FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: MIEDZIAN 50 WP

Product name(s): **MIEDZIAN 50 WP,**

COBRESAL 50 WP, DALION 50 WP, SPATOR 50 WP

Chemical active substance:

Copper as copper oxychloride, 500 g/kg

Central Zone

Zonal Rapporteur Member State: **Poland**

CORE ASSESSMENT

(re-authorization according art. 43 and art. 51, Reg. 1107/2009)

Applicant: **Synthos Agro Sp. z o.o.**

Submission date: **07/2020**

MS Finalisation date: 01/2022; 08/2022

Version history

When	What
07/2020	Renewal of registration of plant protection product according art. 43 and art. 51, Reg. 1107/2009
03/2021	Additional information about GAP approved under first evaluation and under extension to minor uses for the Miedzian 50 WP (Table 7.1). GAP correction – minor uses (Table 7.1-1)
12/2021	Additional residue trials for apples, cherries, French bean
01/2022	Assessment by RMS.
08/2022	The Final RR

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

zRMS conclusions and corrections are marked in grey.

Applicant has presented letters of accesses to the protected data of copper compounds from:

Industrias Quimicas Del Valles, SA (IQV) and Cinkarna metalursko-kemicna industrija Celje, d.d. (members of European Union (EU) Copper Task Force for the renewal of approval of the active substance copper compounds)

Application regarding re-authorization according **art. 43, Reg. 1107/2009** applies to following crops:

- Apple, pear
- Cherry, sweet cherry, Peach
- Walnut, hazelnut
- Tomato (outdoor, indoor)
- Cucumber (outdoor)
- French bean, bean with pods
- Grape (table, wine)
- Currant

Application regarding extension of approval to minor uses (**art.51**) applies to following crops (marked in grey – Table 7.1-1):

- Quince, medlar
- Apricot, plum
- Aubergines (outdoor, indoor)
- Cucumber (indoor)
- Gherkins, Courgette
- Melon (indoor), pumpkins (indoor), watermelon (indoor)
- Peas with pods

Stability of Residues

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

Copper is an element and is inherently stable as it cannot be transformed into any other material. Therefore, under freezer storage conditions, residues of copper in crop commodities will be stable and copper is not expected to metabolise or to form degradation products.

Metabolism in plant and animal

The metabolism in plant and animal was assessed for annex 1 inclusion (approval) of the active substance. The data evaluated is sufficient to support the proposed uses.

The residue definitions agreed for monitoring and risk assessment:

Copper compounds (copper)

No further data are required.

Magnitude of residues in plants

Apple, pear

Proposed uses: 2-4 applications (interval 7-10), BBCH 00-07, BBCH 60-71, 0.75 kg Cu/ha, PHI: 7 days

Six residue new trials on apples were carried out in Poland in 2019 (4 harvest and 2 decline curve studies) and two decline studies in Poland in 2021 and submitted by the applicant in the framework of this application. Trials are accepted.

Trials GAP: 4 x 0.75 kg as/ha, BBCH 77-85, PHI 14d, outdoor

Determinations of residues of total copper were performed using the microwave mineralization with concentrated nitric acid and inductively coupled plasma – mass spectrometry (ICP/MS) method.

The limit of quantification (LOQ) for total copper was 0.5 mg/kg and the limit of detection was 0.15 mg/kg.

Results: 0.88, 0.96, 1.18, 1.72, 1.73, 2.50, 4.62, 4.73 mg/kg

Residues are below MRL for apples.

Additionally applicant refers to the trials on apple and pears evaluated at the EU level (EFSA 2018) and trials evaluated at the 1st approval of PPP- Report BA-06/07-2.

- Trials GAP (EU): 8x 0.375 as/ha, PHI 14, outdoor. Trials are not accepted due to too low application rate.

Results: <1.5, <1.5, <1.5 mg/kg (apples); <1.5, 1.52 mg/kg (pears).

And

Report BA-06/07-2 - – trials are considered as supportive only - GLP for field phase is unclear. The storage time of the sample until the analysis date is not specified. The study was performed due to properly validated method based on AOAC method no 960.40, 'Official Methods of Analysis', 15th ed., 1990, page 248 (GLP statement is available). Limit of quantification for copper residue in examined plant matrices was 0.10 mg/kg and a limit of detection was 0.025 mg/kg.

- Trials GAP: 4 x 0.75 kg as/ha, BBCH 39-73, PHI 14d, outdoor

Results: 0.177 mg/kg (pears), 0.235 mg/kg (apples)

Due to the lack of residue studies at PHI = 7 days, such this PHI cannot be recommended. A PHI of 14 days may be recommended. Apples and pears belong to major crops in CEU. 8 residue trials are required for each crop.

According to the available data, the intended use on apples is considered acceptable, for outdoor uses.

According to the SANTE/2019/12752 extrapolation from apples to whole group pome fruits is possible. Therefore, according to the available data, the intended use on pears is accepted.

Quince, medlar (pome fruits)

No residue trials have been submitted in the context of this evaluation.

According to the SANTE/2019/12752 extrapolation from apples to whole group pome fruits is possible. Therefore, according to the available data, the intended uses on quince and medlar are accepted.

Proposed use on quince and medlar should be same as proposed on apples. Therefore uses on quince and medlar are accepted only with PHI of 14 days.

Cherry, sweet cherry, apricot, plum, peach

Proposed uses:

Cherry

1 application, BBCH 51-61, 1.50 kg Cu/ha, PHI: 14 days

2 applications (interval 7-10), BBCH 65-73, 0.75 kg Cu/ha, PHI: 14 days

Apricot, plum

1 application, BBCH 51-61, 1.50 kg Cu/ha, PHI: 14 days

Peach

1 application, BBCH 00-03, 1.50 kg Cu/ha, PHI: 14 days

Applicant provided eight new trials (cherry)

- Trials GAP (cherries, new accepted trials) : 2 x 1.5 kg as/ha, 1x 0.75 as/ha, BBCH 73-85, PHI 14d, outdoor

Residues: 1.19, 1.88, 1.28, 2.09, 2.15, 2.20, 2.62, 3,84 mg/kg. Residues are below MRLs

- Trials evaluated at the 1st approval (report BA-06/07-2) - – trials are considered as supportive only - GLP for field phase is unclear. The storage time of the sample until the analysis date is not specified. The study was performed due to properly validated method based on AOAC method no 960.40, 'Official Methods of Analysis', 15th ed., 1990, page 248 (GLP statement is available). Limit of quantification for copper residue in examined plant matrices was 0.10 mg/kg and a limit of detection was 0.025 mg/kg.

E: 0.699, 0.416 mg/kg

Conclusion:

There are 8 acceptable trials on cherries available (new trials). Use is accepted.

Proposed uses on apricot, plum and peach are not more critical than uses on cherries.

According to the SANTE/2019/12752 extrapolation from apples (minimum 4 trials on apples) + cherries to Whole group Stone fruits is possible (only in the case of use before forming the edible part).

The same PHI is proposed by zRMS for cherry, sweet cherry, apricot and plum: 14 days. Uses are accepted.

Hazelnuts, walnuts

According to the SANTE/2019/12752 extrapolation from apples (minimum 4 trials on apples) + cherries to Whole group Tree nuts is possible.

Following use is only acceptable 1 x 1.5 kg as/ha (see cherry GAP). 2 applications are not accepted.

Uses are accepted. PHI = n.a. is accepted because application is in before flowering phase.

Tomato, aubergines (outdoor)

Proposed GAP:

3 x 1.25 kg Cu/ha, BBCH 51-85, interval: 7-10 days, PHI: 7 days.

Presented EU data (field tomatoes):

EFSA, 2018a,b (N-EU)

Trials GAP: 6 x 1.25 kg as/ha, BBCH 15-89, PHI 3 (fresh) or 10 (industrial) d, outdoor

E: 0.70, 1.50, 1.60, 1.60, 1.70, 1.70, 2.20, 4.30, 6.60 mg/kg

Above trials are not in line with proposed GAP (number of applications). One trial showed residue levels above current MRL (5 mg/kg). Therefore, these trials are not accepted to cover proposed uses.

New trials (Report 19SGS18) – trials are accepted

Trials GAP: 3 x 1.25 kg as/ha, BBCH 71-85, PHI 7d, outdoor

E: 1.89, 1.62 mg/kg

New trials (Report 451SRPL19R0) – trials are accepted

Trials GAP: 3x 1.125 kg a.s./ha, BBCH 71-85, PHI 7d, outdoor

E: 1.47, 1.02 mg/kg

Trial evaluated at the 1st approval (Report BA-06/07-2) is considered as supportive only - GLP for field phase is unclear. The storage time of the sample until the analysis date is not specified.

