data were from eight trials conducted on leek with a DC formulation at a rate of 2 x 90g as/ha, 12d interval, PHI 14d which is equivalent to the rate proposed for spring onions/green onions and Welsh onions.
Therefore, sufficient trials are available to support the proposed use on spring onions/green onions and Welsh onions. The available submitted data show that no exceedance of the MRL will occur. The use is considered acceptable.

zRMS comments:
Information given by the Applicant is sufficient and accepted.
Spring onions/green onions, Welsh onions are a minor crop in northern Europe and therefore requires four trials in the residue region.

The intended GAP for metalaxyl-M for leek and for Spring onions/green onions, Welsh onions in Central Europe is 2x87.2 g a.s./ha with interval between applications of 12-14 days at BBCH 12-48 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.
According to SANTE/2019/12752, residue trials on leeks (0270060) can be extrapolated to extrapolated to spring onions/green onions and Welsh onions (0220040) before and after forming of the edible part.

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

- Ford K., 2021, report No CEMR-9521, document No VV-901936 - two applications, separated by a 11-13 day interval were made at 90 g ai/ha for metalaxyl-M.

The trials are supported by valid storage stability data and validated analytical methods.

Residues of metalaxyl-M in leek samples taken at 14 DALA (NCH) were between <0.01 – 0.021 mg/kg.

The residues arising from the proposed uses will not exceed the MRL established for metalaxyl-M for spring onions/green onions, Welsh onions of 0.03 mg/kg in Reg. (EU) 2017/1164.
The use on spring onions/green onions, Welsh onions is considered acceptable.

Onion

Onion is a major crop in northern Europe (SANTE/2019/12752); and therefore, generally requires eight trials in the residue region.
The intended GAP for A23109A is 2 x 87.2g as/ha, 7d interval, PHI 14d, field. A total of fourteen trials conducted at 3 x 150 g as/ha, 7d interval, PHI 14d are submitted for onion. These trials have been performed at a more critical GAP, but as the residues were ~~above~~ below the LOQ (<0.02 mg/kg), the use of proportionality was not needed. They can be used to support the intended GAP, in accordance with the

guidance SANTE/2019/12752.
In order to support the use of A23109A (a DC (dispersible concentrate) formulation) on onion, the submitted residue trials on onion have been conducted using a WP (wettable powder) (Kühne, 1998 and Kühne, 1999). Technical Guidelines, SANTE/2019/12752 and OECD 509, state that in general residue trials should be performed with formulations equivalent to the formulations related to the GAP. It also states that according to MacLachlan and Hamilton[1], experience shows that formulations diluted in water prior to application, such as wettable powders (WP) and suspension concentrates (SC), produce comparable residues, especially when the time between application and harvest is greater than 7 days.
WP and DC formulations are both diluted in water in the spray tank prior to application to the crop; both DC and WP formulations will result in solid particles of metalaxyl-M applied to the crop. The PHI of A23109A in the proposed use on onion is 14 days, so differences in formulations are unlikely to have an impact on residue values at harvest. According to SANTE/2019/12752 and OECD 509, DC and WP formulations can therefore be considered to be equivalent.
Considering this, the data provided to support the use of A23109A on onion are sufficient.
Therefore, sufficient trials are available to support the proposed use on onion. The available submitted data show that no exceedance of the MRL will occur. The use is considered acceptable.

zRMS comments:
Information given by the Applicant is sufficient and accepted.
Onion 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 metalaxyl-M for onion in Central Europe is 2x87.2 g a.s./ha with interval between applications of 7 days at BBCH 12-48 with PHI of 14 days.

Five 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, three applications were applied at a nominal rate of 0.15 kg as/ha. The interval between applications was 7 days with PHI of 14 days.
The trials were supported by valid storage stability data for onion and validated analytical methods.

Residues of metalaxyl-M in onion bulb taken at 14 DALA (NCH) were <0.02 mg/kg.

The residues arising from the proposed use will not exceed the MRL established for metalaxyl-M for onion of 0.5 mg/kg in Reg. (EU) 2017/1164.
The use on onions is considered acceptable.

<u>Garlic and shallots</u>
Garlic and shallots are minor crops in northern Europe (SANTE/2019/12752); and therefore, generally require four trials in the residue region.
The intended GAP for A23109A is 2 x 87.2g as/ha, 7d interval, PHI 14d, field. No specific residue trials on garlic and shallots were conducted, instead residues trials conducted on onion were used to extrapolate to garlic and shallots (SANTE/2019/12752). The available data were from fourteen trials conducted on onion at a rate of at 3 x 150 g as/ha, 7d interval, PHI 14d which is more critical than the rate proposed for garlic and shallots.
In order to support the use of A23109A (a DC (dispersible concentrate) formulation) on onion, the submitted residue trials on onion have been conducted using a WP (wettable powder) (Kühne, 1998 and Kühne, 1999). Technical Guidelines, SANTE/2019/12752 and OECD 509, state that in general residue trials should be performed with formulations equivalent to the formulations related to the GAP. It also states that according to MacLachlan and Hamilton (2010), experience shows that formulations diluted in water prior to application, such as wettable powders (WP) and suspension concentrates (SC), produce comparable residues, especially when the time between application and harvest is greater than 7 days.
WP and DC formulations are both diluted in water in the spray tank prior to application to the crop; both DC and WP formulations will result in solid particles of metalaxyl-M applied to the crop. The PHI of A23109A in the proposed use on onion is 14 days, so differences in formulations are unlikely to have an impact on residue values at harvest. According to SANTE/2019/12752 and OECD 509, DC and WP formulations can therefore be considered to be equivalent.
Considering this, the data provided to support the use of A23109A on onion are sufficient.
Therefore, sufficient trials are available to support the proposed use on garlic and shallots. The available

submitted data show that no exceedance of the MRL will occur. The use is considered acceptable.

zRMS comments:
Information given by the Applicant is sufficient and accepted.
Garlic and shallots are the minor crops in northern Europe (EU Technical Guidelines Document SANTE/2019/12752) and therefore requires four trials in the residue region.

The intended GAP for metalaxyl-M for garlic and shallots in Central Europe is 2x87.2 g a.s./ha with interval between applications of 7 days at BBCH 12-48 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. Residue data on onions (0220020) can be extrapolated to garlic (0220010) and to shallots (0220030) before and after forming of the edible part.

Five new studies on the magnitude of residues on onions and nine trials reviewed at EU level are available to support the proposed uses on garlic and shallots. For all the trials, three applications were applied at a nominal rate of 0.15 kg as/ha. The interval between applications was 7 days with PHI of 14 days.
The trials were supported by valid storage stability data for onion and validated analytical methods.
Residues of metalaxyl-M in onion bulb taken at 14 DALA (NCH) were <0.02 mg/kg.

The residues arising from the proposed uses on garlic and shallots will not exceed the MRL established for metalaxyl-M for garlic and shallots of 0.02 mg/kg in Reg. (EU) 2017/1164.
The uses on garlic and shallots are considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

The use of A23109A may result in residues of metalaxyl-M in animal feed items, therefore the possible transfer of residues in animal commodities from the proposed uses should be considered. Livestock intake calculations and feeding studies undertaken are provided below.
The crops (cabbage and kale) in this submission that can be used as animal feed as forages show residues lower than or equal to the ones reported in the latest EFSA reasoned opinion (EFSA, 2015). All other crops in this submission are not fed to animals. Therefore, new animal dietary burden calculations are not deemed necessary, instead the values reported in the latest EFSA reasoned opinion were used to calculate the animal dietary burdens using the EFSA animal model 2017. All input values are given in the table below.

Table 7.2-10: Input values for the dietary burden calculation

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Metalaxyl-M				
Forages				
Cabbage, heads, leaves	0.02	STMR (EFSA, 2015a)	0.04	HR (EFSA, 2015a)
Kale, leaves (forage)	0.05	STMR (EFSA, 2015a)	0.21	HR (EFSA, 2015a)
Rape, forage	0.04	STMR (EFSA, 2015a)	0.04	HR (EFSA, 2015a)
Roots & Tuber				
Potato, culls	0.02	STMR (EFSA, 2015a)	0.02	HR (EFSA, 2015a)
Cereal grains/crop seeds				
Bean, seed (dry)	0.02	STMR (EFSA, 2015a)	0.02	STMR (EFSA, 2015a)
Corn, field (Maize), grain	0.02	STMR (EFSA, 2015a)	0.02	STMR (EFSA, 2015a)
Corn, pop, grain	0.02	STMR (EFSA, 2015a)	0.02	STMR (EFSA, 2015a)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Pea (Field pea), seed (dry)	0.02	STMR (EFSA, 2015a)	0.02	STMR (EFSA, 2015a)
By-products				
Canola (Rape seed), meal	0.04	STMR (EFSA, 2015a) 0.02 x default PF 2	0.04	STMR (EFSA, 2015a) 0.02 x default PF 2
Citrus, dried pulp	0.24	STMR (EFSA, 2015a) 0.096 x PF 2.5	0.24	STMR (EFSA, 2015a) 0.096 x PF 2.5
Corn, field, milled by-pdts	0.02	STMR (EFSA, 2015a) 0.02 x 1 (1)	0.02	STMR (EFSA, 2015a) 0.02 x 1 (1)
Corn, field, hominy meal	0.02	STMR (EFSA, 2015a) 0.02 x 1 (1)	0.02	STMR (EFSA, 2015a) 0.02 x 1 (1)
Corn, field, gluten feed	0.02	STMR (EFSA, 2015a) 0.02 x 1 (1)	0.02	STMR (EFSA, 2015a) 0.02 x 1 (1)
Corn, field, gluten, meal	0.02	STMR (EFSA, 2015a) 0.02 x 1 (1)	0.02	STMR (EFSA, 2015a) 0.02 x 1 (1)
Distiller's grain, dried	0.02	STMR (EFSA, 2015a) 0.02 x 1 (1)	0.02	STMR (EFSA, 2015a) 0.02 x 1 (1)
Flaxseed/Linseed, meal	0.02	STMR (EFSA, 2015a) 0.02 x default PF 2	0.02	STMR (EFSA, 2015a) 0.02 x default PF 2
Potato, process waste	0.02	STMR (EFSA, 2015a) 0.02 x 1 (1)	0.02	STMR (EFSA, 2015a) 0.02 x 1 (1)
Potato, dried pulp	0.02	STMR (EFSA, 2015a) 0.02 x 1 (1)	0.02	STMR (EFSA, 2015a) 0.02 x 1 (1)
Rape, meal	0.02	STMR (EFSA, 2015a) 0.02 x default PF 2	0.02	STMR (EFSA, 2015a) 0.02 x default PF 2
Sunflower, meal	0.02	STMR (EFSA, 2015a) 0.02 x default PF 2	0.02	STMR (EFSA, 2015a) 0.02 x default PF 2

PF = Processing Factor
(1) As residues in the RAC were below LOQ (<0.02 mg/kg), a default processing factor of 1 applies

The results of the calculations are reported in

Table 7.2-11. The calculated dietary burdens for beef cattle, dairy cattle, ram/ewe, lamb and breeding swine were found to exceed the trigger value of 0.004 mg/kg bw/d. Further investigation of residues is therefore only 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: Metalaxyl-M					
Beef cattle*	0.004	0.009	Kales, leaves	0.38	Y
Dairy cattle*	0.006	0.014	Kales, leaves	0.37	Y
Ram/ewe	0.0047	0.008	Kales, leaves	0.20	Y
Lamb	0.0047	0.009	Kales, leaves	0.20	Y
Breeding swine	0.003	0.005	Kales, leaves	0.24	Y
Finishing swine*	0.002	0.002	Potato, culls	0.06	N
Broiler poultry	0.002	0.002	Potato, culls	0.03	N

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)
Layer poultry*	0.003	0.003	Cabbage, heads, leaves	0.04	N
Turkey	0.003	0.003	Potato, culls	0.04	N

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

Evaluator comments:
The calculated dietary burdens for dairy and beef cattle, ram, lamb and breeding swine were found to exceed the trigger value. Further investigation of residues has been performed in all relevant commodities of animal origin.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Feeding studies in poultry are not triggered.
Reference: Belgium, 1999, 2014
Livestock feeding studies for metalaxyl have been conducted in cows and hens and were reviewed during the approval process and are considered to be acceptable; the results are summarised in the table below.
During the peer review, the magnitude of metalaxyl residues in ruminants was investigated in two feeding studies with lactating cows. In the first study, five cows (including two controls) were dosed for up to 28 consecutive days with metalaxyl at a level of 75 mg/kg in the diet (equivalent to 4.28 mg/kg bw). A cow was sacrificed after 14 days (4 hours after dosing), while the other cows were sacrificed after 21 and 28 days, respectively (23.5 hours after dosing). The samples were analysed for total residues of metalaxyl (metalaxyl (sum of isomers) and its metabolites containing the 2,6-dimethylaniline moiety expressed as metalaxyl). In milk, a plateau level was reached immediately. Results of ruminant livestock feeding studies are summarised in the table below. Due to the design of the study the mean values were determined from the average of residue levels found in cows sacrificed at days 21 and 28; the maximum value was taken from the residue levels determined at day 14.
In the second study, three groups of lactating cows, each consisting of three or four animals were dosed for up to 28 consecutive days with metalaxyl at levels of 1.5, 7.5, and 15 mg/kg in the diet (equivalent to 0.07, 0.36 and 0.68 mg/kg bw). One animal from each treatment was sacrificed on days 14, 21 and 28. An additional cow was sacrificed at 40 days (7.5 mg/kg group). The samples were analysed for total residues of metalaxyl (metalaxyl (sum of isomers) and its metabolites containing the 2,6-dimethylaniline moiety expressed as metalaxyl). In milk, a plateau level was reached immediately. Results of ruminant livestock feeding studies are summarised in the table below. The mean values for each treatment group were determined from average of residue levels found in cows sacrificed at days 14, 21, 28 and 40 (7.5 mg/kg group); the maximum value for each treatment group was taken from the highest residue level determined at days 14, 21, 28 and 40 (7.5 mg/kg group).

Table 7.2-12: Overview of feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)(a)	Highest residue (mg/kg)(b)	Calculated MRL (mg/kg)	CF for RA(c)
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Residue definition for enforcement and risk assessment: sum of metalaxyl (sum of isomers) and its metabolites containing the 2,6-dimethylaniline moiety expressed as metalaxyl												
EU reviewed data (Report ABR-82052; Belgium 1999)												
Pig meat	0.003	0.005	4.28(d)	3	0.07	0.15	0.07	0.15	<0.05	<0.05	0.05(*)	-
Pig fat	0.003	0.005	4.28(d)	3	<0.05(*)	<0.05(*)	<0.05(*)	<0.05(*)	<0.05	<0.05	0.05(*)	-
Pig liver	0.003	0.005	4.28(d)	3	0.13	0.96	0.13	0.96	<0.05	<0.05	0.05(*)	-
Pig kidney	0.003	0.005	4.28(d)	3	0.12	5.4	0.12	5.4	<0.05	<0.05	0.05(*)	-
Ruminant meat	0.004	0.009	4.28(d)	3	0.07	0.15	0.07	0.15	<0.05	<0.05	0.05(*)	-
Ruminant fat	0.004	0.009	4.28(d)	3	<0.05(*)	<0.05(*)	<0.05(*)	<0.05(*)	<0.05	<0.05	0.05(*)	-
Ruminant liver	0.004	0.009	4.28(d)	3	0.13	0.96	0.13	0.96	<0.05	<0.05	0.05(*)	-
Ruminant kidney	0.004	0.009	4.28(d)	3	0.12	5.4	0.12	5.4	<0.05	<0.05	0.05(*)	-
Milk	0.006	0.014	4.28(d)	3	0.02(f)	N/A	0.02(i)	N/A	<0.01	N/A	0.01(*)	-
EU reviewed data (Report BIOL-79009/ 5716 I,III,V,VI,VII/ 5716 IV,V,VI,VII Second report / 5716 IV,V,VI,VII Third report; Belgium, 2014)												
Pig meat	0.004	0.005	0.07(e)	3	n.a	n.a	n.a	n.a	<0.05	<0.05	0.05(*)	
			0.36(e)	4	<0.05(*)	<0.05(*)	<0.05(*)	<0.05(*)				
			0.68(e)	3	<0.05(*)	0.05	<0.05(*)	0.05				
Pig fat	0.003	0.005	0.07(e)	3	n.a	n.a	n.a	n.a	<0.05	<0.05	0.05(*)	
			0.36(e)	4	<0.05(*)	<0.05(*)	<0.05(*)	<0.05(*)				
			0.68(e)	3	<0.05(*)	0.05	<0.05(*)	0.05				
Pig liver	0.004	0.005	0.07(e)	3	0.10	0.11	0.10	0.11	<0.05	<0.05	0.05(*)	
			0.36(e)	4	0.16	0.22	0.16	0.22				
			0.68(e)	3	0.17	0.20	0.17	0.20				
Pig kidney	0.003	0.005	0.07(e)	3	0.34	0.64	0.34	0.64	<0.05	<0.05	0.05(*)	
			0.36(e)	4	0.38	0.52	0.38	0.52				

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[(a)]	Highest residue (mg/kg)[(b)]	Calculated MRL (mg/kg)	CF for RA[(c)]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
			0.68[(e)]	3	0.45	0.73	0.45	0.73				
Ruminant meat	0.004	0.009	0.07[(e)]	3	n.a	n.a	n.a	n.a	<0.05	<0.05	0.05[(*)]	
			0.36[(e)]	4	<0.05[(*)]	<0.05[(*)]	<0.05[(*)]	<0.05[(*)]				
			0.68[(e)]	3	<0.05[(*)]	0.05	<0.05[(*)]	0.05				
Ruminant fat	0.004	0.009	0.07[(e)]	3	n.a	n.a	n.a	n.a	<0.05	<0.05	0.05[(*)]	
			0.36[(e)]	4	<0.05[(*)]	<0.05[(*)]	<0.05[(*)]	<0.05[(*)]				
			0.68[(e)]	3	<0.05[(*)]	0.05	<0.05[(*)]	0.05				
Ruminant liver	0.004	0.009	0.07[(e)]	3	0.10	0.11	0.10	0.11	<0.05	<0.05	0.05[(*)]	
			0.36[(e)]	4	0.16	0.22	0.16	0.22				
			0.68[(e)]	3	0.17	0.20	0.17	0.20				
Ruminant kidney	0.006	0.014	0.07[(e)]	3	0.34	0.64	0.34	0.64	<0.05	<0.05	0.05[(*)]	
			0.36[(e)]	4	0.38	0.52	0.38	0.52				
			0.68[(e)]	3	0.45	0.73	0.45	0.73				
Milk	0.004	0.009	0.07[(e)]	3	<0.01[(f)]	N/A	<0.01[(i)]	N/A	<0.01	N/A	0.01[(*)]	
			0.36[(e)]	4	<0.01[(f)]	N/A	<0.01[(i)]	N/A				
			0.68[(e)]	3	<0.01[(f)]	N/A	<0.01[(i)]	N/A				

N/A: Not applicable - only the mean values are considered for calculating MRLs in milk
n.a.: Not analysed
(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).
(b): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).
(c): The median conversion factor for enforcement to risk assessment.
(d): Based on a 572 kg animal consuming 20 kg feed DM/day; cows received feed containing 75 mg metalaxyl/kg.
(e): Based on a 441, 417 and 440 kg animals (average pre-treatment weight per dose group, 1.5, 7.5 and 15 mg.

(f): Maximum values from 14, 21 or 28 days (0.072 and 0.68 mg/kg bw/d doses) and from 14, 21, 28 or 40 days (0.36 mg/kg bw/d dose); one animal sacrificed at each timepoint. Therefore, no mean values available.

(h): Mean of 5 feeding study results, individual values unknown. Values after 14 days of exposure (higher than after 21 and 28 days).

Summary of livestock feeding studies

Reference: Belgium, 2014

"Regarding ruminants and pigs, the findings of the additional cow feeding study evaluated in the RAR (2014) – which was conducted at lower dose levels and thus closer to the maximum dietary burden – support the assumption made by EFSA in the framework of MRL review (cf. EFSA, 2011) that, after exposure to the maximum dietary burden, total residue levels (as determined by DMA common moiety method) are not expected to exceed 0.01 mg/kg in milk, 0.05 mg/kg in meat/muscle and fat and 0.1 mg/kg in liver. Nevertheless, total residue levels in kidney higher than 0.1 mg/kg cannot be excluded, taking into account the high residue value (0.7 mg/kg) found in kidney after 14 days dosing at the lowest dose level in the additional cow feeding study. However, there are unresolved issues concerning the analytical method and the residue definition. Regarding only the parent, it is deemed unlikely that levels of metalaxyl-M would exceed 0.01 mg/kg, taking into account that metalaxyl-M was not detected in the goat metabolism study".

Evaluator comments:

Except for cabbage and kale the crops under evaluation or parts thereof are normally not fed to livestock. The dietary burden was calculated in EFSA reasoned opinion (EFSA, 2015).

Results of the calculation are detailed in table below:

	Maximum dietary burden (mg/kg bw/d)	
	EFSA, 2015b	**Orondis VIP**
Risk assessment residue definition: metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)		
Dairy cattle	0.0211	0.014
Beef cattle	0.0260	0.009
Poultry	0.077	0.005
pigs	0.0126	0.005

The use under consideration in the framework of this dossier does not modify the animal exposure due to uses already authorised. There is no risk for MRLs to be exceeded in animal commodities.

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

As quantifiable residues of metalaxyl-M are expected in the treated crops, a study investigating the nature in processed commodities is required. This data is available and is considered under Section 7.2.2.3.

As residues of metalaxyl-M exceeding 0.1 mg/kg are expected in treated lettuces, investigation of the magnitude of residues in processed commodities is required. Lettuce is extrapolated to crops that require processing studies (spinach, herbs). These crops require processing studies (category II). The specific processing studies required are not covered, but tomato processing studies can be extrapolated to all vegetables. Processing studies for metalaxyl-M have been conducted for tomato. No new data were submitted in the framework of this application.

Table 7.2-13: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Report reference	Source
EU reviewed data						
Enforcement residue definition: Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)						
Tomatoes, washed fruit	4	0.53	1.0	-	04-6048	Belgium, 2014
Tomatoes, wet pomace	4	2.3	1.0	-		
Tomatoes, dry pomace	4	11.2	1.0	-		

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Report reference	Source
Tomatoes, juice	4	0.60	1.0	-		
Tomatoes, puree	4	2.36	1.0	-		
Tomatoes, canned fruit	4	0.31	1.0	-		

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

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

7.2.5.1 Conclusion on processing studies

Processing factors were derived for tomato processed products and can be applied to spinach and herbs. No refinement is required for the acute consumer risk assessment. The magnitude of residues in processed commodities has been sufficiently investigated to support the crops under consideration in this submission.

Evaluator comments:
For the salad plant group including spinach and herbs the residue values are above 0.1 mg/kg. According to Reg. 283/2013 for all crops for which residue values exceed 0.1 mg/kg a processing study is necessary. For metalaxyl-M, this requirement applies to the entire group of salads, spinach and herbs. In this report only the processing data for tomatoes are available.

In the section concerning the processing of products, the Applicant provided the following explanation:
„As residues of metalaxyl-M exceeding 0.1 mg/kg are expected in treated lettuces, investigation of the magnitude of residues in processed commodities is required. Lettuce is extrapolated to crops that require processing studies (spinach, herbs). These crops require processing studies (category II). The specific processing studies required are not covered, but tomato processing studies can be extrapolated to all vegetables. Processing studies for metalaxyl-M have been conducted for tomato. No new data were submitted in the framework of this application."
According to OECD 508, tomato processing data can be extrapolated to all vegetables when vegetable juice, concentrated juices such as puree and tomato paste are prepared. This does not apply, for example, to cooking vegetables, including spinach. From the available data on the cooking of spinach, it would then be possible to extrapolate to all leafy vegetables. Nevertheless, there is no such data.

Applicant submitted additional explanation:
"The Applicant does not believe that additional data are required for metalaxyl-M processing in cooking vegetables. According to OECD 508 category 2 processing studies are often considered optional and are typically required to refine dietary exposure assessments. The dietary risk assessment for metalaxyl-M as demonstrated by the Applicant does not require further refinement. Furthermore, the dietary risk assessment is already conservative as the MRL values are used for all commodities; these values are significantly higher than the residue values seen in provided residue trials, and processing of these commodities is not anticipated to increase residues as demonstrated in the provided processing data. EFSA supported this conclusion in the recent Review of the existing maximum residue levels (MRLs) for metalaxyl-M according to Article 12 of Regulation (EC) No 396/2005. EFSA stated that "Further processing studies are not required because they are not expected to affect the outcome of the risk assessment."

zRMS-PL agrees with the explanation submitted by the Applicant.
No further data are required.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.
Data on the magnitude of residues in succeeding crops are available and are summarised hereafter.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

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

Table 7.2-14: Summary of available studies in field rotational crops

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			Report reference	Source
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)		
EU reviewed data						
Potato	700	Leafy vegetables	Lettuce[(a)]	30	208/98	Belgium, 1999
			Cauliflower[(a)]	27		
		Root and tuber vegetables	Carrot[(a)]	29		
		Cereals	Barley[(a)]	29		
Potato	706	Leafy vegetables	Lettuce[(a)]	29	209/98	Belgium, 1999
			Cauliflower[(a)]	29		
		Root and tuber vegetables	Carrot[(a)]	29		
		Cereals	Wheat[(a)]	29		
Potato	1000	Leafy vegetables	Lettuce[(b)]	29	210/98	Belgium, 1999
			Broccoli[(b)]	29		
		Root and tuber vegetables	Carrot[(b)]	29		
		Cereals	Barley[(b)]	29		
Bare soil	576-609	Leafy vegetables	Spinach[(c)]	28-30, 59-63, 180-185, 365	S11-00510 S11-00511	Belgium, 2013
	576-609	Root and tuber vegetables	Carrot[(c)]	28-30, 59-63, 180-182, 364-365		
	586-597	Cereals	Wheat[(d)]	30, 59-60, 365-464		
	576-583	Cereals	Barley[(a)]	28, 63, 365		

(a): One trial (North EU).
(b): One trial (South EU).
(c): Four trials (2 North EU, 2South EU).
(d): Three trials (2 North EU, 2South EU

Summary of field rotational crop studies in the EU

Reference: Belgium, 2013

"Three field rotational crop studies (conducted in CH, UK and IT) were evaluated in the framework of the review for first inclusion in Annex I of Dir. 91/414/EEC and showed no residues at or above the LOQ of 0.02 mg/kg in any of the crops representative of leafy vegetables, root vegetables, cereals and brassica vegetables installed as succeeding crops after treatment of potatoes with metalaxyl-M at 0.7 – 1 kg a.s./ha, except in immature broccoli (BBCH 16-19) and in immature lettuce (BBCH 17-43), where residues of 0.11 mg/kg and 0.03-0.04 mg/kg were found, respectively.

Considering the exaggerated application rates used in these studies (2.4N – 3.4N compared to highest seasonal application rate recommended for tomatoes in GAP supported for renewal of a.s. approval), residue levels of metalaxyl in consumable parts of rotational crops were not expected to be above 0.05 mg/kg (i.e. previous LOQ) as a result of the representative uses of metalaxyl-M considered in the RAR (2014).

However, the previously evaluated studies had some shortcomings (no cereal grain/straw analysed, only PBI of approximately 30 days investigated, application was made to the primary crop instead of to bare soil) and therefore further investigation was deemed appropriate.

In the RAR (2014), two additional field rotational crop studies (2 trials in NEU and 2 trials in SEU in 2011-2012) have been evaluated, in which metalaxyl-M was applied to bare soil at approximately 600 g a.s./ha,

i.e. 2N compared to the highest seasonal application rate recommended for tomatoes in GAP supported for renewal of a.s. approval. No residues of metalaxyl-M above the LOQ (0.01 mg/kg) were found in cereal grain or carrot root at any plant-back interval (PBI). In the other crop fractions, quantifiable levels were only found at PBI 30 days and PBI 60 days.
Considering those parts representative of commodities used for human consumption, significant residue levels (i.e. > LOQ 0.01 mg/kg) were only observed in spinach leaves (up to 0.03 mg/kg at PBI 30 days). Levels of metalaxyl-M above 0.01 mg/kg were not found at PBI 60 days.
Considering those parts representative of commodities used for livestock feeding, significant residue levels were found in cereal straw (up to 0.06 mg/kg in barley, up to 0.03 mg/kg in wheat), in carrot tops (up to 0.02 mg/kg) and in spinach (representative of other green forage crops; up to 0.03 mg/kg)."

Conclusion on rotational crops studies
For the proposed uses of A23109A, the maximum application rate is 174.4 g metalaxyl-M/ha (2 x 87.2 g a.s./ha). The field rotation studies considered in the RAR (2014) were conducted at approximately 600 g a.s./ha, i.e. approximately three times (3.4N) the maximum rate/ha for A23109A.
Considering the overdosing factor of the above studies and the fact that metalaxyl-M was applied to bare soil (interception of metalaxyl-M by the plants is expected in practice), it can be concluded that metalaxyl-M residue levels in rotational commodities are not expected to exceed 0.01 mg/kg in edible crops or exceed 0.05 mg/kg feed items, provided that metalaxyl-M is applied in compliance with the GAPs supported for this submission.

Evaluator comments:
zRMS-PL agrees with the summary of rotational crops studies reported in the EU proposed by the Applicant.
Based on the available information, it was concluded that significant residue levels are unlikely to occur in rotational crops, provided that the compound is used according to the proposed good agricultural practice (GAP). The crops under consideration can be grown in rotation.

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

According to SANTE/11956/2016 rev. 9 (Commission Services, 2018), herbs and edible flowers are considered to possess melliferous capacity.
A new study has been submitted by the applicant in the framework of this application, using a surrogate crop with high melliferous capacity (spring oilseed rape). This study has been conducted in accordance with SANTE/11956/2016 rev. 9 (Commission Services, 2018).
This study has been summarised in the table below. The detailed assessment of this study is presented in Appendix 2.

Table 7.2-15: Summary of new data supporting the intended uses of A23109A in melliferous crops

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Residue levels (mg/kg) [(a)]	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) [(b)]	MRL compliance
Spring Oilseed rape **cGAP: 2 x 100 g a.s./ha, at BBCH 61-63 (PHI 7-14d)** **Tunnel studies**	New trials	NEU	5 x <0.01	<0.01	<0.01	0.01	0.05	Yes

(a) Definition of residue for enforcement and risk assessment are the same: Metalaxyl and metalaxyl-M (metalaxyl including other mixtures of constituent isomers including Metalaxyl-M (sum of isomers)) (R)
(b) Source of EU MRL: Reg. (EU) 2017/1164

The tunnel residue trials were conducted with two applications at a rate 100 g a.s./ha covering the highest annual application rate (2 x 87.2 g a.s./ha) proposed for the intended uses in herbs and edible flowers. Due to its high melliferous capacity, spring oilseed rape was selected to support the intended uses. Therefore the design of these trials can be considered as the most critical scenario. Considering the data available, it is evident that residues of metalaxyl-M residues are typically <LOQ (0.01 mg/kg) in honey. The data submitted show that no exceedance of the current EU MRL will occur. The uses in herbs and edible flowers are considered acceptable.

zRMS comments:
According to the SANTE/11956/2016 rev. 9, 14 September 2018, the residues are expected in honey after pesticide application when a substance is applied during the flowering stage (BBCH 60-69) of a crop which is foraged by bees and when a substance with systemic properties is applied prior to the flowering stage (before BBCH 60), including treatment of seeds, of a crop which is foraged by bees.
Herbs and edible flowers are considered to possess melliferous capacity.

The Applicant submitted a new honey residue study in the framework of this application.
Five residue trials were conducted with two applications of metalaxyl-M at a rate 100 g a.s./ha on spring oilseed rape. At the time of the first application the BBCH of the crop was between 51 and 64. At the time of the second application the crop was at BBCH 61 to 65.
The study was conducted, under confined semi-field conditions.

Results:
No residues of metalaxyl-M were detected at or above the limit of quantification (0.01 mg/kg) in the honey samples of any of the trials. The residues of metalaxyl-M is below the existing MRL of 0.05* mg/kg (Commission Regulation (EU) No. 2017/1164).
The study is acceptable. No further 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).
The input values used for the chronic and acute risk assessments are the proposed or current EU MRLs contained in Regulation (EU) No. 2017/1164. All crop and animal commodities with a specified MRL were considered in the risk assessments with no refinements.
All MRLs for metalaxyl-M are based on the residue definition for monitoring/enforcement of parent metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers), which is also the residue definition for risk assessment. No Conversion Factor is required to account for the residue definitions, and no processing factors are required.

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-16: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Reference	Input value (mg/kg)	Reference
Risk assessment residue definition: Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)				
Grapefruits	0.7	Reg. (EC) 2017/1164	--	--
Oranges	0.7	Reg. (EC) 2017/1164	--	--
Lemons	0.5	Reg. (EC) 2017/1164	--	--
Limes	0.5	Reg. (EC) 2017/1164	--	--

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Reference	Input value (mg/kg)	Reference
Mandarins	0.5	Reg. (EC) 2017/1164	--	--
Other citrus fruits	0.5	Reg. (EC) 2017/1164	--	--
Apples	1	Reg. (EC) 2017/1164	--	--
Pears	1	Reg. (EC) 2017/1164	--	--
Table grapes	2	Reg. (EC) 2017/1164	--	--
Wine grapes	1	Reg. (EC) 2017/1164	--	--
Strawberries	0.6	Reg. (EC) 2017/1164	--	--
Blackberries	0.02*	Reg. (EC) 2017/1164	--	--
Dewberries	0.02*	Reg. (EC) 2017/1164	--	--
Raspberries (red and yellow)	0.02*	Reg. (EC) 2017/1164	--	--
Others cane fruit	0.02*	Reg. (EC) 2017/1164	--	--
Currants (black, red and white)	0.4	Reg. (EC) 2017/1164	--	--
Gooseberries (green, red and yellow)	0.3	Reg. (EC) 2017/1164	--	--
Kiwi fruit (green, red and yellow)	0.02*	Reg. (EC) 2017/1164	--	--
Potatoes	0.02*	Reg. (EC) 2017/1164	--	--
Beetroots	0.02*	Reg. (EC) 2017/1164	--	--
Carrots	0.1	Reg. (EC) 2017/1164	--	--
Horseradishes	0.1	Reg. (EC) 2017/1164	--	--
Parsnips	0.1	Reg. (EC) 2017/1164	--	--
Radishes	0.06	Reg. (EC) 2017/1164	--	--
Salsifies	0.02*	Reg. (EC) 2017/1164	--	--
Swedes/rutabagas	0.01*	Reg. (EC) 2017/1164	--	--
Turnips	0.01*	Reg. (EC) 2017/1164	--	--
Garlic	0.02*	Reg. (EC) 2017/1164	0.02	HR
Onions	0.5	Reg. (EC) 2017/1164	0.02	HR
Shallots	0.02*	Reg. (EC) 2017/1164	0.02	HR
Spring onions	0.3	Reg. (EC) 2017/1164	0.021	HR
Tomatoes	0.3	Reg. (EC) 2017/1164	--	--
Sweet peppers/bell peppers	0.5	Reg. (EC) 2017/1164	--	--
Aubergines/eggplants	0.01*	Reg. (EC) 2017/1164	--	--
Cucumbers	0.5	Reg. (EC) 2017/1164	--	--
Gherkins	0.01*	Reg. (EC) 2017/1164	--	--
Courgette	0.01*	Reg. (EC) 2017/1164	--	--
Other cucurbits with edible peel	0.01*	Reg. (EC) 2017/1164	--	--
Melons	0.2	Reg. (EC) 2017/1164	--	--
Pumpkins	0.01*	Reg. (EC) 2017/1164	--	--
Watermelons	0.2	Reg. (EC) 2017/1164	--	--
Other cucurbits with inedible peel	0.01*	Reg. (EC) 2017/1164	--	--
Sweet corn	0.05*	Reg. (EC) 2017/1164	--	--

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Reference	Input value (mg/kg)	Reference
Other fruiting vegetables	0.01*	Reg. (EC) 2017/1164	--	--
Broccoli	0.2	Reg. (EC) 2017/1164	0.024	HR
Cauliflowers	0.2	Reg. (EC) 2017/1164	0.01	HR
Other flowering brassica	0.2	Reg. (EC) 2017/1164	--	--
Brussels sprouts	0.15	Reg. (EC) 2017/1164	0.01	HR
Head cabbages	0.06	Reg. (EC) 2017/1164	0.02	HR
Other head brassicas	0.01*	Reg. (EC) 2017/1164	--	--
Chinese cabbages/pe-tsai [1]	~~0.2~~ 0.02*	~~EU proposed MRL~~ Reg. (EC) 2017/1164	0.08	HR
Kales	0.3	Reg. (EC) 2017/1164	0.08	HR
Other leafy brassicas	0.01*	Reg. (EC) 2017/1164	0.08	HR
Kohlrabies	0.02*	Reg. (EC) 2017/1164	--	--
Lamb's lettuces/corn salads	3	Reg. (EC) 2017/1164	0.31	HR
Lettuces	3	Reg. (EC) 2017/1164	0.31	HR
Escaroles/broad-leaved endives	3	Reg. (EC) 2017/1164	0.31	HR
Cresses and other sprouts and shoots	3	Reg. (EC) 2017/1164	0.31	HR
Land cresses	3	Reg. (EC) 2017/1164	0.31	HR
Roman rocket/rucola	3	Reg. (EC) 2017/1164	0.31	HR
Red mustards	3	Reg. (EC) 2017/1164	0.31	HR
Baby leaf crops (including brassica species)	3	Reg. (EC) 2017/1164	0.31	HR
Other lettuce and salad plants	3	Reg. (EC) 2017/1164	--	--
Spinaches	1.5	Reg. (EC) 2017/1164	0.31	HR
Purslanes	1.5	Reg. (EC) 2017/1164	0.31	HR
Chards/beet leaves	1.5	Reg. (EC) 2017/1164	0.31	HR
Other spinaches and similar leaves	1.5	Reg. (EC) 2017/1164	--	--
Watercress	~~0.4~~ 0.01*	~~EU proposed MRL~~ Reg. (EC) 2017/1164	0.31	HR
Witloofs/Belgian endives	3	Reg. (EC) 2017/1164	0.31	HR
Chervil	3	Reg. (EC) 2017/1164	0.31	HR
Chives	3	Reg. (EC) 2017/1164	0.021	HR
Celery leaves	3	Reg. (EC) 2017/1164	0.31	HR
Parsley	3	Reg. (EC) 2017/1164	0.31	HR
Sage	3	Reg. (EC) 2017/1164	0.31	HR
Rosemary	3	Reg. (EC) 2017/1164	0.31	HR
Thyme	3	Reg. (EC) 2017/1164	0.31	HR
Basil and edible flowers	3	Reg. (EC) 2017/1164	0.31	HR
Laurel/bay leaves	3	Reg. (EC) 2017/1164	0.31	HR
Tarragon	3	Reg. (EC) 2017/1164	0.31	HR
Other herbs and edible flowers	3	Reg. (EC) 2017/1164	0.31	HR

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Reference	Input value (mg/kg)	Reference
Beans (with pods)	0.02*	Reg. (EC) 2017/1164	--	--
Beans (without pods)	0.02*	Reg. (EC) 2017/1164	--	--
Peas (with pods)	0.02*	Reg. (EC) 2017/1164	--	--
Peas (without pods)	0.02*	Reg. (EC) 2017/1164	--	--
Lentils	0.01*	Reg. (EC) 2017/1164	--	--
Other legume vegetables	0.01*	Reg. (EC) 2017/1164	--	--
Asparagus	0.02*	Reg. (EC) 2017/1164	--	--
Globe Artichokes	0.05*	Reg. (EC) 2017/1164	--	--
Leeks	0.03	Reg. (EC) 2017/1164	0.021	HR
Beans (Pulses)	0.02*	Reg. (EC) 2017/1164	--	--
Lentils (Pulses)	0.01*	Reg. (EC) 2017/1164	--	--
Peas (Pulses)	0.02*	Reg. (EC) 2017/1164	--	--
Lupins/lupini beans	0.02*	Reg. (EC) 2017/1164	--	--
Other pulses	0.01*	Reg. (EC) 2017/1164	--	--
Linseeds	0.02*	Reg. (EC) 2017/1164	--	--
Poppy seeds	0.02*	Reg. (EC) 2017/1164	--	--
Sunflower seeds	0.02*	Reg. (EC) 2017/1164	--	--
Rapeseed/canola seeds	0.02*	Reg. (EC) 2017/1164	--	--
Soyabeans	0.1*	Reg. (EC) 2017/1164	--	--
Mustards seeds	0.02*	Reg. (EC) 2017/1164	--	--
Cotton seeds	0.01*	Reg. (EC) 2017/1164	--	--
Pumpkin seeds	0.01*	Reg. (EC) 2017/1164	--	--
Gold of Pleasure	0.02*	Reg. (EC) 2017/1164	--	--
Maize/corn	0.02*	Reg. (EC) 2017/1164	--	--
Sorghum	0.01*	Reg. (EC) 2017/1164	--	--
Teas	0.05*	Reg. (EC) 2017/1164	--	--
Herbal Infusions	0.05*	Reg. (EC) 2017/1164	--	--
Cocoa beans	0.1	Reg. (EC) 2017/1164	--	--
Hops	15	Reg. (EC) 2017/1164	--	--
Anise/aniseed	0.05*	Reg. (EC) 2017/1164	--	--
Black caraway/black cumin	0.05*	Reg. (EC) 2017/1164	--	--
Celery	0.05*	Reg. (EC) 2017/1164	--	--
Coriander	0.05*	Reg. (EC) 2017/1164	--	--
Cumin	0.05*	Reg. (EC) 2017/1164	--	--
Dill	0.05*	Reg. (EC) 2017/1164	--	--
Fennel	0.05*	Reg. (EC) 2017/1164	--	--
Fenugreek	0.05*	Reg. (EC) 2017/1164	--	--
Nutmeg	0.05*	Reg. (EC) 2017/1164	--	--
Others seed spices	0.05*	Reg. (EC) 2017/1164	--	--

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Reference	Input value (mg/kg)	Reference
Allspice/pimento	0.1*	Reg. (EC) 2017/1164	--	--
Sichuan pepper	0.1*	Reg. (EC) 2017/1164	--	--
Caraway	0.1*	Reg. (EC) 2017/1164	--	--
Cardamom	0.1*	Reg. (EC) 2017/1164	--	--
Juniper berry	0.1*	Reg. (EC) 2017/1164	--	--
Peppercorn (black, green and white)	0.1*	Reg. (EC) 2017/1164	--	--
Vanilla	0.1*	Reg. (EC) 2017/1164	--	--
Tamarind	0.1*	Reg. (EC) 2017/1164	--	--
Others fruit spices	0.05*	Reg. (EC) 2017/1164	--	--
Sugar beet roots	0.01*	Reg. (EC) 2017/1164	--	--
Swine/bovine/sheep/goat/equine/poultry/others: muscle	0.01*	Reg. (EC) 2017/1164	0.01*	Reg. (EC) 2017/1164
Swine/bovine/sheep/goat/equine/ poultry/others: fat	0.01*	Reg. (EC) 2017/1164	0.01*	Reg. (EC) 2017/1164
Swine/bovine/sheep/goat/equine/poultry/others: liver	0.05*	Reg. (EC) 2017/1164	0.05*	Reg. (EC) 2017/1164
Swine: kidney	0.2	Reg. (EC) 2017/1164	0.2	Reg. (EC) 2017/1164
Bovine/sheep/goat/equine/ others: kidney	0.3	Reg. (EC) 2017/1164	0.3	Reg. (EC) 2017/1164
Poultry: kidney	0.05*	Reg. (EC) 2017/1164	0.05*	Reg. (EC) 2017/1164
Swine: other edible offals	0.2	Reg. (EC) 2017/1164	0.2	Reg. (EC) 2017/1164
Bovine/sheep/goat/ equine/others: other edible offals	0.3	Reg. (EC) 2017/1164	0.3	Reg. (EC) 2017/1164
Poultry: other edible offals	0.05*	Reg. (EC) 2017/1164	0.05*	Reg. (EC) 2017/1164
Swine/bovine/ sheep/goat/equine/poultry/others: other tissues	0.01*	Reg. (EC) 2017/1164	0.01*	Reg. (EC) 2017/1164
Milk	0.01*	Reg. (EC) 2017/1164	0.01*	Reg. (EC) 2017/1164
Birds Eggs	0.01*	Reg. (EC) 2017/1164	0.01*	Reg. (EC) 2017/1164

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 1.