Report BA-06/07-2: Tomatoes cultivated in field were sprayed with 3.0 kg of Miedzian 50 WP preparation /ha. The study was performed due to properly validated method based on AOAC method no 960.40, 'Official Methods of Analysis', 15th ed., 1990, page 248 (GLP statement is available). Limit of quantification for copper residue in examined plant matrices was 0.10 mg/kg and a limit of detection was 0.025 mg/kg.

Trials GAP: 3 x 1.5 kg a.s./ha, BBCH 51-85, PHI 7d, outdoor

E: <0.1 mg/kg

Tomato is a major crop in CEU. Eight trials is required. There is available only four. This allows registration only in Poland where tomato is classified as minor crop. Extrapolation to aubergines/eggplants is possible with trials on tomato.

Tomato, aubergines (indoor)

Proposed GAP:

3 x 1.25 kg Cu/ha, BBCH 56-88, interval: 7-10 days, PHI: 3 days.

EU GAP: 6 x 1.25 kg Cu/ha, BBCH 15-89, interval: 7 days, PHI: 3 days (EFSA Journal 2018;16(3):5212)

3 x 1.25 kg Cu/ha, BBCH 12-89, interval: 7 days, PHI: 3 days, total applied must not exceed 28 kg of copper per hectare over a period of 7 years (SANTE/10506/2018 Rev. 5, 27 November 2018)

Trials GAP:

8 x 1140 – 2150 g a.s./ha, PHI 3d, indoor (6 trials);

6 x 0.78 – 1.37 kg a.s./ha, PHI 3d, indoor (4 trials)

BBCH 12-89.

E: 10x < 2.00

According to the available data, the intended uses on tomato and aubergine are considered acceptable, for indoor uses considering residue trials on tomato reported in the RAR (France, 2017).

Extrapolation to aubergines/eggplants is possible with trials on tomato.

Cucumber (outdoor)

Proposed GAP:

3 x 1.25 kg Cu/ha, BBCH 62-78, interval: 7 days, PHI: 3 days.

France, 2017	N-EU	Trials GAP: 4 x 0.800 kg as/ha, BBCH 10-89 PHI 3d, outdoor E: 1.35, 1.03, 0.92, 1.09, 1.81, 1.72, 1.43, 1.28 RA: n.a.

Above trials are not in line with proposed GAP (too low application rate). Therefore, these trials are not accepted to cover proposed uses.

New trials Report 19SGS17	C-EU	Trials GAP: 3 x 1.25 kg as/ha, BBCH 61-89, PHI 7d, outdoor E: <0.50, 0.99, 0.56, 0.60 RA: n.a.

Above trials are accepted. Due to the lack of accepted residue studies at PHI = 3 days, such this PHI cannot be recommended. A PHI of 7 may be recommended

Trial evaluated at the 1st approval (Report BA-06/07-2) – study is not accepted.

Cucurbits with edible peel are the major crops in CEU, and minor in Poland. Therefore 8 trials is required for CEU, and 4 for Poland (minor crop).

Use on cucumbers as minor crop in Poland is accepted.

Gherkins, Courgette

According to the SANTE/2019/12752 extrapolation from cucumbers to gherkins and courgette is possible.

Use as minor crop in Poland is accepted only. PHI = 7 days is proposed.

Cucumber (indoor)

Proposed GAP:

4 x 0.800 kg Cu/ha, BBCH 10-89, interval: 7 days, PHI: 3 days.

Applicant refers to the following EU data:

France, 2017	N-EU	Trials GAP: 4 x 0.800 kg as/ha, BBCH 10-89, PHI 3 d, indoor E: 4.04, 1.25, 0.89, 1.77, 2.57, 1.08, 1.04 RA: n.a.

Use on cucumber as minor crop in Poland is accepted.

Melon, Pumpkins, Watermelon (indoor)

Proposed GAP:

3 x 1.25 kg Cu/ha, BBCH 10-89, interval: 7 days, PHI: 7 days.

Applicant refers to the following EU data:

France, 2017 - Melon (indoor) EU Trials GAP: 5x 1.178-1.291 kg a.s./ha, BBCH 72-84, PHI 7d, indoor

E: < 2.00, < 2.00, < 2.10, < 1.97, < 2.10, 5.00 mg/kg

Use on melon as minor crop in Poland is accepted.

According to the SANTE/2019/12752 extrapolation from melons to Whole subgroup cucurbits with inedible peel is possible.

Uses on pumpkins, watermelon (indoor) as minor crops in Poland are accepted.

French bean, bean with pods, Peas with pods

Proposed GAP:

2 x 1.50 kg Cu/ha, BBCH 65-69, interval: 7 days, PHI: 7 days.

Applicant refers to the following data:

EFSA, 2018b	N-EU	Trials GAP: 4 x 0.800 kg as/ha, BBCH 61-78, PHI 3d, outdoor E: 2.26, 2.63, 3.22, 3.27, 3.48, 3.66 RA: n.a.
New trials Report 19SGS19	C-EU	Trials GAP: 2 x 1.5 kg as/ha, BBCH 69-81, PHI 7d, outdoor E: 8.05, 7.13 RA: n.a.
New trials Report 21SGS92	C-EU	Trials GAP: 2 x 1.5 kg as/ha, BBCH 71-74, PHI 7d, outdoor E: 1.68, 1.54 RA: n.a.
Evaluated at the 1st approval Report BA-06/07-2	EU	Separate trials with different dose of as/ha 2x 1.25 kg as/ha, BBCH 65-69, PHI 7d, outdoor E: 0.264 2x 1,5 kg as/ha, BBCH 65-69, PHI 7d, outdoor E: 0.843 2x 3.0 kg as/ha, BBCH 65-69, PHI 7d, outdoor E: 0.572 RA: n.a.

EFSA, 2018b trials are not in line with proposed GAP (too low application rate). Therefore, these trials are not accepted to cover proposed uses.

Evaluated at the 1st approval Report BA-06/07-2 study is not accepted.

Four new acceptable trials are were provided by the applicant. Use is accepted as minor use only.

According to the SANTE/2019/12752 extrapolation to peas is possible.

Grape (table, wine)

Proposed GAP:

3 x 1.25 kg Cu/ha, BBCH 13-17, 71-73, 73-77, interval: 10-14 days, PHI: 21 days.

Applicant refers to the following data:

France, 2007, 2017	N-EU	Trials GAP: 4x 2000 g a.s./ha, PHI 21d, outdoor E: <5, 6.9, 8.7, 9.9, 12, 45, 56 RA: n.a.

The data submitted show that exceedance of the MRL (50 mg/kg) will be possible. Trials are not in line with proposed GAP.

Use is not accepted.

Currant (black, red, white)

Proposed GAP:

2 x 1.20 kg Cu/ha, BBCH 59-65, 59-81, interval: 10 days, PHI: 7 days.

Applicant refers to the following data:

EFSA, 2018b	N-EU	Trials GAP: 2 x 1.2 kg as/ha, BBCH 13-57, outdoor E: 0.77, 1.04 RA: n.a.

New trials Report 19SGS20	EU	Trials GAP: 2 x 1.2 kg as/ha, BBCH 81-85, PHI 7d, outdoor E: 4.79, 3.66 (black currant) RA: n.a.

There is insufficient number of trials to cover BBCH 59-81.

Currant is the minor crop in CEU. Therefore 4 trials is required.

Proposed use at BBCH 59-65 is accepted.

Magnitude of residues in livestock

The feeding studies are not required.

Regarding available feeding data, there is no risk for animal MRL to be exceeded.

Industrial Processing and/or Household Preparation

No supplementary studies on the effects of industrial processing and/or household preparations on residue levels have been conducted or are required

Magnitude of residues in representative succeeding crops

EFSA Journal 2018;16(1):5152: *Based on the scientific literature, the experts agreed that plant would not absorb more than the essential nutritional amount. Therefore, field trials on rotational crops were not deemed necessary and a comprehensive survey on the copper background levels in plant commodities was used as a surrogate to assess the residue levels in all off-label crops (including rotational crops).*

No additional studies are required.

Consumer risk assessment

The proposed uses of copper in the formulation MIEDZIAN 50 WP do not represent unacceptable acute and chronic risks for the consumer.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation Miedzian 50 WP are presented in

~~Table 7.1 GAP evaluated and approved under first evaluation (2013) and under extension to minor uses (2016) for the Miedzian 50 WP~~

~~1~~	~~2~~	~~3~~	~~4~~	~~5~~	~~6~~	~~7~~	~~8~~	~~9~~	~~10~~	~~11~~
~~Use~~	~~Crop and/~~	~~Zone~~	~~Product~~	~~F, Fn,~~	~~Pests or Group of~~	~~Formulation~~	~~Application~~	~~Application rate per treatment~~	~~PHI (days)~~	~~Remarks:~~

No. (c)	or situation **		code	Fpn G, Gn, Gpn or I	pests controlled (additionally: developmental stages of the pest or pest group)	Type	Conc. of as	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg as/hL min / max	Water L/ha min / max	kg as/ha min max		
Zonal uses (field or outdoor uses, certain types of protected crops)																
1	Apple, pear	PL	Miedzian 50 WP	F	*Venturia inaequalis, Venturia pirina*	WP	500 g/kg	spraying	BBCH 00-07	1-2	7-10 days	-	500-750	0,75	7	
2	Apple, pear	PL	Miedzian 50 WP	F	*Ervinia amylovora*	WP	500 g/kg	spraying	BBCH 60-71	1-2	7-10 days	-	500-750	0,375-0,75	7	
3	Cherry, sweet cherry	PL	Miedzian 50 WP	F	*Pseudomonas syringae*	WP	500 g/kg	spraying	BBCH 51-61 BBCH 65-71 BBCH 72-73	1-3	7-10 dni	-	500-750	0,75 - 1,5	7	
4	Peach	PL	Miedzian 50 WP	F	*Taphrina deformans*	WP	500 g/kg	spraying	BBCH 00-03	1	-	-	700	3,5	Not applicable	
5	Sugar beet	PL	Miedzian 50 WP	F	*Cercospora beticola*	WP	500 g/kg	spraying	BBCH 39	1-3	7-14	-	200-400	2,5	7	**The crop was deleted in 2014 due to lack of residue trials**
6	Cucumber	PL	Miedzian 50 WP	F	*Pseudomonas syringa Pseudoperonospora cubensis*	WP	500 g/kg	spraying	BBCH 62-78	2-3	7-10 days	-	700	1,5	7	
7	Tomato (field)	PL	Miedzian 50 WP	F	*Phytophtora infestans Pseudomonas syringae*	WP	500 g/kg	spraying	BBCH 51-85	3	7-10 days	-	700	1,5	7	
8	Tomato (indoor)	PL	Miedzian 50 WP	I	*Phytophtora infestans Pseudomonas phaseolicola*	WP	500 g/kg	spraying	BBCH 56-88	3	7-10 days	-	1500-2000	3,0	7	
9	French bean	PL		F	*Botrytis cinerea Colletotrichum lindemuthianum*	WP	500 g/kg	spraying	BBCH 65-69	2	7 days	-	600-800	1,5	7	
Minor uses according to Article 51 (zonal uses)																
10	Grape	PL		F	*Plasmopara viticola*	WP	500 g/kg	spraying	I. BBCH 13-17 II. BBCH 71-73 III. BBCH 73-77	3	10 days	-	500-900	1,25	7	
11	Black currant	PL		F	*Drepanopeziza ribis Cronartium ribicola*	WP	500 g/kg	spraying	BBCH 59 – 81	3	10 days	-	700	1,5	7	

1	2	3	4	5	6	7		8				9			10	11
Use No. (c)	Crop and/ or situation **	Zone	Product code	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: develop-mental stages of the pest or pest group)	Formulation		Application				Application rate per treatment			PHI (days)	Remarks:
						Type	Conc. of as	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg as/hL min max	Water L/ha min / max	kg as/ha min max		
					Mycosphaerella ribis											
12	Walnut	PL		F	*Gnomonia leptostyla, Xantomonas campestris pv. Juglandis*	WP	500 g/kg	spraying	Before flowering	2	10-14 days	-	800-1000	1,5	Not applicable	
13	Huzelnut	PL		F	*Monilia coryli*	WP	500 g/kg	spraying	Before flowering	2	10-14 days	-	800-1000	1,5	Not applicable	
14	*Gonioolimon tataricum*	PL		F	*Peronospora statices*	WP	500 g/kg	spraying	Rosettes with 15-18 leaves	3	7 days	-	1000	1,0	Not applicable	

Table 7.1-1. They have been selected from the individual GAPs in the Central zone for pome fruits, stone fruits, tomato, cucumber, French bean, grape, currant, tree nuts and cucurbits with inedible peel. A list of all intended uses within the Central Zone is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 5 mg/kg for copper compounds for pome fruits, stone fruits, tomato, cucumber, black currant, cucurbits with inedible peel, and 20 mg/kg for beans, 30 mg/kg for tree nuts and 50 mg/kg for grape as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of copper compounds residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, Poland agrees with the authorization of the intended use(s).

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

Data gaps

Residue trials for:
Data gaps for Central Zone (see remarks in GAP Table).

Table 7.1 GAP evaluated and approved under first evaluation (2013) and under extension to minor uses (2016) for the Miedzian 50 WP

1	2	3	4	5	6	7		8				9			10	11
Use No. (c)	Crop and/ or situation **	Zone	Product code	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: develop-mental stages of the pest or pest group)	Formulation		Application				Application rate per treatment			PHI (days)	Remarks:
						Type	Conc. of as	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applica-tions (days)	kg as/hL min - max	Water L/ha min / max	kg as/ha min - max		
Zonal uses (field or outdoor uses, certain types of protected crops)																
1	Apple, pear	PL	Miedzian 50 WP	F	*Venturia inaequalis, Venturia pirina*	WP	500 g/kg	spraying	BBCH 00-07	1-2	7-10 days	-	500-750	0,75	7	
2	Apple, pear	PL	Miedzian 50 WP	F	*Ervinia amylovora*	WP	500 g/kg	spraying	BBCH 60-71	1-2	7-10 days	-	500-750	0,375-0,75	7	
3	Cherry, sweet cherry	PL	Miedzian 50 WP	F	*Pseudomonas syringae*	WP	500 g/kg	spraying	BBCH 51-61 BBCH 65-71 BBCH 72-73	1-3	7-10 dni	-	500-750	0,75 -1,5	7	
4	Peach	PL	Miedzian 50 WP	F	*Taphrina deformans*	WP	500 g/kg	spraying	BBCH 00-03	1	-	-	700	3,5	Not applicable	
5	Sugar beet	PL	Miedzian 50 WP	F	*Cercospora beticola*	WP	500 g/kg	spraying	BBCH 39	1-3	7-14	-	200-400	2,5	7	**The crop was deleted in 2014 due to lack of residue trials**
6	Cucumber	PL	Miedzian 50 WP	F	*Pseudomonas syringa* *Pseudoperonospora cubensis*	WP	500 g/kg	spraying	BBCH 62-78	2-3	7-10 days	-	700	1,5	7	
7	Tomato (field)	PL	Miedzian 50 WP	F	*Phytophtora in-festans* *Pseudomonas syrin-gae*	WP	500 g/kg	spraying	BBCH 51-85	3	7-10 days	-	700	1,5	7	
8	Tomato (indoor)	PL	Miedzian 50 WP	I	*Phytophtora infestans* *Pseudomonas phaseolicola*	WP	500 g/kg	spraying	BBCH 56-88	3	7-10 days	-	1500-2000	3,0	7	

1	2	3	4	5	6	7		8				9			10	11
Use No. (c)	Crop and/ or situation **	Zone	Product code	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: develop-mental stages of the pest or pest group)	Formulation		Application				Application rate per treatment			PHI (days)	Remarks:
						Type	Conc. of as	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applica-tions (days)	kg as/hL min - max	Water L/ha min / max	kg as/ha min - max		
9	French bean	PL		F	*Botrytis cinerea* *Colletotrichum lindemuthianum*	WP	500 g/kg	spraying	BBCH 65-69	2	7 days	-	600-800	1,5	7	
Minor uses according to Article 51 (zonal uses)																
10	Grape	PL		F	*Plasmopara viticola*	WP	500 g/kg	spraying	I. BBCH 13-17 II. BBCH 71-73 III. BBCH 73-77	3	10 days	-	500-900	1,25	7	
11	Black currant	PL		F	*Drepanopeziza ribis* *Cronartium ribicola* *Mycosphaerella ribis*	WP	500 g/kg	spraying	BBCH 59 - 81	3	10 days	-	700	1,5	7	
12	Walnut	PL		F	*Gnomonia leptostyla*, *Xantomonas cam-pestris pv. Juglandis*	WP	500 g/kg	spraying	Before flowering	2	10-14 days	-	800-1000	1,5	Not applicable	
13	Huzelnut	PL		F	*Monilia coryli*	WP	500 g/kg	spraying	Before flowering	2	10-14 days	-	800-1000	1,5	Not applicable	
14	*Goniolimon tataricum*	PL		F	*Peronospora statices*	WP	500 g/kg	spraying	Rosettes with 15-18 leaves	3	7 days	-	1000	1,0	Not applicable	