Table 7.2-17: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo 3.1	31% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	Not required as TMDI < 100%
IESTI RAC (% ARfD) according to EFSA PRIMo*	Escaroles/broad-leaved endives: 2% (based on BE toddler) Lettuces : 2% (based on NL child)
IESTI Processed (% ARfD) according to EFSA PRIMo*	Escaroles/broad-leaved endives / boiled: 4% (based on NL toddler) Chards/beet leaves / boiled: 2% (based on NL child)

* include raw and processed commodities if both values are required for PRIMo 3

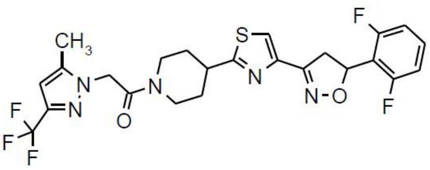
The proposed uses of metalaxyl-M in A23109A do not represent unacceptable acute and chronic risks for the consumer.

Evaluator comments:
The MRLs currently in place for metalaxyl-M (Reg. (EC) 2017/1164) for all crops and animal commodities are given in the Table 7.2-16. The potential chronic dietary exposure was compared to the ADI of 0.08 mg/kg bw/day and TMDI values were achieved. The highest chronic exposure was calculated for NL toddler Diet, representing 31% of the ADI. The highest contributor for this diet was calculated for apples (13% of ADI).
For acute exposure calculation – HR input values from results of supervised residue trials performed for metalaxyl-M for intended uses only and for animal commodities. The potential acute dietary exposure was compared to the ARfD of 0.5 mg/kg bw. According to calculation, no exceedance of the ARfD was identified.
The results indicate that there is no unacceptable chronic and acute risk to human health from the consumption of commodities treated with metalaxyl-M according to the uses considered.

7.3 Oxathiapiprolin

General data on oxathiapiprolin are summarized in the table below.
Oxathiapiprolin is referred to be code DPX-QGU42 in some locations within the document.
Oxathiapiprolin is owned by Corteva Agriscience International Sàrl (formally DuPont International Operations Sarl; change effective January 4, 2021) (hereafter called "Corteva"). Syngenta has a Letter of Access in place to access data owned by DuPont relevant for this evaluation. Residue trial summaries for oxathiapiprolin can be found in Appendix 2. For the actual reports, please refer to the data owner.

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~~ 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	EFSA-Q-2017-00581; EFSA-Q-2017-00582 (Ireland) Hops, bulb onions, garlic, peppers, sunflowers and wine grapes Status: Reasoned opinion available (EFSA Journal 2019;17(7):5759) EFSA-Q-2020-00135 (UK) Citrus fruits, blackberries, raspberries, Chinese cabbage, basil and edible flowers. Asparagus Status: Reasoned opinion available (EFSA Journal 2020;18(6):6155)

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

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 at ≤ - 18°C (unless stated otherwise)

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		
New data				
Animal products				
Honey	Bee	112 days	CEMR-9533	Ford, 2020
Honey	Bee	153 days	CEMR-9822	Ford, 2021

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.”

New data

Storage stability of oxathiapiprolin was demonstrated in honey for 112 days when frozen (approximately -20°C).

Conclusion on stability of residues during storage

The storage stability of oxathiapiprolin and its relevant metabolites has been investigated in different groups, including dry commodities, high water, high oil, high protein, high starch and high acid. The storage stability of oxathiapiprolin has been investigated in honey. Sufficient stability has been demonstrated to support the residue data presented in the 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 new storage stability studies. The study of Ford, 2021; CEMR-9822 has been evaluated by zRMS-PL in RR – Part B7 for A22773A/ Orondis Evo (2023).

Frozen storage stability of oxathiapiprolin in honey was demonstrated for a period of 112 (Ford, 2020; CEMR-9533) and 153 days (Ford, 2021; CEMR-9822) 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

No new data submitted in the framework of this application.

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.

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, 2016 EFSA, 2016

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)		
	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, 2019a
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, 2016 EFSA, 2016
		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, 2019a
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 Tuber(b) 14 $DAT_{2,3}$ 28 DAT_3	Doig, C.; 2013 Report No.: DuPont-28068	Ireland, 2016 EFSA, 2016
		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, 2019a

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

Summary of plant metabolism studies reported in the EU

Reference: EFSA, 2019a

"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 and were found at 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 metabolises to IN-E8S72 in livestock and is expected to similarly metabolise 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 application is sufficiently addressed to support the proposed uses of the product A23109A.

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

No new data submitted in the framework of this application.

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.

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, 2016 EFSA, 2016
		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, 2019a
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, 2016 EFSA, 2016
		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, 2019a
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, 2016
		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, 2019a

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

Summary of metabolism studies in rotational crops reported in the EU

Reference: EFSA, 2019a

"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 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 (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).*

Residue definitions for enforcement and risk assessment derived for primary crops as parent oxathiapiprolin are also applicable to rotational crops.

No additional data are required.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

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.

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, 2016
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 hydrolytically stable under the representative processing conditions and the same residue definitions as for raw agricultural commodities apply.

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, 2019a)
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, 2019a)
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 2019a; Reg. (EU) No 2023/163)
Plant residue definition for risk assessment	Oxathiapiprolin (EFSA, 2016 and 2019a)
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

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

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	2013 Report No.: Du-Pont 28213	Ireland, 2015; EFSA, 2016
						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	2013 Report No.: Du-Pont-34913	Ireland, 2015; EFSA 2016
						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	2013 Report No.: Du-Pont-28244	Ireland, 2015; EFSA 2016
						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-^{14}C]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 is sufficiently addressed to support the proposed uses of the product A23109A.

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) No 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 residue have been submitted by the applicant in the framework of this application. These studies are summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2. For the sake of completeness, also EU reviewed studies are also presented in detail in Appendix 2.

Table 7.3-9: Summary of EU reported and new data supporting the intended uses of A23109A and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[(a)]	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) [(b)]	MRL compliance
Flowering brassica (Broccoli, cauliflowe**r)**	**Intended GAP**	**N-EU**	2 x 15 g as/ha, 7d int, PHI 20d					
	New trials	N-EU	Broccoli Zonal Trials GAP: 2 x 15 g as/ha, PHI 20d 2 x <0.01, 0.0152, 0.0172					
	New trials	N-EU	Cauliflower Zonal Trials GAP: 2 x 15 g as/ha, PHI 14d 4 x <0.01					
	Overall supporting data for intended cGAP	N-EU	6 x <0.01, 0.0152, 0.0172	0.010	0.017	0.023	1.5	Yes
Kale → extrapolated to Chinese cabbage,	**Intended GAP**	**N-EU**	2 x 15 g as/ha, 7d int, PHI 20d					
	New trials	N-EU	Trials GAP: 2 x 15 g as/ha, PHI 20d 2 x <0.01, 0.01, 0.02					

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[(a)]	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) [(b)]	MRL compliance
leafy brassicas and curly kale	Overall supporting data for intended cGAP	N-EU	2 x <0.01, 0.01, 0.02	0.01	0.02	0.033	Kale: 0.01 Chinese cabbage: 9	~~Yes~~ No for kale and curly kale, Yes for Chinese cabbage An MRL application for kale has been submitted to France in August 2021 to increase the MRL from 0.01 mg/kg to 0.04 mg/kg.
Head cabbage → extrapolated to Savoy cabbage	**Intended GAP**	**N-EU**	2 x 15 g as/ha, 7d int, PHI 20d					
	New trials	N-EU	Trials GAP: 2 x 15 g as/ha, PHI 20d 8 x <0.01					
	Overall supporting data for intended cGAP	N-EU	8 x <0.01	0.010	0.010	0.010	0.7	Yes
Brussels sprout	**Intended GAP**	**N-EU**	2 x 15 g as/ha, 7d int, PHI 20d					
	New trials	N-EU	Trials GAP: 2 x 15 g as/ha, PHI 20d 3 x <0.01, 0.01					

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[(a)]	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) [(b)]	MRL compliance
	Overall supporting data for intended cGAP	N-EU	3 x <0.01, 0.01	0.010	0.010	0.015	0.01	Yes An MRL application to increase the MRL to 0.015 mg/kg was submitted to ANSES in August 2021.
Lettuce (open leaf) → extrapolated to Baby leaf, chards and beet leaves, chicory, common purslane, cress, endive, escarole, herbs and edible flowers, parsley, chive, iceberg lettuce, lamb's lettuce, red mustard, watercress, rocket, spinach and chives	**Intended GAP**	**N-EU**	2 x 15 g as/ha, 7d int, PHI 10d (20d for red mustard)					
	Zonal cGAP	**N-EU**	2 x 15 g a.s./ha, 7 d interval, PHI 7d					
	EFSA, 2016	N-EU	Trials GAP: 2 x 15 g as/ha, PHI <u>7</u>-10d <u>0.022</u>, 0.027, <u>0.035</u>, <u>0.069</u>, 0.070, 0.12, 0.13, <u>0.19</u>					
	Overall supporting data for intended cGAP	N-EU	<u>0.022</u>, 0.027, <u>0.035</u>, <u>0.069</u>, 0.070, 0.12, 0.13, <u>0.19</u>	0.070	0.190	0.32	Lettuce, and salad plant: 5 Spinach and similar leaves: 15 Watercress: 0.01* Herbs and edible flowers, chives, parsley: 0.02*	Yes for Lettuce, salad plant, spinach and similar leaves No for herbs and edible flowers except basil and edible flowers (0256080), No for parsley, chives and watercress

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[(a)]	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) [(b)]	MRL compliance
							Basil and edible flowers:10	An MRL application for watercress, herbs and edible flowers to increase the MRL to 0.8 mg/kg was submitted to ANSES. in August 2021.
Leek → extrapolated to Spring onions/green onions, Welsh onions	**Intended GAP**	**N-EU**	2 x 15 g as/ha, 12-14d int, PHI 14d					
	New trials	N-EU	Trials GAP: 2 x 15 g as/ha, PHI 14d 6 x <0.01, 0.0166, 0.0275					
	Overall supporting data for intended cGAP	N-EU	6 x <0.01, 0.0166, 0.0275	0.010	0.028	0.033	Leeks, Spring onions/green onions and Welsh onion:2	Yes
Onion → extrapolated to bulb veges including shallots, garlic	**Intended GAP**	**N-EU**	2 x 15g as/ha, 7d int, PHI 14d					
	EFSA, 2019	N-EU	Trials GAP: 3 x 20 g as/ha, PHI 7d 8 x <0.01					
	Overall supporting data for intended cGAP	N-EU	8 x <0.01	0.010	0.010	0.010	Onion Garlic and shallots: 0.04	Yes

(a) Definition of residue for enforcement and risk assessment are the same: oxathiaîprolin
(b) Source of EU MRL: ~~No 2021/1807~~ Reg. (EU) 2023/163
* denotes MRL at LOQ

7.3.3.2 Conclusion on the magnitude of residues in plants

A23109A is used as a foliar treatment on flowering brassicas, kale, Chinese cabbage, curly kale, head cabbage, Savoy cabbage, Brussels sprout, field and/or indoor lettuce, baby leaf , chards and beet leaves, chicory, common purslane, cress, endive, escarole, herbs and edible flowers, iceberg lettuce, lamb's lettuce, red mustard, watercress, rocket, spinach leek, spring/green onion, Welsh onion, onion, garlic and shallots.

Flowering brassica

Broccoli is a minor crop in northern Europe (SANTE/2019/12752); and therefore, generally requires four trials in the residue region. Cauliflower is a major crop in northern Europe (SANTE/2019/12752); and therefore, generally requires eight trials in the residue region. But according to SANTE/2019/12752, 4 trials on each crop can allow an extrapolation to the whole subgroup flowering brassica.

The intended GAP for A23109A is 2 x 15g as/ha, 7d interval, PHI 20d, field. A total of four trials conducted at 2 x 15 g as/ha, 7d interval, PHI 20d are submitted for broccoli and a total of four trials conducted at 2 x 77.6g as/ha, 7d interval, PHI 20d are submitted for cauliflower. These trials can be used to support the intended GAP, in accordance with the guidance SANTE/2019/12752.

Therefore, sufficient trials are available to support the proposed use on flowering brassica. The available submitted data show that no exceedance of the MRL will occur. The use is considered acceptable.

zRMS comments:
Information given by the Applicant is sufficient and accepted. Cauliflower is the major crop in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of eight trials are required. Broccoli is is a minor crop in northern Europe and therefore requires four trials in the residue region. According to SANTE/2019/12752, four residue trials on cauliflower and four residue trials on broccoli can be combined to support uses on the whole subgroup of flowering brassica. The intended GAP for oxathiapiprolin for flowering brassica in Central Europe is 2x15 g a.s./ha with interval between applications of 7-10 days at BBCH 12-49 with PHI of 20 days. New study on the magnitude of residue have been submitted by the Applicant in the framework of this application. A total of 4 new supervised residue trials on broccoli and 4 trials on cauliflower were performed in Northern Europe during 2020. 1. Meyer M., Poperechna N., 2021, report No IF20-05335380 - the tested application rates and timings, corresponded to the intended GAP for A23109A. The trials are supported by valid storage stability data and validated analytical methods. Residues of oxathiapiprolin in broccoli samples taken at 20 DALA (NCH) were between <0.01 – 0.0172 mg/kg. 2. Mahlo C., 2021, report No IF20-05336777- two applications, separated by a 7-8 day interval were made at 15 g ai/ha for oxathiapiprolin. The residues of oxathiapiprolinin the treated cauliflower (inflorescences) samples taken from all trials at 20 DALA were < 0.01 mg/kg. The trials were supported by valid storage stability data and validated analytical methods. The residues arising from the proposed uses will not exceed the MRLs established for oxathiapiprolinfor broccoli and cauliflower of 1.5 mg/kg in Reg. (EU) 2023/163. The uses are considered acceptable.

Kale

Kale is a minor crop in northern Europe (SANTE/2019/12752); and therefore, generally requires four trials in the residue region.

The intended GAP for A23109A is 2 x 15g as/ha, 7d interval, PHI 20d, field. A total of four trials conducted at 2 x 15 g as/ha, 7d interval, PHI 20d are submitted for kale. These trials can be used to support the intended GAP, in accordance with the guidance SANTE/2019/12752.

Therefore, sufficient trials are available to support the proposed use on kale. The available submitted data show that an exceedance of the MRL will occur. An MRL application to increase the MRL to 0.04 mg/kg was submitted to ANSES in August 2021. The use is considered acceptable.

zRMS comments:

Information given by the Applicant is sufficient and accepted. Kale is a minor crop in northern Europe and therefore requires four trials in the residue region. The intended GAP for oxathiapiprolin for kale in Central Europe is 2x15 g a.s./ha with interval between applications of 7 – 10 days at BBCH 12-49 with PHI of 20 days. New study on the magnitude of residue have been submitted by the Applicant in the framework of this application. A total of 4 new supervised residue trials on kale were performed in Northern Europe during 2020/2021. 1. Brown S., 2021, report No RES-00256 - the tested application rates and timings, corresponded to the intended GAP for A23109A. The trials are supported by valid storage stability data and validated analytical methods. Residues of oxathiapiprolinin kale samples taken at 20 DALA (NCH) were between <0.01 – 0.02 mg/kg. **Considering the intended use on kale, an exceedance of the MRL for oxathiapiprolin, as established in Commission Regulation (EU) 2023/163 (MRL of 0.01 mg/kg for kale) is expected. Therefore until the new MRL for kale come into force, authorization of the GAP will not be possible.** **The proposed use on kale is not considered acceptable.**

Leafy brassicas, Chinese cabbage/pet-tsai, curly kale

Leafy brassicas including Chinese cabbage/pet-tsai and curly kale are minor crops in northern Europe (SANTE/2019/12752); and therefore, generally requires four trials in the residue region.
The intended GAP for A23109A is 2 x 15g as/ha, 7d interval, PHI 20d, field. No specific residue trials on leafy brassicas including Chinese cabbage/pet-tsai and curly kale were conducted, instead residues trials conducted on kale were used to extrapolate to leafy brassicas including Chinese cabbage/pet-tsai and curly kale (SANTE/2019/12752). The available data were from four trials conducted on kale at a rate of 2 x 15g as/ha, 7d interval, PHI 20d which is equivalent to the rate proposed for Chinese cabbage and curly kale.
Therefore, sufficient trials are available to support the proposed use on leafy brassicas including Chinese cabbage/pe-tsai and curly kale. The available submitted data show that no exceedance of the MRL will occur. The use is considered acceptable.

zRMS comments: Leafy brassicas including Chinese cabbage/pet-tsai and curly kale are the minor crops in northern Europe and therefore requires four trials in the residue region. The intended GAP for oxathiapiprolin for leafy brassicas including Chinese cabbage/pet-tsai and curly kale in Central Europe is 2x15 g a.s./ha with interval between applications of 7 – 10 days at BBCH 12-49 with PHI of 20 days. No new studies on the magnitude of residue have been submitted by the Applicant in the framework of this application. Residue data on kales (0243020) can be extrapolated to Whole subgroup (c) leafy brassica (0243000) before and after forming of the edible part. Four supervised residue trials on kale were conducted with the same GAP as for leafy brassica. The trials were supported by valid storage stability data for lettuce and validated analytical methods. Residues of oxathiapiprolinin kale samples taken at 20 DALA (NCH) were between <0.01 – 0.02 mg/kg. The residues arising from the proposed use on Chinese cabbage/pet-tsai will not exceed the MRL established for oxathiapiprolin for Chinese cabbage/pet-tsai of 9 mg/kg in Reg. (EU) 2023/163. **The use on Chinese cabbage/pet-tsai is considered acceptable.** **Considering the intended use on curly kale, an exceedance of the MRL for oxathiapiprolin, as established in Reg. (EU) 2023/163 (MRL of 0.01 mg/kg) is expected. Therefore until the new MRL for curly kale come into force, authorization of the GAP will not be possible.** **The proposed use on curly kale is not considered acceptable.**

Head cabbage

Head cabbage is a major crop in northern Europe (SANTE/2019/12752); and therefore, generally requires
The intended GAP for A23109A is 2 x 15g as/ha, 7d interval, PHI 20d, field. A total of eight trials conducted at 2 x 15 g as/ha, 7d interval, PHI 20d are submitted for head cabbage. These trials can be used to support the intended GAP, in accordance with the guidance SANTE/2019/12752.
Therefore, sufficient trials are available to support the proposed use on head cabbage. The available submitted data show that no exceedance of the MRL will occur. The use is considered acceptable.

zRMS comments:
Information given by the Applicant is sufficient and accepted.
Head cabbage 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 head cabbage in Central Europe is 2x15 g a.s./ha with interval between applications of 7 – 10 days at BBCH 12-49 with PHI of 20 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 on head cabbage were performed in Northern Europe during 2020:

- Ford K., 2021, report No CEMR-9523, document No VV-901921 - two applications, separated by a 7 day interval were made at 15 g ai/ha for oxathiapiprolin. The trials are supported by valid storage stability data and validated analytical methods.

Residues of oxathiapiprolin in head cabbage samples taken at 20 DALA (NCH) were <0.01 mg/kg.

The residues arising from the proposed use on head cabbage will not exceed the MRL established for oxathiapiprolin for head cabbage of 0.7 mg/kg in Reg. (EU) 2023/163.
The use on head cabbage is considered acceptable.

Savoy cabbage

Savoy cabbage is minor crop in northern Europe (SANTE/2019/12752); and therefore, generally requires four trials in the residue region.
The intended GAP for A23109A is 2 x 15g as/ha, 7d interval, PHI 20d, field. No specific residue trials on Savoy cabbage were conducted, instead residues trials conducted on head cabbage were used to extrapolate to Savoy cabbage (SANTE/2019/12752). The available data were from eight trials conducted on head cabbage at a rate of 2 x 15g as/ha, 7d interval, PHI 20d which is equivalent to the rate proposed for Savoy cabbage.
Therefore, sufficient trials are available to support the proposed use on Savoy cabbage. The available submitted data show that no exceedance of the MRL will occur. The use is considered acceptable.

zRMS comments:
Information given by the Applicant is sufficient and accepted.
Savoy cabbage is a minor crop in northern Europe and therefore requires four trials in the residue region.

The intended GAP for oxathiapiprolin for head cabbage and for savoy cabbage in Central Europe is 2x15 g a.s./ha with interval between applications of 7-10 days at BBCH 12-49 with PHI of 20 days.
No new studies on the magnitude of residue on savoy cabbage have been submitted by the Applicant in the framework of this application. According to SANTE/2019/12752, residue trials on head cabbage can be extrapolated to support use on Savoy cabbage.

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 on head cabbage were performed in Northern Europe during 2020:

- Ford K., 2021, report No CEMR-9523, document No VV-901921 - two applications, separated by a 7 day interval were made at 15 g ai/ha for oxathiapiprolin. The trials are supported by valid storage stability data and validated analytical methods.

Residues of oxathiapiprolin in head cabbage samples taken at 20 DALA (NCH) were <0.01 mg/kg.

The residues arising from the proposed use on savoy cabbage will not exceed the MRL established for oxathiapiprolin for head cabbage and savoy cabbage of 0.7 mg/kg in Reg. (EU) 2023/163.
The use on savoy cabbage is considered acceptable.

Brussels sprout

Brussels sprout is a minor crop in northern Europe (SANTE/2019/12752); and therefore, generally requires four trials in the residue region.
The intended GAP for A23109A is 2 x 15g as/ha, 7d interval, PHI 20d, field. A total of four trials conducted at 2 x 15 g as/ha, 7d interval, PHI 20d are submitted for Brussels sprout. These trials can be used to support the intended GAP, in accordance with the guidance SANTE/2019/12752.
Therefore, sufficient trials are available to support the proposed use on Brussels sprout. The available submitted data show that an exceedance of the MRL will occur. An MRL application to increase the MRL

to 0.015 mg/kg was submitted to ANSES in August 2021. The use is considered acceptable.

zRMS comments:
Information given by the Applicant is sufficient and accepted.
Brussels sprout is a minor crop in northern Europe and therefore requires four trials in the residue region.

The intended GAP for oxathiapiprolin for Brussels sprout in Central Europe is 2x15 g a.s./ha with interval between applications of 7 – 10 days at BBCH 12-49 with PHI of 20 days.

New study on the magnitude of residue have been submitted by the Applicant in the framework of this application. A total of 4 new supervised residue trials on Brussels sprout were performed in Northern Europe during 2020:

- Brown S., 2021, report No RES-00257, document No VV-901790 - two applications, separated by a 7 day interval were made at 15 g ai/ha for oxathiapiprolin. The trials are supported by valid storage stability data and validated analytical methods.

Residues of oxathiapiprolinin Brussels sprout samples taken at 20 DALA (NCH) were between <0.01 – 0.01 mg/kg.

The residues arising from the proposed use on Brussels sprout will not exceed the MRL established for oxathiapiprolin for Brussels sprout of 0.01 mg/kg in Reg. (EU) 2023/163.
The use on Brussels sprout is considered acceptable.

Lettuce (field)

Lettuce is a major crop in northern Europe (SANTE/2019/12752); and therefore, generally requires eight trials in the residue region.
The intended GAP for A23109A is 2 x 15g as/ha, 7d interval, PHI 10d, field on maximum 1 crop cycle or 1 x 15g as/ha, PHI 10d on maximum 2 crop cycles. A total of four trials conducted in northern Europe at 2 x 15 g as/ha, 7d interval, PHI 10d are submitted for lettuce (open leaf). Additionally, a total of four trials conducted at 2 x 15 g as/ha, 7d interval, PHI 7d are submitted for lettuce (open leaf). These 4 trials conducted at a more critical GAP can be used to support the intended GAP, because they are presenting a worst case.
In order to support the use of A23109A (a DC (dispersible concentrate) formulation) on field lettuce, the submitted residue trials on field lettuce have been conducted using an OD (oil dispersion) formulation (Report No. Dupont-31734). Technical Guidelines, SANTE/2019/12752 and OECD 509, state that in general residue trials should be performed with formulations equivalent to the formulations related to the GAP. It also states that according to MacLachlan and Hamilton[1], experience shows that formulations diluted in water prior to application, containing oils or organic solvents, such as emulsifiable concentrates (EC) and dispersible concentrates (DC), produce comparable residues, especially when the time between application and harvest is greater than 7 days.
OD and DC formulations are both diluted in water in the spray tank prior to application to the crop; both OD and DC formulations are oil/organic solvent based. The PHI of A23109A in the proposed use on field lettuce is 10 days, so differences in formulations are unlikely to have an impact on residue values at harvest. According to SANTE/2019/12752 and OECD 509, OD and DC formulations can therefore be considered equivalent. Therefore it is considered That these trials can be used to support the intended GAP, in accordance with the guidance SANTE/2019/12752.
Considering this, the data provided to support the use of A23109A on field lettuce are sufficient. Therefore, sufficient trials are available to support the proposed use on lettuce (open leaf). The available submitted data show that no exceedance of the MRL will occur. The use 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.
The intended GAP for oxathiapiprolin for lettuce in Central Europe is 2x15 g a.s./ha with interval between applications of 7 days at BBCH 12-49 with PHI of 10 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 MRL established for oxathiapiprolin for lettuces of 5 mg/kg in Reg. (EU) 2023/163.
The use is considered acceptable.

Baby leaf, chards and beet leaves, chicory, common purslane, cress, endive, escarole, herbs and edible flowers, parsley chives, iceberg lettuce, lamb's lettuce, red mustard, watercress, rocket, spinach (field)

Baby leaf, chards and beet leaves, chicory, common purslane, cress, endive, escarole, herbs and edible flowers, parsley, chives, iceberg lettuce, lamb's lettuce, red mustard, watercress, rocket, spinach are minor crops in northern Europe (SANTE/2019/12752); and therefore, generally requires four trials in the residue region.
The intended GAP for A23109A is 2 x 15g as/ha, 7d interval, PHI 10d, field and 2 x 15g as/ha, 7d interval, PHI 20d, field for red mustard. No specific residue trials on baby leaf, chards and beet leaves, chicory, common purslane, cress, endive, escarole, herbs and edible flowers, parsley, chives, iceberg lettuce, lamb's lettuce, red mustard, watercress, rocket, spinach were conducted, instead residues trials conducted on lettuce open leaf varieties were used to extrapolate to baby leaf, chards and beet leaves, chicory, common purslane, cress, endive, escarole, herbs and edible flowers, parsley, chives, iceberg lettuce, lamb's lettuce, red mustard, watercress, rocket, spinach (SANTE/2019/12752). The available data were from eight trials conducted on lettuce open leaf varieties at a rate of 2 x 15g as/ha, 7d interval, PHI 7-10d which is equivalent to the rate proposed for baby leaf, chards and beet leaves, chicory, common purslane, cress, endive, escarole, herbs and edible flowers, parsley, chives, iceberg lettuce, lamb's lettuce, ~~red mustard,~~ watercress, rocket, spinach and more critical for red mustard with a shorter PHI. The trials available in support of the cGAP were conducted using an OD formulation. In order to support the use of A23109A (a DC (dispersible concentrate) formulation) on field lettuce, the submitted residue trials on field lettuce have been conducted using an OD (oil dispersion) formulation (Report No. Dupont-31734). Technical Guidelines, SANTE/2019/12752 and OECD 509, state that in general residue trials should be performed with formulations equivalent to the formulations related to the GAP. It also states that according to MacLachlan and Hamilton[1], experience shows that formulations diluted in water prior to application, containing oils or organic solvents, such as emulsifiable concentrates (EC) and dispersible concentrates (DC), produce comparable residues, especially when the time between application and harvest is greater than 7 days.
OD and DC formulations are both diluted in water in the spray tank prior to application to the crop; both OD and DC formulations are oil/organic solvent based. The PHI of A23109A in the proposed use on field lettuce is 10 days, so differences in formulations are unlikely to have an impact on residue values at harvest. According to SANTE/2019/12752 and OECD 509, OD and DC formulations can therefore be considered to be equivalent. Therefore it is considered valid to support the intended use with these trials. These trials can be used to support the intended GAP, in accordance with the guidance SANTE/2019/12752.
Considering this, the data provided to support the use of A23109A on field lettuce are sufficient. Therefore, sufficient trials are available to support the proposed use on baby leaf, chards and beet leaves, chicory, common purslane, cress, endive, escarole, herbs and edible flowers, parsley, chives, iceberg lettuce, lamb's lettuce, red mustard, watercress, rocket, spinach. The available submitted data show that no exceedance of the MRL will occur, but show exceedance of the MRL for watercress, herbs and edible flowers. An MRL application for watercress, herbs and edible flowers to increase the MRL to 0.8 mg/kg was submitted to ANSES in August 2021. The use is considered acceptable.

zRMS comments:
The Applicant submitted no residue trials on baby leaf, chards and beet leaves, chicory, common purslane, cress, endive, escarole, herbs and edible flowers, parsley, chives, iceberg lettuce, lamb's lettuce, red mustard, watercress, rocket, spinach (field).
Baby leaf, chards and beet leaves, chicory, common purslane, cress, endive, escarole, herbs and edible flowers, parsley chives, iceberg lettuce, lamb's lettuce, red mustard, watercress, rocket, spinach (field) 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, spinaches and similar leaves and herbs and edible flowers in Central Europe is 2x15 g a.s./ha with interval between applications of 7 days at BBCH 12-49 with PHI of 10 days.

No new studies on the magnitude of residue on lettuce 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 in Reg. (EU) 2023/163. The uses are considered acceptable.

Considering the intended uses on herbs and edible flowers (except basil and edible flowers (0256080)), parsley, chives and Watercress, an exceedance of the MRLs for oxathiapiprolin, as established in Commission Regulation (EU) 2023/163 (MRL of 0.02 mg/kg for herbs and edible flowers and MRL of 0.01 mg/kg for Watercress) is expected. Therefore until the new MRLs for herbs and edible flowers and Watercress come into force, authorization of the GAP will not be possible.
The proposed uses on herbs and edible flowers (except basil and edible flowers (0256080)), parsley, chives and Watercress are not considered acceptable.

Leek

Leek is a major crop in northern Europe (SANTE/2019/12752); and therefore, generally requires eight trials in the residue region.
The intended GAP for A23109A is 2 x 15g as/ha, 12-14d interval, PHI 14d, field. A total of eight trials conducted at 2 x 15 g as/ha, 12d interval, PHI 14d are submitted for leek . These trials can be used to support the intended GAP, in accordance with the guidance SANTE/2019/12752.
Therefore, sufficient trials are available to support the proposed use onleek. The available submitted data show that no exceedance of the MRL will occur. The use 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.

The intended GAP for oxathiapiprolin for leek in Central Europe is 2x15 g a.s./ha with interval between applications of 12-14 days at BBCH 12-48 with PHI of 14 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 on leek were performed in Northern Europe during 2020:

- Ford K., 2021, report No CEMR-9521, document No VV-901936 - two applications, separated by a 11-13 day interval were made at 15 g ai/ha for oxathiapiprolin.

The trials are supported by valid storage stability data and validated analytical methods.

Residues of oxathiapiprolin in leek samples taken at 14 DALA (NCH) were between <0.01 – 0.0275 mg/kg.
The residues arising from the proposed use will not exceed the MRL established for oxathiapiprolin for leek of 2 mg/kg in Reg. (EU) 2023/163.
The use is considered acceptable.

Spring onions/green onions, Welsh onions

Spring onions/green onions, Welsh onions are minor crops in northern Europe (SANTE/2019/12752); and therefore, generally requires four trials in the residue region.

The intended GAP for A23109A is 2 x 15g as/ha, 12-14d interval, PHI 14d, field. No specific residue trials on spring onions/green onions, Welsh onions and chives were conducted, instead residues trials conducted on leek were used to extrapolate to spring onions/green onions, Welsh onions and chives (SANTE/2019/12752). The available data were from eight trials conducted on leek at a rate of 2 x 15g as/ha, 12d interval, PHI 14d which is equivalent to the rate proposed for spring onions/green onions, Welsh onions and chives.

Therefore, sufficient trials are available to support the proposed use on spring onions/green onions, Welsh onions and chives . The available submitted data show that no exceedance of the MRL will occur. The use is considered acceptable.

zRMS comments:

Information given by the Applicant is sufficient and accepted.

Spring onions/green onions, Welsh onions are a minor crop in northern Europe and therefore requires four trials in the residue region.

The intended GAP for oxathiapiprolin for leek and for Spring onions/green onions, Welsh onions in Central Europe is 2x15 g a.s./ha with interval between applications of 12-14 days at BBCH 12-48 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.

According to SANTE/2019/12752, residue trials on leeks (0270060) can be extrapolated to extrapolated to spring onions/green onions and Welsh onions (0220040) before and after forming of the edible part.

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 on leek were performed in Northern Europe during 2020:

- Ford K., 2021, report No CEMR-9521, document No VV-901936 - two applications, separated by a 11-13 day interval were made at 15 g ai/ha for oxathiapiprolin.

The trials are supported by valid storage stability data and validated analytical methods.

Residues of oxathiapiprolin in leek samples taken at 14 DALA (NCH) were between <0.01 – 0.0275 mg/kg.

The residues arising from the proposed use will not exceed the MRL established for oxathiapiprolin for leek and for spring onions/green onions, Welsh onions of 2 mg/kg in Reg. (EU) 2023/163.

The uses are considered acceptable.

Onion

Onion is a major crop in northern Europe (SANTE/2019/12752); and therefore, generally requires eight trials in the residue region.

The intended GAP for A23109A is 2 x 15g as/ha, 7d interval, PHI 14d, field. A total of nine trials conducted at 3 x 150 g as/ha, 7d interval, PHI 14d are submitted for onion. These trials have been performed at a more critical GAP, but as the residues were above the LOQ (<0.02 mg/kg), the use of proportionality was not needed.

In order to support the use of A23109A (a DC (dispersible concentrate) formulation) on onion, the submitted residue trials on onion have been conducted using an OD (oil dispersion) formulation (Report No. Dupont-31988). Technical Guidelines, SANTE/2019/12752 and OECD 509, state that in general residue trials should be performed with formulations equivalent to the formulations related to the GAP. It also states that according to MacLachlan and Hamilton (2010), experience shows that formulations diluted in water prior to application, containing oils or organic solvents, such as emulsifiable concentrates (EC) and dispersible concentrates (DC), produce comparable residues, especially when the time between application and harvest is greater than 7 days.

OD and DC formulations are both diluted in water in the spray tank prior to application to the crop; both OD and DC formulations are oil/organic solvent based. The PHI of A23109A in the proposed use on onion is 14 days, so differences in formulations are unlikely to have an impact on residue values at harvest. According to SANTE/2019/12752 and OECD 509, OD and DC formulations can therefore be considered to be equivalent. Therefore it is considered that these trials can be used to support the intended GAP, in accordance with the guidance SANTE/2019/12752.

Considering this, the data provided to support the use of A23109A on onion are sufficient. Therefore, sufficient trials are available to support the proposed use on onion. The available submitted data show that no exceedance of the MRL will occur. The use is considered acceptable.

zRMS comments: Information given by the Applicant is sufficient and accepted. Onion 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 onion in Central Europe is 2x15 g a.s./ha with interval between applications of 7 days at BBCH 12-48 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, three applications were applied at a nominal rate of 0.02 kg as/ha. The interval between applications was 7 days with PHI of 7-8 days. The trials were supported by valid storage stability data for onion and validated analytical methods. Residues of oxathiapiprolin in onion bulb taken at 7-8 DALA (NCH) were <0.01 mg/kg. The residues arising from the proposed use will not exceed the MRL established for oxathiapiprolin for onion of 0.04 mg/kg in Reg. (EU) 2023/163. The use is considered acceptable.