Table 7.1-1: Acceptability of critical GAP - re-authorization according art. 43, Reg. 1107/2009 and extension to minor uses

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
Zonal uses (field or outdoor uses, certain types of protected crops)																
1	Apple, pear	PL	Miedzian 50 WP	Fpn	*Venturia inaequalis* *Erwinia amylovora*	WP	500 g/kg	spraying	BBCH 00-07 BBCH 60-71	a)2 b)4	7-10 days		500 -750	0.75 kg Cu/ha	~~7~~ 14	A
2	Cherry, sweet cherry	PL	Miedzian 50 WP	Fpn	*Pseudomonas syringae*	WP	500 g/kg	spraying	BBCH 51-61 BBCH 65-73	1 2	7-10 days		500 -750	1.50 kg Cu/ha 0.75 kg Cu/ha	14	A
3	Peach	PL	Miedzian 50 WP	Fpn	*Taphrina deformans*	WP	500 g/kg	spraying	BBCH 00-03	1	-		700	1.50 kg Cu/ha	n.a.	A
Minor uses according to Article 51 (zonal uses)																
2	Quince	PL	Miedzian 50 WP	Fpn	*Venturia inaequalis* *Erwinia amylovora*	WP	500 g/kg	spraying	BBCH 00-07 BBCH 60-71	a)2 b)4	7-10 days		500 -750	0.75 kg Cu/ha	~~7~~ 14	A
3	Medlar	PL	Miedzian 50 WP	Fpn	*Venturia inaequalis* *Erwinia amylovora*	WP	500 g/kg	spraying	BBCH 00-07 BBCH 60-71	a)2 b)4	7-10 days		500 -750	0.75 kg Cu/ha	~~7~~ 14	A
~~**4**~~	~~Cherry, sweet cherry~~	~~PL~~	~~Miedzian 50 WP~~	~~Fpn~~	~~*Pseudomonas syringae*~~	~~WP~~	~~500 g/kg~~	~~spraying~~	~~BBCH 51-61~~ ~~BBCH 65-73~~	~~1~~ ~~2~~	~~7-10 days~~		~~500 -750~~	~~1.50 kg Cu/ha~~ ~~0.75 kg Cu/ha~~	~~14~~	
5	Apricot	PL	Miedzian 50 WP	Fpn	*Pseudomonas syringae*	WP	500 g/kg	spraying	BBCH 51-61	1	-		500 -750	1.50 kg Cu/ha	~~n.a.~~ 14	A
6	Plum	PL	Miedzian 50 WP	Fpn	*Pseudomonas syringae*	WP	500 g/kg	spraying	BBCH 51-61	1	-		500 -750	1.50 kg Cu/ha	~~n.a.~~ 14	A

~~7~~	~~Peach~~	~~PL~~	~~Miedzian 50 WP~~	~~Fpn~~	~~*Taphrina deformans*~~	~~WP~~	~~500 g/kg~~	~~spraying~~	~~BBCH 00-03~~	~~1~~	~~-~~		~~700~~	~~1.50 kg Cu/ha~~	~~n.a.~~		
8	Walnut	PL	Miedzian 50 WP	Fpn	*Gnomonia leptostyla, Xantomonas campestris pv. Juglandis,*	WP	500 g/kg	spraying	Before flowering	~~2~~ 1	~~10-14 days~~		800-1000	1.50 kg Cu/ha	n.a.	A 1application is accepted	
9	Hazelnut	PL	Miedzian 50 WP	Fpn	*Gnomonia leptostyla, Xanthomonas arboricola pv. corylina*	WP	500 g/kg	spraying	Before flowering	~~2~~ 1	~~10-14 days~~		800-1000	1.50 kg Cu/ha	n.a	A 1 application is accepted	
10	Tomato (outdoor)	PL	Miedzian 50 WP	Fpn	*Pseudomonas syringae pv. Tomato, Phytophthora infestans*	WP	500 g/kg	spraying	BBCH 51-85	3	7-10 days		700	1.25 kg Cu/ha	7	A Only in Poland as minor use	R Central zone 4 additional trials on tomato are required
11	Tomato (indoor)	PL	Miedzian 50 WP	I	*Pseudomonas syringae pv. Tomato, Phytophthora infestans*	WP	500 g/kg	spraying	BBCH 56-88	3	7-10 days		1500-2000	1.25 kg Cu/ha	3	A	
12	Aubergines (outdoor)	PL	Miedzian 50 WP	Fpn	*Pseudomonas syringae pv. Tomato, Phytophthora infestans*	WP	500 g/kg	spraying	BBCH 51-85	3	7-10 days		700	1.25 kg Cu/ha	7	A Only in Poland as minor use	R Central zone 4 additional trials on tomato are required
13	Aubergines (indoor)	PL	Miedzian 50 WP	I	*Pseudomonas syringae pv. Tomato, Phytophthora infestans*	WP	500 g/kg	spraying	BBCH 56-88	3	7-10 days		1500-2000	1.25 kg Cu/ha	3	A	
14	Cucumber (outdoor)	PL	Miedzian 50 WP	Fpn	*Pseudomonas syringae pv. Lachrymans, Pseudoperonospora*	WP	500 g/kg	spraying	BBCH 62-78	3	7 days		700	1.25 kg Cu/ha	~~3~~ 7	A Only in	R Central

					cubensis											Poland as minor use	zone 4 additional trials on cucumbers are required
15	Cucumber (indoor)	PL	Miedzian 50 WP	I	*Pseudomonas syringae pv. Lachrymans, Pseudoperonospora cubensis*	WP	500 g/kg	spraying	BBCH 10-89	4	7		500-1500	0.80 kg Cu/ha	3	A Only in Poland as minor use	R Central zone 1 additional trial on cucumbers is required
16	Gherkins	PL	Miedzian 50 WP	Fpn	*Pseudomonas syringae pv. Lachrymans, Pseudoperonospora cubensis*	WP	500 g/kg	spraying	BBCH 62-78	3	7 days		700	1.25 kg Cu/ha	~~3~~ 7	A Only in Poland as minor use	R Central zone 4 additional trials on cucumbers are required
17	Courgette	PL	Miedzian 50 WP	Fpn	*Pseudomonas syringae pv. Lachrymans, Pseudoperonospora cubensis*	WP	500 g/kg	spraying	BBCH 62-78	3	7 days		700	1.25 kg Cu/ha	~~3~~ 7	A Only in Poland as	R Central zone 4

																minor use	additional trials on cucumbers are required
18	Melon (indoor)	PL	Miedzian 50 WP	I	*Pseudoperonospora cubensis* *Alternaria spp Colletotrichum orbiculare* *Bacterial diseases*	WP	500 g/kg	spraying	BBCH 10-89	3	7 days		500-1500	1.25 kg Cu/ha	7	A Only in Poland as minor use	R Central zone 2 additional trials are required
19	Pumpkins (indoor)	PL	Miedzian 50 WP	I	*Pseudoperonospora cubensis* *Alternaria spp Colletotrichum orbiculare* *Bacterial diseases*	WP	500 g/kg	spraying	BBCH 10-89	3	7 days		500-1500	1.25 kg Cu/ha	7	A Only in Poland as minor use	R Central zone 2 additional trials are required
20	Watermelon (indoor)	PL	Miedzian 50 WP	I	*Pseudoperonospora cubensis* *Alternaria spp Colletotrichum orbiculare* *Bacterial diseases*	WP	500 g/kg	spraying	BBCH 10-89	3	7 days		500-1500	1.25 kg Cu/ha	7	A Only in Poland as minor use	R Central zone 2 additional trials are required

21	French bean, bean with pods	PL	Miedzian 50 WP	Fpn	*Pseudomonas syringae pv. Phaseolicola, Colletotrichum lindemuthianum, Botritis cinerea*	WP	500 g/kg	spraying	BBCH 65-69	2	7 days		600-800	1.50 kg Cu/ha	7	A Only in Poland as minor use	R Central zone 4 additional trials are required
22	Peas with pods	PL	Miedzian 50 WP	Fpn	*Pseudomonas syringae pv. Phaseolicola, Colletotrichum lindemuthianum, Botritis cinerea*	WP	500 g/kg	spraying	BBCH 65-69	2	7 days		600-800	1.50 kg Cu/ha	7	A Only in Poland as minor use	R Central zone 4 additional trials are required
23	Grape (table, wine)	PL	Miedzian 50 WP	Fpn	*Plasmopara viticola*	WP	500 g/kg	spraying	BBCH 13-17, 71-73, 73-77	3	10-14 days		500-900	1.25 kg Cu/ha	21	N	
24	Currant	PL	Miedzian 50 WP	Fpn	*Drepanopeziza ribis, Mycosphaerella ribis* *Cronartium ribicola,*	WP	500 g/kg	spraying	BBCH 59-65 ~~BBCH 59–81~~	2	10 days		700	1.20 kg Cu/ha	7	A Accepted BBCH: 59-65	

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

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

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

Explanation for Column 11 “Conclusion”

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

7.1.2 Summary of the evaluation

The preparation Miedzian 50 WP is composed of copper oxychloride.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of copper compounds (copper oxychloride)

Reference value	Source	Year	Value	Study relied upon	Safety factor
Copper compounds (copper oxychloride)					
ADI	EFSA	2008	0.15 mg/kg bw per day	1-year dogs	100
				Human data in children (based on copper intake established by WHO	No safety factor
ARfD	EFSA	2008	Not applicable		

7.1.2.1 Summary for copper compounds (copper oxychloride)

Table 7.1-3: Summary for copper oxychloride

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Apple	Yes	Yes	Yes	n.a.	Yes	No	No
2	Pear	Yes	Yes	Yes	n.a.	Yes		No
3	Quince	Yes	Yes	Yes	n.a.	Yes		No
4	Medlar	Yes	Yes	Yes	n.a.	Yes		No
5	Cherry, sweet cherry	Yes	Yes	Yes	n.a.	Yes	No	No
6	Apricot	Yes	Yes	Yes	n.a.	Yes		No
7	Peach	Yes	Yes	Yes	n.a.	Yes		No
8	Plum	Yes	Yes	Yes	n.a.	Yes		No
9	Hazelnuts	Yes	Yes	Yes	n.a.	Yes	No	No
10	Walnuts	Yes	Yes	Yes	n.a.	Yes		No
11	Cucumber (outdoor, indoor)	Yes	Yes	Yes	n.a.	Yes	No	No
12	Gherkins	Yes	Yes	Yes	n.a.	Yes		No
13	Courgette	Yes	Yes	Yes	n.a.	Yes		No
14	Melon	Yes	Yes	Yes	n.a.	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?
15	Pumpkins	Yes	Yes	Yes	n.a.	Yes	No	No
16	Watermelon	Yes	Yes	Yes	n.a.	Yes		No
17	Tomato (outdoor, indoor)	Yes	Yes	Yes	n.a.	Yes	No	No
18	Aubergines	Yes	Yes	Yes	n.a.	Yes		No
19	French bean, beans with pods	Yes	Yes	Yes	n.a.	Yes	No	No
20	Peas with pods	Yes	Yes	Yes	n.a.	Yes		No
21	Currant	Yes	Yes	Yes	n.a.	Yes	No	No
~~22~~	~~Wine grapes~~	~~Yes~~	~~Yes~~	~~Yes~~	~~n.a.~~	~~Yes~~		No
~~23~~	~~Table grapes~~	~~Yes~~	~~Yes~~	~~Yes~~	~~n.a.~~	~~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

7.1.2.2 Summary for Miedzian 50 WP

Table 7.1-4: Information on Miedzian 50 WP (KCA 6.8)

Crop	PHI for Miedzian 50 WP proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for Miedzian 50 WP proposed by zRMS	zRMS Comments (if different PHI proposed)
		Copper compounds (copper oxychloride)		
Apple	7	Yes		
Pear	7	Yes		14
Quince	7	Yes		14
Medlar	7	Yes		14
Cherry, sweet cherry	14	Yes		
Apricot	n.a.	Yes		14
Peach	n.a.	Yes		
Plum	n.a.	Yes		14
Hazelnuts	n.a.	Yes		
Walnuts	n.a.	Yes		
Cucumber (outdoor, indoor)	3	Yes		Cucumber (outdoor): 7
Gherkins	3	Yes		7
Courgette	3	Yes		7

Crop	PHI for Miedzian 50 WP proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for Miedzian 50 WP proposed by zRMS	zRMS Comments (if different PHI proposed)
		Copper compounds (copper oxychloride)		
Melon	7	Yes		
Pumpkins	7	Yes		
Watermelon	7	Yes		
Tomato (outdoor, indoor)	7 (outdoor), 3 (indoor)	Yes		
Aubergines (outdoor, indoor)	7 (outdoor), 3 (indoor)	Yes		
French bean, beans with pods	7	Yes		
Peas with pods	7	Yes		
Black currant	7	Yes		
~~Grapes (table, wine)~~	~~21~~	~~Yes~~		

NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Table 7.1-5: Waiting periods before planting succeeding crops

Not relevant. Copper is a natural element, it is also present in soil, which is essential for normal plant growth development.

Assessment

7.2 Copper compounds (copper oxychloride)

General data on copper oxychloride are summarized in the table below (last updated 2020/07)

Table 7.2-1: General information on copper oxychloride

Active substance (ISO Common Name)	Copper oxychloride
IUPAC	dicopper(II) chloride trihydroxide
Chemical structure	$[Cu_2Cl(OH)_3]_n$,with n=1 or 2
Molecular formula	$[ClCu_2H_3O_3]_n$ n= 1 or 2
Molar mass	213.6 n with n=1 or 2
Chemical group	Inorganic compound
Mode of action (if available)	Absorbed copper disrupts the enzyme systems of pathogens. Multi-site activity.
Systemic	No
Company (ies)	Albaugh, Cinkarna, IQV, Isagro, Manica, Montanwerke, Prince Erachem and Saldeco Spiess-Urania.
Rapporteur Member State (RMS)	France
Approval status	Approved Date of (01/01/2019) and reference to decision (COMMISSION DIRECTIVE YYYY/XX/EC - REGULATION (EU) No 2018/1981) active hyperlinks. https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1544804833561&uri=CELEX:32018R1981
Restriction	Only uses resulting in a total application of maximum 28 kg of copper per hectare over a period of 7 years shall be authorised.
Review Report	SANTE/10506/2018 Rev. 5 27/11/2018
Current MRL regulation	Regulation (EC) No 149/2008
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-Q-2014-00657 (EFSA, 2018a)
EFSA Journal: conclusion on article 12	Yes EFSA-Q-2010-00183 (EFSA, 2018b)
Current MRL applications on intended uses	Regulation (EC) No 149/2008

* Notifier in the EU process to whom the a.s. belong(s)
** If yes: EFSA, YYYY - see list of references

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.
During the EU review of copper compounds, no studies investigating the storage stability of copper were provided.
Studies on the stability of residues during storage are not required.

Conclusion on stability of residues during storage

Copper is an element and is inherently stable as it cannot be transformed into any other material. Therefore, under freezer storage conditions, residues of copper in crop commodities will be stable. The analysis for copper in crop commodities involves quantitation in the atomic state to measure the total copper content irrespective of its chemical form following aggressive acid digestion to dissolve the residue. Thus, since copper cannot degrade and since the analytical techniques measure total copper content irrespective of form, studies to measure the stability of copper residues in crop or other commodities are not required (France, 2007).

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Procedural recoveries from experiments carried out concurrently with residue sample analysis were acceptable confirming the stability of residue in sample extracts.

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.

Summary of plant metabolism studies reported in the EU

Copper is an essential micronutrient and is present in all tissues of plants, animals and fungi. It is naturally present in agricultural soils. In plants, copper is absorbed from soil through the roots. From the roots, copper is transported to the rest of the plant in the sap bound to nitrogen containing compounds. In plants copper is necessary for a wide range of metabolic processes such as respiration and photosynthesis. Upon foliar application, transportation and distribution of copper in plants are limited.
Copper is a mono-atomic charged element and inherently stable. It cannot be transformed into related degradation products or metabolites. Therefore, once on the leaves or fruit of treated crops it does not metabolise or form degradation products. Therefore, the relevant residue in plant commodities is copper alone.
Since copper does not degrade in plants and since transportation and distribution of copper in plants following application as a plant protection product is limited compared to the copper already present in the plant arising from uptake from the soil specific studies to evaluate the metabolism, distribution and expression of the residue in plants following application as a plant protection product have not been conducted.