Garlic and shallots

Garlic and shallots are minor crops in northern Europe (SANTE/2019/12752); and therefore, generally requires four trials in the residue region.
The intended GAP for A23109A is 2 x 15g as/ha, 7d interval, PHI 14d, field. No specific residue trials on garlic and shallots were conducted, instead residues trials conducted on onion were used to extrapolate to garlic and shallots (SANTE/2019/12752). The available data were from nine trials conducted on onion at a rate of at 3 x 150 g as/ha, 7d interval, PHI 14d which is more critical than the rate proposed for garlic and shallots. No residues were above the LOQ (<0.02 mg/kg).
In order to support the use of A23109A (a DC (dispersible concentrate) formulation) on onion, the submitted residue trials on onion have been conducted using an OD (oil dispersion) formulation (Report No. Dupont-31988). Technical Guidelines, SANTE/2019/12752 and OECD 509, state that in general residue trials should be performed with formulations equivalent to the formulations related to the GAP. It also states that according to MacLachlan and Hamilton (2010), experience shows that formulations diluted in water prior to application, containing oils or organic solvents, such as emulsifiable concentrates (EC) and dispersible concentrates (DC), produce comparable residues, especially when the time between application and harvest is greater than 7 days.
OD and DC formulations are both diluted in water in the spray tank prior to application to the crop; both OD and DC formulations are oil/organic solvent based. The PHI of A23109A in the proposed use on onion is 14 days, so differences in formulations are unlikely to have an impact on residue values at harvest. According to SANTE/2019/12752 and OECD 509, OD and DC formulations can therefore be considered to be equivalent. Therefore it is considered that hese trials can be used to support the intended GAP, in accordance with the guidance SANTE/2019/12752.
Considering this, the data provided to support the use of A23109A on onion are sufficient. Therefore, sufficient trials are available to support the proposed use on garlic and shallots. The available submitted data show that no exceedance of the MRL will occur. The use is considered acceptable.

zRMS comments: Information given by the Applicant is sufficient and accepted. Garlic and shallots are the minor crops in northern Europe (EU Technical Guidelines Document SANTE/2019/12752) and therefore requires four trials in the residue region. The intended GAP for oxathiapiprolin for onion, garlic and shallots in Central Europe is 2x15 g a.s./ha with interval between applications of 7 days at BBCH 12-48 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. Residue data on onions (0220020) can be extrapolated to garlic (0220010) and to shallots (0220030) before and after forming of the edible part.

Eight trials on the magnitude of residues on onions reviewed at EU level are available to support the proposed uses on garlic and shallots. For all the trials, three applications were applied at a nominal rate of 0.02 kg as/ha. The interval between applications was 7 days with PHI of 7-8 days.
The trials were supported by valid storage stability data for onion and validated analytical methods.
Residues of oxathiapiprolin in onion bulb taken at 7-8 DALA (NCH) were <0.01 mg/kg.

The residues arising from the proposed use will not exceed the MRL established for oxathiapiprolin for onion, garlic and shallots of 0.04 mg/kg in Reg. (EU) 2023/163.
The uses are considered acceptable.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

The use of A23109A may result in residues of oxathiapiprolin in animal feed items from cabbage and kale, therefore the possible transfer of residues in animal commodities from the proposed uses should be considered. Livestock intake calculations are provided below, and cover all uses of oxathiapiprolin in the EU, in addition to the intended uses in the current submission.
The contribution of oxathiapiprolin residues to the total livestock exposure was insignificant, and therefore, a modification of the existing MRLs for commodities of animal origin was considered unnecessary.

Table 7.3-10: Input values for the dietary burden calculation (considering the uses authorized in the country of the zRMS/authorized within the zone and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: oxathiapiprolin				
Cabbage, heads, leaves	0.01	STMR	0.01	HR
Kale, leaves (forage)	0.01	STMR	0.02	HR
Potato culls	0.01	STMR (EFSA, 2016)	0.01	STMR (EFSA, 2016)
Potato process waste	0.01	STMR[(a)] (EFSA, 2019)	0.01	STMR[(a)] (EFSA, 2019)
Potato dried pulp	0.01	STMR[(a)] (EFSA, 2019)	0.01	STMR[(a)] (EFSA, 2019)
Sunflower seeds meal	0.01	STMR[(b)](EFSA, 2019)	0.01	STMR[(b)](EFSA 2019)
Citrus group, dried pulp	0.012	STMR x PF[(c)] (EFSA, 2020)	0.012	STMR x PF[(c)] (EFSA, 2020)

(a) For potato process waste and potato dried pulp, the default processing factors were not applied as residues in RAC were below the LOQ and reside concentration in processed fractions are not expected
(b) 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.
(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 the following table. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.004 mg/kg bw/d, further investigation of residues in commodities of animal origin is not necessary.

Table 7.3-11: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition 1: oxathiapiprolin					
Beef cattle*	0.002	0.003	Kale, leaves (forage)	0.08	No
Dairy cattle*	0.002	0.003	Kale, leaves (forage)	0.07	No
Ram/ewe	0.002	0.002	Kale, leaves (forage)	0.06	No
Lamb	0.002	0.002	Kale, leaves (forage)	0.06	No
Breeding swine	0.001	0.001	Kale, leaves (forage)	0.06	No
Finishing swine*	0.001	0.001	Kale, leaves (forage)	0.06	No
Broiler poultry	0.001	0.001	Cabbage, heads, leaves	0.01	No
Layer poultry*	0.001	0.001	Cabbage, heads, leaves	0.01	No
Turkey	0.001	0.001	Potato, culls	0.01	No

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

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.”

Reference: Ireland, 2016
“No feeding study was provided for fish. Farmed fish are usually fed on a combination of pellets made from ground fishmeal or vegetable matter with corn, soy and grain products being the main vegetarian ingredients. Oxathiapiprolin is not used to treat cereals or pulse crops. Therefore, the fish dietary burden will be low and a fish feeding study 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)

The supervised residue trials for lettuce (extrapolated to spinach and the herbs and edible flowers subgroup) show residues of oxathiapiprolin above 0.1 mg/kg. Therefore, magnitude of the residues processing studies should be considered, according to the criteria set out in Regulation (EC) No 283/2013. According to The OECD Guidance on Magnitude of Pesticide Residues in Processed Commodities (ENV/JM/MONO(2008)23), there are no major industrial processes relevant to the crops under consideration in this evaluation report. Dehydration is a category-2 process and is relevant to fresh herbs. During the peer review of the active substance oxathiapiprolin (EFSA 2016), a raisin processing study was evaluated and is summarised in Table 7.3.5.1 below. The raisin processing study is provided as a representative to support the fresh herbs dehydration process. Some other category 2 processes, such as, preparation of canned vegetables and cooking vegetables in water) are relevant to spinach. During the peer review of the active substance oxathiapiprolin (EFSA 2016), a tomato processing study was evaluated and is summarised in Table 7.3.5.1 below. The tomato processing study is provided as a representative to support the spinach processes.
These processing factors have not been used in risk assessment as no assessment of acute risk is required for oxathiapiprolin.

7.3.5.1 Available data for all crops under consideration

No new data were submitted in the framework of this application.
Tomato and grape processing studies have been included for information. Processing studies for oxathiapiprolin and its metabolites have been conducted for grape (juice, raisin, red wine and white wine) and tomato (washed, sun dried, peeled, canned, juice, wet pomace, paste and puree) and were reviewed during the approval process and are considered to be acceptable; the results are summarised in the table below.

Table 7.3-12: Overview of the available processing studies

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 2019a
Grape/Juice	4	0.16	1	-	Spence, C. and Woodmansey, L.; 2012 Report No.: DuPont-30045	Ireland, 2016 EFSA, 2016
Grape/Raisin	4	1.45	1	-		
Grape/Red wine	2	0.14 (mean)	1	-		
Grape/White wine	2	0.15 (mean)	1	-		
Grape/Red and white wine	4	0.15	1	-		
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	-		

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Report reference	Source
Tomato/Paste	3	1.10	1	-		
Tomato/Puree	3	0.60	1	-		

* 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.

Reference: EFSA, 2019a

"Processing studies with grapes, tomatoes and potatoes have been submitted for the EU pesticides peer review where various processing factors were derived (EFSA, 2016) […]."

Reference: Ireland, 2016

"The processing trial on grapes is considered acceptable. The application rate is slightly higher than the cGAP, with the total seasonal dose at 0.150 kg as/ha/season which equates to approximately 1.25 times the cGAP with the exception of trial 2 which had an exaggerated rate of 0.540 kg as/ha/season or 4.5 times the cGAP. Processing of the RAC with quantifiable residues of DPX-QGU42 resulted in the concentration of residues in certain grape fractions but not in others. Residues of DPX-QGU42 concentrated slightly in raisins (median transfer factor of 1.45x and mean transfer factor of 2.0x), but not in juice (mean 0.17x), red wine (mean 0.14x) or white wine (mean 0.13x 0.15x). There was no significant difference between processing to white or red wine."

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)."

7.3.5.2 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 A23109A.

zRMS comments:

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.

For the salad plant group including spinach and herbs the residue values are above 0.1 mg/kg. According to Reg. 283/2013 for all crops for which residue values exceed 0.1 mg/kg a processing study is necessary. However, all processing procedures relevant to the aforementioned crops, that is cooking and canning, are category 2 processes as per OECD 508 guidance, and are considered optional and typically only required to refine the consumer risk assessment. Since there is no ARfD for oxathiapiprolin, there is no need for refinement of the consumer risk assessment. Therefore, processing studies on spinach/salad plants are not considered to be necessary.

No additional data are required to support the proposed uses.

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
No new data submitted in the framework of this application.
In addition to the confined rotational crop study, several rotational crop field trials were evaluated in the framework of the EU 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.

Table 7.3-13: 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						
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, 2015
			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		
			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	Ireland, 2016

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)**		
		Cereals	Oat (forage hay, grain, straw)	8-15 120-140 334-344	Report No.: DuPont-31740	
			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 inflorescence)	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		
Bare soil	2x 0.140 (n.a.)	Berries and small fruits	Strawberry (fruit)	5-8	Shepard, E.; 2013b Report No.: DuPont-33929	Ireland, 2015
		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		

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, 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

Summary of field rotational crop studies reported in the EU

Reference: EFSA, 2019a

"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 30 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)

According to SANTE/11956/2016 rev. 9 (Commission Services, 2018), herbs and edible flower are considered to possess melliferous capacity.
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 trial 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).
These studies have been summarised in the table below. The detailed assessment of this study is presented in Appendix 2.

Table 7.3-14: Summary of new data supporting the intended uses of A23109A in melliferous crops

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Residue levels (mg/kg) [(a)]	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) [(b)]	MRL compliance
Spring Oilseed rape **cGAP: 2 x 60 g a.s./ha, at BBCH 55-63** **Tunnel studies**	New trials	NEU	2 x <0.01 in mature honey					
Winter Oilseed rape **cGAP: 2 x 60 g a.s./ha, at BBCH 55-64** **Tunnel studies**	New trials	NEU + SEU	4 x <0.01 in mature honey					
Honey	New trials	NEU + SEU	6 x <0.01	<0.01	<0.01	0.01	0.05	Yes

(a) Definition of residue for enforcement and risk assessment are the same: oxathiapiprolin
(b) Source of EU MRL: ~~Reg. (EU) No 2021/1807~~ Reg. (EU) No 2023/163

Considering the data available, it is evident that residues of oxathiapiprolin residues are typically <LOQ (0.01 mg/kg). The data submitted show that no exceedance of the current EU MRL will occur. The uses in herbs and edible flowers are considered acceptable.

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

The Applicant submitted two new residue trials. These studies have been evaluated by zRMS-PL in RR – Part B7 for A22773A/ Orondis Evo (2023).
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 in honey below the limit of quantification (LOQ, 0.01 mg/kg) and below the MRL value of 0.05 mg/kg (Reg. (EU) No 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).
The input values used for the chronic assessment are the proposed or current EU MRLs contained in Regulation (EU) No. ~~2021/1807~~ 2023/163.
All MRLs for oxathiapiprolin are based on the residue definition for monitoring/enforcement of parent oxathiapiprolin only, which is also the residue definition for risk assessment. No Conversion Factor is required to account for the residue definitions, and no processing factors are required.

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 SANTE/10518/2021 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 7.3-15: 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
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

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
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
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

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
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~~ 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 7.3-16: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo 3.1	~~11~~ 12% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	Not calculated as TMDI passes
IESTI RAC (% ARfD) according to EFSA PRIMo*	Not applicable (no ARfD set)
IESTI Processed (% ARfD) according to EFSA PRIMo*	Not applicable (no ARfD)

* include raw and processed commodities if both values are required for PRIMo 3

The proposed uses of oxathiapiprolin in A23109A do 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) 2023/163 led to a utilisation of the ADI of 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.

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)	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 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.

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.

Evaluator comments:
A harmonised approach is not yet available, and currently no specific consideration is warranted in the scope of

this evaluation. The uses under consideration provides only a minor contribution to the overall chronic exposure of consumers to pesticide residues. The combined exposure to two active substances: metalaxyl-M and oxathiapiprolin in A23109A is not expected to present a consumer risk.

7.5 References

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EC (European Commission), 2021. Review report for the active substance oxathiapiprolin. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 07 December 2016 in view of the approval of oxathiapiprolin as active substance in accordance with Regulation (EC) No 1107/2009. SANTE/11169/2016 rev 3, 25 March 2021.

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EFSA (European Food Safety Authority), 2019. Reasoned opinion on the modification of the existing MRL(s) and setting of import tolerances for oxathiapiprolin in various commodities. EFSA Journal 2019;17(7):5759 [49 pp.] doi:10.2903/ /j.efsa.2017.4929.

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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.

FAO (Food and Agriculture Organization of the United Nations), 2018. Pesticide residues in food 2018. Oxathiapiprolin in – Report on the Joint FAO/WHO Meeting on pesticide residues, FAO Plant Production and Protection Paper 234.

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Ireland, 2019. Draft evaluation report on the setting of an MRL for oxathiapiprolin in wine grapes, bulb onions, peppers, sunflowers and hops, February 2019 [261 pp.]

Maclachlan and Hamilton (2010) A new tool for the evaluation of crop residue trial data (day-zero-plus decline) Food Additives & Contaminants: Part A Volume 27, 2010 - Issue 3

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	Previously evaluated
			Metalaxyl-M			
KCA1 6.1.1	Baumy, G.	09/03/2021	Metalaxyl-M – Storage Stability of Residues of Metalaxyl-M in Crop Matrices Stored Frozen for up to Two Years Report No. RNB19-00020 - INT Document No. VV-894456 Test Facility SGS France - Laboratoire de Rouen GLP Unpublished	N	SYN	N
KCA1 6.3.1	Meyer, M. Poperechna, N.	24/06/2021	Oxathiapiprolin and Metalaxyl-M - Residue Study on Broccoli in Germany, Hungary, Poland and the United Kingdom 2020 Report No. IF20-05335380 Document No. VV-908189 Test Facility SGS Institut Fresenius GmbH GLP Unpublished	N	SYN	N
KCA1 6.3.1	Yozgatli, H. Breyer, N.	13/06/2014	Metalaxyl-M - Residue study on Cauliflower in the United Kingdom and Northern France in 2013 Report No. S13-03434 Document No. VV-407968 , A13947A_11297 Test Facility Eurofins - Dr Specht & Partner GLP Unpublished	N	SYN	N
KCA1 6.3.2	Brown, S.	06/05/2021	Oxathiapiprolin/Metalaxyl-M – Determination of residues of Oxathiapiprolin and metalaxyl-M in Kale from Trials conducted in NEU in 2020 Report No. RES-00256 Document No. VV-901782 Test Facility ResChem Analytical Limited GLP Unpublished	N	SYN	N

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	Previously evaluated
KCA1 6.3.3	Ford, K.	06/05/2021	Oxathiapiprolin/Metalaxyl-M – Residue Study on Cabbage in Northern France, Austria, Hungary and Poland in 2020 Report No. CEMR-9523 Document No. VV-901921 Test Facility CEM Analytical Services Limited (CEMAS) GLP Unpublished	N	SYN	N
KCA1 6.3.4	Brown, S.	06/05/2021	Oxathiapiprolin/Metalaxyl-M – Determination of residues of Oxathiapiprolin and metalaxyl-M in Brussels Sprouts from Trials conducted in NEU in 2020 Report No. RES-00257 Document No. VV-901790 Test Facility ResChem Analytical Limited GLP Unpublished	N	SYN	N
KCA1 6.3.5	Brown, S.	29/04/2021	Oxathiapiprolin / Metalaxyl-M - Determination of residues of Oxathiapiprolin and metalaxyl-M in Lettuce from trials conducted in NEU in 2020 Report No. RES-00259 Document No. VV-901318 Test Facility ResChem Analytical Limited GLP Unpublished	N	SYN	N
KCA1 6.3.5	Brown, S.	13/04/2022	Metalaxyl-M – Determination of residues of Metalaxyl-M in Lettuce from Trials conducted in NEU in 2021 Report No. RES-00332 Document No. VV-946819 Test Facility ResChem Analytical Limited GLP Unpublished	N	SYN	N
KCA1 6.3.5	Fritsch S	04/03/2020	Metalaxyl-M - Residue Study on Open Leaf Lettuce in Germany in 2019. Report No. S19-02726 Document No. VV-749044 Syngenta AG, Basel, Switzerland GLP Unpublished	N	SYN	N

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	Previously evaluated
KCA1 6.3.5	Lakaschus S, Fritzsch S	18/04/2019	Metalaxyl-M - Residue Study on Open Leaf Lettuce in the United Kingdom, Northern France and Germany in 2018. Report No. S18-04345 Document No. VV-471900 Syngenta AG, Basel, Switzerland GLP Unpublished	N	SYN	N
KCA1 6.3.6	Ford, K.	05/05/2021	Oxathiapiprolin/Metalaxyl-M – Residue Study on Leek in Northern France, Poland, United Kingdom and Germany in 2020 Report No. CEMR-9521 Document No. VV-901936 Test Facility CEM Analytical Services Limited (CEMAS) GLP Unpublished	N	SYN	N
KCA1 6.3.7	Kuhne, R.	08/07/1998	CGA 329351 + Mancozeb (ASF 21), WP 68, A-9407 A, Onions, Switzerland Report No. 2338/97 Document No. VV-357405 , CGA329351/0905 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN	N
KCA1 6.3.7	Kuhne, R.	08/07/1998	CGA 329351 + Mancozeb (ASF 21), WP 68, A-9407 A, Onions, Switzerland Report No. 2340/97 Document No. VV-357408 , CGA329351/0906 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN	N
KCA1 6.3.7	Kuhne, R.	09/07/1998	CGA 329351 + ASF 41 (Chlorothalonil / CGA 329351 + ASF 21 (Mancozeb), SC 537.5/WP68, A-9652 B/A-9407 A, Onions, Spain, United Kingdom Report No. 116/97 Document No. VV-376089 , CGA329351/0914 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN	N

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	Previously evaluated
KCA1 6.3.7	Kuhne, R.	09/09/1999	Residue Study with Metalaxyl-M (CGA 329351) + Chlorothalonil (ASF 41) and Metalaxyl-M (CGA 329351) + Mancozeb (ASF 21) in or on Onions in Switzerland Report No. 2077/98 Document No. VV-312825 , CGA329351/1138 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN	N
KCA1 6.10	Knabe, S.	12/02/2021	Metalaxyl-M - Honey Residue Study on Spring Oilseed Rape in Northern Europe in 2020 Report No. S20-03602 Document No. VV-881362 Test Facility Eurofins Agroscience Services EcoTox GmbH GLP Unpublished	N	SYN	N
Oxathiapiprolin						
KCA2 6.1.1	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	Yes, in RR, Part B7 for A22773A/ Orondis Evo (2023)
KCA2 6.3.1	Meyer, M. Poperechna, N.	24/06/2021	Oxathiapiprolin and Metalaxyl-M - Residue Study on Broccoli in Germany, Hungary, Poland and the United Kingdom 2020 Report No. IF20-05335380 Document No. VV-908189 Test Facility SGS Institut Fresenius GmbH GLP Unpublished	N	SYN	N
KCA2 6.3.1	Mahlo, C. Wolfgarten, E.	30/04/2021	Oxathiapiprolin and Metalaxyl-M - Residue Study on Cauliflower in Germany, Poland, the United Kingdom and Denmark in 2020 Report No. IF20-05336777 Document No. VV-901124 Test Facility SGS Institut Fresenius GmbH GLP Unpublished	N	SYN	N

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	Previously evaluated
KCA2 6.3.2	Brown, S.	06/05/2021	Oxathiapiprolin/Metalaxyl-M – Determination of residues of Oxathiapiprolin and metalaxyl-M in Kale from Trials conducted in NEU in 2020 Report No. RES-00256 Document No. VV-901782 Test Facility ResChem Analytical Limited GLP Unpublished	N	SYN	N
KCA2 6.3.3	Ford, K.	06/05/2021	Oxathiapiprolin/Metalaxyl-M – Residue Study on Cabbage in Northern France, Austria, Hungary and Poland in 2020 Report No. CEMR-9523 Document No. VV-901921 Test Facility CEM Analytical Services Limited (CEMAS) GLP Unpublished	N	SYN	N
KCA2 6.3.4	Brown, S.	06/05/2021	Oxathiapiprolin/Metalaxyl-M – Determination of residues of Oxathiapiprolin and metalaxyl-M in Brussels Sprouts from Trials conducted in NEU in 2020 Report No. RES-00257 Document No. VV-901790 Test Facility ResChem Analytical Limited GLP Unpublished	N	SYN	N
KCA2 6.3.6	Ford, K.	2021	Oxathiapiprolin/Metalaxyl-M – Residue Study on Leek in Northern France, Poland, United Kingdom and Germany in 2020. Report No CEMR-9521. Syngenta document No VV-901936 GLP Unpublished	N	SYN	N
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	Yes, in RR, Part B7 for A22773A/ Orondis Evo (01.2023)

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	Previously evaluated
KCA2 6.10	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	Yes, in RR, Part B7 for A22773A/ Orondis Evo (2023)
KCA2 6.3.7	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 Applications of OD and SC Formulations- - USA, 2014 Report No. TK0221427|81123 Document No. VV-511306 , A20941A_50004 Test Facility The Carringers, Inc. GLP Unpublished	N	SYN	Yes, in RR, Part B7 for A22773A/ Orondis Evo (2023)
KCA2 6.3.8	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-511308 , A20941A_50006 Test Facility The Carringers, Inc. GLP Unpublished	N	SYN	Yes, in RR, Part B7 for A22773A/ Orondis Evo (2023)
KCA2 6.3.9	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-511264 , A20941A_50008 Test Facility The Carringers, Inc. GLP Unpublished	N	SYN	Yes, in RR, Part B7 for A22773A/ Orondis Evo (2023)

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	Previously evaluated
KCA2 6.3.10	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-511262 , A21008A_50006 Test Facility The Carringers, Inc. GLP Unpublished	N	SYN	Yes, in RR, Part B7 for A22773A/ Orondis Evo (2023)

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
Metalaxyl-M					
KCA1 6.5.1	Anderson, L	2005	Metalaxyl-M (CGA329351) and chlorothalonil (R44686): Residue in or on tomato and processed products in Spain, Syngenta, Crop Protection AG, Basel, Switzerland, 16 June 2004 to 27 September 2005 Report No. 04-6048 Document No. CGA329351/2148, Syngenta File No. VV-333047 GLP Unpublished	N	SYN
KCA1 6.5.1	Klimmek, S, Breyer, N	2012	Metalaxyl-M – Residue study on wine grapes processed specimens in southern Europe, Eurofins Agroscience Services Chem GmbH, Hamburg, Germany, 19 July 2010 to 16 December 2011 Report No. S10-01347 Document No. A9651D_10111, Syngenta File No. VV-402460 GLP Unpublished	N	SYN
Oxathiapiprolin					
KCA2 6.3.5	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. Report No 696296, document No Dupont-31734. GLP Not published	N	Corteva (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
KCA2 6.3.5	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. Report No 696296, document No Dupont-31734. GLP Not published	N	Corteva (SYN LoA)
KCA2 6.3.7	Spence, C. Brown, D.	2015	Decline and magnitude of residues of DPX-QGU42 and its metabolites in dry bulb onions (Bulb vegetables) following foliar application of DPX-QGU42 100 g/L OD or DPX-QGU42 100 g/L SE - Europe 2012-2013 Report No. DuPont - 31988 GLP Not published	N	Corteva (SYN LoA)
KCA2 6.5.2	Spence, C. Woodmansey, L.	2012	Magnitude of residues of DPX-QGU42 and its metabolites in processed commodities of grapes following application of DPX-QGU42 100 g/L OD - Europe, 2010-2011. Charles River Laboratories (UK) DuPont-30045, Charles River Study Number 695753 GLP Not published	N	Corteva (SYN LoA)
KCA2 6.5.2	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 GLP Not Published	N	Corteva (SYN LoA)
KCA2 6.5.3	Spence, C. Brown, D.	2015	Decline and magnitude of residues of DPX-QGU42 and its metabolites in dry bulb onions (Bulb vegetables) following foliar application of DPX-QGU42 100 g/L OD or DPX-QGU42 100 g/L SE - Europe 2012-2013, Report No. Dupont-31988. GLP Not published	N	Corteva (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 Metalaxyl-M

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

A 2.1.1.1.1.1 Study RNB19-00020

Comments of zRMS:	The stability was tested in four crop matrices following deep frozen storage for 24 months. There was no significant decrease (> 30% as compared to the nominal fortification level) in the observed residue levels of metalaxyl-M in the following four crop matrices over two years (24 months) of frozen storage at ≤ -18°C: - high water content: lettuce, - high oil content: oilseed rape (seed), - high starch content: wheat (grain), - high acid content: orange (whole fruit)) The samples were analysed for metalaxyl-M using procedures described in residue analytical method REM181.13A. The limit of quantification (LOQ) of the method was 0.01 mg/kg. Conclusion: The residues of metalaxyl-M have been shown to be stable in oil seed rape seed, orange whole fruit, lettuce and wheat grain when stored deep frozen at ≤ -18°C for up to 24 months. The study is acceptable.

Reference:	KCA 6.1.1/01
Report	Metalaxyl-M – Storage Stability of Residues of Metalaxyl-M in Crop Matrices Stored Frozen for up to Two Years, Baumy. G, 2022, Report No. RNB19-00020, Syngenta document No. VV-894456
Guideline(s):	OECD Guideline for the Testing of Chemicals No. 506, Stability of Pesticide Residues in Stored Commodities, adopted 16 October 2007. EPA Residue Chemistry Test Guidelines, OPPTS 860.1380, Storage Stability Data, August 1996. Commission of the European Communities, Storage Stability of Residue Samples; 7032/VI/95 (Appendix H, rev.5), dated 22/7/97. OECD ENV/JM/MONO(2007)17-Guidance Document on Pesticide Residue Analytical Methods
Deviations:	No
GLP:	Yes, conducted under GLP/Officially recognised testing facilities
Acceptability:	Yes

Materials and methods

Homogenised sub-samples of each test commodity (10 g) were fortified with standard solutions of metalaxyl-M in methanol to give a fortification rate of 0.1 mg/kg. 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 1, 3, 6, 12, 18 and 24 months.
After the scheduled storage periods, the required number of fortified samples were removed from frozen storage, along with one 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 metalaxyl-M using method REM181.13A, previously validated for representative crop commodities of the relevant types to a limit of quantification (LOQ) of 0.01 mg/kg.
For analysis of the zero-time, after 1, 3, 6, 12 and 18 months of frozen storage:
In summary, 10 g subsamples of crops were extracted using methanol with water content correction. After homogenisation using an ultra-turrax mixer and centrifugation, an aliquot of the supernatant was transferred into a plastic tube and diluted in water. The extract was then purified using SPE cartridges (Oasis HLB 60 mg, 3 cc) and elution with isohexane/dichloromethane (50/50 v/v). After nitrogen evaporation to dryness, the extract was dissolved in acidified water (0.2% formic acid) / methanol (70/30 v/v) and homogenised in an ultrasonic bath. The extract was filtered prior to quantification of metalaxyl-M by LC MS/MS, monitoring two transitions.
Minor method modification for analysis after 24 months of frozen storage:
In summary, 10 g subsamples of crops were extracted using methanol with water content correction. After homogenisation using an ultra-turrax mixer and centrifugation, an aliquot of the supernatant was transferred into a plastic tube and diluted with acidified water (0.2% formic acid) / methanol (70/30 v/v). The mixture was homogenized few seconds prior to quantification of metalaxyl-M by LC MS/MS, monitoring two transitions.
This modification was justified by fresh concurrent recoveries which were comparable with all other timepoints.

Results and discussions

Residues of metalaxyl-M found in stored frozen oil seed rape seed, orange whole fruit, lettuce, wheat grain commodities tested at each interval are shown in Table A2. There was no significant change in the levels of metalaxyl-M in any commodity over a 24-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 1: Summary of concurrent recoveries of metalaxyl-M from crop matrices.

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± std dev
Oil seed rape seed	0.1	0	3	91, 82, 85	86 ±5.6
	0.1	32	2	89, 90	89 ± 1.3
	0.1	93	2	108, 106	107 ± 2.0
	0.1	183	2	109, 110	110 ± 1.0
	0.1	368	2	100, 92	96 ± 8.0
	0.1	550	2	78, 77	78 ± 0.6
	0.1	735	2	107, 103	105 ± 4.0
Orange whole fruit	0.1	0	3	95, 91, 94	93 ± 2.2
	0.1	32	2	107, 107	107 ± 0.0
	0.1	93	2	109, 93	101 ± 16.0
	0.1	183	2	110, 110	110 ±0.0
	0.1	368	2	110, 108	109 ± 2.0
	0.1	550	2	84, 97	91 ± 13.0
	0.1	735	2	105, 105	105 ± 0.5
Lettuce	0.1	0	3	96, 90, 92	92 ± 3.4
	0.1	32	2	88, 90	89 ± 2.2

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± std dev
	0.1	93	2	110, 110	110 ± 0.0
	0.1	183	2	107, 105	106 ± 2.0
	0.1	374	2	89, 91	90 ± 2.4
	0.1	550	2	103, 102	103 ± 1.0
	0.1	735	2	109, 109	109 ± 0.1
Wheat grain	0.1	0	3	71, 94, 93	86 ± 14.8
	0.1	32	2	88, 88	88 ± 0.1
	0.1	93	2	105, 101	103 ± 4.0
	0.1	183	2	107, 110	109 ± 3.0
	0.1	374	2	86, 74	80 ± 12.1
	0.1	550	2	83, 84	84 ± 0.8
	0.1	735	2	108, 104	106 ± 4.1

Table A 2: Stability of metalaxyl-M residues in crop matrices following storage at ≤ -18°C

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)
Oil seed rape seed	0.1	0	0.0875, 0.0865, 0.0864	88, 87, 86
	0.1	32	0.0965, 0.0990	97, 100
	0.1	93	0.1014, 0.0998	101, 100
	0.1	183	0.0987, 0.0914	99, 91
	0.1	368	0.1017, 0.1005	102, 101
	0.1	550	0.0782, 0.0775	78, 78
	0.1	735	0.0918, 0.0893	92, 89
Orange whole fruit	0.1	0	0.0920, 0.0951, 0.0975	92, 95, 98
	0.1	32	0.1110, 0.1141	111, 114
	0.1	93	0.0995, 0.0912	100, 91
	0.1	183	0.1083, 0.1089	108, 109
	0.1	368	0.1102, 0.1089	110, 109
	0.1	550	0.0932, 0.1003	93, 100
	0.1	735	0.1078, 0.1081	108, 108
Lettuce	0.1	0	0.0952, 0.0937, 0.0927	95, 94, 93
	0.1	32	0.0943, 0.1012	94, 101
	0.1	93	0.0996, 0.1122	100, 112
	0.1	183	0.0874, 0.0974	87, 97
	0.1	374	0.0931, 0.0847	93, 85
	0.1	550	0.1006, 0.0987	101, 99
	0.1	735	0.1031, 0.1103	103, 110
Wheat grain	0.1	0	0.0914, 0.0958, 0.0912	91, 96, 91
	0.1	32	0.0838, 0.0823	84, 82
	0.1	93	0.0871, 0.0937	87, 94
	0.1	183	0.0949, 0.0927	95, 93
	0.1	374	0.0804, 0.0770	80, 77
	0.1	550	0.0759, 0.0760	76, 76

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)
	0.1	735	0.0972, 0.0978	97, 98

Conclusion
Metalaxyl-M has been shown to be stable in oil seed rape seed, orange whole fruit, lettuce and wheat grain, representative of high oil content, high acid content, high water content and high starch content matrices covered for at least 24 months when stored frozen at ≤ -18°C.

A 2.1.1.1.2 Storage stability of residues in animal products

A 2.1.1.1.2.1 Study 1 – S20-03602

Comments of zRMS:	The storage stability samples fortified at 10xLOQ (0.1 mg/kg) were analysed for residues of metalaxyl-M. The residues of metalaxyl-M showed no significant decrease (30% as compared to the initial lresidue level in the stored samples) in honey after storage at ≤-18°C for up to 51 days. The method REM 181.13A has been successfully validated for the determination of residues of metalaxyl-M in honey with the LOQ of 0.01 mg/kg with satisfactory accuracy, precision and repetibility using LC-MS/MS detection. <u>Conclusion:</u> Residues of metalaxyl-M in honey have been shown to be stable under stored frozen at ≤-18°C for 51 days.

Reference:	KCA 6.1.1/02
Report:	Metalaxyl-M - Honey Residue Study on Spring Oilseed Rape in Northern Europe in 2020, Knäbe, S., 2021, Report No. S20-03602. Syngenta document No. VV-881362
Guideline(s):	Yes: 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
Acceptability:	Yes

Materials and methods
The stability of metalaxyl-M has been tested in honey following deep frozen storage for up to 1.5 months. Individual samples of honey were fortified with standard solutions containing metalaxyl-M 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 metalaxyl-M. Duplicate samples were removed after 51 days of frozen storage at a nominal temperature of -18°C, and analysed for metalaxyl-M using procedures in residue analytical method RAM 181.13A, previously validated for honey to a limit of quantification (LOQ) of 0.01 mg/kg.
Residues of metalaxyl-M were extracted by high speed homogenization with methanol followed by centrifugation. An aliquot is diluted to a sample concentration of 0.01 g/mL and subjected to a solid phase extraction (SPE) clean up. Final determination was by high performance liquid chromatography with triple quadrupole mass spectrometric detection (LC-MS/MS).

Results and discussions

Residues of metalaxyl-M found in stored frozen honey tested are shown below. There was no significant change in the levels of metalaxyl-M over a 51-day 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 3: Summary of concurrent recoveries of metalaxyl-M from honey.

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± std dev
Metalaxyl-M					
Honey	0.1	51	2	94, 95	95

Table A 4: Stability of metalaxyl-M residues in honey following storage at ≤-18°C

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)
Metalaxyl-M				
Honey	0.1	0	0.087, 0.087, 0.083	87, 87, 83 (86)
	0.1	51	0.095, 0.101	95, 101 (98)

Conclusion

Metalaxyl-M has been shown to be stable in samples of honey for at least 51 days when stored frozen at ≤-18°C.

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

No new data submitted.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Flowering brassica (Broccoli, Cauliflower)

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)
Intended cGAP – NEU (AT-3, AT-7, BE-3, BE-7, CZ-3, CZ-7, DE-3, DE-7, NL-3, NL-7, PL-3, PL-3a, PL-7, PL-7a, SK-3, SK7*)	2	87.2 g as/ha	7-10 days	BBCH 12 - 49	20

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

A 2.1.3.1.1 Study 1 - IF20-05335380 - New data

Comments of zRMS:	Four residue field trials (two decline and two harvest) on broccoli were successfully conducted in Germany, Hungary, Poland and the United Kingdom during 2020. Two decline trials and two harvest trials were conducted. Oxathiapiprolin and metalaxyl-M were applied to broccoli as A23109A, dispersible concentrate DC formulation containing nominally 30 g of oxathiapiprolin and 180 g of metalaxyl-M per litre. Two applications on plot P2, separated by a 5-7 day interval, were made at a nominal rate of 15 g oxathiapiprolin/ha and 90 g metalaxyl-M/ha. The first application on plot P2 was done at 25-28 days before harvest (DBH) and the second

application was done at 20-21 DBH.

One application on plot P3 was made at a nominal rate of 15 g oxathiapiprolin/ha and 90 g metalaxyl-M/ha. The application on plot P3 was conducted at 20-21 DBH.

For decline trials following the final application samples were collected from plots P2 and P3 at 0 days after last application (DALA), 6-7 DALA, 13-14 DALA, 20-21 DALA (NCH (normal commercial harvest)) and 28 DALA with untreated broccoli being collected 20 DALA (NCH).

For harvest trials following the final application untreated and treated samples from all plots were collected at 20-21 DALA (NCH (normal commercial harvest)).

Field samples for residue analysis were analysed for oxathiapiprolin using method DuPont-30422, Supplement No. 1 and metalaxyl-M using method REM 181.13A with LOQ of 0.01 mg/kg. No residues of oxathiapiprolin and metalaxyl-M at or above the limit of quantification were found in any of the untreated broccoli specimens.

Samples were stored frozen for a maximum period of 204 days (7 months) for oxathiapiprolin and for a maximum of 300 days (10 months) for metalaxyl-M from sampling to analysis.

Results:

Actual Sampling Interval (days)	Oxathiapiprolin Residues in the range (mg/kg)	Metalaxyl-M Residues in the range (mg/kg)
broccoli (whole plant (roots and leaves removed))		
Treated Plot (P2)	at a rate of 2 x 15 g ai/ha*	at a rate of 2 x 90 g ai/ha**
0 DALA	0.13 – 0.16	0.53 – 0.61
6 - 7 DALA	0.015 – 0.029	0.049 – 0.074
13 - 14 DALA	< 0.01 – 0.028	< 0.01 – 0.028
20 - 21 DALA (NCH)	< 0.01 – 0.017	0.011 – 0.024
28 DALA	< 0.01 – 0.012	< 0.01
Treated Plot (P3)	at a rate of 1 x 15 g ai/ha*	at a rate of 1 x 90 g ai/ha**
0 DALA	0.050 – 0.065	0.33 – 0.39
6 - 7 DALA	< 0.01	0.033 – 0.043
13 - 14 DALA	< 0.01	< 0.01 – 0.013
20 - 21 DALA (NCH)	< 0.01 – 0.026	< 0.01 – 0.026
28 DALA	< 0.01	< 0.01
Control Plot (C1) No residues of oxathiapiprolin and metalaxyl-M at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in any of the untreated broccoli specimens.		

NCH: normal commercial harvest, DALA: days after last application,
*application rate of oxathiapiprolin,
** application rate of metalaxyl-M

The study is acceptable.

Reference:	KCA 6.3.1/01
Report	Oxathiapiprolin and Metalaxyl-M - Residue Study on Broccoli in Germany, Hungary, Poland and the United Kingdom 2020, Meyer M., Poperechna N., 2021, report No IF20-05335380, document No VV-908189
Guideline(s):	Yes OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009. Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).

Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 6: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) : Oxathiapiprolin and Metalaxyl-M - Residue Study on Broccoli in Germany, Hungary, Poland and the United Kingdom 2020			
Active Substance (common name):	Metalaxyl-M	**Commercial Product (name):**	
Crop/Crop Group:	Broccoli	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	GERMANY, HUNGARY, POLAND, UNITED KINGDOM	**Other active substance in the formulation (common name and content):**	A23109A: oxathiapiprolin (30 g/L)
Content of active substance (g/kg or g/L):	A23109A: 180 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	DC		
Analytical Method:	Metalaxyl-M (Whole plant) REM 181.13A; 0.01 mg/kg		
Recovery data:	Metalaxyl-M Whole plant Mean = 98% RSD = 6% (n = 11 in 0.01022 - 1.028 spiking range)		

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment g a.s./ ha	Application rate per treatment Water (L/ha)	Application rate per treatment g a.s./hL	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg) Metalaxyl-M	PHI (days) (d)	Details on trial (e)
20-00246-01 GERMANY (49685) Europe North 2020	Broccoli / Marathon	1.19 May 2020 2 – 3 -	1. 89.1015 2. 90.599	1. 297.5 2. 302.5	- -	1. 16 Jul 2020 2. 21 Jul 2020	1. BBCH 43-43 2. BBCH 45-45	Whole plant	0.6058	0	Field SP (max days): 301
								Whole plant	0.0742	7	
								Whole plant	< 0.01	13	
								Whole plant	0.0107	20	
								Whole plant	< 0.01	28	
	Broccoli / Marathon	1.19 May 2020 2 – 3 -	1. 89.6007	1. 299.1667	- -	1. 21 Jul 2020	1. BBCH 45-45	Whole plant	0.3873	0	Field SP (max days): 288
								Whole plant	0.0432	7	
								Whole plant	< 0.01	13	
								Whole plant	< 0.01	20	
								Whole plant	< 0.01	28	
20-00246-02 HUNGARY (H-4400) Europe North 2020	Broccoli / Agassi	1.10 Aug 2020 2 – 3 -	1. 86.7249 2. 87.9734	1. 385.9259 2. 391.4815	- -	1. 02 Oct 2020 2. 09 Oct 2020	1. BBCH 43-43 2. BBCH 45-45	Whole plant	0.5291	0	Field SP (max days): 215
								Whole plant	0.0492	6	
								Whole plant	0.0279	14	
								Whole plant	0.0238	20	
								Whole plant	< 0.01	28	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (L/ha)	g a.s./hL				Metalaxyl-M		
	Broccoli / Agassi	1.10 Aug 2020 2 – 3 -	1. 91.3025	1. 406.2963	-	1. 09 Oct 2020	1. BBCH 45-45	Whole plant	0.3278	0	Field SP (max days): 208
								Whole plant	0.0332	6	
								Whole plant	0.0126	14	
								Whole plant	0.0103	20	
								Whole plant	< 0.01	28	
20-00246-03 POLAND (88-400) Europe North	Broccoli / Triton	1.20 May 2020 2 – 3 -	1. 92.5658 2. 91.2681	1. 309.111 2. 304.7777	- -	1. 31 Jul 2020 2. 07 Aug 2020	1. BBCH 41-41 2. BBCH 43-43	Whole plant	<u>0.0239</u>	20	Field SP (max days): 264
	Broccoli / Triton	1.20 May 2020 2 – 3 -	1. 92.0667	1. 307.4443	-	1. 07 Aug 2020	1. BBCH 43-43	Whole plant	0.0259	20	Field SP (max days): 246
20-00246-04 UNITED KINGDOM (GL55 6NW) Europe North	Broccoli / Steel	1.25 Jun 2020 2 – 3 -	1. 92.6873 2. 92.7654	1. 412.4583 2. 412.459	- -	1. 08 Sep 2020 2. 15 Sep 2020	1. BBCH 41-41 2. BBCH 43-43	Whole plant	<u>< 0.01</u>	21	Field SP (max days): 224
	Broccoli / Steel	1.25 Jun 2020 2 – 3 -	1. 92.6873	1. 412.4583	-	1. 15 Sep 2020	1. BBCH 43-43	Whole plant	< 0.01	21	Field SP (max days): 211

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

A 2.1.3.1.2 Study 2 - S13-03434 - New data

Comments of zRMS:	Four residue field trials on cauliflower were conducted in the United Kingdom and northern France during 2013. Metalaxyl-M was applied to cauliflower as A13947A, a soluble concentrate (SL) formulation containing 480 g metalaxyl-M per litre. Two applications, separated by a 14 - 17 day interval were made at 77.6 g ai/ha for metalaxyl-M. Treated samples were collected immediately before and after last application and at 14, 21 and 30 days after the final application. <u>Results:</u> The residues of metalaxyl-M in the treated cauliflower (whole plant) samples taken from trials S13-0-03434-01 and S13-0-03434-02 at 0 days before last application (DBLA) were in the range < 0.01 mg/kg to 0.06 mg/kg and at 0 days after last application (DALA) were in the range 0.55 mg/kg to 0.61 mg/kg. The residues of metalaxyl-M in the treated cauliflower (inflorescences) samples taken from trials S13-0-03434-03 and S13-0-03434-05 at 0 DBLA were below the limit of quantification (LOQ, 0.01 mg/kg) and at 0 DALA were in the range 0.01 mg/kg to 0.02 mg/kg. The residues of metalaxyl-M in the treated cauliflower (inflorescences) samples taken from all trials at 14 DALA were in the range < 0.01 mg/kg to 0.02 mg/kg, **at 21 DALA were in the range < 0.01 mg/kg to 0.01 mg/kg** and at 30 DALA were below limit of quantification (LOQ, 0.01 mg/kg). No residues of metalaxyl-M were found at or above the limit of quantification (LOQ, 0.01 mg/kg) in the untreated cauliflower (whole plant and inflorescences) samples. Specimens were stored frozen for a maximum period of 7 months from sampling to analysis for metalaxyl-M. Field samples for residue analysis were analysed for metalaxyl-M using method REM 181.13A with LOQ of 0.01 mg/kg. The study is acceptable.

Reference:	KCA 6.3.1/02
Report	Metalaxyl-M - Residue study on Cauliflower in the United Kingdom and Northern France in 2013, Yozgatli H.P., Breyer N. 2014, report No S13-03434, document No VV-407968
Guideline(s):	Yes 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).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 7: Summary of the study 2 trials

Field Trials, Crop Residue (Summary) : Metalaxyl-M - Residue study on Cauliflower in the United Kingdom and Northern France in 2013			
Active Substance (common name):	Metalaxyl-M	**Commercial Product (name):**	
Crop/Crop Group:	Cauliflower	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	France, United Kingdom	**Other active substance in the formulation (common name and content):**	None
Content of active substance (g/kg or g/L):	A13947A: 480 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A13947A SL		
Analytical Method:	Metalaxyl-M (Inflorescence, Whole Plant) REM 181.13A; 0.01 mg/kg		
Recovery data:	Metalaxyl-M Inflorescence Mean = 81% RSD = N/A (n = 2 in 0.01 - 0.1 spiking range) Metalaxyl-M Whole Plant Mean = 72% RSD = 7% (n = 3 in 0.01 - 1 spiking range)		

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (L/ha)	g a.s./hL				Metalaxyl-M		
S13-03434-01 United Kingdom (PR4) Europe North 2013	Cauliflower / Raleigh	1.21 Jun 2013 2 – 3 -	1. 78.2469 2. 80.1869	1. 403.34 2. 413.34	- -	1. 16 Aug 2013 2. 30 Aug 2013	1. BBCH 14-18 2. BBCH 18-41	Whole Plant	< 0.01	0	Field SP (max days): 213
								Whole Plant	0.61	0	
								Inflorescence	< 0.01	14	
								Inflorescence	< 0.01	21	
								Inflorescence	< 0.01	30	
S13-03434-02 United Kingdom (DE73 8DN) Europe North 2013	Cauliflower / Galiote	1.15 May 2013 2 – 3 -	1. 72.174 2. 78.8501	1. 371.42 2. 405.77	- -	1. 07 Oct 2013 2. 24 Oct 2013	1. BBCH 39-41 2. BBCH 41	Whole Plant	0.06	0	Field SP (max days): 158
								Whole Plant	0.55	0	
								Inflorescence	< 0.01	14	
								Inflorescence	< 0.01	21	
								Inflorescence	< 0.01	30	
S13-03434-03		1.25 Jun 2013	1. 82.5311		-			Inflorescence	< 0.01	0	SP (max days):

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (L/ha)	g a.s./hL				Metalaxyl-M		
France (91140) Europe North 2013	Cauliflower / Optimist	2 – 3 -	2. 81.1276	1. 424.71 2. 417.49	-	1. 10 Sep 2013 2. 24 Sep 2013 (N/A, 14)	1. BBCH 41 2. BBCH 41-42	Inflorescence	0.01	0	188
								Inflorescence	0.02	14	
								Inflorescence	<u>0.01</u>	21	
								Inflorescence	< 0.01	30	
S13-03434-05 United Kingdom (PE20 3LU) Europe North 2013	Cauliflower / Brigantine	1.14 Aug 2013 2 – 3 -	1. 76.964 2. 76.5331	1. 396.88 2. 394.66	- -	1. 01 Nov 2013 2. 15 Nov 2013	1. BBCH 19-42 2. BBCH 41-45	Inflorescence	0.02	0	Field SP (max days): 136
								Inflorescence	< 0.01	0	
								Inflorescence	< 0.01	14	
								Inflorescence	<u>0.01</u>	21	
								Inflorescence	< 0.01	30	

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

A 2.1.3.2 Kale

Table A 8: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-23, CZ-24, DE-23, PL-23, PL-23a, SK-20, SK-22*)	2	87.2 g as/ha	7-10 days	BBCH 12 - 49	20

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

Kale - (extrapolation to Leafy brassicas, Chinese cabbage and curly kale)

Table A 9: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-14, AT-26, AT-37, BE-11, BE-21, BE-28, CZ-14, CZ-29, CZ-40, DE-14, DE-26, DE-37, NL-10, NL-20, NL-27, PL-14, PL-14a, PL-26, PL-26a, PL-37, PL-37a, SK-13, SK-33*)	2	87.2 g as/ha	7-10 days	BBCH 12 - 49	20

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

A 2.1.3.2.1 Study 1 - RES-00256 - New data

Comments of zRMS:	Four residue field trials on kale were successfully conducted in France, Austria and the United Kingdom during 2020/2021. Oxathiapiprolin and metalaxyl-M were applied to kale as A23109A, a dispensive concentrate DC formulation containing 30 g of oxathipiprolin and 180 g of metalaxyl-M per litre. Two applications (applied at 7 days before last application and 20 days before harvest), separated by a 7 day interval were made at a nominal rate of 15 g ai/ha for oxathiprolin and 90 g ai/ha for metalaxyl-M for P2 plot and one application (applied 20 days before harvest) was made at a nominal rate of 15 g ai/ha for oxathiprolin and 90 g ai/ha for metalaxyl-M for P3 plot. Treated samples were collected at 0, 6 - 7, 13 - 14, 19 - 20 and 26 - 28 days after the last application (DALA) for decline trials and at 20 days after the last application (DALA) for harvest trials. Untreated samples were collected at 19 - 20 DALA.

	Residues of oxathiapiprolin and metalaxyl-M are summarised in the table below. (see table below) Samples were analysed for residues of oxathiapiprolin using DuPont method DuPont-30422 and metalaxyl-M was analysed using method REM 181.13A with LOQ of 0.01 mg/kg. Samples were stored frozen for a maximum period of ca 6 months (178 days) from sampling to analysis for oxathiapiprolin and ca 6 months (185 days) for metalaxyl-M. The study is acceptable.

Actual Sampling Interval (days)	Oxathiapiprolin Residues in the range (mg/kg)	Metalaxyl-M Residues in the range (mg/kg)
Treated Plot (P2): at a rate of 90 g ai/ha (metalaxyl-M) and 15 g ai/ha (oxathiapiprolin)		
Kale (whole plant)		
0 DALA	0.24 – 0.18	0.82 – 1.52
6 - 7 DALA	0.07 – 0.02	0.15 – 0.23
13 - 14 DALA	0.02 – 0.02	0.06 – 0.07
19 - 20 DALA (NCH)	<0.01 – 0.02	<0.01 – 0.08
26 - 28 DALA	<0.01 - <0.01	<0.01 – 0.02
Treated Plot (P3): at a rate of 90 g ai/ha (metalaxyl-M) and 15 g ai/ha (oxathiapiprolin)		
Kale (whole plant)		
0 DALA	0.22 – 0.15	1.43 – 0.73
6 - 7 DALA	0.02 – 0.05	0.08 – 0.12
13 - 14 DALA	<0.01 – 0.03	0.04 – 0.04
19 - 20 DALA (NCH)	<0.01 – 0.02	<0.01 – 0.03
26 - 28 DALA	<0.01 – <0.01	<0.01 – 0.01
Control plot (C1) No residues of oxathiapiprolin or metalaxyl-M at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in any of the untreated kale samples.		

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

Reference:	KCA 6.3.2/01
Report	Oxathiapiprolin/Metalaxyl-M – Determination of residues of Oxathiapiprolin and Metalaxyl-M in Kale from Trials conducted in NEU in 2020, Brown S., 2021, report No RES-00256, document No VV-901782
Guideline(s):	Yes OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009. Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 10: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) : Oxathiapiprolin / Metalaxyl-M - Determination of residues of Oxathiapiprolin and Metalaxyl-M in Kale from Trials conducted in NEU in 2020			
Active Substance (common name):	Metalaxyl-M	**Commercial Product (name):**	
Crop/Crop Group:	Kale	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	UNITED KINGDOM, AUSTRIA, FRANCE	**Other active substance in the formulation (common name and content):**	A23109A: oxathiapiprolin (30 g/L)
Content of active substance (g/kg or g/L):	A23109A: 180 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A23109A DC		
Analytical Method:	Metalaxyl-M (Whole plant) REM 181.13A; 0.01 mg/kg		
Recovery data:	Metalaxyl-M Whole plant Mean = 91% RSD = 4% (n = 15 in 0.01 - 2.5 spiking range)		

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (L/ha)	g a.s./hL				Metalaxyl-M		
684539 UNITED KINGDOM (KY10 3XB) Europe North 2020	Kale / Reflex	1.15 Jun 2020 2 – 3 -	1. 86.2984 2. 85.04994	1. 384.02778 2. 378.4722	- -	1. 12 Jan 2021 2. 19 Jan 2021	1. BBCH 49 2. BBCH 49	Whole plant	1.52	0	Field SP (max days): 41
								Whole plant	0.15	7	
								Whole plant	0.07	14	
								Whole plant	<u>0.04</u>	20	
								Whole plant	0.02	28	
	Kale / Reflex	1.15 Jun 2020 2 – 3 -	1. 87.5468	1. 389.5833	-	1. 19 Jan 2021	1. BBCH 49	Whole plant	1.43	0	Field SP (max days): 41
								Whole plant	0.08	7	
								Whole plant	0.04	14	
								Whole plant	0.03	20	
								Whole plant	0.01	28	
MLI-20-45526 AT04 AUSTRIA (2471) Europe North 2020	Kale / Oldenbor F1	1.17 Jun 2020 2 – 3 -	1. 89.4 2. 90	1. 298 2. 300	- -	1. 12 Aug 2020 2. 19 Aug 2020	1. BBCH 45-45 2. BBCH 47-47	Whole plant	<u>< 0.01</u>	20	Field SP (max days): 171
	Kale / Oldenbor F1	1.17 Jun 2020 2 – 3 -	1. 87.3	1. 291	-	1. 19 Aug 2020	1. BBCH 47-47	Whole plant	< 0.01	20	Field SP (max days): 171
MLI-20-45526 FR01	Kale / Nebraska	1.23 Jun 2020			-			Whole plant	0.82	0	Field

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (L/ha)	g a.s./hL				Metalaxyl-M		
FRANCE (62232) Europe North 2020		2 – 3 -	1. 88.8 2. 96.8551	1. 493.3333 2. 538.6222	-	1. 27 Aug 2020 2. 04 Sep 2020	1. BBCH 41-42 2. BBCH 43-45	Whole plant	0.23	6	SP (max days): 178
								Whole plant	0.06	13	
								Whole plant	<u>0.03</u>	19	
								Whole plant	< 0.01	26	
	Kale / Nebraska	1.23 Jun 2020 2 – 3 -	1. 92.8591	1. 516.4	-	1. 04 Sep 2020	1. BBCH 43-45	Whole plant	0.73	0	Field SP (max days): 178
								Whole plant	0.12	6	
								Whole plant	0.04	13	
								Whole plant	0.01	19	
								Whole plant	< 0.01	26	
MLI-20-45526 GB03 UNITED KINGDOM (GL55 6LB) Europe North 2020	Kale / Oldenbor	1.08 Jun 2020 2 – 3 -	1. 92.08734 2. 92.08734	1. 307.7767 2. 307.7767	- -	1. 17 Sep 2020 2. 25 Sep 2020	1. BBCH 47-47 2. BBCH 48-48	Whole plant	<u>0.08</u>	20	Field SP (max days): 134
	Kale / Oldenbor	1.08 Jun 2020 2 – 3 -	1. 88.09798	1. 294.4433	-	1. 25 Sep 2020	1. BBCH 48-48	Whole plant	0.03	20	

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

A 2.1.3.3 Head cabbage

Table A 11: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-20, BE-17, CZ-20, DE-20, NL-16, PL-20, PL-20a, SK-17*)	2	87.2 g as/ha	7-10 days	BBCH 12 - 49	20

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

Head cabbage - (Savoy cabbage)

Table A 12: 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)
f	2	87.2 g as/ha	7-10 days	BBCH 12 - 49	20

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

A 2.1.3.3.1 Study 1- CEMS-9523 - New data

Comments of zRMS:	Eight residue field trials on cabbages were successfully conducted in Northern France, Austria, Hungary and Poland during 2020. Oxathiapiprolin/metalaxyl-M was applied to cabbages as A23109A, a dispersible concentrate (DC) formulation containing nominal 30 g oxathiapiprolin and 180 g metalaxyl-M per litre. Two applications to plot P2, applied at 27±1 and 20±1 days before normal commercial harvest were made at a nominal rate of 15 g ai/ha for oxathiapiprolin and 90 g ai/ha for metalaxyl-M. One application to plot P3, applied at 20±1 days before normal commercial harvest was made at a nominal rate of 15 g ai/ha for oxathiapiprolin and 90 g ai/ha for metalaxyl-M. For decline trials treated samples of cabbage were collected at 0, 7 – 8, 14 – 15, 19 – 21 and 27 – 29 days after the last application (DALA) with untreated cabbage samples being collected at 19 – 21 DALA. For harvest trials untreated and treated samples of cabbage were collected at 20 days after the last application (DALA) to the treated plots.

Residues of oxathiapiprolin and metalaxyl-M are summarised in the table below.

Sampling Interval (days)	Oxathiapiprolin Residues (mg/kg)	Metalaxyl-M Residues (mg/kg)
Treated Plot (P2): at a rate of 2 x 15 g ai/ha oxathiapiprolin and 2 x 90 g ai/ha metalaxyl-M		
Cabbage-Whole Plant		
0 DALA	<0.01 – 0.09	0.01 – 0.63
7 DALA	<0.01	<0.01 – 0.05
14 - 15 DALA	<0.01	<0.01 – 0.02
19 - 21 DALA (NCH)	<0.01	<0.01 – 0.02
27 - 28 DALA	<0.01	<0.01 – 0.01
Treated Plot (P3): at a rate of 1 x 15 g ai/ha oxathiapiprolin and 1 x 90 g ai/ha metalaxyl-M		
Cabbage-Whole Plant		
0 DALA	<0.01 – 0.20	<0.01 – 1.14
7 DALA	<0.01	<0.01 – 0.06
14 - 15 DALA	<0.01	<0.01 – 0.02
19 - 21 DALA (NCH)	<0.01	<0.01
27 - 28 DALA	<0.01	<0.01
Control plot (C1) No residues of oxathiapiprolin or metalaxyl-M at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in any of the untreated cabbage samples.		

DALA: days after the last application
NCH: Normal Commercial Harvest

Specimens were stored frozen for a maximum period of 218 days (approximately 6 months) from sampling to analysis for oxathiapiprolin and metalaxyl-M.

Cabbage whole plant samples were analysed for oxathiapiprolin using method DuPont 30422 Supplement No. 1 and metalaxyl-M using method REM 181.13A with LOQ of 0.01 mg/kg.

The study is acceptable.

Reference: KCA 6.3.3/01

Report: Oxathiapiprolin/Metalaxyl-M – Residue Study on Cabbage in Northern France, Austria, Hungary and Poland in 2020, Ford K., 2021, report No CEMR-9523, document No VV-901921

Guideline(s): Yes
OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009.
Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).

Deviations: No

GLP: Yes

Acceptability: Yes

Table A 13: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) : Oxathiapiprolin/Metalaxyl-M - Residue Study on Cabbage in Northern France, Austria, Hungary and Poland in 2020			
Active Substance (common name):	Metalaxyl-M	**Commercial Product (name):**	
Crop/Crop Group:	Cabbage	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	FRANCE, AUSTRIA, POLAND, HUNGARY	**Other active substance in the formulation (common name and content):**	A23109A: oxathiapiprolin (30 g/L)
Content of active substance (g/kg or g/L):	A23109A: 180 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A23109A DC		
Analytical Method:	Metalaxyl-M (Whole plant) REM 181.13A; 0.01 mg/kg		
Recovery data:	Metalaxyl-M Whole plant Mean = 97% RSD = 10% (n = 21 in 0.01 - 1 spiking range)		

Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (c)	**Growth stage at last treatment or date**	**Portion analyzed**	**Residues (mg/kg)**	**PHI (days)** (d)	**Details on trial** (e)
			g a.s./ ha	**Water (L/ha)**	**g a.s./hL**				**Metalaxyl-M**		
MLI-20-45525 AT03 AUSTRIA (2471) Europe North 2020	Cabbage / Redma F1	1.17 Jun 2020 2 – 3 -	1. 88.05 2. 91.2	1. 293.5 2. 304	- -	1. 26 Aug 2021 2. 02 Sep 2021	1. BBCH 43-43 2. BBCH 44-44	Whole plant	0.63	0	Field SP (max days): 190
								Whole plant	0.054	7	
								Whole plant	0.021	14	
								Whole plant	< 0.01	19	
								Whole plant	< 0.01	29	
	Cabbage / Redma F1	1.17 Jun 2020 2 – 3 -	1. 91.25	1. 304.1667	-	1. 02 Sep 2021	1. BBCH 44-44	Whole plant	1.14	0	Field SP (max days): 190
								Whole plant	0.061	7	
								Whole plant	0.015	14	
								Whole plant	< 0.01	19	
								Whole plant	< 0.01	29	
MLI-20-45525 AT07 AUSTRIA (4470) Europe North	Cabbage / var. alba (Braunschweiger)	1.24 Jun 2020 2 – 3 -	1. 94.2 2. 94.5	1. 314 2. 315	- -	1. 08 Sep 2020 2. 15 Sep 2020	1. BBCH 47-47 2. BBCH 48-48	Whole plant	< 0.01	20	Field SP (max days): 157

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (L/ha)	g a.s./hL				Metalaxyl-M		
	Cabbage / var. alba (Braunschweiger)	1.24 Jun 2020 2 – 3 -	1. 88	1. 293.3333	-	1. 15 Sep 2020	1. BBCH 48-48	Whole plant	< 0.01	20	Field SP (max days): 157
MLI-20-45525 FR01 FRANCE (62232) Europe North 2020	Cabbage / Bloktor	1.23 Jun 2020 2 – 3 -	1. 89.25 2. 89.3258	1. 396.6667 2. 397.5	- -	1. 27 Aug 2020 2. 02 Sep 2020	1. BBCH 41-42 2. BBCH 43-45	Whole plant	0.014	0	Field SP (max days): 188
								Whole plant	< 0.01	8	
								Whole plant	< 0.01	15	
								Whole plant	<u>< 0.01</u>	21	
								Whole plant	< 0.01	28	
	Cabbage / Bloktor	1.23 Jun 2020 2 – 3 -	1. 87.8277	1. 390.8333	-	1. 02 Sep 2020	1. BBCH 43-45	Whole plant	< 0.01	0	Field SP (max days): 188
								Whole plant	< 0.01	8	
								Whole plant	< 0.01	15	
								Whole plant	< 0.01	21	
								Whole plant	< 0.01	28	
MLI-20-45525 FR05 FRANCE (41350) Europe North 2020	Cabbage / Platidou	1.29 Jul 2020 2 – 3 -	1. 96.05395 2. 82.8671	1. 534.1667 2. 460.8333	- -	1. 04 Nov 2020 2. 10 Nov 2020	1. BBCH 43-45 2. BBCH 44-47	Whole plant	<u>< 0.01</u>	20	Field SP (max days): 101
	Cabbage / Platidou	1.29 Jul 2020 2 – 3 -	1. 98.4515	1. 547.5	-	1. 10 Nov 2020	1. BBCH 44-48	Whole plant	< 0.01	20	Field SP (max days): 101
MLI-20-45525 HU09	Cabbage / Busoni	1.05 Jul 2020	1. 92.6282		-			Whole plant	0.41	0	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (L/ha)	g a.s./hL				Metalaxyl-M		
HUNGARY (6060) Europe North 2020		2 – 3 -	2. 96.6247	1. 309.02833 2. 322.3617	-	1. 14 Oct 2020 2. 21 Oct 2020	1. BBCH 43-43 2. BBCH 44-44	Whole plant	0.013	7	Field SP (max days): 139
								Whole plant	0.017	14	
								Whole plant	0.02	21	
								Whole plant	0.01	27	
	Cabbage / Busoni	1.05 Jul 2020 2 – 3 -	1. 93.1277	1. 310.695		1. 21 Oct 2020	1. BBCH 44-44	Whole plant	0.16	0	Field SP (max days): 139
								Whole plant	< 0.01	7	
								Whole plant	< 0.01	14	
								Whole plant	< 0.01	21	
								Whole plant	< 0.01	27	
MLI-20-45525 HU10 HUNGARY (6793) Europe North 2020	Cabbage / Busido	1.25 Jun 2020 2 – 3 -	1. 91.009626 2. 92.5113	1. 404.04333 2. 410.71		1. 21 Nov 2020 2. 27 Nov 2020	1. BBCH 47-48 2. BBCH 47-48	Whole plant	< 0.01	20	Field SP (max days): 84
	Cabbage / Busido	1.25 Jun 2020 2 – 3 -	1. 891326	1. 395.71		1. 27 Nov 2020	1. BBCH 47-48	Whole plant	< 0.01	20	Field SP (max days): 84
MLI-20-45525 PL04		1.06 Jun 2020	1. 90.4213					Whole plant	0.103	0	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (L/ha)	g a.s./hL				Metalaxyl-M		
POLAND (99-321) Europe North 2020	Cabbage / Pierwszy zbiór	2 – 3 -	2. 89.2978	1. 402.375 2. 397.375		1. 29 Jul 2020 2. 05 Aug 2020	1. BBCH 44-46 2. BBCH 46-47	Whole plant	0.013	7	Field SP (max days): 218
								Whole plant	< 0.01	14	
								Whole plant	< 0.01	20	
								Whole plant	< 0.01	27	
	Cabbage / Pierwszy zbiór	1.06 Jun 2020 2 – 3 -	1. 92.6685	1. 412.375		1. 05 Aug 2020	1. BBCH 46-47	Whole plant	0.032	0	Field SP (max days): 218
								Whole plant	< 0.01	7	
								Whole plant	< 0.01	14	
								Whole plant	< 0.01	20	
								Whole plant	< 0.01	27	
MLI-20-45525 PL08 POLAND (63-304) Europe North 2020	Cabbage / Zuleima	1.11 May 2020 2 – 3 -	1. 89.2297 2. 94.2276	1. 297.5567 2. 314.2233		1. 25 Jul 2020 2. 01 Aug 2020	1. BBCH 43-43 2. BBCH 44-44	Whole plant	< 0.01	20	Field SP (max days): 202
	Cabbage / Zuleima	1.11 May 2020 2 – 3 -	1. 92.2284	1. 307.5567 L/ha		1. 01 Aug 2020	1. BBCH 44-44	Whole plant	< 0.01	20	Field SP (max days): 202

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

A 2.1.3.4 Brussels sprout

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)
Intended cGAP – NEU (AT-5, BE-5, CZ-5, DE-5, NL-5, PL-5, PL-5a, SK-5*)	2	87.2 g as/ha	7-10 days	BBCH 12 - 49	20

A 2.1.3.4.1 Study 1 - RES-00257 - New data

Comments of zRMS:

Two residue decline field trials and two harvest trials on brussels sprouts were conducted in northern Europe during 2020. Oxathiapiprolin and metalaxyl-M was applied to brussels sprouts as A23109[A], a dispersible concentrate (DC) formulation containing nominally 30 g of oxathiapiprolin per litre and 180 g of metalaxyl-M per litre.
For the harvest/decline trials and harvest only trials,
- To treated plot P2, two applications were made at a nominal rate of 15 g ai/ha for oxathiapiprolin (this equates to 90 g ai/ha for metalaxyl-M) at 27 - 28 DBH and the other at a nominal rate of 15 g ai/ha for oxathiapiprolin (this equates to 90 g ai/ha for metalaxyl-M) 7-8 days (9 days for harvest trial AT05) later at 20 - 21 DBH (19 DBH for harvest trial AT05). Following the applications, treated plot P2 samples for the harvest/decline trials of brussels sprouts buttons were collected at 0, 7, 14, 19 - 21 (NCH) and 27 - 28 days after last application (DALA). The harvest only trials for plot P2 were collected at 19 - 20 days (NCH) after last application (DALA).
- To treated plot P3, one application was made at a nominal rate of 15 g ai/ha for oxathiapiprolin (this equates to 90 g ai/ha for metalaxyl-M) at 19 - 21 DBH. Following the application, treated plot P3 samples for the harvest/decline and harvest only trials of brussels sprouts buttons were collected at 0, 7, 14, 20 - 21 (NCH) and 27 - 28 days after last application (DALA). The harvest only trials for plot P3 were collected at 19 - 20 days (NCH) after last application (DALA).
- Untreated brussels sprouts buttons samples were collected at 19 - 21 DALA (NCH) for the harvest/decline trial and harvest only trials.

Residues of oxathiapiprolin and metalaxyl-M are summarised in the table below.

Actual Sampling Interval (days)	Oxathiapiprolin Residues in the range (mg/kg)	Metalaxyl-M Residues in the range (mg/kg)
Treated Plot (P2): at a rate of 90 g ai/ha (metalaxyl-M) and 15 g ai/ha (oxathiapiprolin)		
Brussels Sprouts (buttons)		
0 DALA	<0.01 - <0.01	0.02 - 0.04
7 DALA	<0.01 - <0.01	<0.01 - 0.02
14 DALA	<0.01 - <0.01	<0.01 - 0.01
19 - 21 DALA (NCH)	<0.01 - 0.01	<0.01 - 0.01
27 - 28 DALA	<0.01 - <0.01	<0.01 - <0.01
Treated Plot (P3): at a rate of 90 g ai/ha (metalaxyl-M) and 15 g ai/ha (oxathiapiprolin)		
Brussels Sprouts (buttons)		
0 DALA	<0.01 - <0.01	<0.01 - 0.04
7 DALA	<0.01 - <0.01	<0.01 - 0.01
14 DALA	<0.01 - <0.01	<0.01 - 0.01
19 - 21 DALA (NCH)	<0.01 - <0.01	<0.01 - 0.01
27 - 28 DALA	<0.01 - <0.01	<0.01 - <0.01
Control plot (C1) No residues of oxathiapiprolin or metalaxyl-M at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in any of the untreated brussels sprouts samples.		

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

Field samples for residue analysis were analysed for oxathiapiprolin and metalaxyl-M using method DuPont-30422 and REM 181.13A with LOQ of 0.01 mg/kg.

	Samples were stored frozen for a maximum period of ca 4 months (121 days) from sampling to analysis for oxathiapiprolin and ca 4 months (119 days) for metalaxyl-M. The study is acceptable.

Reference:	KCA 6.3.4/01
Report	Oxathiapiprolin/Metalaxyl-M – Determination of residues of Oxathiapiprolin and Metalaxyl-M in Brussels Sprouts from Trials conducted in NEU in 2020, Brown S., 2021, report No RES-00257, document No VV-901790
Guideline(s):	Yes OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009. Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 15: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) : Oxathiapiprolin / Metalaxyl-M - Determination of residues of Oxathiapiprolin and Metalaxyl-M in Brussels Sprouts from Trials conducted in NEU in 2020			
Active Substance (common name):	Metalaxyl-M	**Commercial Product (name):**	
Crop/Crop Group:	Brussels sprouts	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	FRANCE, POLAND, AUSTRIA	**Other active substance in the formulation (common name and content):**	A23109A: oxathiapiprolin (30 g/L)
Content of active substance (g/kg or g/L):	A23109A: 180 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A23109A DC		
Analytical Method:	Metalaxyl-M (Sprouts) REM 181.13A; 0.01 mg/kg		
Recovery data:	Metalaxyl-M Sprouts Mean = 90% RSD = 1% (n = 10 in 0.01 - 0.1 spiking range)		

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (L/ha)	g a.s./hL				Metalaxyl-M		
MLI-20-45527 AT05 AUSTRIA (3462) Europe North 2020	Brussels sprouts / Marte F1	1.28 Apr 2020 2 – 3 -	1. 81.5 2. 91.6	1. 271.6667 2. 305.3333		1. 06 Oct 2020 2. 15 Oct 2020	1. BBCH 47-47 2. BBCH 48-48	Sprouts	< 0.01	19	Field SP (max days): 120
	Brussels sprouts / Marte F1	1.28 Apr 2020 2 – 3 -	1. 87.4	1. 291.3333		1. 15 Oct 2020	1. BBCH 48-48	Sprouts	< 0.01	19	Field SP (max days): 120
MLI-20-45527 FR01		1.29 May 2020						Sprouts	0.02	0	Field

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (L/ha)	g a.s./hL				Metalaxyl-M		
FRANCE (08190) Europe North 2020	Brussels sprouts / Gustus	2 – 3 -	1. 93.9875 2. 87.004514	1. 314.055 2. 290.7217		1. 06 Jan 2021 2. 14 Jan 2021	1. BBCH 48-49 2. BBCH 48-49	Sprouts	< 0.01	7	SP (max days): 48
								Sprouts	< 0.01	14	
								Sprouts	< 0.01	21	
								Sprouts	< 0.01	27	
	Brussels sprouts / Gustus	1.29 May 2020 2 – 3 -	1. 88.9997	1. 297.3883		1. 14 Jan 2021	1. BBCH 48-49	Sprouts	< 0.01	0	Field SP (max days): 48
								Sprouts	< 0.01	7	
								Sprouts	< 0.01	14	
								Sprouts	< 0.01	21	
								Sprouts	< 0.01	27	
MLI-20-45527 FR06		1.10 May 2020						Sprouts	0.04	0	Field

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (L/ha)	g a.s./hL				Metalaxyl-M		
FRANCE (59236) Europe North 2020	Brussels sprouts / Albarus	2 – 3 -	1. 89.25 2. 90	1. 396.6667 2. 400		1. 05 Nov 2020 2. 12 Nov 2020	1. BBCH 44-45 2. BBCH 44-45	Sprouts	0.02	7	SP (max days): 111
								Sprouts	0.01	14	
								Sprouts	<u>< 0.01</u>	20	
								Sprouts	< 0.01	28	
	Brussels sprouts / Albarus	1.10 May 2020 2 – 3 -	1. 90	1. 400		1. 12 Nov 2020	1. BBCH 44-45	Sprouts	0.04	0	Field SP (max days): 111
								Sprouts	0.01	7	
								Sprouts	0.01	14	
								Sprouts	< 0.01	20	
								Sprouts	< 0.01	28	
MLI-20-45527 PL04 POLAND (63-304) Europe North 2020	Brussels sprouts / Cyrus	1.11 May 2020 2 – 3 -	1. 88.2301 2. 89.2297	1. 294.2233 2. 297.5567		1. 19 Oct 2020 2. 26 Oct 2020	1. BBCH 46-47 2. BBCH 47-48	Sprouts	<u>0.01</u>	20	Field SP (max days): 108
	Brussels sprouts / Cyrus	1.11 May 2020 2 – 3 -	1. 92.2284	1. 307.5567		1. 26 Oct 2020	1. BBCH 47-48	Sprouts	0.01	20	Field SP (max days): 108

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

A 2.1.3.5 Lettuce (open leaf)

Table A 16: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-29, BE-24, CZ-32, DE-29, NL-23, PL-29, SK-25*)	2	87.2 g as/ha	7 days	BBCH 12 - 49	10

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

Lettuce - (extrapolation to Baby leaf, chards and beet leaves, chicory, common purslane, cress, endive, escarole, herbs and edible flowers,persley, chives, iceberg lettuce, lamb's lettuce, red mustard, watercress, rocket, spinach)

Table A 17: Comparison of intended and critical EU GAPs – baby leaf

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-1, BE-1,CZ-1, DE-1, NL-1, PL-1, SK-1 *)	2	87.2 g as/ha	7 days	BBCH 08 - 49	10

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

Table A 18: Comparison of intended and critical EU GAPs – chards and beet leaves

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-8, CZ-8, DE-8, PL-8, SK-8*)	2	87.2 g as/ha	7 days	BBCH 12 - 49	10

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

Table A 19: Comparison of intended and critical EU GAPs – chicory

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-9, CZ-9, DE-9, PL-9*)	2	87.2 g as/ha	7 days	BBCH 12 - 49	10

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

Table A 20: Comparison of intended and critical EU GAPs – common purslane

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-11, CZ-11, DE-11, PL-11, SK-10*)	2	87.2 g as/ha	7 days	BBCH 12 - 49	10

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

Table A 21: Comparison of intended and critical EU GAPs – cress

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-12, BE-9, CZ-12, DE-12, PL-12, SK-11*)	2	87.2 g as/ha	7 days	BBCH 12 - 49	10

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

Table A 22: Comparison of intended and critical EU GAPs – endive

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-15, BE-12, CZ-15, DE-15, NL-11, PL-15*)	2	87.2 g as/ha	7 days	BBCH 12 - 49	10

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

Table A 23: Comparison of intended and critical EU GAPs – escarole

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-16, BE-13, CZ-16, DE-16, NL-12, PL-16*)	2	87.2 g as/ha	7 days	BBCH 12 - 49	10

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

Table A 24: Comparison of intended and critical EU GAPs – parsley, herbs and edible flowers

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-21, AT-33, BE-18, CZ-21, CZ-36, DE-21, DE-33, NL-17, PL-21, PL-33, SK-18, SK-29*)	2	87.2 g as/ha	7 days	BBCH 12 - 49	10

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

Table A 25: Comparison of intended and critical EU GAPs – iceberg lettuce

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (CZ-22*)	2	87.2 g as/ha	7 days	BBCH 12 - 49	10

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

Table A 26: Comparison of intended and critical EU GAPs – lamb's lettuce

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-24, BE-19, CZ-27, DE-24, NL-18, PL-24*)	2	87.2 g as/ha	7 days	BBCH 12 - 49	10

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

Table A 27: Comparison of intended and critical EU GAPs – red mustard

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-30, CZ-33, DE-30, PL-30, SK-26*)	2	87.2 g as/ha	7 days	BBCH 12 - 49	10

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

Table A 28: Comparison of intended and critical EU GAPs – watercress

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-46, BE-35, CZ-49, DE-46, PL-46, SK-41*)	2	87.2 g as/ha	7 days	BBCH 12 - 49	10

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

Table A 29: Comparison of intended and critical EU GAPs – rocket

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-38, BE-29, CZ-41, DE-38, NL-28, PL-38*)	2	87.2 g as/ha	7 days	BBCH 12 - 49	10

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

Table A 30: Comparison of intended and critical EU GAPs – spinach

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-43, BE-32, CZ-46, DE-43, NL-31, PL-43, SK-38*)	2	87.2 g as/ha	7 days	BBCH 12 - 49	10

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

Table A 31: Comparison of intended and critical EU GAPs - chives

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-10, CZ-10, DE-10, PL-10, SK-9*)	2	87.2 g as/ha	7 days	BBCH 12 - 49	10

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

A 2.1.3.5.1 Study 1 - RES-00259 - New data

Comments of zRMS:	Seven residue field trials on lettuce were successfully conducted in France, Austria, Poland and Hungary during 2020. Oxathiapiprolin and metalaxyl-M were applied to lettuce as A23109A, a dispersible concentrate (DC) formulation containing 30 g of oxathipiprolin and 180 g of metalaxyl-M per litre. Two applications (applied at 7 days before last application and 10 days before harvest), separated by a 7 day interval were made at a nominal rate of 15 g ai/ha for oxathiprolin and 90 g ai/ha for metalaxyl-M for P2 plot. And one application (applied 10 days before harvest) was made at a nominal rate of 15 g ai/ha for oxathiprolin and 90 g ai/ha for metalaxyl-M for P3 plot. Treated samples were collected at 0, 3, 7, 9-10 and 14 days after the last application (DALA)

for decline trials and at 10 days after the last application (DALA) for harvest trials. Untreated samples were collected at 10 DALA.

Residues of oxathiapiprolin and metalaxyl-M are summarised in the table below.

Actual Sampling Interval (days)	Oxathiapiprolin Residues in the range (mg/kg)	Metalaxyl-M Residues in the range (mg/kg)
Treated Plot (P2): at a rate of 90 g ai/ha (metalaxyl-M)		
Lettuce (whole plant)		
0 DALA	-	0.89 – 2.27
3 DALA	-	0.12 – 0.24
7 DALA	-	0.03 – 0.06
9-10 DALA (NCH)	-	<0.01 – 0.31
14 DALA	-	<0.01 – <0.01
Treated Plot (P3): at a rate of 15 g ai/ha (oxathiapiprolin)		
Lettuce (whole plant)		
0 DALA	0.24 – 0.35	-
3 DALA	0.05 – 0.12	-
7 DALA	0.02 – 0.03	-
9-10 DALA (NCH)	<0.01 – 0.07	-
14 DALA	<0.01 – 0.02	-
Control plot (C1) No residues of oxathiapiprolin or metalaxyl-M at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in any of the untreated lettuce samples.		

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

Samples were analysed for residues of oxathiapiprolin (P3 plot only) using DuPont method DuPont-30422 and metalaxyl-M (P2 plot only) was analysed using method REM 181.13A.

Samples were stored frozen for a maximum period of ca 4 months (115 days) from sampling to analysis for oxathiapiprolin and ca 6 months (173 days) for metalaxyl-M.

Remark:
The intended GAP for A23109A / Orondis VIP for lettuce is covered by trials GAP for metalaxyl-M only (P2 plot – 2 applications with 7 day interval, at a rate of 90 g ai/ha for metalaxyl-M). There is a lack of residue results for oxathiapiprolin for P2 plot.