Conclusion on metabolism in primary crops

Additional plant metabolism studies were not required and not relevant. The relevant residue for monitoring and risk assessment was defined as total copper, including copper residues arising from all variants of copper because the analytical methods for enforcement convert them into mineral copper (EFSA, 2018a).

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.

Summary of plant metabolism studies reported in the EU

Specific studies to evaluate reside uptake from soil, metabolism and residue levels in succeeding crops have not been conducted and submitted.
Since copper does not degrade in plants and since transportation and distribution of copper in plants following application as a plant protection product is limited compared to the copper already present in the plant arising from uptake from the soil specific studies to evaluate the metabolism, distribution and expression of the residue in plants following application as a plant protection product have not been conducted.

Conclusion on metabolism in rotational crops

Crops presented in this application are usually not followed by other crops. The studies are not 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.

Conclusion on nature of residues in processed commodities

During the initial and renewal Review of copper, no studies investigating the nature of residue in processing matrices were provided.
Copper is an element and is inherently stable, as it cannot be transformed into any other material. The analysis for copper in crop commodities involves quantitation in the atomic state to measure the total copper content irrespective of its chemical form following aggressive acid digestion to dissolve the residue. Thus, since copper cannot be degrade since the analytical techniques measure total copper content irrespective of form, studies to measure the effects of industrial processing or household preparation on the nature of residues are not required (France, 2007; France, 2017).

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

Table 7.2-2: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Not required. Copper cannot be transformed into related degradation products or metabolites.
Rotational crops covered	Not relevant. Copper cannot be transformed into related degradation products or metabolites.
Metabolism in rotational crops similar to metabolism	Not applicable

in primary crops?	
Processed commodities	Not required. Copper cannot be transformed into related degradation products or metabolites.
Residue pattern in processed commodities similar to pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	Total copper (Regulation(EC) No 149/2008)
Plant residue definition for risk assessment	Total copper (EFSA, 2008)
Conversion factor from enforcement to RA	Not applicable.

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.

Summary of plant metabolism studies reported in the EU

During the initial and renewal EU Review of copper, no studies investigating the metabolism in animals were provided.
Copper is an essential micronutrient and is present in all tissues of plants, animals and fungi. In domestic animals, copper has a fundamental role in many metabolic processes. Copper is frequently added to the diet of intensively reared species such as pigs and poultry along with other minerals and vitamins. Copper absorption, metabolism and excretion are similar in most species of mammals.

Conclusion on metabolism in livestock

Copper used as a plant protection product is recommended for use in pome, stone fruits, tree nuts, tomatoes, cucumbers, grapes. These crops are not listed as potential feed items for domestic animals. Therefore, intake of copper by domestic animals following the consumption of diet containing residues of copper in these commodities will not occur. Then, specific studies to evaluate the metabolism, distribution and expression of the residue in livestock (poultry, lactating ruminants and pigs) following application of copper as a plant protection product for proposed uses are not required.
The definition of residue in animal origin is total copper.

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

Table 7.2-3: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	No studies, not required
Time needed to reach a plateau concentration	Not applicable
Animal residue definition for monitoring	Total copper (Regulation (EC) No 149/2008)
Animal residue definition for risk assessment	Total copper (France, 2007)
Conversion factor	Not applicable
Metabolism in rat and ruminant similar	Not applicable

Fat soluble residue	Not applicable

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 7.2-4: Summary of EU reported and new data supporting the intended uses of Miedzian 50 WP and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Apple → extrapolated to Pears, Quinces, Medlar	EFSA, 2018b	N-EU	~~Trials GAP: 8x 0.375 as/ha, PHI 14, outdoor~~ ~~E: <1.5, <1.5, <1.5 (apples); <1.5, 1.52 (pears).~~ ~~RA: n.a~~	N/A				
	New trials Report 19SGS15	C-EU	Trials GAP: 4 x 0.75 kg as/ha, BBCH 77-85, PHI 14d, outdoor E: 2.50, 0.96, 0.88, 1.72, 1.73, 1.18 RA: n.a.					
	New trials Report 21SGS90		Trials GAP: 4 x 0.75 kg as/ha, BBCH 78-88, PHI 14d, outdoor E: 4.62, 4.73 RA: n.a.					

	~~Evaluated at the 1st approval Report BA 06/07 2~~	~~C EU~~	~~Trials GAP: 4 x 0.75 kg as/ha, BBCH 39 73, PHI 14d, outdoor E: 0.177 (pears), 0.235 (apples) RA: n.a~~					
	Overall supporting data for cGAP	C-EU	E: ~~4 x <1.50, 1.52~~, 2.50, 0.96, 0.88, 1.72, 1.73, 1.18, ~~0.177, 0.235~~ 4.62, 4.73 RA: n.a.	E: ~~1.50~~ 1,73 RA: -	E~~: 2.50~~ 4,73 RA: -	~~4.0~~ 8.53	5.0	Yes
Cherry → extrapolated to sweet cherry	New trials Report 19SGS16 New trials Report 21SGS89	C-EU	Trials GAP: 2 x 1.5 kg as/ha, 1x 0.75 as/ha, BBCH 73-85, PHI 14d, outdoor E: 2.09, 2.20, 2.62, 3,84 RA: n.a. Trials GAP: 2 x 1.5 kg as/ha, 1x 0.75 as/ha, BBCH 73-81, PHI 14d, outdoor E: 1.88, 1.19, 1.28, 2.15 RA: n.a.	N/A				
	~~Evaluated at the 1st approval Report BA 06/07 2~~	~~C EU~~	~~Trials GAP: 2 x 1.5 kg as/ha, BBCH 53 71, PHI 14d, outdoor E: 0.699, 0.416 RA: n.a.~~					
	Overall supporting data for cGAP	C-EU	E: 1.19, 1.28, 1.88, 2.09, 2.15, 2.20, 2.62, 3,84, ~~0.699, 0.416~~, RA: n.a.	~~E: 2.15~~ 2.12 RA: -	E: 3.84 RA: -	7.0	5.0	Yes
Apple (min. 4 trials) + stone fruits → extrapolated to Apricots, Peaches, Plums, Hazelnuts, Walnuts	Overall supporting data for cGAP	C-EU	E~~: 4 x <1.50, 1.52~~, 2.50, 0.96, 0.88, 1.72, 1.73, 1.18, ~~0.177, 0.235~~, 2.09, 2.20, 2.62, 3,84, ~~0.699, 0.416~~ 1.88, 2.15, 1.19, 1.28 RA: n.a.	N/A				
				~~E: 1.50 RA:~~	~~E: 3.84 RA:~~	~~6.0~~	5.0 – pome and stone fruits 30.0 - nuts	Yes
Cucumber (cucurbit with	~~France, 2017~~	~~N EU~~	~~Trials GAP: 4 x 0.800 kg as/ha, BBCH 10 89 PHI 3d, outdoor~~	N/A				

edible peel) (openfield) → extrapolated to gherkins, courgetts			~~E: 1.35, 1.03, 0.92, 1.09, 1.81, 1.72, 1.43, 1.28~~ ~~RA: n.a.~~					
	New trials Report 19SGS17	C-EU	Trials GAP: 3 x 1.25 kg as/ha, BBCH 61-89, PHI 7d, outdoor E: <0.50, 0.99, 0.56, 0.60 RA: n.a.					
	~~Evaluated at the 1st approval Report BA 06/07 2~~	~~C-EU~~	~~Trials GAP: 3x 1.5 kg as/ha, BBCH 62-78 PHI 7d, outdoor~~ ~~E: < 0.1~~ ~~RA: n.a.~~					
	Overall supporting data for cGAP	C-EU	E: ~~1.35, 1.03, 0.92, 1.09, 1.81, 1.72, 1.43, 1.28~~, <0.50, 0.99, 0.56, 0.60, ~~< 0.1~~. RA: n.a.	E: 1.03 RA: -	E: 1.81 RA: -	3.0	5.0	Yes
Cucumber (indoor) → extrapolated to gherkins, courgetts	France, 2017	N-EU	Trials GAP: 4 x 0.800 kg as/ha, BBCH 10-89, PHI 3 d, indoor E: 4.04, 1.25, 0.89, 1.77, 2.57, 1.08, 1.04 RA: n.a.	N/A				
	Overall supporting data for cGAP	C-EU	E: 4.04, 1.25, 0.89, 1.77, 2.57, 1.08, 1.04 RA: n.a.	E: 1.25 RA: -	E: 4.04 RA: -	7.0	5.0	Yes
Melon (indoor) → extrapolated to Whole subgroup cucurbits with inedible peel (pampkins, watermelon)	France, 2017	EU	Trials GAP: 5x 1.178-1.291 kg a.s./ha, BBCH 72-84, PHI 7d, indoor E: < 2.00, < 2.00, < 2.10, < 1.97, < 2.10, 5.00 R: n.a.	N/A				
	Overall supporting data for cGAP	EU	E: < 2.00, < 2.00, < 2.10, < 1.97, < 2.10, 5.00 R: n.a.	E:2.05 R: -	E:5.00 R: -	8.0	5.0	Yes