The lettuce varities used in the trials in study RES-00259:

Study Report Number	Trial Number	Lettuce Variety	Variety Type
RES-00259	MLI-20-45529 FR01	Ruffian	Semi-open
	MLI-20-45529 AT02	Kisheri	Open
	MLI-20-45529 PL03	Locarno	Open
	MLI-20-45529 FR05	Analotta	Semi-open
	MLI-20-45529 AT06	Lollo Rosso	Open
	MLI-20-45529 PL09	Iska	Unknown
	MLI-20-45529 HU10	Rolina	Open

It should be noted that the variesties of Ruffian, Analotta and Iska are not representative of open leaf varieties.

The study is acceptable.

Reference: KCA 6.3.5/01

Report: Oxathiapiprolin / Metalaxyl-M - Determination of residues of Oxathiapiprolin and Metalaxyl-M in Lettuce from trials conducted in NEU in 2020, Brown S., 2021, report No RES-00259, document No VV-901318

Guideline(s):	Yes OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009. Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 32: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) : Oxathiapiprolin / Metalaxyl-M - Determination of residues of Oxathiapiprolin and Metalaxyl-M in Lettuce from trials conducted in NEU in 2020			
Active Substance (common name):	Metalaxyl-M	**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, POLAND, AUSTRIA, HUNGARY	**Other active substance in the formulation (common name and content):**	A23109A: oxathiapiprolin (30 g/L)
Content of active substance (g/kg or g/L):	A23109A: 180 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A23109A DC		
Analytical Method:	Metalaxyl-M (Whole plant) REM 181.13A; 0.01 mg/kg		
Recovery data:	Metalaxyl-M Whole plant Mean = 91% RSD = 6% (n = 7 in 0.01 - 5 spiking range)		

Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (c)	**Growth stage at last treatment or date**	**Portion analyzed**	**Residues (mg/kg)**	**PHI (days)** (d)	**Details on trial** (e)
			g a.s./ ha	**Water (L/ha)**	**g a.s./hL**				**Metalaxyl-M**		
MLI-20-45529 AT02 AUSTRIA (2471) Europe North 2020	Lettuce / Oak leaf, Open leaf variety (Kisheri)	1.09 Jun 2020 2 – 3 -	1. 91.3 2. 90.45	1. 304.3333 2. 301.5		1. 08 Jul 2020 2. 15 Jul 2020 (N/A, 7)	1. BBCH 46-46 2. BBCH 48-48	Whole plant	0.89	0	Field SP (max days): 106
								Whole plant	0.12	3	
								Whole plant	0.03	7	
								Whole plant	<u>0.02</u>	9	
								Whole plant	< 0.01	14	
MLI-20-45529 AT06 AUSTRIA (4070) Europe North 2020	Lettuce / Lollo Rosso (open leaf variety, Antonet RZ)	1.02 Jul 2020 2 – 3 -	1. 92.8 2. 89.5	1. 309.3333 2. 298.3333		1. 14 Jul 2020 2. 21 Jul 2020	1. BBCH 41-41 2. BBCH 45-45	Whole plant	<u>< 0.01</u>	10	Field SP (max days): 174
MLI-20-45529 FR01 FRANCE (08190) Europe North 2020	Lettuce / RUFFIAN (Semi-open)	1.28 May 2020 2 – 3 -	1. 86.5057 2. 85.5082	1. 289.055 2. 285.7217		1. 03 Jul 2020 2. 10 Jul 2020	1. BBCH 45-46 2. BBCH 46-47	Whole plant	1.39	0	Field SP (max days): 111
								Whole plant	0.22	3	
								Whole plant	0.06	7	
								Whole plant	<u>0.03</u>	10	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (L/ha)	g a.s./hL				Metalaxyl-M		
								Whole plant	< 0.01	14	
MLI-20-45529 FR05 FRANCE (37110) Europe North 2020	Lettuce / ANALOTTA (Semi-open)	1.15 Jul 2020 2 – 3 -	1. 94.1732 2. 87.5116	1. 314.1489 2. 291.9267		1. 04 Aug 2020 2. 11 Aug 2020	1. BBCH 16-19 2. BBCH 44-44	Whole plant	0.02	10	Field SP (max days): 153
MLI-20-45529 HU10 HUNGARY (6762) Europe North 2020	Lettuce / Rolina/ open leaf	1.11 Oct 2020 2 – 3 -	1. 95.89 2. 91.2908	1. 425.71 2. 407.3767		1. 07 Nov 2020 2. 15 Nov 2020	1. BBCH 18-19 2. BBCH 23-29	Whole plant	0.34 , 0.3 , 0.28 (Mean=0.3067)	10	Field SP (max days): 76
MLI-20-45529 PL03 POLAND (62-095) Europe North 2020	Lettuce / Locarno (open)	1.30 Jun 2020 2 – 3 -	1. 91.04825 2. 92.04659	1. 304 2. 307.3333		1. 14 Jul 2020 2. 21 Jul 2020	1. BBCH 17-19 2. BBCH 42-42	Whole plant	2.27	0	Field SP (max days): 100
								Whole plant	0.24	3	
								Whole plant	0.04	7	
								Whole plant	0.01	10	
								Whole plant	< 0.01	14	
MLI-20-45529 PL09 POLAND (99-321) Europe North 2020	Lettuce / Iska (Unknown)	1.25 Jul 2020 2 – 3 -	1. 98.2566 2. 96.2578	1. 327.7233 2. 321.05667		1. 05 Aug 2020 2. 12 Aug 2020	1. BBCH 42-44 2. BBCH 47-48	Whole plant	0.03	10	Field SP (max days): 152

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.3.5.2 Study 2 - RES-00332 - New data

<table>
<tr><td>Comments of zRMS:</td><td>
One residue field trial on lettuce (open leaf variety) was successfully conducted in the United Kingdom during 2021.
Metalaxyl-M and Oxathiapiprolin were applied to lettuce as A23109A, a dispersible concentrate (DC) formulation containing 30 g of oxathiapiprolin and 180 g of metalaxyl-M per litre. Two applications, separated by a 7-day interval were made at a nominal rate of 15 g ai/ha for oxathiopiprolin and 90 g ai/ha for metalaxyl-M for P2 plot.
Treated samples were collected at 0, 3, 6, 10 and 14 days after the last application (DALA). Untreated samples were collected at 10 days. Samples were analysed for residues of <u>metalaxyl-M only</u> using method REM 181.13A.
Residues of metalaxyl-M are summarised in the table below.
<table>
<tr><th>Actual Sampling Interval
(days)</th><th>Metalaxyl-M
Residues in the range
(mg/kg)</th></tr>
<tr><td colspan="2">Treated Plot (P2): at a rate of 90 g ai/ha (metalaxyl-M)</td></tr>
<tr><td colspan="2">Lettuce (whole plant)</td></tr>
<tr><td>0 DALA</td><td>2.134</td></tr>
<tr><td>3 DALA</td><td>0.220</td></tr>
<tr><td>6 DALA</td><td>0.063</td></tr>
<tr><td>10 DALA (NCH)</td><td>0.031</td></tr>
<tr><td>14 DALA</td><td>0.015</td></tr>
<tr><td colspan="2">Control plot (C1)
No residues of metalaxyl-M at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in the untreated lettuce samples.</td></tr>
</table>
DALA = days after last application to the treated plot,
NCH = normal commercial harvest
The validated method (REM 181 .13A) has additionally been fully verified (5 recoveries at the LOQ and a higher level, selectivity and linearity) within ResChem Analytical for high water crops (protected lettuce) as part of RES-00258. Further method verification (3 recoveries at the LOQ and a higher level, selectivity and linearity) lettuce whole plant matrix was carried out within this study.
The LOQ was 0.01 mg/kg.
Samples were stored frozen for a maximum period of ca 3 months (90 days) from sampling to analysis for metalaxyl-M.
The study is acceptable.
</td></tr>
</table>

Reference:	KCA 6.3.5/02
Report	Metalaxyl-M – Determination of residues of Metalaxyl-M in Lettuce from Trials conducted in NEU in 2021, Brown S., 2022, report No RES-00332, document No VV-946819
Guideline(s):	Yes 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. OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009.

	SANTE/2020/12830, Rev.1: Guidance document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes. OECD Guidance Document on Pesticide Residue Analytical Methods, ENV/JM/MONO(2007)17 (Unclassified, 13 Aug 2007). Technical Guideline on the Evaluation of the Extraction Efficiency of Residue Analytical Methods, SANTE 2017/10632 Rev.3 (22.11.2017).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 33: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) : Oxathiapiprolin / Metalaxyl-M - Determination of residues of Oxathiapiprolin and Metalaxyl-M in Lettuce from trials conducted in NEU in 2020			
Active Substance (common name):	Metalaxyl-M	**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):**	A23109A: oxathiapiprolin (30 g/L)
Content of active substance (g/kg or g/L):	A23109A: 180 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A23109A DC		
Analytical Method:	Metalaxyl-M (Whole plant) REM 181.13A; 0.01 mg/kg		
Recovery data:	Metalaxyl-M Whole plant Mean = 96% RSD = 5% (n = 9 in 0.01 – 10 mg/kg spiking range)		

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (L/ha)	g a.s./hL				Metalaxyl-M		
JBL-21-51683 GB01 UNITED KINGDOM (NG14 6DN) Europe North 2021	Lettuce / Open leaf variety (Extranet)	1. 01 Sep 2021 2. – 3. 25 Oct 2021	1. 94.26 2. 94.26	1. 210 2. 210		1. 08 Oct 2021 2. 15 Oct 2021 (7 day interval)	1. BBCH 46-47 2. BBCH 47-47	Whole plant	2.134	0	Field SP (max days): 90
								Whole plant	0.220	3	
								Whole plant	0.063	6	
								Whole plant	<u>0.031</u>	10	
								Whole plant	0.015	14	

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

A 2.1.3.5.3 Study 3 - S18-04345 – New Data

Comments of zRMS:

Six residue field trials on lettuce were successfully conducted in United Kingdom, Northern France and Germany during 2018.
Metalaxyl-M and acibenzolar-S-methyl were applied to open leaf lettuce as A9522B, a water dispersible granule (WG) formulation containing 400 g/kg metalaxyl-M and 40 g/kg acibenzolar-S-methyl. One application, applied 10 days before harvest (10 DBH), was made at a nominal rate of 140 g ai/ha for metalaxyl-M and 14 g ai/ha acibenzolar-S-methyl.
In trials S18-04345-01, -02 and -03, treated whole plant samples were collected immediately after the last application (0 DALA), 3 days after the last application (3 DALA), 5 days after the last application (5 DALA), 7 days after application (7 DALA) and 10 days after the last application at normal commercial harvest (10 DALA (NCH)).
In tirals S18-04345-05, -06 and -07, treated whole plant samples were collected 10 days after the last application at normal commercial harvest (10 DALA (NCH)).
In all trials, untreated whole plant samples were collected 10 days after the last application at normal commercial harvest (10 DALA (NCH))

Samples were analysed for metalaxyl-M

Sampling Interval (days)	Metalaxyl-M Residues in the range (mg/kg)
Treated Plot (P2): at a rate of 1 x 140 g Metalaxyl-M/ha	
0 DAA	3.0 - 3.5
3 DAA	0.11 - 0.64
5 DAA	0.05 – 0.23
7 DAA	0.03 - 0.04
10 DAA (NCH)	0.01 - 0.19

Samples were analysed for residues of metalaxyl-M using method REM 181.13A.
Samples were stored frozen for a maximum period of 99 days from sampling to analysis for metalaxyl-M.

Remark:
Each trial was conducted with one application at rates of 140 g a.s./ha. This application rate exceeds the ±25% acceptance range, however, as these trials are overdosed in comparison, they are considered more critical than the intended GAP. The residues in lettuce leaves at a PHI of 10 days were in the range of 0.01-0.19 mg/kg and therefore comparable to studies conduct-ed at 2 x 90 g as/ha.

The lettuce varities used in the trials in study S18-04345:

Study Report Number	Trial Number	Lettuce Variety	Variety Type
S18-04345	S18-04345-01	Exponent	Open
	S18-04345-02	Feuille de Chene rouge Macai	Open
	S18-04345-03	Kirinia	Open
	S18-04345-05	Extender	Open
	S18-04345-06	Kisheri RZ	Open
	S18-04345-07	Kiribati	Open

It should be noted that all of the variesties of lettuce are open.
The study is acceptable.

Reference: KCA1 6.3.5

Report: Metalaxyl-M - Residue Study on Open Leaf Lettuce in the United Kingdom, Northern France and Germany in 2018.

	Lakaschus S, and Fritzsch S, 2019 Report No. S18-04345, Syngenta File No. VV-471900
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. 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:	Supplementary weather data were provided by the local meteorological office, crop maintenance records were provided by the grower. These records were not generated according to GLP principles
Acceptability:	Yes

Table A 34: Summary of the study S18-04345 trials

Field Trials, Crop Residue (Summary) :Metalaxyl-M - Residue study on Open Leaf Lettuce in the United Kingdom, Northern France, Germany and Hungary in 2018			
Active Substance (common name):	Metalaxyl-M	**Commercial Product (name):**	Mefenoxam
Crop/Crop Group:	Leaf lettuce	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	UNITED KINGDOM, HUNGARY, GERMANY, FRANCE	**Other active substance in the formulation (common name and content):**	A9522B: metalaxyl-M (140 g ai/ha) A9522B: acibenzolar-S-methyl (14 g ai/ha)
Content of active substance (g/kg or g/L):	A9522B: 140 g ai/ha A9522B: 14 g ai/ha	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A9522B WG		
Analytical Method:	metalaxyl-M (Whole plant) REM 181.13A; 0.01 mg/kg		
Recovery data:	metalaxyl-M Whole plant Mean= 109% RSD= 2% (n= 3 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 Analysed	(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)				metalaxyl-m			
S18-04345 S18-04345-01 UNITED KINGDOM (EU Submissions) (L40 1UH)	exponent	1. 2. 3. 17 Sep 2018	-	-	-	- (-)	- (-)	-	Whole plant	< 0.01 mg/kg	10	17 Sep 2018/	Field SP (max days): 17
										-	10	17 Sep 2018/	
			foliar	-	306.3333 L/ha	metalaxyl-M: 142.9556 g ai/ha A9522B (-)	07 Sep 2018 (-)	BBCH 43		3 mg/kg	0	07 Sep 2018/	Field SP (max days): 27
										-	0	07 Sep 2018/	
										0.11 mg/kg	3	10 Sep 2018/	
										-	3	10 Sep 2018/	
										0.05 mg/kg	5	12 Sep 2018/	

(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 Treat-ment	(8) Portion Ana-lysed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sam-ple Date/ Cut Date (d)	(12) Trial De-tails (e)
				Conc'n	Water	Rate Formula-tion (Additive Type, Rate)				metalaxyl-m			
										-	5	12 Sep 2018/	
										-	7	14 Sep 2018/	
										0.04 mg/kg	7	14 Sep 2018/	
											10	17 Sep 2018/	
										0.03 mg/kg	10	17 Sep 2018/	
S18-04345 S18-04345-02 FRANCE (EU Sub-missions) (67880)	Feuille de Chêne rouge Macaï	1. 2. 3. 07 Jul 2018	-	-	-	- (-)	- (-)	-	Whole plant	< 0.01 mg/kg	10	07 Jul 2018/	Field SP (max days): 89
										-	10	07 Jul 2018/	
			foliar	-	292.2222 L/ha	metalaxyl-M: 136.3704 g ai/ha A9522B (-)	27 Jun 2018 (-)	BBCH 43		3.3 mg/kg	0	27 Jun 2018/	Field SP (max days): 99
										-	0	27 Jun 2018/	
										0.43 mg/kg	3	30 Jun 2018/	
										-	3	30 Jun 2018/	
										0.17 mg/kg	5	02 Jul 2018/	

(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 Treat-ment	(8) Portion Ana-lysed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sam-ple Date/ Cut Date (d)	(12) Trial De-tails (e)
				Conc'n	Water	Rate Formula-tion (Additive Type, Rate)				metalaxyl-m			
										-	5	02 Jul 2018/	
										0.03 mg/kg	7	04 Jul 2018/	
										-	7	04 Jul 2018/	
										-	10	07 Jul 2018/	
										<u>0.01 mg/kg</u>	10	07 Jul 2018/	
S18-04345 S18-04345-03 GER-MANY (EU Sub-missions) (69124)	Kirinia	1. 2. 3. 09 Aug 2018	-	-	-	- (-)	- (-)	-	Whole plant	< 0.01 mg/kg	10	09 Aug 2018/	Field SP (max days): 56
										-	10	09 Aug 2018/	
			foliar		400 L/ha	metalaxyl-M: 140 g ai/ha A9522B (-)	30 Jul 2018 (-)	BBCH 43		-	0	30 Jul 2018/	Field SP (max days): 66
										3.5 mg/kg	0	30 Jul 2018/	
										0.64 mg/kg	3	02 Aug 2018/	
										-	3	02 Aug 2018/	
										0.23 mg/kg	5	04 Aug 2018/	

(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 Treat-ment	(8) Portion Ana-lysed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sam-ple Date/ Cut Date (d)	(12) Trial De-tails (e)
				Conc'n	Water	Rate Formula-tion (Additive Type, Rate)				metalaxyl-m			
										-	5	04 Aug 2018/	
										0.04 mg/kg	7	06 Aug 2018/	
										-	7	06 Aug 2018/	
										0.04 mg/kg	10	09 Aug 2018/	
										-	10	09 Aug 2018/	
S18-04345 S18-04345-05 UNITED KING-DOM (EU Sub-missions) (PO18 8EZ)	Extender 79	1. 2. 3. 04 Oct 2018	-	-	-	- (-)	- (-)	-	Whole plant	< 0.01 mg/kg	10	04 Oct 2018/	Field SP (max days): 0
										-	10	04 Oct 2018/	
			foliar	-	500 L/ha	metalaxyl-M: 139.5556 g ai/ha A9522B (-)	24 Sep 2018 (-)	BBCH 43		**0.19 mg/kg**	10	04 Oct 2018/	
										-	10	04 Oct 2018/	
S18-04345 S18-04345-06 FRANCE (EU Sub-missions)	Kisheri RZ	1. 2 3. 27 Aug 2018	-	-	-	- (-)	- (-)	-	Whole plant	< 0.01 mg/kg	10	27 Aug 2018/	Field SP (max days): 38
										-	10	27 Aug 2018/	

(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 Treat-ment	(8) Portion Ana-lysed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sam-ple Date/ Cut Date (d)	(12) Trial De-tails (e)
				Conc'n	Water	Rate Formula-tion (Additive Type, Rate)				metalaxyl-m			
(45570)			foliar	-	301 L/ha	metalaxyl-M: 140.4667 g ai/ha A9522B (-)	17 Aug 2018 (-)	BBCH 42-43		**0.01 mg/kg**	10	27 Aug 2018/	
										-	10	27 Aug 2018/	
S18-04345 S18-04345-07 GER-MANY (EU Sub-missions) (71706)	Kiribati	1. 2. 3. 13 Aug 2018	-	-	-	- (-)	- (-)	-	Whole plant	< 0.01 mg/kg	10	13 Aug 2018/	Field SP (max days): 52
										-	10	13 Aug 2018/	
			foliar	-	506.6667 L/ha	metalaxyl-M: 141.8667 g ai/ha A9522B (-)	03 Aug 2018 (-)	BBCH 43		-	10	13 Aug 2018/	
										0.04 mg/kg	10	13 Aug 2018/	

(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 2.1.3.5.4 Study 4 - S19-02726 – New Data

<table>
<tr><td>Comments of zRMS:</td><td>
Two residue field trials on lettuce were successfully conducted in Germany during 2019.
Metalaxyl-M and acibenzolar-S-methyl were applied to opean leaf lettuce as A9522B, a water dispersible granule (WG) formulation containing 400 g/kg metalaxyl-M and 40 g/kg acibenzolar-S-methyl. One application, applied 10 days before harvest (10 DBH), was made at a nominal rate of 140 g ai/ha for metalaxyl-M and 14 g ai/ha acibenzolar-s-methyl.
In trial S19-02726-01 treated whole plant samples were collected immediately after the last application (0 DALA), 3 days after the last application (3 DALA), 5 days after the last application (5 DALA), 7 days after application (7 DALA) and 10 days after the last application at normal commercial harvest (10 DALA (NCH)).
In trial S19-02726-02 treated whole plant samples were collected 10 days after the last application at normal commercial harvest (10 DALA (NCH)).
In all trials, untreated whole plant samples were collected 10 days after the last application at normal commercial harvest (10 DALA (NCH)).
Samples were analysed for metalaxyl-M.
<table>
<tr><th>Sampling Interval (days)</th><th>Metalaxyl-M Residues in the range (mg/kg)</th></tr>
<tr><td colspan="2">Treated Plot (P2): at a rate of 1 x 140 g Metalaxyl-M/ha</td></tr>
<tr><td>0 DAA</td><td>4.0</td></tr>
<tr><td>3 DAA</td><td>0.094</td></tr>
<tr><td>5 DAA</td><td>0.094</td></tr>
<tr><td>7 DAA</td><td>0.085</td></tr>
<tr><td>10 DAA (NCH)</td><td>0.018 – 0.056</td></tr>
</table>
Samples were analysed for residues of metalaxyl-M using method REM 181.13A.
Samples were stored frozen for a maximum period of 3 months from sampling to analysis for metalaxyl-M.
Remark:
Each trial was conducted with one application at rates of 140 g a.s./ha. This application rate exceeds the ±25% acceptance range, however, as these trials are overdosed in comparison, they are considered more critical than the intended GAP. The residues in lettuce leaves at a PHI of 10 days were in the range of 0.018-0.056 mg/kg and therefore comparable to studies conduct-ed at 2 x 90 g as/ha.
The lettuce varities used in the trials in study S19-02726:
<table>
<tr><th>Study Re-port Number</th><th>Trial Number</th><th>Lettuce Variety</th><th>Variety Type</th></tr>
<tr><td rowspan="2">S19-02726</td><td>S19-02726-01</td><td>Vizir nas</td><td>Open</td></tr>
<tr><td>S19-02726-02</td><td>Crispa</td><td>Open</td></tr>
</table>
It should be noted that all of the variesties of lettuce are open.
The study is acceptable
</td></tr>
</table>

Reference: KCA2 6.3.5

Report: Metalaxyl-M - Residue Study on Open Leaf Lettuce in Germany in 2019.
Fritsch S, 2020
Report No. S19-02726, Syngenta File No. . VV-749044

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. 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 35: Summary of the study S19-02726 trials

Field Trials, Crop Residue (Summary) : Metalaxyl M - Residue study on Open Leaf Lettuce in GermOpenn 2019			
Active Substance (common name):	metalaxyl-M		
Crop/Crop Group:	Leaf lettuce	**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):**	A9522B: acibenzolar-S-methyl (40 g/kg)
Content of active substance (g/kg or g/L):	A9522B: 400 g/kg	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A9522B WG		

(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 (c)**	**(5) Application rate per treatment**			**(6) Date of treatment(s) or no of treatment(s) and last date (d)**	**(7) Growth Stage at Treatment (e)**	**(8) Portion Analysed**	**(9) Residue found (Uncorrected)**	**(10) PHI (f)**	**(11) Sample Date / Cut Date**	**(12) Remarks (g)**
				Concentration	**Water**	**Rate Formulation (Additive Type, Rate)**				**Metalaxyl-M (mg/kg)**			
S19-02726 S19-02726-01 GER-MANY (Europe North) (69124)	Leaf lettuce / Vizir NAS	1.04 Jul 2019 2 – 3 -	-	-	-	(-)	-		Whole plant	< 0.01	10	05 Aug 2019/ -	Field
	Leaf lettuce / Vizir NAS	1.04 Jul 2019 2 – 3 -	1. Foliar	-	1. 391 L/ha	1. 137 g ai/ha A9522B (-)	1. 26 Jul 2019	1. BBCH 41-42	Whole plant	4.00	0	26 Jul 2019/ -	Field
									Whole plant	0.09	3	29 Jul 2019/ -	
									Whole plant	0.09	5	31 Jul 2019/ -	
									Whole plant	0.09	7	02 Aug 2019/ -	
									Whole plant	**0.02**	10	05 Aug 2019/ -	
S19-02726 S19-02726-02 GER-MANY	Leaf lettuce / Crispa	1.24 Jul 2019 2 – 3 -	-	-	-	(-)	-		Whole plant	< 0.01	10	02 Sep 2019/ -	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 (c)	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date (d)	(7) Growth Stage at Treatment (e)	(8) Portion Analysed	(9) Residue found (Uncorrected)	(10) PHI (f)	(11) Sample Date / Cut Date	(12) Remarks (g)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Metalaxyl-M (mg/kg)			
(Europe North) (71706)	Leaf lettuce / Crispa	1.24 Jul 2019 2 – 3 -	1. Foliar	-	1. 423 L/ha	1. 148 g ai/ha A9522B (-)	1. 23 Aug 2019	1. BBCH - 43	Whole plant	**<u>0.06</u>**	10	02 Sep 2019/ -	Field

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

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^) PHI calculated using cut date

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4),

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(g) Climatic conditions; Reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date.

(+) Indicates calculated Residue value

(DAA) Days After Application

(DBA) Days Before Application

A 2.1.3.6 Leek

Table A 36: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-27, AT-28, BE-22, BE-23, CZ-30, CZ-31, DE-27, DE-28, NL-21, NL-22, PL-27, PL-28, SK-23, SK-24*)	2	87.2 g as/ha	12-14 days	BBCH 12 - 48	14

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

Leek - (extrapolation to Spring onions/green onions, Welsh onions)

Table A 37: Comparison of intended and critical EU GAPs - Spring /green/Welsh onions

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-44, AT-45, BE-33, BE-34, CZ-47, CZ-48, DE-44, DE-45, NL-32, NL-33, PL-44, PL-45, SK-39, SK-40*)	2	87.2 g as/ha	12-14 days	BBCH 12 - 48	14

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

A 2.1.3.6.1 Study 1 - CEMS-9521 - New data

Comments of zRMS:	Eight independent residue field trials on leeks were successfully conducted in Northern France, Poland, United Kingdom and Germany during 2020. Oxathiapiprolin/metalaxyl-M was applied to leeks as A23109A, a dispersible concentrate (DC) formulation containing nominal 30 g oxathiapiprolin and 180 g metalaxyl-M per litre. Two applications to plot P2, applied at 26±2 and 14±1 days before normal commercial harvest were made at a nominal rate of 15 g ai/ha for oxathiapiprolin and 90 g ai/ha for metalaxyl-M. One application to plot P3, applied at 14±1 days before normal commercial harvest was made at a nominal rate of 15 g ai/ha for oxathiapiprolin and 90 g ai/ha for metalaxyl-M. For decline trials, treated samples of leek were collected at 0, 3, 7-8, 14-15 and 20-22 days after the last application (DALA) with untreated leek samples being collected at 14-15 DALA. For harvest trials, untreated and treated samples of leek were collected at 14-15 days after the last application (DALA) to the treated plots. Residues of oxathiapiprolin and metalaxyl-M are summarised in the table below.

Sampling Interval (days)	Oxathiapiprolin Residues (mg/kg)	Metalaxyl-M Residues (mg/kg)
Leek-Whole Plant		
Treated Plot (P2): at a rate of 2 x 15 g ai/ha oxathiapiprolin and 2 x 90 g ai/ha metalaxyl-M		
0 DALA	0.018 – 0.19	0.010 – 0.680
3 DALA	0.011 – 0.077	<0.01 – 0.140
7-8 DALA	<0.01 – 0.036	<0.01 – 0.012
14-15 DALA (NCH)	<0.01 – 0.028	<0.01 – 0.021
20-22 DALA	<0.01	<0.01
Treated Plot (P3): at a rate of 1 x 15 g ai/ha for oxathiapiprolin and 1 x 90 g ai/ha for metalaxyl-M		
0 DALA	0.010 – 0.10	<0.01 – 0.52
3 DALA	<0.01 – 0.062	<0.01 – 0.14
7-8 DALA	<0.01 – 0.016	<0.01 – 0.011
14-15 DALA (NCH)	<0.01 – 0.015	<0.01 – 0.019
20-22 DALA	<0.01	<0.01
Control plot (C1) No residues of oxathiapiprolin or metalaxyl-M at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in any of the untreated leek samples.		

DALA: days after the last application
NCH: Normal Commercial Harvest

Leek whole plant samples were analysed for oxathiapiprolin using method DuPont 30422 Supplement No. 1 and for metalaxyl-M using method REM 181.13A with LOQ of 0.01 mg/kg.

Specimens were stored frozen for a maximum period of 188 days (approximately 6 months) from sampling to analysis for oxathiapiprolin and metalaxyl-M.
The study is acceptable.

Reference:	KCA 6.3.6/01
Report	Oxathiapiprolin/Metalaxyl-M – Residue Study on Leek in Northern France, Poland, United Kingdom and Germany in 2020, Ford K., 2021, report No CEMR-9521, document No VV-901936
Guideline(s):	Yes OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009. Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 38: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) : Oxathiapiprolin/Metalaxyl-M – Residue Study on Leek in Northern France, Poland, United Kingdom and Germany in 2020			
Active Substance (common name):	Metalaxyl-M	**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, GERMANY, FRANCE, POLAND	**Other active substance in the formulation (common name and content):**	A23109A: oxathiapiprolin (30 g/L)
Content of active substance (g/kg or g/L):	A23109A: 180 g/L	**Residues calculated as:**	
Formulation (e.g. WP):	A23109A DC		
Analytical Method:	Metalaxyl-M (Whole plant) REM 181.13A; 0.01		
Recovery data:	Metalaxyl-M Whole plant Mean = 97% RSD = 5% (n = 16 in 0.01 – 1 spiking range)		

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date €	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial €
			g a.s./ ha	Water (L/ha)	g a.s./hL				Metalaxyl-M		
SRDE20-120-037FR GERMANY (74206) Europe North 2020	Leek / Megaton	1.11 Apr 2020 2 – 3 -	12. 88.3299 2. 95.8206	1. 393.06818 2. 426.4015		12. 13 Jul 2020 2. 24 Jul 2020	1. BBCH 47-48 2. BBCH 48-48	Whole plant	0.4726	0	Field SP (max days): 194
								Whole plant	0.0186	3	
								Whole plant	< 0.01	7	
								Whole plant	< 0.01	14	
								Whole plant	< 0.01	21	
	Leek / Megaton	1.11 Apr 2020 2 – 3 -	12. 95.1396	1. 423.3712		12. 24 Jul 2020	1. BBCH 48-48	Whole plant	0.4689	0	Field SP (max days): 194
								Whole plant	0.028	3	
								Whole plant	< 0.01	7	
								Whole plant	< 0.01	14	
								Whole plant	< 0.01	21	
SRDE20-121-037FR GERMANY	Leek / Elefant	1.05 May 2020 2 – 3 -	12. 87.9627 2. 87.07707	1. 391.2503 2. 387.3109		12. 31 Jul 2020 2. 12 Aug 2020	1. BBCH 47-49 2. BBCH 48-49	Whole plant	< 0.01	14	Field SP (max days): 161

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date €	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial €
			g a.s./ ha	Water (L/ha)	g a.s./hL				Metalaxyl-M		
(85748) Europe North 2020	Leek / Elefant	1.05 May 2020 2 – 3 -	12. 85.6464	1. 380.9473		12. 12 Aug 2020	1. BBCH 48-49	Whole plant	< 0.01	14	Field SP (max days): 161
SRFR20-045-037FR FRANCE (71570) Europe North 2020	Leek / Portura	1.17 Jun 2020 2 – 3 -	12. 94.2276 2. 86.2309	1. 314.2233 2. 287.5567		12. 04 Sep 2020 2. 15 Sep 2020	1. BBCH 47-47 2. BBCH 48-48	Whole plant	0.4398	0	Field SP (max days): 143
								Whole plant	0.0831	3	
								Whole plant	0.0116	7	
								Whole plant	< 0.01	14	
								Whole plant	< 0.01	20	
			12. 92.2284	1. 307.5567		12. 15 Sep 2020	1. BBCH 48-48	Whole plant	0.3376	0	Field SP (max days): 143
								Whole plant	0.0579	3	
								Whole plant	0.011	7	
								Whole plant	< 0.01	14	
								Whole plant	< 0.01	20	
SRFR20-046-037FR FRANCE	Leek / Portura	1.18 Jun 2020 2 – 3 -	12. 92.2284 2. 95.2272	1. 307.5567 2. 317.5567		12. 03 Sep 2020 2. 16 Sep 2020	1. BBCH 47-47 2. BBCH 48-48	Whole plant	< 0.01	15	Field SP (max days): 125

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment g a.s./ ha	Water (L/ha)	g a.s./hL	Dates of treatment or no. of treatments and last date €	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg) Metalaxyl-M	PHI (days) (d)	Details on trial €
(71290) Europe North 2020	Leek / Portura	1.18 Jun 2020 2 – 3 -	12. 86.9	1. 290.89		12. 16 Sep 2020	1. BBCH 48-48	Whole plant	< 0.01	15	Field SP (max days): 125
SRPL20-030-037FR POLAND (05-870) Europe North 2020	Leek / Jolant	1.10 Jun 2020 2 – 3 -	12. 89.3812 2. 88.9808	1. 595.3333 2. 592.6667		12. 08 Sep 2020 2. 21 Sep 2020	1. BBCH 48- 2. BBCH 48-	Whole plant	0.6802	0	Field SP (max days): 135
								Whole plant	0.1395	3	
								Whole plant	0.0121	7	
								Whole plant	< 0.01	14	
								Whole plant	< 0.01	21	
	Leek / Jolant	1.10 Jun 2020 2 – 3 -	12. 89.8316	1. 598.3333		12. 21 Sep 2020	1. BBCH 48-	Whole plant	0.521	0	Field SP (max days): 135
								Whole plant	0.1398	3	
								Whole plant	0.01	7	
								Whole plant	< 0.01	14	
								Whole plant	< 0.01	21	
SRPL20-031-037FR POLAND (88-400) Europe North 2020	Leek / Porbella	1.05 May 2020 2 – 3 -	12. 84.4 2. 86.05	1. 375.1111 2. 382.4444		12. 06 Aug 2020 2. 19 Aug 2020	1. BBCH 45- 2. BBCH 47-49	Whole plant	0.01	0	Field SP (max days): 168
								Whole plant	< 0.01	3	
								Whole plant	< 0.01	8	
								Whole plant	< 0.01	15	
								Whole plant	< 0.01	22	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date €	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial €
			g a.s./ ha	Water (L/ha)	g a.s./hL				Metalaxyl-M		
	Leek / Porbella	1.05 May 2020 2 – 3 -	12. 87.75	1. 390		12. 19 Aug 2020	1. BBCH 47-49	Whole plant	< 0.01	0	Field SP (max days): 168
								Whole plant	< 0.01	3	
								Whole plant	< 0.01	8	
								Whole plant	< 0.01	15	
								Whole plant	< 0.01	22	
SRUK20-009-037FR UNITED KINGDOM (LN4 4UY) Europe North 2020	Leek / Warwick	1.09 Apr 2020 2 – 3 -	12. 95.2685 2. 97.02642	1. 318.8867 2. 321		12. 18 Sep 2020 2. 29 Sep 2020	1. BBCH 49-49 2. BBCH 49-49	Whole plant	<u>< 0.01</u>	14	Field SP (max days): 115
	Leek / Warwick	1.09 Apr 2020 2 – 3 -	12. 95.3271	1. 317.89		12. 29 Sep 2020	1. BBCH 49-49	Whole plant	< 0.01	14	Field SP (max days): 115
SRUK20-010-037FR UNITED KINGDOM (CB6 2BJ) Europe North 2020	Leek / Lexton Gostar	1.23 Jun 2020 2 – 3 -	12. 97.02642 2. 92.3284	1. 323.5567 2. 307.89		12. 05 Nov 2020 2. 17 Nov 2020	1. BBCH 49-49 2. BBCH 49-49	Whole plant	<u>0.0211</u>	14	Field SP (max days): 66
	Leek / Lexton Gostar	1.23 Jun 2020 2 – 3 -	12. 95.2272	1. 317.5567		12. 17 Nov 2020	1. BBCH 49-49	Whole plant	0.0195	14	Field SP (max days): 66

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

A 2.1.3.7 Onion

Table A 39: 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 EU (EFSA, 2015)	3	150 g as/ha	7 days	BBCH 12 – 48	14
Intended cGAP – NEU (AT-31, AT-32, BE-25, BE-26, CZ-34, CZ-35, DE-31, DE-32, NL-24, NL-25, PL-31, PL-32, SK-27, SK-28*)	2	87.2 g as/ha	7 days	BBCH 12 – 48	14

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

Onion – (bulb veges including shallots, garlic)

Table A 40: 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 EU (EFSA, 2015)	3	150 g as/ha	7 days	BBCH 12 – 48	14
Intended cGAP – NEU (AT-17, AT-18, AT-41, AT-42, BE-14, BE-15, BE-30, BE-31, CZ-17, CZ-18, CZ-44, CZ-45, DE-17, DE-18, DE-41, DE-42, NL-13, NL-14,NL-29, NL30, PL-17, PL-18, PL-41, PL-42, SK-14, SK-15, SK-36, SK-37*)	2	87.2 g as/ha	7 days	BBCH 12 – 48	14

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

A 2.1.3.7.1 Study 1 – 2338/97 – New data

<table>
<tr>
<td>Comments of zRMS:</td>
<td>One residue field trial on onions bulbs was conducted in Switzerland during 1997.
Three applications, separated by a 9-day interval were made at a nominal rate of 150 g ai/ha for metalaxyl-M (BBCH 41-44).
Treated samples were collected at 0, 7, 14 and 21 days after the last application (DALA).
Residues of Metalaxyl-M (CGA 329351) decline from 0.04 mg/kg (0 DALA) to <0.02 mg/kg (7 DALA and later).

Onions samples were analysed for metalaxyl-M using method DFG S19 with LOQ of 0.02 mg/kg.
Data on recovery:
<table>
<tr><th>Substrate (control)</th><th>fortification level [mg/kg]</th><th>CGA 329351</th></tr>
<tr><td>onions (bulbs)</td><td>0.02</td><td>91</td></tr>
<tr><td>onions (bulbs)</td><td>0.20</td><td>97</td></tr>
</table>

Specimens were stored frozen for a maximum period of 333 days from sampling to analysis for metalaxyl-M.

<u>Remark:</u>
Description of the many details on field trials, the analytical method used for field trials and storage stability samples are missing. According to the OECD 509 (June 2021) detailed description of these data in report should be provided.
In our opinion, this study can be considered informative.</td>
</tr>
</table>

Reference:	KCA 6.3.7/01
Report	Residue study with Metalaxyl-M (CGA 329351) and Mancozeb (ASF 21) in or on onions in Switzerland, Kühne R.O., 1998, report No 2338/97, document No VV-357405
Guideline(s):	Yes FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials (Rome,1990).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 41: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) : Residue study with Metalaxyl-M (CGA 329351) and mancozeb (ASF 21) in or on onions in Switzerland			
Active Substance (common name):	Metalaxyl-M	**Commercial Product (name):**	$Commercial.Name$
Crop/Crop Group:	Onion	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	SWITZERLAND	**Other active substance in the formulation (common name and content):**	None
Content of active substance (g/kg or g/L):	40 g/kg	**Residues calculated as:**	$Residue.Units$
Formulation (e.g. WP):	A9407A WP		
Analytical Method: Metalaxyl-M (Bulbs) DFG S19, modified; 0.02 mg/kg			
Recovery data: CGA329351 Bulbs Mean = 94% RSD = N/A (n = 2 in 0.02 – 0.2 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** €	**Growth stage at last treatment or date**	**Portion analyzed**	**Residues (mg/kg)**	**PHI (days)** (d)	**Details on trial** €
			g a.s./ ha	**Water (L/ha)**	**g a.s./hL**				**Metalaxyl-M**		
2338/97 2338/97 SWITZERLAND (Europe North) (CH-1896 Vouvry)	Onion (Burgos F1)	1.15 Apr 1997 2 – 3 -		800 L/ha 800 L/ha 800 L/ha	150.00 g as/ha 150.00 g as/ha 150.00 g as/ha (-)	16 Jun 1997 25 Jun 1997 04 Jul 1997 (9, 9)	BBCH 41 BBCH 42 BBCH 44	Bulbs	< 0.02	0*	Field SP (max days): Bulbs: 333
								Bulbs	0.04	0	
								Bulbs	< 0.02	7	
								Bulbs	<u>< 0.02</u>	14	
								Bulbs	< 0.02	21	

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

A 2.1.3.7.2 Study 2 – 2340/97 – New data

<table>
<tr>
<td>Comments of zRMS:</td>
<td>One residue field trial on onions bulbs was conducted in Switzerland during 1997.
Three applications, separated by a 8-day interval were made at a nominal rate of 150 g ai/ha for metalaxyl-M (BBCH 45-49).
Treated samples were collected at 0, 7, 14 and 21 days after the last application (DALA).
Residues of Metalaxyl-M (CGA 329351) are <0.02 mg/kg (0 DALA and later).

Onions samples were analysed for metalaxyl-M using method DFG S19 with modified extraction with LOQ of 0.02 mg/kg.
Data on recovery:
<table>
<tr><th>Substrate (control)</th><th>fortification level [mg/kg]</th><th>CGA 329351</th></tr>
<tr><td>onions (bulbs)</td><td>0.02</td><td>93</td></tr>
<tr><td>onions (bulbs)</td><td>0.20</td><td>99</td></tr>
</table>
Specimens were stored frozen for a maximum period of 293 days from sampling to analysis for metalaxyl-M.

<u>Remark:</u>
Description of the many details on field trials, the analytical method used for field trials and storage stability samples are missing. According to the OECD 509 (June 2021) detailed description of these data in report should be provided.
In our opinion, this study can be considered informative.</td>
</tr>
</table>

Reference:	KCA 6.3.7/02
Report	Residue study with Metalaxyl-M (CGA 329351) and Mancozeb (ASF 21) in or on onions in Switzerland, Kühne R.O., 1998, report No 2340/97, document No VV-357408
Guideline(s):	Yes FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials (Rome,1990).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 42: Summary of the study 2 trials

Field Trials, Crop Residue (Summary) : Residue study with Metalaxyl-M (CGA 329351) and mancozeb (ASF 21) in or on onions in Switzerland			
Active Substance (common name):	Metalaxyl-M	**Commercial Product (name):**	$Commercial.Name$
Crop/Crop Group:	Onion	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	SWITZERLAND	**Other active substance in the formulation (common name and content):**	None
Content of active substance (g/kg or g/L):	40 g/kg	**Residues calculated as:**	$Residue.Units$
Formulation (e.g. WP):	A9407A WP		
Analytical Method: Metalaxyl-M (Bulbs) DFG S19, modified; 0.02 mg/kg			
Recovery data: CGA329351 Bulbs Mean = 96% RSD = N/A (n = 2 in 0.02 – 0.2 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** €	**Growth stage at last treatment or date**	**Portion analyzed**	**Residues (mg/kg)**	**PHI (days)** (d)	**Details on trial** €
			g a.s./ ha	**Water (L/ha)**	**g a.s./hL**				**Metalaxyl-M**		
2340/97 2340/97 SWITZERLAND (Europe North) (CH-1926 Fully)	Onion (Copra F1)	1.02 May 1997 2 – 3 -		800 L/ha 800 L/ha 800 L/ha	150.00 g as/ha 150.00 g as/ha 150.00 g as/ha (-)	28 Jul 1997 05 Aug 1997 13 Aug 1997 (8, 8)	BBCH 43 BBCH 44 BBCH 45	Bulbs	< 0.02	0*	Field SP (max days): Bulbs: 293
								Bulbs	< 0.02	0	
								Bulbs	< 0.02	7	
								Bulbs	< 0.02	14	
								Bulbs	< 0.02	21	

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

A 2.1.3.7.3 Study 3 – 116/97 – New data

Comments of zRMS:

Four residue field trials (2 in UK and 2 in Spain) on onions bulbs with two formulations was conducted during 1997.
Three applications of SC 537.5 (A-9652 B) or WP 68 (A-9407 A), separated by a 8-day interval were made at a nominal rate of 100 g ai/ha (A-9652 B) or 150 g ai/ha (A-9407 A) for metalaxyl-M.
Treated samples were collected at 14 days after the last application (DALA).
Residues of Metalaxyl-M (CGA 329351) were below LOQ (<0.02 mg/kg; 14 days).

Onions samples were analysed for metalaxyl-M using method REM 181.01 with modificatios with LOQ of 0.02 mg/kg.
Data on recovery:

Recoveries

Recoveries in percent (%). The lowest fortification level is at the limit of quantitation (CGA 32
and chlorothalonil):

Substrate (control)	fortification level [mg/kg]	CGA 329351	chlorothalonil	mancozeb (CS_2)
onions (bulbs)	0.01	–	98	–
onions (bulbs)	0.01	–	120	–
onions (bulbs)	0.02	92	–	–
onions (bulbs)	0.20	97	128	–
onions (bulbs)	0.29	–	–	91
onions (bulbs)	0.51	–	–	110

Specimens were stored frozen for a maximum period of 216 days from sampling to analysis for metalaxyl-M.

<u>Remark:</u>
Description of the many details on field trials, the analytical method used for field trials and storage stability samples are missing. According to the OECD 509 (June 2021) detailed description of these data in report should be provided.
In our opinion, this study can be considered informative.

Reference:	KCA 6.3.7/03
Report	Magnitude of residues of Metalaxyl-M (CGA 329351), Chlorothalonil (ASF 41) and Mancozeb (ASF 21) in onions applied as formulations SC 537.5 and WP 65 in side-by-side trials in Spain and in the United Kingdom, Kühne R.O., 1998, report No 116/97, document No VV-376089
Guideline(s):	Yes FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials (Rome,1990).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 43: Summary of the study 3 trials

Field Trials, Crop Residue (Summary) : Magnitude of residues of Metalaxyl-M (CGA 329351), chlorothalonil (ASF 41) and mancozeb (ASF 21) in onions applied as formulations SC 537.5 and WP 68 in side-by-side trials in Spain and in the United Kingdom			
Active Substance (common name):	Metalaxyl-M	**Commercial Product (name):**	$Commercial.Name$
Crop/Crop Group:	Onion	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	UNITED KINGDOM, SPAIN	**Other active substance in the formulation (common name and content):**	None
Content of active substance (g/kg or g/L):	40 g/kg	**Residues calculated as:**	$Residue.Units$
Formulation (e.g. WP):	A9407A WP		
Analytical Method: Metalaxyl-M (Bulbs) REM 181.01, modified; 0.02 mg/kg			
Recovery data: CGA329351 Mean = 95% RSD = N/A (n = 2 in 0.02 – 0.2 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** €	**Growth stage at last treatment or date**	**Portion analyzed**	**Residues (mg/kg)**	**PHI (days)** (d)	**Details on trial** €
			g a.s./ ha	**Water (L/ha)**	**g a.s./hL**				**Metalaxyl-M**		
116/97 2094/97 UNITED KINGDOM (Europe North) (Whittlesey Cambs.) 116/97 2096/97 UNITED KINGDOM (Europe North) (Babraham Cambs.)	Onion (sherpa) Onion (sherpa)	1.16 Mar 1997 2 – 3 – 1.03 Mar 1997 2 – 3 -		196 L/ha 198 L/ha 208 L/ha	147.00 g as/ha 148.00 g as/ha 156.00 g as/ha (-)	28 Jul 1997 05 Aug 1997 13 Aug 1997 (8, 8)	BBCH 402 BBCH 405 BBCH 407	Bulbs	< 0.02	14	Field SP (max days): Bulbs: 209
								Bulbs	< 0.02	14	
116/97 2096/97 UNITED	Onion (sherpa)	1.03 Mar 1997 2 – 3 -		195 L/ha 192 L/ha 196 L/ha	146.00 g as/ha 144.00 g as/ha	21 Jul 1997 29 Jul 1997 06 Aug 1997	BBCH 402 BBCH 404 BBCH 407	Bulbs	< 0.02	14	Field SP (max days): Bulbs: 216

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date €	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial €
			g a.s./ ha	Water (L/ha)	g a.s./hL				Metalaxyl-M		
KINGDOM (Europe North) (Babraham Cambs.)					147.00 g as/ha (-)	(8, 8)		Bulbs	< 0.02	14	

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

A 2.1.3.7.4 Study 4 – 2077/98 – New data

Comments of zRMS:

Two side be side trials on onions bulbs was conducted in Switzerland during 1998.
Three applications of SC 537.5 (A-9652 B) or WP 68 (A-9407 A), separated by a 8-10-day interval were made at a nominal rate of 100 g ai/ha (A-9652 B) or 150 g ai/ha (A-9407 A) for metalaxyl-M.
Treated samples were collected at 14 days after the last application (DALA).
Residues of Metalaxyl-M (CGA 329351) in both trials were below LOQ (<0.02 mg/kg; 14 days).

Onions samples were analysed for metalaxyl-M using method REM 181.01 with modificatios with LOQ of 0.02 mg/kg.
Data on recovery:

Recoveries in percent (%). The lowest fortification level is at the limit of quantitation:

Substrate (control)	metalaxyl-M fortification level [mg/kg]	recovery [%]
onions (bulbs)	0.02	88 #
onions (bulbs)	0.20	97 #

#: these recovery experiments were conducted with control specimens from other origin.

Specimens were stored frozen for a maximum period of 194 days from sampling to analysis for metalaxyl-M.

<u>Remark:</u>
Description of the many details on field trials, the analytical method used for field trials and storage stability samples are missing. According to the OECD 509 (June 2021) detailed description of these data in report should be provided.
In our opinion, this study can be considered informative.

Reference:	KCA 6.3.7/04
Report	Residue study with Metalaxyl-M (CGA 329351) + Chlorothanlonil (ASF 41) and Metalaxyl-M (CGA 329351) + Mancozeb (ASF 21) in or on onions in Switzerland, Kühne R.O., 1999, report No 2077/98, document No VV-312825
Guideline(s):	Yes 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).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 44: Summary of the study 4 trials

Field Trials, Crop Residue (Summary) : Residue Study with Metalaxyl-M (CGA 329351) + Chlorothalonil (ASF 41) and Metalaxyl-M (CGA 329351) + Mancozeb (ASF 21) in or on Onions in Switzerland			
Active Substance (common name):	Metalaxyl-M	**Commercial Product (name):**	$Commercial.Name$
Crop/Crop Group:	Onion	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	SWITZERLAND	**Other active substance in the formulation (common name and content):**	None
Content of active substance (g/kg or g/L):	40 g/kg	**Residues calculated as:**	$Residue.Units$
Formulation (e.g. WP):	A9407A WP		
Analytical Method: Metalaxyl-M (Bulb) REM 181.01, modified; 0.01 mg/kg			
Recovery data: Metalaxyl-M Bulbs Mean = 93% RSD = N/A (n = 2 in 0.02 – 0.2 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** €	**Growth stage at last treatment or date**	**Portion analyzed**	**Residues (mg/kg)**	**PHI (days)** (d)	**Details on trial** €
			g a.s./ ha	**Water (L/ha)**	**g a.s./hL**				**Metalaxyl-M**		
2077/98-2 SWITZERLAND (Europe North) (1896 Vouvry (VS))	Onion (Copra F1)	1.22 Apr 1998 2 – 3 -		800 L/ha 800 L/ha 800 L/ha	150.00 g as/ha 150.00 g as/ha 150.00 g as/ha (-)	29 Jun 1998 09 Jul 1998 17 Jul 1998 (10, 8)	BBCH 42 BBCH 43 BBCH 45	Bulb	< 0.02	14	Field SP (max days): Bulb: 194
								Bulb	<u>< 0.02</u>	14	

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

A 2.1.4 Magnitude of residues in livestock

No new data submitted.

A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

No new data submitted.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new data submitted.

A 2.1.7 Other/Special Studies

A 2.1.7.1 Study 1 – S20-03602

Comments of zRMS:	Five residue trials were conducted with two applications of metalaxyl-M at a rate 100 g a.s./ha on spring oilseed rape. At the time of the first application the BBCH of the crop was between 51 and 64. At the time of the second application the crop was at BBCH 61 to 65. The study was conducted, under confined semi-field conditions. The analytical method REM 181.13A has been successfully validated for the determination of residues of metalaxyl-M in honey with the LOQ of 0.01 mg/kg with satisfactory accuracy, precision and repetibility using LC-MS/MS detection. Results: No residues of metalaxyl-M at or above the limit of quantitation (LOQ, 0.01 mg/kg) were found in the untreated honey samples. The residues of metalaxyl-M in all treated honey samples were below the limit of quantification (LOQ of 0.01 mg/kg) in all trials. The study is acceptable.

Reference:	KCA 6.10/01
Report	Metalaxyl-M – Honey Residue Study on Spring Oilseed Rape in Northern Europe in 2020, Knäbe, S., 2021, Report No. S20-03602. Syngenta document No. VV-881362
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC OECD (2009) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32) SANTE/11956/2016 (rev. 9) Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey EU (2010) Guidance Document SANCO/825/00 rev. 8.1 on analytical methods for the determination of residues (Post-registration monitoring and control)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Executive Summary

Five residue trials were conducted on spring oilseed rape in Germany and Austria in 2020 where honey was sampled following the exposure of bees to treated crop. Trials were located more than 50 km apart. 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 five trial locations of the study consisted of test item treatment group T and a control group C.

Two applications of metalaxyl-M, 20.8 g/kg WG as A15605D at a rate of 100 g a.s./ha at BBCH 63 to oilseed rape within the tunnels. A beehive was placed in each tunnel before the second application and the bees were allowed to forage freely on the treated crop. All applications were carried out with a spray volume of 400 L/ha and an application rate of 100 g a.s./ha for Metalaxyl-M. At the time of the first application the BBCH of the crop was between 51 and 64. At the time of the second application the crop was at BBCH 61 to 65. The application interval was 5 to 6 days for trial 01 to -04 and 8 days for trial -05.

The health effects on the bee colonies were also monitored by two brood assessments (once before start of exposure and once after the sampling of honey). The health status of all colonies was good throughout the trial, all colonies were free of visible symptoms of diseases.

Honey was collected successfully from honeybee hives.

Samples of honey were analysed for residues of metalaxyl-M.

The method RAM 181.13A for the determination of residues of metalaxyl-M was successfully validated for use on honey as part of this study.

The residues of metalaxyl-M in all treated honey samples were below the limit of quantification (LOQ, 0.01 mg/kg). No residues of metalaxyl-M at or above the limit of quantitation (LOQ, 0.01 mg/kg) were found in the untreated honey samples of trial 01 to 04. No honey could be sampled in the control in trial 05.

Materials	
Test Material	A15605D (Ridomil Gold R)
Lot/Batch #:	SOL9A9407
Description:	WG
Reanalysis/expiry date:	31 Jan 2022
Active ingredient 1	Metalaxyl-M
Active ingredient 2	copper oxychloride
Actual content of active ingredient Metalaxyl-M	2.08 % w/w or 20.8 g/kg
Actual content of active ingredient copper oxychloride	24.6 % w/w or 246 g/kg
Treatment	
Test concentrations:	5 kg A15605D /ha (100 g a.s./ha for metalaxyl-M)
Spray volume:	400 L/ha
Application method:	Spray application
Number of applications:	2
Test System	
Crop	Oilseed rape (Brassica napus)
Pollinator:	Honeybee (Apis mellifera)
Processed Commodities:	Honey
Study Design and Methods	
Test Facilities	
Field Phase:	Eurofins Agroscience Services Ecotox GmbH Eutinger Str. 24, D-75223 Niefern-Öschelbronn, Germany Eurofins Agroscience Services GmbH Carl-Goerdeler-Weg 5, D-21684 Stade, Germany Eurofins Agroscience Services AUSTRIA GMBH Am Tieberhof 21, A-8200 Gleisdorf, Austria
Analytical Phase:	Eurofins Agroscience Services Chem GmbH Am Neuländer Gewerbepark 2, D-21079 Hamburg, Germany

Field Phase

Five residue trials (S20-03602-01 to S16-02006-05) were conducted with A15605D (metalaxyl-M, 20 g/kg

WG) on spring oilseed rape in Germany and Austria in 2020. Each trial consisted of two treatment groups; test item treatment group T and a control group C. The actual application rate was two times 100 g a.s./ha for Ridomil Gold R (A15605D) with a planned application interval of 5±1 day. All applications were carried out with a spray volume of 400 L/ha. At the time of the first application the BBCH of the crop was between 51 and 64. At the time of the second application the crop was at BBCH 61 to 65. A beehive was placed in each tunnel in the evening or in the early morning before the second application. Bees were allowed to forage freely on the treated crop. The honeybee hives were located in tunnel tents (5.0 m x 40.0 m and a height of ~3.5 m) placed over plots of spring oilseed rape (from installation of hives in the tunnels to the sampling it was 6 days for trial -01, 10 days for trial -02 and 8 days for trial -03, 10 days for trial 4 and 30 days for trial -05).
Honey was sampled at with a water content below 20% in trial -01 to 04 during the tunnel phase. For trial -05 sampling of the treated hive took place at the monitoring site. No honey could be sampled from the control hive of this trial.
The health effects on the bee colonies were also monitored by two brood assessments (once before start of exposure and once after the sampling of honey). The health status of all colonies was good throughout the trial, all colonies were free of visible symptoms of diseases.

Analytical Phase

Samples were stored frozen for a maximum period of 47 days from sampling to extraction.
The storage stability samples fortified at 10 x LOQ (0.1 mg/kg) were analysed for residues of metalalxyl-M.
The residues of metalalxyl-M showed no significant decrease (> 30% as compared to the initial residue level in the stored sample (% of nominal) i.e. at Day 0) in honey after storage at < -18 °C for up to 51 days.
Honey samples were analysed for residues of metalaxyl-M using the method REM 181.13A with a limit of quantification of 0.01 mg/kg. Samples is extracted by high speed homogenization with methanol followed by centrifugation. An aliquot is diluted to a sample concentration of 0.01 g/mL and subjected to a solid phase extraction (SPE) clean up. The final sample extracts are analysed by liquid chromatography with tandem mass spectrometry (LC-MS/MS)

Procedural Recovery Data – Field Samples Metalaxyl-M

Substrate (control)	Fortification level (mg/kg)	Metalaxyl-M (%)
Honey	0.01	97
	0.1	79
Mean		88

Recoveries in percent (%). The lowest fortification level is at the limit of quantification.

RESULTS AND DISCUSSION

Residues of metalaxyl-M in honey are presented below:

Results Trial S20-03602-01

Sample Trial -01	Metalaxyl-M (g a.s./ha)	Interval (days)	Sample type	Metalaxyl-M Residue (mg/kg)
Treated Plot				
S20-03602-01-T-S1-HO-S	2 x 100	6	Honey	< 0.01
Control Plot				
S20-03602-01-C-S1-HO-S	Control	-	Honey	< 0.01#

No correction of results for either control residues or recovery values has been performed. (LOQ, 0.01 mg/kg)
the residues in the untreated samples were <30% LOQ

Results Trial S20-03602-02

Sample Trial -02	Metalaxyl-M (g a.s./ha)	Interval (days)	Sample type	Metalaxyl-M Residue (mg/kg)
Treated Plot				

S20-03602-02-T-S1-HO-S	2 x 100	5	Honey	< 0.01
Control Plot				
S20-03602-02-C-S1-HO-S	Control	-	Honey	< 0.01#

No correction of results for either control residues or recovery values has been performed. (LOQ, 0.01 mg/kg)
the residues in the untreated samples were <30% LOQ

Results Trial S20-03602-03

Sample Trial -03	Metalaxyl-M (g a.s./ha)	Interval (days)	Sample type	Metalaxyl-M Residue (mg/kg)
Treated Plot				
S20-03602-03-T-S1-HO-S	2 x 100	5	Honey	< 0.01
Control Plot				
S20-03602-03-C-S1-HO-S	Control	-	Honey	< 0.01#

No correction of results for either control residues or recovery values has been performed. (LOQ, 0.01 mg/kg)
the residues in the untreated samples were <30% LOQ

Results Trial S20-03602-04

Sample Trial -01	Metalaxyl-M (g a.s./ha)	Interval (days)	Sample type	Metalaxyl-M Residue (mg/kg)
Treated Plot				
S20-03602-04-T-S1-HO-S	2 x 100	5	Honey	< 0.01
Control Plot				
S20-03602-4-C-S1-HO-S	Control	-	Honey	< 0.01#

No correction of results for either control residues or recovery values has been performed. (LOQ, 0.01 mg/kg)
the residues in the untreated samples were <30% LOQ

Results Trial S20-03602-05

Sample Trial -01	Metalaxyl-M (g a.s./ha)	Interval (days)	Sample type	Metalaxyl-M Residue (mg/kg)
Treated Plot				
S20-03602-05-T-S1-HO-S	2 x 100	8	Honey	< 0.01
Control Plot				
S20-03602-052-C-S1-HO-S	Control	-	Honey	n.a.

n.a. = no sample available
No correction of results for either control residues or recovery values has been performed. (LOQ, 0.01 mg/kg)

Validity criteria

The test was considered valid. A sufficient amount of honey for analysis with a water content below 20% could be sampled in all treatment of 4 trials and in the treatment tunnel of the fifth trial

Conclusion

No residues of metalaxyl-M were found at or above the limit of quantification (0.01 mg/kg) in any of the treated honey specimens taken.
No residues of metalaxyl-M at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in the untreated honey samples.
The health effects on the bee colonies were also monitored by two brood assessments (once before start of exposure and once after the sampling of honey). The health status of all colonies was good throughout the trial, all colonies were free of visible symptoms of diseases.

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 data is submitted

A 2.2.1.1.2 Storage stability of residues in animal products

A 2.2.1.1.2.1 Study 1 – CEMS-9822

Comments of zRMS:	The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for A22773A/ Orondis Evo (2023). 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 6.1/01
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: 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
Acceptability:	Yes

Materials and methods

The stability of oxathiapiprolin has been tested in honey following deep frozen storage for up to 5 months. Individual samples of honey (5g) 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, 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 and discussions

Residues of oxathiapiprolin found in stored frozen honey tested are shown below. 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 45: Summary of concurrent recoveries of oxathiapiprolin from honey.

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± std dev
Oxathiapiprolin					
Honey	0.1	0	2	98, 94	96
	0.1	96	2	104, 103	104
	0.1	153	2	103, 102	102

Table A 46: Stability of oxathiapiprolin residues in honey following storage at ≤-18°C

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)
Oxathiapiprolin				
Honey	0.1	0	0.092, 0.098, 0.097	92, 98, 97 (96)
	0.1	96	0.100, 0.097	100, 97 (98)
	0.1	153	0.097, 0.0104	97, 104 (100)

Conclusion

Oxathiapiprolin has been shown to be stable in samples of honey for at least 5 months when stored frozen at ≤-18°C.

A 2.2.2 Nature of residues in plants, livestock and processed commodities

No new data is submitted.

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 Flowering brassica (Broccoli, Cauliflower)

Table A 47: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-3, AT-7, BE-3, BE-7, CZ-3, CZ-7, DE-3, DE-7, NL-3, NL-7, PL-3, PL-3a, PL-7, PL-7a, SK-3, SK7*)	2	15 g as/ha	7-10 days	BBCH 12 – 49	20

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

A 2.2.3.1.1 Study 1 – IF20-05335380 – New data

Comments of zRMS:	Four residue field trials (two decline and two harvest) on broccoli were successfully conducted in Germany, Hungary, Poland and the United Kingdom during 2020. Two decline trials and two harvest trials were conducted. Oxathiapiprolin and metalaxyl-M were applied to broccoli as A23109A, dispersible concentrate DC formulation containing nominally 30 g of oxathiapiprolin and 180 g of metalaxyl-M per litre. Two applications on plot P2, separated by a 5-7 day interval, were made at a nominal rate of 15 g oxathiapiprolin/ha and 90 g metalaxyl-M/ha. The first application on plot P2 was done at 25-28 days before harvest (DBH) and the second application was done at 20-21 DBH. One application on plot P3 was made at a nominal rate of 15 g oxathiapiprolin/ha and 90 g metalaxyl-M/ha. The application on plot P3 was conducted at 20-21 DBH. For decline trials following the final application samples were collected from plots P2 and P3 at 0 days after last application (DALA), 6-7 DALA, 13-14 DALA, 20-21 DALA (NCH (normal commercial harvest)) and 28 DALA with untreated broccoli being collected 20 DALA (NCH). For harvest trials following the final application untreated and treated samples from all plots were collected at 20-21 DALA (NCH (normal commercial harvest)). Field samples for residue analysis were analysed for oxathiapiprolin using method DuPont-30422, Supplement No. 1 and metalaxyl-M using method REM 181.13A with LOQ of 0.01 mg/kg. No residues of oxathiapiprolin and metalaxyl-M at or above the limit of quantification were found in any of the untreated broccoli specimens. Samples were stored frozen for a maximum period of 204 days (7 months) for oxathiapiprolin and for a maximum of 300 days (10 months) for metalaxyl-M from sampling to analysis. Results:

Actual Sampling Interval (days)	Oxathiapiprolin Residues in the range (mg/kg)	Metalaxyl-M Residues in the range (mg/kg)
broccoli (whole plant (roots and leaves removed))		
Treated Plot (P2)	at a rate of 2 x 15 g ai/ha*	at a rate of 2 x 90 g ai/ha**
0 DALA	0.13 – 0.16	0.53 – 0.61
6 - 7 DALA	0.015 – 0.029	0.049 – 0.074
13 - 14 DALA	< 0.01 – 0.028	< 0.01 – 0.028
20 - 21 DALA (NCH)	< 0.01 – 0.017	0.011 – 0.024
28 DALA	< 0.01 – 0.012	< 0.01
Treated Plot (P3)	at a rate of 1 x 15 g ai/ha*	at a rate of 1 x 90 g ai/ha**
0 DALA	0.050 – 0.065	0.33 – 0.39
6 - 7 DALA	< 0.01	0.033 – 0.043
13 - 14 DALA	< 0.01	< 0.01 – 0.013
20 - 21 DALA (NCH)	< 0.01 – 0.026	< 0.01 – 0.026
28 DALA	< 0.01	< 0.01
Control Plot (C1) No residues of oxathiapiprolin and metalaxyl-M at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in any of the untreated broccoli specimens.		

NCH: normal commercial harvest, DALA: days after last application,
*application rate of oxathiapiprolin,
** application rate of metalaxyl-M

The study is acceptable.

Reference:	KCA2 6.3.1/01
Report	Oxathiapiprolin and Metalaxyl-M – Residue Study on Broccoli in Germany, Hungary, Poland and the United Kingdom 2020, Meyer M., 2021, report No IF20-05335380, document No VV-908189
Guideline(s):	Yes OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009. Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 48: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) : Oxathiapiprolin and Metalaxyl-M – Residue Study on Broccoli in Germany, Hungary, Poland and the United Kingdom 2020			
Active Substance (common name):	oxathiapiprolin	**Commercial Product (name):**	
Crop/Crop Group:	Broccoli	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	GERMANY, HUNGARY, POLAND, UNITED KINGDOM	**Other active substance in the formulation (common name and content):**	A23109A: Metalaxyl-M (180 g/L)
Content of active substance (g/kg or g/L):	A23109A: 30 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A23109A DC		
Analytical Method:	Oxathiapiprolin (Whole plant) DuPont-30422; 0.01 mg/kg		
Recovery data:	Oxathiapiprolin Whole plant Mean = 100% RSD = 6% (n = 12 in 0.0103 – 1.028 spiking range)		

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment g a.s./ ha	Application rate per treatment Water (L/ha)	Application rate per treatment g a.s./hL	Dates of treatment or no. of treatments and last date €	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg) Oxathiapiprolin	PHI (days) (d)	Details on trial €
20-00246-01 GERMANY (49685) Europe North 2020	Broccoli / Marathon	1.19 May 2020 2 – 3 -	1. 14.8502 2. 15.09983	1. 297.5 2. 302.5		1. 16 Jul 2020 2. 21 Jul 2020	1. BBCH 43-43 2. BBCH 45-45	Whole plant	0.127	0	Field SP (max days): 204
								Whole plant	0.0149	7	
								Whole plant	< 0.01	13	
								Whole plant	< 0.01	20	
								Whole plant	< 0.01	28	
	Broccoli / Marathon	1.19 May 2020 2 – 3 -	1. 14.9334	1. 299.1667		12. 21 Jul 2020	1. BBCH 45-45	Whole plant	0.0646	0	Field SP (max days): 204
								Whole plant	< 0.01	7	
								Whole plant	< 0.01	13	
								Whole plant	< 0.01	20	
								Whole plant	< 0.01	28	
20-00246-02 HUNGARY (H-4400) Europe North 2020	Broccoli / Agassi	1.10 Aug 2020 2 – 3 -	1. 14.4542 2. 14.6622	1. 385.9259 2. 391.4815		12. 02 Oct 2020 2. 09 Oct 2020	1. BBCH 43-43 2. BBCH 45-45	Whole plant	0.1589	0	Field SP (max days): 124
								Whole plant	0.0288	6	
								Whole plant	0.028	14	
								Whole plant	0.0172	20	
								Whole plant	0.012	28	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date €	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial €
			g a.s./ ha	Water (L/ha)	g a.s./hL				Oxathiapiprolin		
	Broccoli / Agassi	1.10 Aug 2020 2 – 3 -	1. 15.2171	1. 406.2963		12. 09 Oct 2020	1. BBCH 45-45	Whole plant	0.0505	0	Field SP (max days): 124
								Whole plant	< 0.01	6	
								Whole plant	< 0.01	14	
								Whole plant	< 0.01	20	
								Whole plant	< 0.01	28	
20-00246-03 POLAND (88-400) Europe North	Broccoli / Triton	1.20 May 2020 2 – 3 -	1. 15.4276 2. 15.2114	1. 309.111 2. 304.7777		12. 31 Jul 2020 2. 07 Aug 2020	1. BBCH 41-41 2. BBCH 43-43	Whole plant	0.0152	20	Field SP (max days): 161
	Broccoli / Triton	1.20 May 2020 2 – 3 -	12. 15.3445	1. 307.4443		12. 07 Aug 2020	1. BBCH 43-43	Whole plant	0.0257	20	Field SP (max days): 167
20-00246-04 UNITED KINGDOM (GL55 6NW) Europe North	Broccoli / Steel	1.25 Jun 2020 2 – 3 -	1. 15.4479 2. 15.4609	1. 412.4583 2. 412.459		12. 08 Sep 2020 2. 15 Sep 2020	1. BBCH 41-41 2. BBCH 43-43	Whole plant	< 0.01	21	Field SP (max days): 127
	Broccoli / Steel	1.25 Jun 2020 2 – 3 -	12. 15.4479	1. 412.4583		12. 15 Sep 2020	1. BBCH 43-43	Whole plant	< 0.01	21	Field SP (max days): 127

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

A 2.2.3.1.2 Study 2 – IF20-05336777 – New data

Comments of zRMS:

Four residue trials on cauliflower were successfully conducted in Germany, Poland, the United Kingdom and Denmark during 2020. Two trials were conducted as decline trials and two trials as harvest trials.
Metalaxyl-M and oxathiapiprolin was applied to cauliflower as A23109A, dispersible concentrate DC formulation containing nominally 180 g of metalaxyl-M per litre and 30 g of oxathiapiprolin per litre.
Two applications on plot P2, separated by a 7-8 day interval, were made at a nominal rate of 15 g oxathiapiprolin/ha and 90 g metalaxyl-M/ha. The first application on plot P2 was done at 27-29 days before harvest (DBH) and the second application was done at 20-22 DBH.
One application on plot P3 was made at a nominal rate of 15 g oxathiapiprolin/ha and 90 g metalaxyl-M/ha. The application on plot P3 was conducted at 20-22 DBH.
For decline trials following the final application samples were collected from plots P2 and P3 at 0 days after last application (DALA), 7 DALA, 13-14 DALA, 20 DALA (NCH (normal commercial harvest)) and 26-28 DALA with untreated cauliflower being collected 20 DALA (NCH).
For harvest trials following the final application untreated and treated samples from all plots were collected at 21-22 DALA (NCH (normal commercial harvest)).

The ranges of residues of oxathiapiprolin and metalaxyl-M are summarised in the table below.

Actual Sampling Interval (days)	Oxathiapiprolin Residues in the range (mg/kg)	Metalaxyl-M Residues in the range*** (mg/kg)
Cauliflower (whole plant (Head with stem – roots and leaves removed))		
Treated Plot (P2)	at a rate of 2 x 15 g ai/ha*	at a rate of 2 x 90 g ai/ha**
0 DALA	0.01 – 0.03	--
7 DALA	< 0.01	--
13 - 14 DALA	< 0.01	--
20 - 22 DALA (NCH)	< 0.01	--
26 - 28 DALA	< 0.01	--
Treated Plot (P3)	at a rate of 1 x 15 g ai/ha*	at a rate of 1 x 90 g ai/ha**
0 DALA	< 0.01 – 0.01	0.02 – 0.10
7 DALA	< 0.01	< 0.01
13 - 14 DALA	< 0.01	< 0.01
20 - 22 DALA (NCH)	< 0.01	< 0.01 – 0.02
26 - 28 DALA	< 0.01	< 0.01
<u>**Control Plot (C1)**</u> No residues of oxathiapiprolin and metalaxyl-M at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in any of the untreated cauliflower specimens.		

NCH: normal commercial harvest, DALA: days after last application, *application rate of oxathiapiprolin,
** application rate of metalaxyl-M
*** was not determined for Plot P2

Field samples for residue analysis were analysed for oxathiapiprolin using method DuPont-30422, Supplement No. 1 and metalaxyl-M using method REM 181.13A.
Samples were stored frozen for a maximum period of 196 days (6.5 months) for oxathiapiprolin and for a maximum of 204 days (7 months) for metalaxyl-M from sampling to analysis.
<u>Remark:</u>
The intended GAP for A23109A / Orondis VIP for cauliflower is covered by trials GAP for oxathiapiprolin only (P2 plot – 2 applications with 7 day interval, at a rate of 15 g ai/ha for oxathiapiprolin). There is a lack of residue results for metalaxyl-M for P2 plot.

The study is acceptable.

Reference:	KCA2 6.3.1/02
Report	Oxathiapiprolin and Metalaxyl-M – Residue Study on Cauliflower in Germany, Poland, the United Kingdom and Denmark 2020, Mahlo C., 2021,

	report No IF20-05336777, document No VV-901124
Guideline(s):	Yes OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009. Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 49: Summary of the study 2 trials

Field Trials, Crop Residue (Summary) : Oxathiapiprolin and Metalaxyl-M – Residue Study on Cauliflower in Germany, Poland, the United Kingdom and Denmark 2020			
Active Substance (common name):	oxathiapiprolin	**Commercial Product (name):**	
Crop/Crop Group:	Cauliflower	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	GERMANY, POLAND, DENMARK, UNITED KINGDOM	**Other active substance in the formulation (common name and content):**	A23109A: Metalaxyl-M (180 g/L)
Content of active substance (g/kg or g/L):	A23109A: 30 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A23109A DC		
Analytical Method:	Oxathiapiprolin (Whole plant) DuPont-30422; 0.01 mg/kg		
Recovery data:	Oxathiapiprolin Whole plant Mean = 101% RSD = 6% (n = 12 in 0.01034 – 1.034 spiking range)		

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date €	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial €
			g a.s./ ha	Water (L/ha)	g a.s./hL				Oxathiapiprolin		
20-00247-01 GERMANY (49685) Europe North 2020	Cauliflower / Alpha	1.19 May 2020 2 – 3 -	12. 14.6839 2. 15.09983	1. 294.1667 2. 302.5		12. 21 Jul 2020 2. 29 Jul 2020	1. BBCH 43-43 2. BBCH 45-45	Whole plant	0.0255	0	Field SP (max days): 196
								Whole plant	< 0.01	7	
								Whole plant	< 0.01	13	
								Whole plant	< 0.01	20	
								Whole plant	< 0.01	26	
	Cauliflower / Alpha	1.19 May 2020 2 – 3 -	1. 15.01664	1. 300.8333		12. 29 Jul 2020	1. BBCH 45-45	Whole plant	0.0134	0	Field SP (max days): 196
								Whole plant	< 0.01	7	
								Whole plant	< 0.01	13	
								Whole plant	< 0.01	20	
								Whole plant	< 0.01	26	
20-00247-02		1.20 May 2020						Whole plant	0.0149	0	Field

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL				Oxathiapiprolin		
	(a)	(b)				€				(d)	€
POLAND (88-400) Europe North 2020	Cauliflower / Almagro	2 – 3 -	12. 15.4261 2. 15.3134	1. 309.305 2. 306.8055		12. 03 Aug 2020 2. 10 Aug 2020	1. BBCH 39-39 2. BBCH 43-43	Whole plant	< 0.01	7	SP (max days): 185
								Whole plant	< 0.01	14	
								Whole plant	< 0.01	20	
								Whole plant	< 0.01	28	
	Cauliflower / Almagro	1.20 May 2020 2 – 3 -	12. 14.9058	1. 298.6388		12. 10 Aug 2020	1. BBCH 43-43	Whole plant	< 0.01	0	Field SP (max days): 185
								Whole plant	< 0.01	7	
								Whole plant	< 0.01	14	
								Whole plant	< 0.01	20	
								Whole plant	< 0.01	28	
20-00247-04 UNITED KINGDOM (GL55 6NW) Europe North 2020	Cauliflower / Naruto	1.15 Jun 2020 2 – 3 -	12. 14.7612 2. 15.6417	1. 394.125 2. 417.4587		12. 08 Sep 2020 2. 15 Sep 2020	1. BBCH 41-41 2. BBCH 43	Whole plant	< 0.01	22	Field SP (max days): 126
	Cauliflower / Naruto	1.15 Jun 2020 2 – 3 -	12. 15.4739	1. 412.4597		12. 15 Sep 2020	1. BBCH 43	Whole plant	< 0.01	22	Field SP (max days): 126
20-00247-05 DENMARK (5610) Europe North 2020	Cauliflower / Momentum	1.07 Aug 2020 2 – 3 -	12. 15.6751 2. 15.6544	1. 209.5238 2. 261.4286		12. 16 Sep 2020 2. 23 Sep 2020	1. BBCH 39 2. BBCH 39	Whole plant	< 0.01	21	Field SP (max days): 119
	Cauliflower / Momentum	1.07 Aug 2020 2 – 3 -	12. 15.3693	1. 256.6667		12. 23 Sep 2020	1. BBCH 39	Whole plant	< 0.01	21	Field SP (max days): 119

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

A 2.2.3.2 Kale

Table A 50: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-23, CZ-24, DE-23, PL-23, PL-23a, SK-20, SK-22*)	2	15 g as/ha	7-10 days	BBCH 12 – 49	20

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

Kale – (extrapolation to Leafy brassicas, Chinese cabbage and curly kale)

Table A 51: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-14, AT-26, AT-37, BE-11, BE-21, BE-28, CZ-14, CZ-29, CZ-40, DE-14, DE-26, DE-37, NL-10, NL-20, NL-27, PL-14, PL-14a, PL-26, PL-26a, PL-37, PL-37a, SK-13, SK-33*)	2	15 g as/ha	7-10 days	BBCH 12 – 49	20

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

A 2.2.3.2.1 Study 1 – RES-00256 – New data

Comments of zRMS:	Four residue field trials on kale were successfully conducted in France, Austria and the United Kingdom during 2020/2021. Oxathiapiprolin and metalaxyl-M were applied to kale as A23109A, a dispensive concentrate DC formulation containing 30 g of oxathipiprolin and 180 g of metalaxyl-M per litre. Two applications (applied at 7 days before last application and 20 days before harvest), separated by a 7 day interval were made at a nominal rate of 15 g ai/ha for oxathiprolin and 90 g ai/ha for metalaxyl-M for P2 plot and one application (applied 20 days before harvest) was made at a nominal rate of 15 g ai/ha for oxathiprolin and 90 g ai/ha for metalaxyl-M for P3 plot. Treated samples were collected at 0, 6 – 7, 13 – 14, 19 – 20 and 26 – 28 days after the last application (DALA) for decline trials and at 20 days after the last application (DALA) for harvest trials. Untreated samples were collected at 19 – 20 DALA.

Residues of oxathiapiprolin and metalaxyl-M are summarised in the table below.