Tomato (openfield) → extrapolated to aubergines/eggplants	~~EFSA, 2018a,b~~	~~N EU~~	~~Trials GAP: 6 x 1.25 kg as/ha, BBCH 15-89, PHI 3 (fresh) or 10 (industrial) d, outdoor~~ ~~E: 0.70, 1.50, 1.60, 1.60, 1.70, 1.70, 2.20, 4.30, 6.60~~ ~~RA: n.a.~~	N/A				
	New trials Report 19SGS18 Report 451SRPL19R0	C-EU	Trials GAP: 3 x 1.25 kg as/ha, BBCH 71-85, PHI 7d, outdoor E: 1.89, 1.62 RA: n.a. Trials GAP: 3x 1.125 kg a.s./ha, BBCH 71-85, PHI 7d, outdoor E: 1.47, 1.02 RA: n.a.					
	~~Evaluated at the 1st approval~~ ~~Report BA-06/07-2~~	~~C-EU~~	~~Trials GAP: 3 x 1.5 kg a.s./ha, BBCH 51-85, PHI 7d, outdoor~~ ~~E: <0.1~~ ~~RA: n.a.~~					
	Overall supporting data for cGAP	C-EU	~~E: 0.70, 1.50, 1.60, 1.60, 1.70, 1.70, 2.20, 4.30, 6.60,~~ 1.89, 1.62, ~~<0.1~~, 1.47, 1.02 RA: n.a.	E: 1.61 RA: -	E: 6.60 RA: -	9.0	5.0	Yes
Tomato (indoor) → extrapolated to aubergines/eggplants	France, 2017	EU	Trials GAP: 1140 – 2150 g a.s./ha, PHI 3d, indoor (6 trials); 6 x 0.78 – 1.37 kg a.s./ha, PHI 3d, indoor (4 trials) BBCH 12-89. E: 10x < 2.00 R: n.a.	N/A				
	Overall supporting data for cGAP	EU	E: 10x < 2.00 R: n.a.	E: 2.00 R: n.a.	E: 2.00 R: n.a.	6.0	5.0	Yes
Freanch beans,	~~EFSA, 2018b~~	~~N EU~~	~~Trials GAP: 4 x 0.800 kg as/ha, BBCH 61-78, PHI 3d,~~	N/A				

beans with pods → extrapolated to peas with pods			~~outdoor~~ ~~E: 2.26, 2.63, 3.22, 3.27, 3.48, 3.66~~ ~~RA: n.a.~~					
	New trials Report 19SGS19 New trials Report 21SGS92	C-EU	Trials GAP: 2 x 1.5 kg as/ha, BBCH 69-81, PHI 7d, outdoor E: 8.05, 7.13 RA: n.a. Trials GAP: 2 x 1.5 kg as/ha, BBCH 71-74, PHI 7d, outdoor E: 1.68, 1.54 RA: n.a.					
	~~Evaluated at the 1st approval~~ ~~Report BA 06/07 2~~	~~EU~~	~~Separate trials with different dose of as/ha~~ ~~2x 1.25 kg as/ha, BBCH 65-69, PHI 7d, outdoor~~ ~~E: 0.264~~ ~~2x 1,5 kg as/ha, BBCH 65-69, PHI 7d, outdoor~~ ~~E: 0.843~~ ~~2x 3.0 kg as/ha, BBCH 65-69, PHI 7d, outdoor~~ ~~E: 0.572~~ ~~RA: n.a.~~					
	Overall supporting data for cGAP	EU	~~E: 2.26, 2.63, 3.22, 3.27, 3.48, 3.66~~, 8.05, 7.13, ~~0.264, 0.843, 0.572~~ 1.68, 1.54 RA: n.a.	~~E: 3.22~~ ~~RA: -~~ 4.41	~~E: 8.05~~ ~~RA: -~~ 8.05	~~15.0~~ 20	20.0	Yes
Currant (black, red, white)	EFSA, 2018b	N-EU	Trials GAP: 2 x 1.2 kg as/ha, BBCH 13-57, outdoor E: 0.77, 1.04 RA: n.a.	N/A				
	New trials Report 19SGS20	EU	Trials GAP: 2 x 1.2 kg as/ha, BBCH 81-85, PHI 7d, outdoor E: 4.79, 3.66 (black currant) RA: n.a.					
	Overall supporting data for cGAP	EU	E: 0.77, 1.04, 4.79, 3.66 RA: n.a.	E: 2.35 RA: -	E: 4.79 RA: -	10.0	5.0	Yes

Wine grapes → extrapolated on Table grapes	~~France, 2007, 2017~~	~~N EU~~	~~Trials GAP: 4x 1.09-3.84 g a.s./ha, PHI 21d, outdoor~~ ~~E: <5, 6.9, 8.7, 9.9, 12, 45, 56~~ ~~RA: n.a.~~	N/A				
	~~Overall supporting data for cGAP~~	~~EU~~	~~E: <5, 6.9, 8.7, 9.9, 12, 45, 56~~ ~~RA: n.a.~~	E: 7.35 RA: -	E: 56.00 RA: -	100.0	50.0	Yes

* Source of EU MRL: Reg. (EC) No 149/2008

7.2.3.2 Conclusion on the magnitude of residues in plants

~~All extrapolation for minor crops are presented refer to use in Poland.~~
~~According to the available data, the intended uses on apple and cherry are considered acceptable, for outdoor uses.~~
~~According to appendix D of EU guidelines, extrapolation to whole group of pome fruit (pear, quinces, medlar) is possible with 8 trials on apple, which is the case here.~~
~~According to appendix D of EU guidelines, extrapolation to stone fruit (apricots, peaches, plums) and tree nuts (hazelnut and walnut) is possible with minimum 4 trials on apple and stone fruits, which is the case here. According to appendix D of EU guidelines, extrapolation to sweet cherry is possible with 4 trials on cherry.~~
~~According to the available data, the intended uses on cucumber (cucurbits with edible peel) are considered acceptable, both for indoor and outdoor uses. According to appendix D of EU guidelines, extrapolation to whole subgroup of cucurbits with edible peel (gherkins, courgettes) is possible with trials on cucumbers, which is case here.~~
~~According to the available data, the intended uses on melon (cucurbits with inedible peel) are considered acceptable, for indoor uses. According to appendix D of EU guidelines, extrapolation to whole subgroup of cucurbits with inedible peel (pumpkins and watermelon) is possible with trials on melon, which is case here.~~
~~According to the available data, the intended uses on tomato are considered acceptable, for both indoor and outdoor uses. According to appendix D of EU guidelines, extrapolation to aubergines/eggplants is possible with trials on tomato, which is case here.~~
~~According to the available data, the intended uses on French bean are considered acceptable, for outdoor uses. According to appendix D of EU guidelines, extrapolation to other beans with pods and peas with pods are possible with trials on French beans (beans with pods).~~
~~According to the available data, the intended uses on currant (black, red, white) are acceptable for outdoor uses. For currants, scaling was carried out and the proposed dose was reduced (Appendix 2).~~
~~According to the available data, the intended uses on wine grape are acceptable for outdoor uses. According to appendix D of EU guidelines, extrapolation to table grapes are possible with trials on wine grapes.~~
~~The data submitted show that no exceedance of the MRL will occur.~~
~~The uses are considered acceptable.~~
~~To support the GAP for grapes, 7 trials on wine grapes were considered as sufficient to derive MRL and data for the risk assessment. In Poland wine grapes and table grapes are the minor crops, therefore it is acceptable to submit 4 studies for use in Poland. The residue levels in grapes ranged between <5 and 56 mg/kg. It should be noted that the residue levels at the sites in Germany were higher than sites in Northern France. The difference is thought to be related to the practice of defoliation of the vine, i.e. removing leaves around the grape bunches prior to application, which is reported to be widespread in Germany. The purpose of defoliation is to improve aeration, increase sunlight penetration and to help prevent disease development (France, 2017).~~
~~The data submitted for grapes show exceedance of the MRL only in one trial. The trial GAP was 4x 2.01 – 2.10 kg a.s./ha, PHI 21, outdoor. The study was accepted at the EU level, and it was also concluded that the use of Copper at a dose of 3x 1.25 kg a.s./ ha does not pose a risk to the consumer.~~
~~In the current application, the recommended dose of Miedzian 50 for grapes is 3x 1.25 kg a.s./ha. For this reason, the MRL for Copper is not expected to be exceeded after the use of Miedzian 50 WP in the proposed dose. The uses are considered acceptable.~~