Actual Sampling Interval (days)	Oxathiapiprolin Residues in the range (mg/kg)	Metalaxyl-M Residues in the range (mg/kg)
Treated Plot (P2): at a rate of 90 g ai/ha (metalaxyl-M) and 15 g ai/ha (oxathiapiprolin)		
Kale (whole plant)		
0 DALA	0.24 – 0.18	0.82 – 1.52
6 - 7 DALA	0.07 – 0.02	0.15 – 0.23
13 - 14 DALA	0.02 – 0.02	0.06 – 0.07
19 - 20 DALA (NCH)	<0.01 – 0.02	<0.01 – 0.08
26 - 28 DALA	<0.01 - <0.01	<0.01 – 0.02
Treated Plot (P3): at a rate of 90 g ai/ha (metalaxyl-M) and 15 g ai/ha (oxathiapiprolin)		
Kale (whole plant)		
0 DALA	0.22 – 0.15	1.43 – 0.73
6 - 7 DALA	0.02 – 0.05	0.08 – 0.12
13 - 14 DALA	<0.01 – 0.03	0.04 – 0.04
19 - 20 DALA (NCH)	<0.01 – 0.02	<0.01 – 0.03
26 - 28 DALA	<0.01 – <0.01	<0.01 – 0.01
Control plot (C1) No residues of oxathiapiprolin or metalaxyl-M at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in any of the untreated kale samples.		

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

Samples were analysed for residues of oxathiapiprolin using DuPont method DuPont-30422 and metalaxyl-M was analysed using method REM 181.13A with LOQ of 0.01 mg/kg.

Samples were stored frozen for a maximum period of ca 6 months (178 days) from sampling to analysis for oxathiapiprolin and ca 6 months (185 days) for metalaxyl-M.

The study is acceptable.

Reference:	KCA2 6.3.2/01
Report	Oxathiapiprolin/Metalaxyl-M – Determination of residues of Oxathiapiprolin and Metalaxyl-M in Kale from Trials conducted in NEU in 2020, Brown S., 2021, report No RES-00256, document No VV-901782
Guideline(s):	Yes OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009. Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 52: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) : Oxathiapiprolin / Metalaxyl-M – Determination of residues of Oxathiapiprolin and Metalaxyl-M in Kale from Trials conducted in NEU in 2020			
Active Substance (common name):	oxathiapiprolin	**Commercial Product (name):**	
Crop/Crop Group:	Kale	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	UNITED KINGDOM, AUSTRIA, FRANCE	**Other active substance in the formulation (common name and content):**	A23109A: Metalaxyl-M (180 g/L)
Content of active substance (g/kg or g/L):	A23109A: 30 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A23109A DC		
Analytical Method:	Oxathiapiprolin (Whole plant) DuPont-30422; 0.01 mg/kg		
Recovery data:	Oxathiapiprolin Whole plant Mean = 90% RSD = 4% (n = 15 in 0.01 – 0.5 spiking range)		

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date €	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial €
			g a.s./ ha	Water (L/ha)	g a.s./hL				Oxathiapiprolin		
684539 UNITED KINGDOM (KY10 3XB) Europe North 2020	Kale / Reflex	1.15 Jun 2020 2 – 3 -	1. 14.3831 2. 14.175	1. 384.02778 2. 378.4722		12. 12 Jan 2021 2. 19 Jan 2021	1. BBCH 49 2. BBCH 49	Whole plant	0.24	0	Field SP (max days): 37
								Whole plant	0.02	7	
								Whole plant	0.02	14	
								Whole plant	<u>0.01</u>	20	
								Whole plant	< 0.01	28	
	Kale / Reflex	1.15 Jun 2020 2 – 3 -	1. 14.5911	1. 389.5833		12. 19 Jan 2021	1. BBCH 49	Whole plant	0.22	0	Field SP (max days): 37
								Whole plant	0.02	7	
								Whole plant	< 0.01	14	
								Whole plant	< 0.01	20	
								Whole plant	< 0.01	28	
MLI-20-45526 AT04 AUSTRIA (2471) Europe North 2020	Kale / Oldenbor F1	1.17 Jun 2020 2 – 3 -	1. 14. 2. 15	1. 298 2. 300		12. 12 Aug 2020 2. 19 Aug 2020	1. BBCH 45-45 2. BBCH 47-47	Whole plant	<u>< 0.01</u>	20	Field SP (max days): 170

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date €	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial €
			g a.s./ ha	Water (L/ha)	g a.s./hL				Oxathiapiprolin		
	Kale / Oldenbor F1	1.17 Jun 2020 2 – 3 -	12. 14.55	1. 291		12. 19 Aug 2020	1. BBCH 47-47	Whole plant	< 0.01	20	Field SP (max days): 170
MLI-20-45526 FR01 FRANCE (62232) Europe North 2020	Kale / Nebraska	1.23 Jun 2020 2 – 3 -	1. 14.8 2. 16.1425	1. 493.3333 2. 538.6222		12. 27 Aug 2020 2. 04 Sep 2020	1. BBCH 41-42 2. BBCH 43-45	Whole plant	0.18	0	Field SP (max days): 174
								Whole plant	0.07	6	
								Whole plant	0.02	13	
								Whole plant	0.02	19	
								Whole plant	< 0.01	26	
	Kale / Nebraska	1.23 Jun 2020 2 – 3 -	1. 15.4765	1. 516.4		12. 04 Sep 2020	1. BBCH 43-45	Whole plant	0.15	0	Field SP (max days): 174
								Whole plant	0.05	6	
								Whole plant	0.03	13	
								Whole plant	0.02	19	
								Whole plant	< 0.01	26	
MLI-20-45526 GB03 UNITED KINGDOM (GL55 6LB) Europe North 2020	Kale / Oldenbor	1.08 Jun 2020 2 – 3 -	1. 15.3479 2. 15.3479	1. 307.7767 2. 307.7767		12. 17 Sep 2020 2. 25 Sep 2020	1. BBCH 47-47 2. BBCH 48-48	Whole plant	< 0.01	20	Field SP (max days): 133
	Kale / Oldenbor	1.08 Jun 2020 2 – 3 -	1. 14.683	1. 294.4433		12. 25 Sep 2020	1. BBCH 48-48	Whole plant	< 0.01	20	Field SP (max days): 133

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

A 2.2.3.3 Head cabbage

Table A 53: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-20, BE-17, CZ-20, DE-20, NL-16, PL-20, PL-20a, SK-17*)	2	15 g as/ha	7-10 days	BBCH 12 – 49	20

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

Head cabbage – (Savoy cabbage)

Table A 54: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-40, CZ-43, DE-40, PL-40, PL-40a, SK-35*)	2	15 g as/ha	7-10 days	BBCH 12 – 49	20

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

A 2.2.3.3.1 Study 1 – CEMS-9523– New data

Comments of zRMS:	Eight residue field trials on cabbages were successfully conducted in Northern France, Austria, Hungary and Poland during 2020. Oxathiapiprolin/metalaxyl-M was applied to cabbages as A23109A, a dispersible concentrate (DC) formulation containing nominal 30 g oxathiapiprolin and 180 g metalaxyl-M per litre. Two applications to plot P2, applied at 27±1 and 20±1 days before normal commercial harvest were made at a nominal rate of 15 g ai/ha for oxathiapiprolin and 90 g ai/ha for metalaxyl-M. One application to plot P3, applied at 20±1 days before normal commercial harvest was made at a nominal rate of 15 g ai/ha for oxathiapiprolin and 90 g ai/ha for metalaxyl-M. For decline trials treated samples of cabbage were collected at 0, 7 – 8, 14 – 15, 19 – 21 and 27 – 29 days after the last application (DALA) with untreated cabbage samples being collected at 19 – 21 DALA. For harvest trials untreated and treated samples of cabbage were collected at 20 days after the last application (DALA) to the treated plots.

Residues of oxathiapiprolin and metalaxyl-M are summarised in the table below.

Sampling Interval (days)	Oxathiapiprolin Residues (mg/kg)	Metalaxyl-M Residues (mg/kg)
Treated Plot (P2): at a rate of 2 x 15 g ai/ha oxathiapiprolin and 2 x 90 g ai/ha metalaxyl-M		
Cabbage-Whole Plant		
0 DALA	<0.01 – 0.09	0.01 – 0.63
7 DALA	<0.01	<0.01 – 0.05
14 - 15 DALA	<0.01	<0.01 – 0.02
19 - 21 DALA (NCH)	<0.01	<0.01 – 0.02
27 - 28 DALA	<0.01	<0.01 – 0.01
Treated Plot (P3): at a rate of 1 x 15 g ai/ha oxathiapiprolin and 1 x 90 g ai/ha metalaxyl-M		
Cabbage-Whole Plant		
0 DALA	<0.01 – 0.20	<0.01 – 1.14
7 DALA	<0.01	<0.01 – 0.06
14 - 15 DALA	<0.01	<0.01 – 0.02
19 - 21 DALA (NCH)	<0.01	<0.01
27 - 28 DALA	<0.01	<0.01
Control plot (C1) No residues of oxathiapiprolin or metalaxyl-M at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in any of the untreated cabbage samples.		

DALA: days after the last application
NCH: Normal Commercial Harvest

Specimens were stored frozen for a maximum period of 218 days (approximately 6 months) from sampling to analysis for oxathiapiprolin and metalaxyl-M.

Cabbage whole plant samples were analysed for oxathiapiprolin using method DuPont 30422 Supplement No. 1 and metalaxyl-M using method REM 181.13A with LOQ of 0.01 mg/kg.

The study is acceptable.

Reference: KCA 6.3.3/01

Report: Oxathiapiprolin/Metalaxyl-M – Residue Study on Cabbage in Northern France, Austria, Hungary and Poland in 2020, Ford K., 2021, report No CEMR-9523, document No VV-901921

Guideline(s): Yes
OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009.
Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).

Deviations: No

GLP: Yes

Acceptability: Yes

~~Reference:~~ ~~KCA2 6.3.3/01~~

~~Report~~ ~~Oxathiapiprolin/Metalaxyl-M – Residue Study on Cabbage in Northern France, Austria, Hungary and Poland in 2020, Ford K., 2021, report No CEMR-9523, document No VV-901921~~

~~Guideline(s):~~ ~~Yes~~
~~OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009.~~
~~Commission of the European Communities, General Recommendations for the~~

	~~Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).~~
~~Deviations:~~	~~No~~
~~GLP:~~	~~Yes~~
~~Acceptability:~~	~~Yes~~

Table A 55: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) : Oxathiapiprolin/Metalaxyl-M – Residue Study on Cabbage in Northern France, Austria, Hungary and Poland in 2020			
Active Substance (common name):	oxathiapiprolin	**Commercial Product (name):**	
Crop/Crop Group:	Cabbage	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	FRANCE, AUSTRIA, POLAND, HUNGARY	**Other active substance in the formulation (common name and content):**	A23109A: Metalaxyl-M (180 g/L)
Content of active substance (g/kg or g/L):	A23109A: 30 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A23109A DC		
Analytical Method:	Oxathiapiprolin (Whole plant) DuPont-30422; 0.01 mg/kg		
Recovery data:	Oxathiapiprolin Whole plant Mean = 80% RSD = N/A (n = 21 in 0.01 – 1 spiking range)		

Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment** g a.s./ ha	**Water (L/ha)**	**g a.s./hL**	**Dates of treatment or no. of treatments and last date** €	**Growth stage at last treatment or date**	**Portion analyzed**	**Residues (mg/kg)** Oxathiapiprolin	**PHI (days)** (d)	**Details on trial** €
MLI-20-45525 AT03 AUSTRIA (2471) Europe North 2020	Cabbage / Redma F1	1.17 Jun 2020 2 – 3 -	12. 14.675 2. 15.2	1. 293.5 2. 304		12. 26 Aug 2021 2. 02 Sep 2021	1. BBCH 43-43 2. BBCH 44-44	Whole plant	0.091, 0.1, 0.072 (Mean=0.0877)	0	Field SP (max days): 188
								Whole plant	< 0.01	7	
								Whole plant	< 0.01	14	
								Whole plant	<u>< 0.01</u>	19	
								Whole plant	< 0.01	29	
	Cabbage / Redma F1	1.17 Jun 2020 2 – 3 -	12. 15.2083	1. 304.1667		12. 02 Sep 2021	1. BBCH 44-44	Whole plant	0.2, 0.2, 0.2 (Mean=0.2)	0	Field SP (max days): 188
								Whole plant	< 0.01	7	
								Whole plant	< 0.01	14	
								Whole plant	< 0.01	19	
								Whole plant	< 0.01	29	
MLI-20-45525 AT07 AUSTRIA (4470) Europe North	Cabbage / var. alba (Braunschweiger)	1.24 Jun 2020 2 – 3 -	12. 15.7 2. 15.75	1. 314 2. 315		12. 08 Sep 2020 2. 15 Sep 2020	1. BBCH 47-47 2. BBCH 48-48	Whole plant	<u>< 0.01</u>	20	Field SP (max days): 150

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment g a.s./ ha	Water (L/ha)	g a.s./hL	Dates of treatment or no. of treatments and last date €	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg) Oxathiapiprolin	PHI (days) (d)	Details on trial €
	Cabbage / var. alba (Braunschweiger)	1.24 Jun 2020 2 – 3 -	12. 14.6667	1. 293.3333		12. 15 Sep 2020	1. BBCH 48-48	Whole plant	< 0.01	20	Field SP (max days): 150
MLI-20-45525 FR01 FRANCE (62232) Europe North 2020	Cabbage / Bloktor	1.23 Jun 2020 2 – 3 -	1. 14.875 2. 14.8876	1. 396.6667 2. 397.5		12. 27 Aug 2020 2. 02 Sep 2020	1. BBCH 41-42 2. BBCH 43-45	Whole plant	< 0.01	0	Field SP (max days): 181
								Whole plant	< 0.01	8	
								Whole plant	< 0.01	15	
								Whole plant	< 0.01	21	
								Whole plant	< 0.01	28	
	Cabbage / Bloktor	1.23 Jun 2020 2 – 3 -	12. 14.638	1. 390.8333		12. 02 Sep 2020	1. BBCH 43-45	Whole plant	< 0.01	0	Field SP (max days): 181
								Whole plant	< 0.01	8	
								Whole plant	< 0.01	15	
								Whole plant	< 0.01	21	
								Whole plant	< 0.01	28	
MLI-20-45525 FR05 FRANCE (41350) Europe North 2020	Cabbage / Platidou	1.29 Jul 2020 2 – 3 -	1. 16.008991 2. 13.8112	1. 534.1667 2. 460.8333		12. 04 Nov 2020 2. 10 Nov 2020	1. BBCH 43-45 2. BBCH 44-47	Whole plant	< 0.01	20	Field SP (max days): 94
	Cabbage / Platidou	1.29 Jul 2020 2 – 3 -	12. 16.4086	1. 547.5		12. 10 Nov 2020	1. BBCH 44-48	Whole plant	< 0.01	20	Field SP (max days): 94
	Cabbage / Busoni	1.05 Jul 2020						Whole plant	0.041	0	Field

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL				Oxathiapiprolin		
	(a)	(b)				€				(d)	€
MLI-20-45525 HU09 HUNGARY (6060) Europe North 2020		2 – 3 -	12. 15.438 2. 16.1041	1. 309.02833 2. 322.3617		12. 14 Oct 2020 2. 21 Oct 2020	1. BBCH 43-43 2. BBCH 44-44	Whole plant	< 0.01	7	SP (max days): 132
								Whole plant	< 0.01	14	
								Whole plant	< 0.01	21	
								Whole plant	< 0.01	27	
	Cabbage / Busoni	1.05 Jul 2020 2 – 3 -	12. 15.5213	1. 310.695		12. 21 Oct 2020	1. BBCH 44-44	Whole plant	0.027	0	Field SP (max days): 132
								Whole plant	< 0.01	7	
								Whole plant	< 0.01	14	
								Whole plant	< 0.01	21	
								Whole plant	< 0.01	27	
MLI-20-45525 HU10 HUNGARY (6793) Europe North 2020	Cabbage / Busido	1.25 Jun 2020 2 – 3 -	12. 15.1683 2. 15.4185	1. 404.04333 2. 410.71		12. 21 Nov 2020 2. 27 Nov 2020	1. BBCH 47-48 2. BBCH 47-48	Whole plant	< 0.01	20	Field SP (max days): 77
	Cabbage / Busido	1.25 Jun 2020 2 – 3 -	12. 14.8554	1. 395.71		12. 27 Nov 2020	1. BBCH 47-48	Whole plant	< 0.01	20	Field SP (max days): 77
		1.06 Jun 2020						Whole plant	0.012	0	Field

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date €	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial €
			g a.s./ ha	Water (L/ha)	g a.s./hL				Oxathiapiprolin		
MLI-20-45525 PL04 POLAND (99-321) Europe North 2020	Cabbage / Pierwszy zbiór	2 – 3 -	12. 15.07022 2. 14.883	1. 402.375 2. 397.375		12. 29 Jul 2020 2. 05 Aug 2020	1. BBCH 44-46 2. BBCH 46-47	Whole plant	< 0.01	7	SP (max days): 211
								Whole plant	< 0.01	14	
								Whole plant	<u>< 0.01</u>	20	
								Whole plant	< 0.01	27	
	Cabbage / Pierwszy zbiór	1.06 Jun 2020 2 – 3 -	12. 15.4448	1. 412.375		12. 05 Aug 2020	1. BBCH 46-47	Whole plant	< 0.01	0	Field SP (max days): 211
								Whole plant	< 0.01	7	
								Whole plant	< 0.01	14	
								Whole plant	<u>< 0.01</u>	20	
								Whole plant	< 0.01	27	
MLI-20-45525 PL08 POLAND (63-304) Europe North 2020	Cabbage / Zuleima	1.11 May 2020 2 – 3 -	12. 14.8716 2. 15.7046	1. 297.5567 2. 314.2233		12. 25 Jul 2020 2. 01 Aug 2020	1. BBCH 43-43 2. BBCH 44-44	Whole plant	<u>< 0.01</u>	20	Field SP (max days): 195
	Cabbage / Zuleima	1.11 May 2020 2 – 3 -	12. 15.3714	1. 307.5567 L/ha		12. 01 Aug 2020	1. BBCH 44-44	Whole plant	< 0.01	20	Field SP (max days): 195

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

A 2.2.3.4 Brussels sprout

Table A 56: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-5, BE-5, CZ-5, DE-5, NL-5, PL-5, PL-5a, SK-5*)	2	15 g as/ha	7-10 days	BBCH 12 – 49	20

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

A 2.2.3.4.1 Study 1 – RES-00257 – New data

Comments of zRMS:

Two residue decline field trials and two harvest trials on brussels sprouts were conducted in northern Europe during 2020. Oxathiapiprolin and metalaxyl-M was applied to brussels sprouts as A23109[A], a dispersible concentrate (DC) formulation containing nominally 30 g of oxathiapiprolin per litre and 180 g of metalaxyl-M per litre.
For the harvest/decline trials and harvest only trials,
- To treated plot P2, two applications were made at a nominal rate of 15 g ai/ha for oxathiapiprolin (this equates to 90 g ai/ha for metalaxyl-M) at 27 – 28 DBH and the other at a nominal rate of 15 g ai/ha for oxathiapiprolin (this equates to 90 g ai/ha for metalaxyl-M) 7-8 days (9 days for harvest trial AT05) later at 20 – 21 DBH (19 DBH for harvest trial AT05). Following the applications, treated plot P2 samples for the harvest/decline trials of brussels sprouts buttons were collected at 0, 7, 14, 19 – 21 (NCH) and 27 – 28 days after last application (DALA). The harvest only trials for plot P2 were collected at 19 – 20 days (NCH) after last application (DALA).
- To treated plot P3, one application was made at a nominal rate of 15 g ai/ha for oxathiapiprolin (this equates to 90 g ai/ha for metalaxyl-M) at 19 – 21 DBH. Following the application, treated plot P3 samples for the harvest/decline and harvest only trials of brussels sprouts buttons were collected at 0, 7, 14, 20 – 21 (NCH) and 27 – 28 days after last application (DALA). The harvest only trials for plot P3 were collected at 19 – 20 days (NCH) after last application (DALA).
- Untreated brussels sprouts buttons samples were collected at 19 – 21 DALA (NCH) for the harvest/decline trial and harvest only trials.

Residues of oxathiapiprolin and metalaxyl-M are summarised in the table below.

Actual Sampling Interval (days)	Oxathiapiprolin Residues in the range (mg/kg)	Metalaxyl-M Residues in the range (mg/kg)
Treated Plot (P2): at a rate of 90 g ai/ha (metalaxyl-M) and 15 g ai/ha (oxathiapiprolin)		
Brussels Sprouts (buttons)		
0 DALA	<0.01 - <0.01	0.02 - 0.04
7 DALA	<0.01 - <0.01	<0.01 - 0.02
14 DALA	<0.01 - <0.01	<0.01 - 0.01
19 - 21 DALA (NCH)	<0.01 - 0.01	<0.01 - 0.01
27 - 28 DALA	<0.01 - <0.01	<0.01 - <0.01
Treated Plot (P3): at a rate of 90 g ai/ha (metalaxyl-M) and 15 g ai/ha (oxathiapiprolin)		
Brussels Sprouts (buttons)		
0 DALA	<0.01 - <0.01	<0.01 - 0.04
7 DALA	<0.01 - <0.01	<0.01 - 0.01
14 DALA	<0.01 - <0.01	<0.01 - 0.01
19 - 21 DALA (NCH)	<0.01 - <0.01	<0.01 - 0.01
27 - 28 DALA	<0.01 - <0.01	<0.01 - <0.01
Control plot (C1) No residues of oxathiapiprolin or metalaxyl-M at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in any of the untreated brussels sprouts samples.		

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

Field samples for residue analysis were analysed for oxathiapiprolin and metalaxyl-M using

	method DuPont-30422 and REM 181.13A with LOQ of 0.01 mg/kg. Samples were stored frozen for a maximum period of ca 4 months (121 days) from sampling to analysis for oxathiapiprolin and ca 4 months (119 days) for metalaxyl-M. The study is acceptable.

Reference:	KCA2 6.3.4/01
Report	Oxathiapiprolin/Metalaxyl-M – Determination of residues of Oxathiapiprolin and Metalaxyl-M in Brussels Sprouts from Trials conducted in NEU in 2020, Brown S., 2021, report No RES-00257, document No VV-901790
Guideline(s):	Yes OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009. Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 57: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) : Oxathiapiprolin / Metalaxyl-M – Determination of residues of Oxathiapiprolin and Metalaxyl-M in Brussels Sprouts from Trials conducted in NEU in 2020			
Active Substance (common name):	oxathiapiprolin	**Commercial Product (name):**	
Crop/Crop Group:	Brussels sprouts	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	FRANCE, POLAND, AUSTRIA	**Other active substance in the formulation (common name and content):**	A23109A: Metalaxyl-M (180 g/L)
Content of active substance (g/kg or g/L):	A23109A: 30 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A23109A DC		
Analytical Method:	Oxathiapiprolin (Sprouts) DuPont-30422 ; 0.01 mg/kg		
Recovery data:	Oxathiapiprolin Sprouts Mean = 89% RSD = 6% (n = 10 in 0.01 – 0.1 spiking range)		

Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** €	**Growth stage at last treatment or date**	**Portion analyzed**	**Residues (mg/kg)**	**PHI (days)** (d)	**Details on trial** €
			g a.s./ ha	**Water (L/ha)**	**g a.s./hL**				**Oxathiapiprolin**		
MLI-20-45527 AT05 AUSTRIA (3462) Europe North 2020	Brussels sprouts / Marte F1	1.28 Apr 2020 2 – 3 -	12. 13.5833 2. 15.2667	1. 271.6667 2. 305.3333		12. 06 Oct 2020 2. 15 Oct 2020	1. BBCH 47-47 2. BBCH 48-48	Sprouts	0.01	19	Field SP (max days): 122
	Brussels sprouts / Marte F1	1.28 Apr 2020 2 – 3 -	12. 14.5667	1. 291.3333		12. 15 Oct 2020	1. BBCH 48-48	Sprouts	< 0.01	19	Field SP (max days): 122
MLI-20-45527 FR01		1.29 May 2020						Sprouts	< 0.01	0	Field

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date €	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial €
			g a.s./ ha	Water (L/ha)	g a.s./hL				Oxathiapiprolin		
FRANCE (08190) Europe North 2020	Brussels sprouts / Gustus	2 – 3 -	12. 15.6646 2. 14.5008	1. 314.055 2. 290.7217		12. 06 Jan 2021 2. 14 Jan 2021	1. BBCH 48-49 2. BBCH 48-49	Sprouts	< 0.01	7	SP (max days): 50
								Sprouts	< 0.01	14	
								Sprouts	< 0.01	21	
								Sprouts	< 0.01	27	
	Brussels sprouts / Gustus	1.29 May 2020 2 – 3 -	12. 14.8333	1. 297.3883		12. 14 Jan 2021	1. BBCH 48-49	Sprouts	< 0.01	0	Field SP (max days): 50
								Sprouts	< 0.01	7	
								Sprouts	< 0.01	14	
								Sprouts	< 0.01	21	
								Sprouts	< 0.01	27	
MLI-20-45527 FR06		1.10 May 2020						Sprouts	< 0.01	0	Field

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date €	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial €
			g a.s./ ha	Water (L/ha)	g a.s./hL				Oxathiapiprolin		
FRANCE (59236) Europe North 2020	Brussels sprouts / Albarus	2 – 3 -	12. 14.875 2. 15	1. 396.6667 2. 400		12. 05 Nov 2020 2. 12 Nov 2020	1. BBCH 44-45 2. BBCH 44-45	Sprouts	< 0.01	7	SP (max days): 113
								Sprouts	< 0.01	14	
								Sprouts	<u>< 0.01</u>	20	
								Sprouts	< 0.01	28	
	Brussels sprouts / Albarus	1.10 May 2020 2 – 3 -	12. 15	1. 400		12. 12 Nov 2020	1. BBCH 44-45	Sprouts	< 0.01	0	Field SP (max days): 113
								Sprouts	< 0.01	7	
								Sprouts	< 0.01	14	
								Sprouts	< 0.01	20	
								Sprouts	< 0.01	28	
MLI-20-45527 PL04 POLAND (63-304) Europe North 2020	Brussels sprouts / Cyrus	1.11 May 2020 2 – 3 -	12. 14.705 2. 14.8716	1. 294.2233 2. 297.5567		12. 19 Oct 2020 2. 26 Oct 2020	1. BBCH 46-47 2. BBCH 47-48	Sprouts	<u>< 0.01</u>	20	Field SP (max days): 110
	Brussels sprouts / Cyrus	1.11 May 2020 2 – 3 -	12. 15.3714	1. 307.5567		12. 26 Oct 2020	1. BBCH 47-48	Sprouts	< 0.01	20	

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

A 2.2.3.5 Lettuce (open leaf)

Table A 58: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-29, BE-24, CZ-32, DE-29, NL-23, PL-29, SK-25*)	2	15 g as/ha	7 days	BBCH 12 – 49	10

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

Lettuce – (extrapolation to Baby leaf, chards and beet leaves, chicory, common purslane, cress, endive, escarole, herbs and edible flowers,231arsley, chives, iceberg lettuce, lamb's lettuce, red mustard, watercress, rocket, spinach)

Table A 59: Comparison of intended and critical EU GAPs – baby leaf

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-1, BE-1,CZ-1, DE-1, NL-1, PL-1, SK-1 *)	2	15 g as/ha	7 days	BBCH 08 – 49	10

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

Table A 60: Comparison of intended and critical EU GAPs – chards and beet leaves

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-8, CZ-8, DE-8, PL-8, SK-8*)	2	15 g as/ha	7 days	BBCH 12 – 49	10

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

Table A 61: Comparison of intended and critical EU GAPs – chicory

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-9, CZ-9, DE-9, PL-9*)	2	15 g as/ha	7 days	BBCH 12 – 49	10

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

Table A 62: Comparison of intended and critical EU GAPs – common purslane

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-11, CZ-11, DE-11, PL-11, SK-10*)	2	15 g as/ha	7 days	BBCH 12 – 49	10

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

Table A 63: Comparison of intended and critical EU GAPs – cress

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-12, BE-9, CZ-12, DE-12, PL-12, SK-11*)	2	15 g as/ha	7 days	BBCH 12 – 49	10

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

Table A 64: Comparison of intended and critical EU GAPs – endive

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-15, BE-12, CZ-15, DE-15, NL-11, PL-15*)	2	15 g as/ha	7 days	BBCH 12 – 49	10

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

Table A 65: Comparison of intended and critical EU GAPs – escarole

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-16, BE-13, CZ-16, DE-16, NL-12, PL-16*)	2	15 g as/ha	7 days	BBCH 12 – 49	10

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

Table A 66: Comparison of intended and critical EU GAPs – parsley, herbs and edible flowers

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-21, AT-33, BE-18, CZ-21, CZ-36, DE-21, DE-33, NL-17, PL-21, PL-33, SK-18, SK-29*)	2	15 g as/ha	7 days	BBCH 12 – 49	10

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

Table A 67: Comparison of intended and critical EU GAPs – iceberg lettuce

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (CZ-22*)	2	15 g as/ha	7 days	BBCH 12 – 49	10

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

Table A 68: Comparison of intended and critical EU GAPs – lamb's lettuce

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-24, BE-19, CZ-27, DE-24, NL-18, PL-24*)	2	15 g as/ha	7 days	BBCH 12 – 49	10

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

Table A 69: Comparison of intended and critical EU GAPs – red mustard

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-30, CZ-33, DE-30, PL-30, SK-26*)	2	15 g as/ha	7 days	BBCH 12 – 49	10

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

Table A 70: Comparison of intended and critical EU GAPs – watercress

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-46, BE-35, CZ-49, DE-46, PL-46, SK-41*)	2	15 g as/ha	7 days	BBCH 12 – 49	10

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

Table A 71: Comparison of intended and critical EU GAPs – rocket

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-38, BE-29, CZ-41, DE-38, NL-28, PL-38*)	2	15 g as/ha	7 days	BBCH 12 – 49	10

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

Table A 72: Comparison of intended and critical EU GAPs – spinach

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-43, BE-32, CZ-46, DE-43, NL-31, PL-43, SK-38*)	2	15 g as/ha	7 days	BBCH 12 – 49	10

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

Table A 73: Comparison of intended and critical EU GAPs – chives

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-10, CZ-10, DE-10, PL-10, SK-9*)	2	15 g as/ha	7 days	BBCH 12 – 49	10

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

A 2.2.3.5.1 Study 1 – 696296– EU reviewed data

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

Reference:	KCA2 6.3.5/01
Report	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, Spence C., Brown D., 2011/12, report No 696296, document No Dupont-31734.

Guideline(s):	Yes OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009.
Deviations:	Not stated
GLP:	Yes
Acceptability:	Yes

Table A 74: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) : 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, UK, Germany	**Other active substance in the formulation (common name and content):**	
Content of active substance (g/kg or g/L):	Oxathiapiprolin 100 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	Oxathiapiprolin SE		
Analytical Method:	Oxathiapiprolin (Leaves) Charles river analytical method 1846a (Based on DuPont method 30422); 0.01 mg/kg		
Recovery data:	Oxathiapiprolin Mean = ≤8.0% RSD = 82-94% (n=2-10)		

Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** €	**Growth stage at last treatment or date**	**Portion analyzed**	**Residues (mg/kg)**	**PHI (days)** (d)	**Details on trial** €
			g a.s./ ha	**Water (L/ha)**	**g a.s./hL**				**Oxathiapiprolin**		
DuPont – 31734 01 NORTH FRANCE Europe north 2011	Open field Lettuce (Quello)	2011 2 – 3 – -	14 15	948 1018	0.0015 0.0015	05 Oct 2011 13 Oct 2011	BBCH 46 BBCH 48-49	Leaves	0.051 0.41	0* 0	Field SP (max Months): < 10 Months
			15 15	982 998	0.0015 0.0015	05 Oct 2011 12 Oct 2011	BBCH 46 BBCH 48	Leaves	0.24	1	
			16 15	1045 985	0.0015 0.0015	03 Oct 2011 10 Oct 2011	BBCH 45 BBCH 47	Leaves	0.31	3	
			15 15	1017 1023	0.0015 0.0015	29 Sep 2011 05 Oct 2011	BBCH 19 BBCH 46	Leaves	0.11	8	
			15 15	1014 990	0.0015 0.0015	27 Sep 2011 03 Oct 2011	BBCH 19 BBCH 45	Leaves	0.13	10	
DuPont – 31734 02 NORTH FRANCE Europe north 2011	Open field Lettuce (Maruschka)	2011 2 – 3 –	14 15	952 976	0.0015 0.0015	31 May 2011 08 Jun 2011	BBCH 75 BBCH 77	Leaves	0.048	7	Field SP (max Months): < 10 Months
			15 15	1000 1014	0.0015 0.0015	31 May 2011 08 Jun 2011	BBCH 74 BBCH 76	Leaves	0.069	7	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date €	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial €
			g a.s./ ha	Water (L/ha)	g a.s./hL				Oxathiapiprolin		
DuPont – 31734 06 GERMANY Europe north 2011	Open field Lettuce (Lollo Bionda)	2011 2 – 3 –	16 16	1020 988	0.0016 0.0016	15 Sep 2011 22 Sep 2011	BBCH 47 BBCH 49	Leaves	0.033 0.85	0* 0	Field SP (max Months): < 10 Months
			17 17	1028 1044	0.0016 0.0016	14 Sep 2011 21 Sep 2011	BBCH 17 BBCH 49	Leaves	0.59	1	
			16 16	972 972	0.0016 0.0016	12 Sep 2011 19 Sep 2011	BBCH 16 BBCH 48	Leaves	0.52	3	
			16 17	980 1044	0.0016 0.0016	05 Sep 2011 12 Sep 2011	BBCH 16 BBCH 16	Leaves	0.044	7	
			17 15	1044 956	0.0016 0.0016	08 Sep 2011 15 Sep 2011	BBCH 16 BBCH 47	Leaves	<u>0.070</u>	10	
DuPont – 31734 08 GERMANY Europe north 2011	Open field Lettuce (Eichblatt Rot Prunai)	2011 2 – 3 –	15 15	1007 1020	0.0015 0.0015	17 Jun 2011 25 Jun 2011	BBCH 47 BBCH 49	Leaves	0.019 0.25	0* 0	Field SP (max Months): < 10 Months
			15 15	1000 1013	0.0015 0.0015	17 Jun 2011 24 Jun 2011	BBCH 47 BBCH 49	Leaves	0.12	1	
			15 15	980 1000	0.0015 0.0015	15 Jun 2011 22 Jun 2011	BBCH 45 BBCH 48	Leaves	0.061	3	
			15 15	993 1013	0.0015 0.0015	11 Jun 2011 17 Jun 2011	BBCH 43 BBCH 47	Leaves	0.043	8	
			15 15	993 1007	0.0015 0.0015	08 Jun 2011 15 Jun 2011	BBCH 43 BBCH 45	Leaves	<u>0.027</u>	10	
DuPont – 31734 09 GERMANY	Open field Lettuce (Kitare)	2011 2 – 3 –	15 15	1013 1020	0.0015 0.0015	08 Jun 2011 15 Jun 2011	BBCH 43 BBCH 47	Leaves	<u>0.022</u>	7	Field SP (max Months):

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date €	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial €
			g a.s./ ha	Water (L/ha)	g a.s./hL				Oxathiapiprolin		
Europe north 2011			15 15	1007 933	0.0015 0.0015	08 Jun 2011 15 Jun 2011	BBCH 43 BBCH 47	Leaves	0.015	7	< 10 Months
DuPont – 31734 12 SOUTH UK Europe north 2011	Open field Lettuce (Emocion (Green Batavia))	2012 2 – 3 –	15 15	1017 994	0.0015 0.0015	17 May 2012 24 May 2012	BBCH 43 BBCH 47	Leaves	<u>0.19</u>	7	Field SP (max Months): < 10 Months
DuPont – 31734 16 SOUTH UK Europe north 2011	Open field Lettuce (Madrigon Multi Red Rossa)	2012 2 – 3 –	15 15	1017 994	0.0015 0.0015	17 May 2012 24 May 2012	BBCH 46 BBCH 46	Leaves	0.046 0.30	0* 0	Field SP (max Months): < 10 Months
			15 15	1010 1019	0.0015 0.0015	15 Oct 2012 22 Oct 2012	BBCH 47-48 BBCH 49	Leaves	0.26	1	
			15 15	1000 965	0.0015 0.0015	13 Oct 2012 22 Oct 2012	BBCH 47 BBCH 48-49	Leaves	0.082	3	
			15 15	1028 1005	0.0015 0.0015	09 Oct 2012 16 Oct 2012	BBCH 46-47 BBCH 47-48	Leaves	0.15	7	
			16 15	1063 1031	0.0015 0.0015	06 Oct 2012 13 Oct 2012	BBCH 46 BBCH 47	Leaves	<u>0.12</u>	10	
DuPont – 31734 17 GERMANY Europe north	Open field Lettuce (Lollo rosso)	2012 2 – 3 –	15 15	1013 1027	0.0015 0.0015	08 Jun 2012 15 Jun 2012	BBCH 19 BBCH 43	Leaves	<u>0.035</u>	7	Field SP (max Months): < 10 Months

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date €	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial €
			g a.s./ ha	Water (L/ha)	g a.s./hL				Oxathiapiprolin		
2011											

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

A 2.2.3.6 Leek

Table A 75: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-27, AT-28, BE-22, BE-23, CZ-30, CZ-31, DE-27, DE-28, NL-21, NL-22, PL-27, PL-28, SK-23, SK-24*)	2	15 g as/ha	12-14 days	BBCH 12 – 48	14

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

Leek – (extrapolation to Spring onions/green onions, Welsh onions)

Table A 76: Comparison of intended and critical EU GAPs – Spring /green/Welsh onions

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP – NEU (AT-44, AT-45, BE-33, BE-34, CZ-47, CZ-48, DE-44, DE-45, NL-32, NL-33, PL-44, PL-45, SK-39, SK-40*)	2	15 g as/ha	12-14 days	BBCH 12 – 48	14

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

A 2.2.3.6.1 Study 1 – CEMS-9521 – New data

Comments of zRMS:	Eight independent residue field trials on leeks were successfully conducted in Northern France, Poland, United Kingdom and Germany during 2020. Oxathiapiprolin/metalaxyl-M was applied to leeks as A23109A, a dispersible concentrate (DC) formulation containing nominal 30 g oxathiapiprolin and 180 g metalaxyl-M per litre. Two applications to plot P2, applied at 26±2 and 14±1 days before normal commercial harvest were made at a nominal rate of 15 g ai/ha for oxathiapiprolin and 90 g ai/ha for metalaxyl-M. One application to plot P3, applied at 14±1 days before normal commercial harvest was made at a nominal rate of 15 g ai/ha for oxathiapiprolin and 90 g ai/ha for metalaxyl-M. For decline trials, treated samples of leek were collected at 0, 3, 7-8, 14-15 and 20-22 days after the last application (DALA) with untreated leek samples being collected at 14-15 DALA. For harvest trials, untreated and treated samples of leek were collected at 14-15 days after the last application (DALA) to the treated plots. Residues of oxathiapiprolin and metalaxyl-M are summarised in the table below.

Sampling Interval (days)	Oxathiapiprolin Residues (mg/kg)	Metalaxyl-M Residues (mg/kg)
Leek-Whole Plant		
Treated Plot (P2): at a rate of 2 x 15 g ai/ha oxathiapiprolin and 2 x 90 g ai/ha metalaxyl-M		
0 DALA	0.018 – 0.19	0.010 – 0.680
3 DALA	0.011 – 0.077	<0.01 – 0.140
7-8 DALA	<0.01 – 0.036	<0.01 – 0.012
14-15 DALA (NCH)	<0.01 – 0.028	<0.01 – 0.021
20-22 DALA	<0.01	<0.01
Treated Plot (P3): at a rate of 1 x 15 g ai/ha for oxathiapiprolin and 1 x 90 g ai/ha for metalaxyl-M		
0 DALA	0.010 – 0.10	<0.01 – 0.52
3 DALA	<0.01 – 0.062	<0.01 – 0.14
7-8 DALA	<0.01 – 0.016	<0.01 – 0.011
14-15 DALA (NCH)	<0.01 – 0.015	<0.01 – 0.019
20-22 DALA	<0.01	<0.01
Control plot (C1) No residues of oxathiapiprolin or metalaxyl-M at or above the limit of quantification (LOQ, 0.01 mg/kg) were found in any of the untreated leek samples.		

DALA: days after the last application
NCH: Normal Commercial Harvest

Leek whole plant samples were analysed for oxathiapiprolin using method DuPont 30422 Supplement No. 1 and for metalaxyl-M using method REM 181.13A with LOQ of 0.01 mg/kg.

Specimens were stored frozen for a maximum period of 188 days (approximately 6 months) from sampling to analysis for oxathiapiprolin and metalaxyl-M.
The study is acceptable.

Reference:	KCA2 6.3.6/01
Report	Oxathiapiprolin/Metalaxyl-M – Residue Study on Leek in Northern France, Poland, United Kingdom and Germany in 2020, Ford K., 2021, report No CEMR-9521, document No VV-901936
Guideline(s):	Yes OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009. Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 77: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) : Oxathiapiprolin/Metalaxyl-M - Residue Study on Leek in Northern France, Poland, United Kingdom and Germany 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, GERMANY, FRANCE, POLAND	**Other active substance in the formulation (common name and content):**	A23109A: Metalaxyl-M (180 g/L)
Content of active substance (g/kg or g/L):	A23109A: 30 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A23109A DC		
Analytical Method:	Oxathiapiprolin (Whole plant) DuPont-30422; 0.01 mg/kg		
Recovery data:	Oxathiapiprolin Whole plant Mean = 88% RSD = 14% (n = 23 in 0.01 - 1 spiking range)		

Trial No./ Location/ EU zone/ Year	**Commodity/ Variety**	**Date of 1.Sowing or planting 2.Flowering 3. Harvest**	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Portion analyzed**	**Residues (mg/kg)**	**PHI (days)**	**Details on trial**
			g a.s./ ha	**Water (L/ha)**	**g a.s./hL**				**Oxathiapiprolin**		
	(a)	(b)				(c)				(d)	(e)
SRDE20-120-037FR GERMANY (74206) Europe North 2020	Leek / Megaton	1.11 Apr 2020 2 – 3 -	1. 14.7217 2. 15.9701	1. 393.06818 2. 426.4015		1. 13 Jul 2020 2. 24 Jul 2020	1. BBCH 47-48 2. BBCH 48-48	Whole plant	0.0842	0	Field SP (max days): 198
								Whole plant	0.0209	3	
								Whole plant	0.0116	7	
								Whole plant	< 0.01	14	
								Whole plant	< 0.01	21	
	Leek / Megaton	1.11 Apr 2020 2 – 3 -	1. 15.8566	1. 423.3712		1. 24 Jul 2020	1. BBCH 48-48	Whole plant	0.0912	0	Field SP (max days): 198
								Whole plant	0.0131	3	
								Whole plant	< 0.01	7	
								Whole plant	< 0.01	14	
								Whole plant	< 0.01	21	
SRDE20-121-037FR GERMANY	Leek / Elefant	1.05 May 2020 2 – 3 -	1. 14.6605 2. 14.5128	1. 391.2503 2. 387.3109		1. 31 Jul 2020 2. 12 Aug 2020	1. BBCH 47-49 2. BBCH 48-49	Whole plant	< 0.01	14	Field SP (max days): 164

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment g a.s./ ha	Water (L/ha)	g a.s./hL	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg) Oxathiapiprolin	PHI (days) (d)	Details on trial (e)
(85748) Europe North 2020	Leek / Elefant	1.05 May 2020 2 – 3 -	1. 14.2744	1. 380.9473		1. 12 Aug 2020	1. BBCH 48-49	Whole plant	< 0.01	14	Field SP (max days): 164
SRFR20-045-037FR FRANCE (71570) Europe North 2020	Leek / Portura	1.17 Jun 2020 2 – 3 -	1. 15.7046 2. 14.3718	1. 314.2233 2. 287.5567		1. 04 Sep 2020 2. 15 Sep 2020	1. BBCH 47-47 2. BBCH 48-48	Whole plant	0.0793	0	Field SP (max days): 143
								Whole plant	0.0166	3	
								Whole plant	0.0095	7	
								Whole plant	< 0.01	14	
								Whole plant	< 0.01	20	
			1. 15.3714	1. 307.5567		1. 15 Sep 2020	1. BBCH 48-48	Whole plant	0.065	0	Field SP (max days): 143
								Whole plant	0.0125	3	
								Whole plant	< 0.01	7	
								Whole plant	< 0.01	14	
								Whole plant	< 0.01	20	
SRFR20-046-037FR FRANCE (71290) Europe North 2020	Leek / Portura	1.18 Jun 2020 2 – 3 -	1. 15.3714 2. 15.8712	1. 307.5567 2. 317.5567		1. 03 Sep 2020 2. 16 Sep 2020	1. BBCH 47-47 2. BBCH 48-48	Whole plant	< 0.01	15	Field SP (max days): 127
	Leek / Portura	1.18 Jun 2020 2 – 3 -	1. 14.5384	1. 290.89		1. 16 Sep 2020	1. BBCH 48-48	Whole plant	< 0.01	15	Field SP (max days): 127
SRPL20-030-037FR	Leek / Jolant	1.10 Jun 2020 2 –	1. 14.8969 2. 14.8301	1. 595.3333 2. 592.6667		1. 08 Sep 2020 2. 21 Sep 2020	1. BBCH 48- 2. BBCH 48-	Whole plant	0.1915	0	Field
								Whole plant	0.0768	3	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL				Oxathiapiprolin		
	(a)	(b)				(c)				(d)	(e)
POLAND (05-870) Europe North 2020		3 -						Whole plant	0.0357	7	SP (max days): 137
								Whole plant	0.0166	14	
								Whole plant	< 0.01	21	
	Leek / Jolant	1.10 Jun 2020 2 – 3 -	1. 14.9719	1. 598.3333		1. 21 Sep 2020	1. BBCH 48-	Whole plant	0.1041	0	Field SP (max days): 137
								Whole plant	0.0616	3	
								Whole plant	0.0159	7	
								Whole plant	0.0113	14	
								Whole plant	< 0.01	21	
SRPL20-031-037FR POLAND (88-400) Europe North 2020	Leek / Porbella	1.05 May 2020 2 – 3 -	1. 14.06667 2. 14.3417	1. 375.1111 2. 382.4444		1. 06 Aug 2020 2. 19 Aug 2020	1. BBCH 45- 2. BBCH 47-49	Whole plant	0.0179	0	Field SP (max days): 170
								Whole plant	0.0113	3	
								Whole plant	< 0.01	8	
								Whole plant	< 0.01	15	
								Whole plant	< 0.01	22	
	Leek / Porbella	1.05 May 2020 2 – 3 -	1. 14.625	1. 390		1. 19 Aug 2020	1. BBCH 47-49	Whole plant	0.0103	0	Field SP (max days): 170
								Whole plant	< 0.01	3	
								Whole plant	< 0.01	8	
								Whole plant	< 0.01	15	
								Whole plant	< 0.01	22	
SRUK20-009-037FR UNITED KINGDOM	Leek / Warwick	1.09 Apr 2020 2 – 3 -	1. 15.8781 2. 16.3	1. 318.8867 2. 321		1. 18 Sep 2020 2. 29 Sep 2020	1. BBCH 49-49 2. BBCH 49-49	Whole plant	< 0.01	14	Field SP (max days): 116

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (L/ha)	g a.s./hL				Oxathiapiprolin		
(LN4 4UY) Europe North 2020	Leek / Warwick	1.09 Apr 2020 2 – 3 -	1. 15.8879	1. 317.89		1. 29 Sep 2020	1. BBCH 49-49	Whole plant	< 0.01	14	Field SP (max days): 116
SRUK20-010-037FR UNITED KINGDOM (CB6 2BJ) Europe North 2020	Leek / Lexton Gostar	1.23 Jun 2020 2 – 3 -	1. 16.1711 2. 15.3881	1. 323.5567 2. 307.89		1. 05 Nov 2020 2. 17 Nov 2020	1. BBCH 49-49 2. BBCH 49-49	Whole plant	<u>0.0275</u>	14	Field SP (max days): 67
	Leek / Lexton Gostar	1.23 Jun 2020 2 – 3 -	1. 15.8712	1. 317.5567		1. 17 Nov 2020	1. BBCH 49-49	Whole plant	0.0151	14	Field SP (max days): 67

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

A 2.2.3.7 Onion

Table A 78: 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 EU (EFSA, 2015)	3	20 g as/ha	7 days	BBCH 12 - 48	14
Intended cGAP – NEU (AT-31, AT-32, BE-25, BE-26, CZ-34, CZ-35, DE-31, DE-32, NL-24, NL-25, PL-31, PL-32, SK-27, SK-28*)	2	15 g as/ha	7 days	BBCH 12 - 48	14

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

Onion - (bulb veges including shallots, garlic)

Table A 79: 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 EU (EFSA, 2015)	3	150 g as/ha	7 days	BBCH 12 - 48	14
Intended cGAP – NEU (AT-17, AT-18, AT-41, AT-42, BE-14, BE-15, BE-30, BE-31, CZ-17, CZ-18, CZ-44, CZ-45, DE-17, DE-18, DE-41, DE-42, NL-13, NL-14,NL-29, NL30, PL-17, PL-18, PL-41, PL-42, SK-14, SK-15, SK-36, SK-37*)	2	87.2 g as/ha	7 days	BBCH 12 - 48	14

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

A 2.2.3.7.1 Study 1 – Dupont-31988 – EU reviewed data

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

Reference:	KCA2 6.3.7/01
Report	Decline and magnitude of residues of DPX-QGU42 and its metabolites in dry bulb onions (Bulb vegetables) following foliar application of DPX-QGU42 100 g/L OD or DPX-QGU42 100 g/L SE - Europe 2012-2013, Spence, C. Brown, D., 2015, document No Dupont-31988.
Guideline(s):	Yes OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009. SANCO/825/00 rev. 8.1 (2010)
Deviations:	Not stated
GLP:	Yes
Acceptability:	Yes

Table A 80: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) : Decline and magnitude of residues of DPX-QGU42 and its metabolites in dry bulb onions (Bulb vegetables) following foliar application of DPX-QGU42 100 g/L OD or DPX-QGU42 100 g/L SE - Europe 2012-2013			
Active Substance (common name):	Oxathiapiprolin	**Commercial Product (name):**	
Crop/Crop Group:	Onion	**Producer of commercial product:**	DuPont
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	Austria, Czech Republic, France, United Kingdom, Poland, Italy, Germany, Greece, Hungary, Spain	**Other active substance in the formulation (common name and content):**	
Content of active substance (g/kg or g/L):	Oxathiapiprolin 100 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	Oxathiapiprolin OD or oxathiapiprolin SE		
Analytical Method:	Oxathiapiprolin Onion (Dry bulb) DuPont-30422 supplement No. 1		
Recovery data:	Oxathiapiprolin Onion (Dry bulb) Mean = 87% RSD =88.7% (n=12)		

Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (c)	**Growth stage at last treatment or date**	**Portion analyzed**	**Residues (mg/kg)**	**PHI (days)** (d)	**Details on trial** (e)
			g a.s./ ha	**Water (L/ha)**	**g a.s./hL**				**Oxathiapiprolin**		
DuPont – 31988 01 AUSTRIA North Europe 2012	Dry bulb Onions (Spirit)	11 April 2011 NR 28 Aug 2012	19.87 20.19 20.67 OD	399 405 415	4.98 4.98 4.98	06 Aug 2012 13 Aug 2012 20 Aug 2012	BBCH 45 BBCH 46-47 BBCH 47	Bulb	<0.01	8	field SP (max months): <11 months
	Dry bulb Onions (Spirit)	11 April 2011 NR 28 Aug 2012	19.29 20.26 19.34 SE	397 417 398	4.86 4.86 4.86	06 Aug 2012 13 Aug 2012 20 Aug 2012	BBCH 45 BBCH 46-47 BBCH 47	Bulb	<0.01	8	field SP (max months): <11 months
DuPont – 31988 02 CZECH REPUBLIC North Europe 2012	Dry bulb Onions (Hybelle)	20 Mar 2012 NR 23 Aug 2012 -	20.28 20.30 20.52 OD	407 408 412	4.98 4.98 4.98	01 Aug 2012 08 Aug 2012 15 Aug 2012	BBCH 44 BBCH 45-46 BBCH 48	Bulb	<0.01	8	field SP (max months): <11 months
DuPont – 31988 02 CZECH REPUBLIC North Europe 2012	Dry bulb Onions (Hybelle)	20 Mar 2012 NR 23 Aug 2012	20.21 19.73 20.08 SE	416 406 414	4.86 4.86 4.86	01 Aug 2012 08 Aug 2012 15 Aug 2012	BBCH 44 BBCH 45-46 BBCH 48	Bulb	<0.01	8	field SP (max months): <11 months

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (L/ha)	g a.s./hL				Oxathiapiprolin		
DuPont – 31988 03 NORTH FRANCE North Europe 2012	Dry bulb Onions (Bennito)	26 Mar 2012 NR 18 Sep 2012	18.64 18.45 20.20 SE	384 380 415	4.85 4.86 4.87	28 Aug 2012 04 Sep 2012 11 Sep 2012	BBCH 47-48 BBCH 48 BBCH 48-49	Bulb	<0.01	0*	field SP (max months): <11 months field SP (max months): <11 months field SP (max months): <11 months
								Bulb	<0.01	0	
								Bulb	<0.01	1	
								Bulb	<0.01	3	
								Bulb	<0.01	7	
								Bulb	<0.01	10	
DuPont – 31988 04 UNITED KINGDOM North Europe 2012	Dry bulb onions (Arthur)	25 Feb 2012 NR 03 Sep 2012	20.10 19.71 19.23 SE	414 406 395	4.86 4.85 4.87	13 Aug 2012 20 Aug 2012 27 Aug 2012	BBCH 43 BBCH 43 BBCH 46	Bulb	<0.01	0*	field SP (max months): <11 months
								Bulb	<0.01	0	
								Bulb	<0.01	1	
								Bulb	<0.01	3	
								Bulb	<0.01	7	
								Bulb	<0.01	10	
DuPont – 31988 05 POLAND North Europe 2012	Dry bulb onions (Stuttgarter Riese)	15 May 2012 NR 15 Aug 2012	19.51 19.51 19.16 SE	402 402 395	4.86 4.86 4.86	25 Jul 2012 01 Aug 2012 08 Aug 2012	BBCH 43-45 BBCH 45 BBCH 47	Bulb	<0.01	0*	field SP (max months): <11 months
								Bulb	<0.01	0	
								Bulb	<0.01	1	
								Bulb	<0.01	3	
								Bulb	<0.01	7	
								Bulb	<0.01	10	
DuPont – 31988 06 SOUTH FRANCE South Europe 2012	Dry bulb onions (Carlos)	03 April 2012 NR 03 Sep 2012	20.83 19.72 20.62 OD	417 395 413	4.99 4.99 4.99	13 Aug 2012 20 Aug 2012 27 Aug 2012	BBCH 45 BBCH 45 BBCH 47	Bulb	<0.01	0*	field SP (max months): <11 months
								Bulb	<0.01	0	
								Bulb	<0.01	1	
								Bulb	<0.01	3	
								Bulb	<0.01	7	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (L/ha)	g a.s./hL				Oxathiapiprolin		
								Bulb	<0.01	10	
DuPont – 31988 07 GREECE South Europe 2012	Dry bulb onions (Morada de Amposta)	12 April 2012 NR 13 Aug 2012	20.02 19.96 19.89 OD	402 401 399	4.98 4.98 4.98	23 Jul 2012 30 Jul 2012 06 Aug 2012	BBCH 44-47 BBCH 45-47 BBCH 47-49	Bulb	<0.01	0*	field SP (max months): <11 months
								Bulb	<0.01	0	
								Bulb	<0.01	1	
								Bulb	<0.01	3	
								Bulb	<u><0.01</u>	7	
								Bulb	<0.01	10	
DuPont – 31988 08 SPAIN South Europe 2012	Dry bulb onions (Babosa)	08 March 2012 NR 05 June 2012	20.22 20.22 19.82 OD	406 405 397	4.98 4.99 4.99	14 May 2012 21 May 2012 28 May 2012	BBCH 45 BBCH 47 BBCH 48	Bulb	<0.01	0*	field SP (max months): <11 months
								Bulb	<0.01	0	
								Bulb	<0.01	1	
								Bulb	<0.01	3	
								Bulb	<u><0.01</u>	7	
								Bulb	<0.01	10	
DuPont – 31988 09 ITALY South Europe 2012	Dry Bulb Onions (Ramata di Milano)	23 March 2012 NR 20 Aug 2012	19.22 19.92 20.72 OD	386 400 415	4.98 4.98 4.98	30 Jul 2012 06 Aug 2012 13 Aug 2012	BBCH 43 BBCH 45 BBCH 47	Bulb	<u><0.01</u>	7	field SP (max months): <11 months
			18.55 19.52 19.42 SE	382 402 400	4.86 4.86 4.86	30 Jul 2012 06 Aug 2012 13 Aug 2012	BBCH 43 BBCH 45 BBCH 47	Bulb	<0.01	7	field SP (max months): <11 months
DuPont – 31988 10 ITALY South Europe 2012	Dry Bulb Onions (Early Figeres)	05 March 2012 NR 30 May 2012	19.62 20.42 19.42 OD	393 410 408	4.99 4.98 4.98	09 Mar 2012 16 May 2012 23 May 2012	BBCH 45 BBCH 45 BBCH 47	Bulb	<u><0.01</u>	7	field SP (max months): <11 months

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (L/ha)	g a.s./hL				Oxathiapiprolin		
DuPont – 31988 10 ITALY South Europe 2012	Dry Bulb Onions (Early Figeres)	05 March 2012 NR 30 May 2012	19.91 19.13 19.52 SE	409 393 401	4.87 4.87 4.87	09 Mar 2012 16 May 2012 23 May 2012	BBCH 45 BBCH 45 BBCH 47	Bulb	<0.01	7	field SP (max months): <11 months
DuPont – 31988 11 GERMANY North Europe 2013	Dry Bulb Onions (Wellington)	10 April 2013 NR 04 Sep 2013	19.91 19.13 19.52 OD	390 397 410	5.01 5.01 5.01	14 Aug 2013 21 Aug 2013 28 Aug 2013	BBCH 45 BBCH 45-47 BBCH 47	Bulb	<0.01	7	field SP (max months): <11 months
DuPont – 31988 12 HUNGARY North Europe 2013	Dry Bulb Onions (Elenka)	09 April 2013 NR 26 Aug 2013	19.87 19.93 19.59 OD	397 399 392	5.00 5.00 5.00	05 Aug 2013 12 Aug 2013 19 Aug 2013	BBCH 48 BBCH 48 BBCH 48	Bulb	<0.01	7	field SP (max months): <11 months
DuPont – 31988 13 NORTH FRANCE North Europe 2013	Dry Bulb Onions (Hyskin)	20 Mar 2013 NR 10 Sep 2013	18.92 19.62 19.92 OD	378 391 397	5.01 5.02 5.02	21 Aug 2013 28 Aug 2013 03 Sep 2013	BBCH 47 BBCH 47-48 BBCH 48	Bulb	<0.0	0*	field SP (max months): <11 months
								Bulb	<0.0	0	
								Bulb	<0.01	1	
								Bulb	<0.01	3	
								Bulb	<0.01	7	
								Bulb	<0.01	10	
DuPont – 31988 15 GREECE South Europe	Dry Bulb Onions (Local Thivas)	05 May 2013 NR 18 Jul 2013	20.08 20.02 20.19 OD	401 399 403	5.00 5.00 5.00	27 Jun 2013 04 Jul 2013 11 Jul 2013	BBCH 45-47 BBCH 47-48 BBCH 48-49	Bulb	<0.01	7	field SP (max months): <11 months

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (L/ha)	g a.s./hL				Oxathiapiprolin		
2013											
DuPont – 31988 16 ITALY South Europe 2013	Dry Bulb Onions (Bionda)	20 Apr 2013 NR 17 Aug 2013	20.62 19.42 20.92 OD	412 387 317	5.00 5.02 5.02	27 Jul 2013 03 Aug 2013 09 Aug 2013	BBCH 43 BBCH 45 BBCH 47	Bulb	<0.01	8	field SP (max months): <11 months
DuPont – 31988 17 SOUTH FRANCE South Europe 2013	Dry Bulb Onions (Turbo)	08 Apr 2013 NR 29 Sep 2013	19.32 19.72 19.92 OD	386 394 397	5.01 5.01 5.02	06 Sep 2013 12 Sep 2013 19 Sep 2013	BBCH 45 BBCH 45-47 BBCH 49	Bulb	<0.01	0*	field SP (max months): <11 months
								Bulb	<0.01	0	
								Bulb	<0.01	1	
								Bulb	<0.01	3	
								Bulb	<0.01	7	
								Bulb	<0.01	10	

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

A 2.2.4 Magnitude of residues in livestock

No new studies submitted

A 2.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

No new studies submitted

A 2.2.6 Magnitude of residues in representative succeeding crops

No new data is 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 evaluated and accepted by zRMS-PL in RR – Part B7 for A22773A/ Orondis Evo (2023). 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.s./ha during the flowering period of the oilseed rape. A commercial beehive 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 honeycombs 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. Beehives 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:	Honeybee (*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.s./ha. A commercial beehive 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 honeycombs, 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. Beehives 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 81: 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 82: Residues of oxathiapiprolin in honey - Trial SRFR20-001-037FC09

Sample No. Trial -001	Number and Nominal Rate of Application (g as/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 83: Residues of oxathiapiprolin in honey - Trial SRFR20-005-037FC09

Sample No. Trial -005	Number and Nominal Rate of Application (g as/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:	The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for A22773A/ Orondis Evo (2023). 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:	KCA2 6.10/2
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 (honeybee, *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.s./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 (honeybee, *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.s./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 84: 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 85: Application and use pattern of end-use product A20941A tested at Nîmes, Gard, Languedoc-Rousillon, France in 2021

Method/ Timing	**Rate g as/ha**	**Vol L/ha**	**Spray interval days**	**Total rate g as/ha**	**Tank mix adjuvants**
Foliar Spray	60.92	305	-	126.1	None
	65.20	326	7		None

Table A 86: 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 as/ha**	**Vol L/ha**	**Spray interval days**	**Total rate g as/ha**	**Tank mix adjuvants**
Foliar Spray	61.0	254	-	117.0	None
	56.0	233	7		None

Table A 87: Application and use pattern of end-use product A20941A tested at Macey, Aube, Champagne-Ardennes, France in 2021

Method/ Timing	**Rate g as/ha**	**Vol L/ha**	**Spray interval days**	**Total rate g as/ha**	**Tank mix adjuvants**
Foliar Spray	61.09	255	-	119.9	None
	58.77	245	28		None

Table A 88: Application and use pattern of end-use product A20941A tested at La Roda, Albacete, Castilla-La-Mancha, Spain in 2021

Method/ Timing	Rate g as/ha	Vol L/ha	Spray interval days	Total rate g as/ha	Tank mix adjuvants
Foliar Spray	60.08	401	-	117.0	None
	56.90	380	9		None

Table A 89: 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 90: 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 91: 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 92: 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.s./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 (honeybee, *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.s./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.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

A 3.1.1 Metalaxyl-M

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Metalaxyl-M

LOQs (mg/kg) range from:	0.01	to:	0.10
Toxicological reference values			
ADI (mg/kg bw/day):	0.08	ARfD (mg/kg bw):	0.5
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2015	Year of evaluation:	2015

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)
31%	NL toddler	24.45	13%	Apples	5%	Pears	4%	Table grapes	1%	
28%	DE child	22.01	16%	Apples	4%	Oranges	3%	Table grapes	0.5%	
16%	NL child	12.92	7%	Apples	3%	Table grapes	2%	Pears	0.7%	
10%	GEMS/Food G06	7.74	3%	Table grapes	1%	Tomatoes	1%	Apples	0.5%	
9%	FR child 3 15 yr	7.45	3%	Oranges	2%	Apples	0.9%	Table grapes	0.6%	
9%	DE women 14-50 yr	7.26	3%	Apples	2%	Oranges	1%	Wine grapes	0.4%	
9%	GEMS/Food G07	6.94	2%	Wine grapes	1%	Apples	1%	Oranges	0.7%	
9%	GEMS/Food G11	6.88	2%	Apples	1%	Wine grapes	1%	Table grapes	0.9%	
8%	FR toddler 2 3 yr	6.73	4%	Apples	1%	Oranges	0.5%	Mandarins	0.6%	
8%	DE general	6.66	3%	Apples	1%	Oranges	1%	Wine grapes	0.4%	
8%	GEMS/Food G08	6.40	2%	Apples	1%	Wine grapes	0.8%	Table grapes	0.7%	
8%	GEMS/Food G10	6.33	1%	Lettuces	1.0%	Oranges	0.9%	Apples	0.8%	
8%	PT general	6.23	3%	Wine grapes	1%	Apples	0.7%	Table grapes	0.3%	
8%	IE adult	6.15	2%	Wine grapes	0.9%	Oranges	0.9%	Apples	0.4%	
7%	DK child	5.89	3%	Apples	1%	Cucumbers	0.8%	Pears	0.4%	
7%	GEMS/Food G15	5.86	1%	Apples	1%	Wine grapes	0.8%	Table grapes	0.7%	
7%	ES child	5.76	2%	Oranges	2%	Lettuces	1%	Apples	0.4%	
7%	RO general	5.75	2%	Wine grapes	2%	Apples	0.7%	Tomatoes	0.4%	
7%	NL general	5.27	2%	Apples	0.9%	Oranges	0.7%	Wine grapes	0.4%	
7%	FR adult	5.25	3%	Wine grapes	1.0%	Apples	0.6%	Other lettuce and other salad plants	0.2%	
6%	ES adult	5.17	2%	Lettuces	1%	Oranges	1.0%	Apples	0.2%	
6%	UK toddler	5.15	2%	Apples	2%	Oranges	0.6%	Table grapes	0.5%	
6%	SE general	5.08	2%	Lettuces	1%	Apples	0.7%	Oranges	0.4%	
5%	IT adult	4.39	1%	Lettuces	1.0%	Apples	0.6%	Other lettuce and other salad plants	0.1%	
5%	IT toddler	4.27	1%	Apples	1%	Lettuces	0.5%	Tomatoes	0.2%	
5%	UK infant	4.09	2%	Apples	1%	Oranges	0.5%	Milk: Cattle	0.8%	
5%	PL general	3.81	3%	Apples	0.8%	Table grapes	0.4%	Pears	0.1%	
5%	DK adult	3.72	1%	Apples	1%	Wine grapes	0.4%	Table grapes	0.2%	
5%	FI 3 yr	3.64	1%	Apples	0.6%	Cucumbers	0.6%	Table grapes	0.2%	
4%	UK vegetarian	3.56	1%	Wine grapes	0.8%	Oranges	0.7%	Apples	0.2%	
4%	FR infant	3.34	2%	Apples	0.5%	Spinaches	0.2%	Pears	0.3%	
4%	UK adult	3.09	1%	Wine grapes	0.5%	Apples	0.5%	Oranges	0.2%	
4%	LT adult	2.93	2%	Apples	0.2%	Cucumbers	0.2%	Lettuces	0.2%	
4%	FI 6 yr	2.89	0.7%	Apples	0.4%	Cucumbers	0.4%	Table grapes	0.2%	
4%	FI adult	2.85	0.7%	Apples	0.5%	Lettuces	0.4%	Wine grapes	0.4%	
1.0%	IE child	0.77	0.4%	Apples	0.1%	Table grapes	0.1%	Oranges	0.1%	

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

A 3.1.2 Oxathiapiprolin

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)
11%	NL toddler	16.06	8%	Spinaches	0.9%	Escaroles/broad-leaved endives	0.8%	Table grapes		
5%	DE child	7.11	2%	Spinaches	0.7%	Table grapes	0.3%	Grape leaves and similar species		
5%	IT adult	7.05	1%	Lettuces	1%	Spinaches	0.7%	Other spinach and similar		
5%	SE general	6.71	1%	Lettuces	1%	Chinese cabbages/pe-tsai	0.7%	Spinaches		
5%	NL child	6.63	3%	Spinaches	0.5%	Table grapes	0.3%	Escaroles/broad-leaved endives		
4%	ES adult	6.21	2%	Lettuces	0.9%	Chards/beet leaves	0.8%	Spinaches		
4%	GEMS/Food G10	6.20	1%	Lettuces	1%	Chinese cabbages/pe-tsai	0.5%	Spinaches		
4%	FR infant	5.81	3%	Spinaches	0.4%	Leeks	0.3%	Chards/beet leaves		
4%	IE adult	5.69	1%	Spinaches	0.6%	Wine grapes	0.3%	Lettuces		
4%	IT toddler	5.59	1%	Lettuces	0.6%	Chards/beet leaves	0.6%	Spinaches		
4%	ES child	5.54	1%	Lettuces	0.9%	Spinaches	0.9%	Chards/beet leaves		
4%	GEMS/Food G06	5.48	1%	Tomatoes	0.5%	Table grapes	0.5%	Spinaches		
4%	NL general	5.11	2%	Spinaches	0.4%	Escaroles/broad-leaved endives	0.3%	Lettuces		
4%	GEMS/Food G11	5.00	1.0%	Spinaches	0.5%	Wine grapes	0.4%	Leeks		
3%	GEMS/Food G07	4.67	0.9%	Lettuces	0.7%	Wine grapes	0.4%	Spinaches		
3%	GEMS/Food G08	4.39	0.7%	Lettuces	0.5%	Wine grapes	0.3%	Tomatoes		
3%	FR adult	4.35	1%	Wine grapes	0.6%	Spinaches	0.5%	Other lettuce and other salad plants		
3%	FR toddler 2 3 yr	4.31	2%	Spinaches	0.4%	Leeks	0.3%	Cauliflowers		
3%	FR child 3 15 yr	4.23	1%	Spinaches	0.4%	Other lettuce and other salad plants	0.3%	Leeks		
3%	RO general	3.51	0.8%	Wine grapes	0.7%	Head cabbages	0.6%	Tomatoes		
3%	DE women 14-50 yr	3.50	0.5%	Spinaches	0.4%	Wine grapes	0.4%	Lettuces		
2%	GEMS/Food G15	3.49	0.5%	Wine grapes	0.4%	Head cabbages	0.4%	Lettuces		
2%	DE general	3.29	0.5%	Spinaches	0.4%	Wine grapes	0.3%	Lettuces		
2%	PT general	2.98	1%	Wine grapes	0.4%	Lettuces	0.3%	Tomatoes		
2%	UK vegetarian	2.81	0.5%	Lettuces	0.4%	Wine grapes	0.4%	Spinaches		
2%	FI 3 yr	2.53	0.7%	Spinaches	0.2%	Tomatoes	0.1%	Cucumbers		
2%	FI 6 yr	2.35	0.6%	Spinaches	0.3%	Lettuces	0.2%	Chinese cabbages/pe-tsai		
2%	UK adult	2.30	0.5%	Wine grapes	0.4%	Lettuces	0.2%	Spinaches		
1%	DK adult	2.00	0.5%	Wine grapes	0.3%	Lettuces	0.1%	Tomatoes		
1%	FI adult	1.92	0.5%	Lettuces	0.2%	Tomatoes	0.2%	Wine grapes		
1%	DK child	1.86	0.5%	Lettuces	0.2%	Cucumbers	0.2%	Tomatoes		
1%	PL general	1.53	0.3%	Tomatoes	0.2%	Head cabbages	0.2%	Table grapes		
1%	UK toddler	1.52	0.3%	Spinaches	0.2%	Tomatoes	0.1%	Table grapes		
0.7%	LT adult	0.96	0.2%	Lettuces	0.2%	Head cabbages	0.2%	Tomatoes		
0.6%	UK infant	0.90	0.3%	Cauliflowers	0.1%	Spinaches	0.1%	Tomatoes		
0.2%	IE child	0.33	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.

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

Not required.

A 3.3 IESTI calculations - Raw commodities

A 3.3.1 Metalaxyl-M

Unprocessed commodities

Results for children				**Results for adults**			
No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Escaroles/broad-leaved	3 / 0.31	12	1%	Escaroles/broad-leaved	3 / 0.31	6.3
2%	Lettuces	3 / 0.31	12	1%	Chards/beet leaves	1.5 / 0.31	5.9
1%	Spinaches	1.5 / 0.31	7.0	0.8%	Lettuces	3 / 0.31	3.8
1.0%	Chards/beet leaves	1.5 / 0.31	4.8	0.4%	Chinese cabbages/pe-tsai	0.2 / 0.08	2.0
0.7%	Kales	0.3 / 0.08	3.5	0.3%	Red mustards	3 / 0.31	1.6
0.5%	Chinese cabbages/pe-tsai	0.2 / 0.08	2.6	0.3%	Kales	0.3 / 0.08	1.5
0.4%	Bovine: Edible offals (other	0.3 / 0.3	2.2	0.2%	Spinaches	1.5 / 0.31	1.2
0.2%	Milk: Cattle	0.01 / 0.01	1.2	0.2%	Bovine: Edible offals (other	0.3 / 0.3	1.00
0.2%	Leeks	0.03 / 0.02	1.2	0.2%	Head cabbages	0.06 / 0.02	0.84
0.2%	Bovine: Kidney	0.3 / 0.3	1.1	0.1%	Bovine: Kidney	0.3 / 0.3	0.63
0.2%	Broccoli	0.2 / 0.02	1.00	0.1%	Purslanes	1.5 / 0.31	0.59
0.2%	Head cabbages	0.06 / 0.02	0.88	0.1%	Lamb's lettuce/corn salads	3 / 0.31	0.58
0.2%	Lamb's lettuce/corn salads	3 / 0.31	0.87	0.1%	Broccoli	0.2 / 0.02	0.57
0.2%	Roman rocket/rucola	3 / 0.31	0.83	0.1%	Swine: Edible offals (other	0.2 / 0.2	0.52
0.1%	Swine: Edible offals (other	0.2 / 0.2	0.60	0.09%	Swine: Kidney	0.2 / 0.2	0.44
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

A 3.3.2 Oxathiapiprolin

Not applicable; no ARfD set.

A 3.4 IESTI calculations - Processed commodities

A 3.4.1 Metalaxyl-M

Processed commodities

Results for children				**Results for adults**			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
4%	Escaroles/broad-leaved endi	3 / 0.31	21	1%	Escaroles/broad-leaved	3 / 0.31	6.3
2%	Chards/beet leaves / boiled	1.5 / 0.31	9.6	0.8%	Chards/beet leaves / boiled	1.5 / 0.31	3.9
0.9%	Spinaches / frozen; boiled	1.5 / 0.31	4.3	0.5%	Spinaches / frozen; boiled	1.5 / 0.31	2.6
0.4%	Kales / boiled	0.3 / 0.08	2.2	0.3%	Purslanes / boiled	1.5 / 0.31	1.3
0.4%	Broccoli / boiled	0.2 / 0.02	1.9	0.1%	Broccoli / boiled	0.2 / 0.02	0.58
0.2%	Leeks / boiled	0.03 / 0.02	1.2	0.08%	Cauliflowers / boiled	0.2 / 0.01	0.42
0.1%	Cauliflowers / boiled	0.2 / 0.01	0.70	0.07%	Leeks / boiled	0.03 / 0.02	0.37
0.1%	Shallots / boiled	0.02 / 0.02	0.32	0.04%	Onions / boiled	0.5 / 0.02	0.19
0.0%	Brussels sprouts / boiled	0.15 / 0.01	0.10	0.02%	Shallots / boiled	0.02 / 0.02	0.12
0.0%	Head cabbages / canned	0.06 / 0.01	0.06	0.02%	Head cabbages / canned	0.06 / 0.01	0.09
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
Expand/collapse list							

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Metalaxyl-M is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

A 3.4.2 Oxathiapiprolin

Not applicable; no ARfD set.

Appendix 4 Additional information provided by the applicant

zRMS comments:
Additional data on the comparability of residue levels resulting from the application of Oxathiapiprolin DC, Oxathiapiprolin OD and Oxathiapiprolin SC formulations has been accepted.

A 4.1 Assessment of the comparability of residue levels resulting from the application of Oxathiapiprolin DC, Oxathiapiprolin OD and Oxathiapiprolin SC formulations

Introduction

The proposed EU protected lettuce use of the new (Oxathiapiprolin DC) formulation A23109A is supported by residue studies conducted with an SC formulation. The studies presented below demonstrate comparability of oxathiapiprolin SC and OD formulations. According to MacLachlan and Hamilton (2010), experience shows that formulations diluted in water prior to application, containing oils or organic solvents, such as emulsifiable concentrates (EC) and dispersible concentrates (DC), produce comparable residues, especially when the time between application and harvest is greater than 7 days.
OD and DC formulations are both diluted in water in the spray tank prior to application to the crop; both OD and DC formulations are oil/organic solvent based. The PHI of A23109A in the proposed use on field lettuce is 10 days, so differences in formulations are unlikely to have an impact on residue values at harvest. According to SANTE/2019/12752 and OECD 509, OD and DC formulations can therefore be considered to be equivalent. Taking into account the formulation bridging studies summarised below, demonstrating comparability of SC and OD formulations, SC and DC formulations can also subsequently be considered to be equivalent.

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.

Materials and Methods

Comparative residue trials on crops from three different crop groupings 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 A91. Therefore, the following studies evaluating the comparability of SC and OD formulations are considered appropriate in the context of this submission.

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 (an OD formulation) and A21008A (an SC formulation). 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 93. 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 93: GAPs for side-by-side trials of the OD and SC formulations

Crop	Application rate (1x), g as/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 as/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)

Reference:	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, Hampton, M., 2015, Syngenta File No. VV-511307, Syngenta Report No. TK0221427.
Guideline(s):	United States Environmental Protection Agency, Residue Chemistry Test Guidelines, OPPTS 860.1000 (1996), Background. United States Environmental Protection Agency, Residue Chemistry Test Guidelines, OPPTS 860.1500 (1996), Crop Field Trials.
Deviations:	None
GLP:	Yes
Validity of the study:	Acceptable

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 93. Residue levels were determined as below.

Table A 94: 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 95 and indicate that the residues resulting from SC and OD formulations are not statistically different.

Table A 95: 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			
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)

Reference: 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, Hampton, M., 2015, Syngenta File No. VV-511309, Syngenta Report No. TK0221426.

Guideline(s): United States Environmental Protection Agency, Residue Chemistry Test Guidelines, OPPTS 860.1000 (1996), Background.
United States Environmental Protection Agency, Residue Chemistry Test Guidelines, OPPTS 860.1500 (1996), Crop Field Trials.

Deviations: None

GLP: Yes

Validity of the study: Acceptable

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 93. Residue levels were determined as below.

Table A 96: 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 97 and, with the exception of trial 2, indicate that the residues resulting from SC and OD formulations are not statistically different.

Table A 97: 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			
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)

Reference: 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, Hampton, M., 2015, Syngenta File No. VV-511263, Syngenta Report No. TK0221431.
Guideline(s): United States Environmental Protection Agency, Residue Chemistry Test Guidelines, OPPTS 860.1000 (1996), Background.
United States Environmental Protection Agency, Residue Chemistry Test Guidelines, OPPTS 860.1500 (1996), Crop Field Trials.
Deviations: None
GLP: Yes
Validity of the study: Acceptable

I

n 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 93. Residue levels were determined as below.

Table A 98: 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 99 and indicate that the residues resulting from SC and OD formulations are not statistically different.

Table A 99: 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)

Reference:	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, Hampton, M., 2015, Syngenta File No. VV-511265, Syngenta Report No. TK0221432.
Guideline(s):	United States Environmental Protection Agency, Residue Chemistry Test Guidelines, OPPTS 860.1000 (1996), Background. United States Environmental Protection Agency, Residue Chemistry Test Guidelines, OPPTS 860.1500 (1996), Crop Field Trials.
Deviations:	None
GLP:	Yes
Validity of the study:	Acceptable

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 93. Residue levels were determined as below.

Table A 100: 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 101 and indicate that the residues resulting from SC and OD formulations are not statistically different, with the exception of trial 3 where the results from the SC formulation were statistically lower.

Table A 101: 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	
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.

OD and DC formulations are both diluted in water in the spray tank prior to application to the crop; both OD and DC formulations are oil/organic solvent based. The PHI of A23109A in the proposed use on field lettuce is 10 days, so differences in formulations are unlikely to have an impact on residue values at harvest. According to SANTE/2019/12752 and OECD 509, OD and DC formulations can therefore be considered to be equivalent. Taking into account the formulation bridging studies demonstrating comparability of SC and OD formulations, SC and DC formulations can also subsequently be considered to be equivalent.

It can therefore be concluded that the residue data conducted using the SC formulation can be considered relevant to support the proposed EU GAPs for this DC formulation on protected lettuce 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
Hampton, M. M.	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 Number: TK0221426 Syngenta File Number: VV -511309 GLP Not published
Hampton, M. M.	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 Number: TK0221432 Syngenta File Number: VV -511265 GLP Not published
Hampton, M M.	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 Number: TK0221431 Syngenta File Number: VV -511263 GLP Not published