See 7.1

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Table 7.2-5: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Total copper				
Apple, pomace, wet	1.03	Median residue x PF (EFSA, 2018)	1.03	Median residue x PF (EFSA, 2018b)

Table 7.2-6: Results of the dietary burden calculation (Animal model 2017)

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)
Total copper					
Beef cattle	0.062	0.062	Apple pomace, wet	2.58	Yes
Dairy cattle	0.050	0.050	Apple pomace, wet	1.29	Yes
Lamb	0.055	0.055	Apple pomace, wet	1.29	Yes
Ram/Ewe	0.043	0.043	Apple pomace, wet	1.29	Yes

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

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

No new data were submitted in the framework of this application.
The feeding studies are not required.
All recommended uses of product Miedzian 50 WP, excepted apples are not listed as potential feed for domestic animals in OECD Guidance documents n° 64/32 and 73. Under EU evaluation of copper compounds, the livestock feeding studies in poultry, lactating ruminants or pigs have not been conducted. Copper is used as feed additive for all animal species. It should be mentioned that copper is also used as veterinary drug in the feeding of pigs and that environment content of copper linked to animal feeding should be considered.

The EFSA Scientific Opinion on the safety and efficacy of copper compounds (E4) as feed additives for all animal species, concluded that “no concerns for consumer safety are expected from the use of copper compounds under application in animal nutrition when used up to the maximum EU-authorised levels in feed”. Therefore it can be concluded that the livestock dietary burden calculation based on the method in Animal Burden Calculation according to OECD 505 is not suitable for the risk assessment of a micronutrient like copper. However, the use of copper as a plant protection product can be considered acceptable because, despite the residue or natural background level found, it is still necessary to add copper as feed additives, indicating that, according to animal nutritionists, the initial residue level found in raw agricultural commodities do not provide enough copper in the diet of domesticated livestock. (France, 2017).

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

7.2.5.1 Available data for all crops under consideration

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

Table 7.2-7: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Total copper					
Grapes, raisin	3	2.70			EFSA, 2008
Grapes, must	18	1.90			EFSA, 2008
Grapes, juice	10	0.40			EFSA, 2008
Grapes, wine	24	0.19			EFSA, 2008
Grapes, wet pomace	7	2.80			EFSA, 2008
Apples, juice	8	0.51			EFSA, 2018b
Cherries, canned	8	0.36			EFSA, 2018b
Peaches, canned	8	0.19			EFSA, 2018b
Plums, dried (prunes)	8	3.62			EFSA, 2018b
Apples, wet pomace	2	0.73			EFSA, 2018b
Cucumber, washed	2	0.76			France, 2017
Tomato, canned	10	0.5			France, 2017
Tomato, washed	6	0.6			France, 2017

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

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

7.2.5.2 Conclusion on processing studies

Studies investigating the magnitude of residues in processed commodities allowed deriving robust processing factors for tomato (washed and canned), wine grapes (must, juice, wine, wet pomace), table grapes (raisins) and cucumber (washed) (France, 2017).

The residues in tomato commodities were determined in wash-water, juice, puree and canned fruit. Residues of copper in the treated fruit were reduced by washing in all trials and ranged from 1.0 to 1.2 mg/kg. The mean transfer factor (TF) was 0.6. Residues in a juice were ranged from 1.8 to 5.9 mg/kg. The mean TF was 2.0. Residues in the treated canned fruit were ranged from 0.7 to 1.2 mg/kg. The mean TF was 0.5. The residues in wine grapes was determined in different fractions: must, wet pomace, dry pomace and juice. A total 7 trials were carried out in wine grapes in Northern EU countries. Residues of copper in the treated must and pomace were higher than in the corresponding unprocessed fruit and the median transfer factors for these two were 0.85 and 1.2, respectively. Residues of copper in treated juice and wine were lower than in the corresponding unprocessed fruit and the median transfer factor for these two commodities were 0.39 and 0.04, respectively. The median residue for copper in wine was 0.48 mg/kg.

Two residue trials on cucumber were conducted in Northern Europe. The residues in cucumbers were determined after fruits washing. Residues of copper in cucumber were reduced by washing (median transfer factor of 0.76) (France, 2017).
The PFs for enforcement and risk assessment in EU level were derived for juices (apples and wine grapes), canned commodities (peaches, cherries), dry fruits (plums and table grapes), wines (red and white). With regard to feed processed commodities, however, only tentative PF could be derived for apples as it was not sufficiently supported by studies. Based on two available data, a tentative PF of 0.73 could be proposed for apple wet pomace. Further processing studies are not required (EFSA, 2018b).

7.2.6 Magnitude of residues in representative succeeding crops

Crops under evaluation, excluded tomato, cucumber and beans with pods are not expected to be grown in rotation. Further investigation of residues in rotational crops is therefore not required.
Copper is a ubiquitous molecule which may also be present in plant commodities that are not supposed to undergo pesticide treatments with copper. As copper is a natural element, it is also present in soil, which is essential for normal plant growth development. Therefore, all soil-grown crops may contain copper. Although copper can have significant phytotoxicity at high soil concentrations, it is also known that plants can accumulate copper to various extents, depending on plant species and copper content in soils (EFSA, 2018b). Based on the scientific literature, the experts agreed that plant would not absorb more than the essential nutritional amount. Therefore, field trials on rotational crops were not deemed necessary and a comprehensive survey on the copper background levels in plant commodities was used as a surrogate to assess the residue levels in all off-label crops (including rotational crops) (EFSA, 2018a).

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Not required.

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

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of Miedzian 50 WP. Therefore, other special studies are not needed.

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

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

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-8: Input values for the consumer risk assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Total copper		
Apple	~~1.50~~ 1.73	~~Median residue (Report BA 06/07 2; Report 19SGS15)~~ Median residue (Report 19SGS15; Report 21SGS90)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Pear	1.41	Median residue (EFSA, 2018b)
Quince	1.41	Median residue (EFSA, 2018b)
Medlar	1.41	Median residue (EFSA, 2018b)
Cherry, sweet cherry	~~2.15~~ 2.12	~~Median residue (Report BA 06/07 2; Report 19SGS16)~~ Median residue (Report 19SGS16, Report 21SGS89)
Apricot	1.50	Median residue (EFSA, 2018b)
Peach	2.35	Median residue (EFSA, 2018b)
Plum	1.15	Median residue (EFSA, 2018b)
Hazelnuts	11.7	Median residue (EFSA, 2018b)
Walnuts	11.7	Median residue (EFSA, 2018b)
Cucumber	2.00	Median residue (EFSA, 2018b)
Gherkins	2.00	Median residue (EFSA, 2018b)
Courgette	2.00	Median residue (EFSA, 2018b)
Melon	4.20	STMR (tentative) x PF (peeling) (EFSA, 2018b)
Pumpkins	4.20	STMR (tentative) x PF (peeling) (EFSA, 2018b)
Watermelon	4.20	STMR (tentative) x PF (peeling) (EFSA, 2018b)
Tomato	2.50	Median residue (EFSA, 2018b)
Aubergines/eggplants	2.50	Median residue (EFSA, 2018b)
French bean	3.25	Median residue (EFSA, 2018b)
Peas with pods	3.25	Median residue (EFSA, 2018b)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Black currant	1.0	Median residue (EFSA, 2018b)
Wine grapes	2.55	Scenario 1: STMR x 0.75 (yield factor for juice) x PF (juice) (EFSA, 2018b)
	0.35	Scenario 2: Median background levels x 0.75 (yield factor for juice) x PF (juice) (EFSA, 2018b)
Table grapes	8.70	Median residue (EFSA, 2018b)

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-9: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo rev. 3.1.	31 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	See results for TMDI
IESTI (% ARfD) according to EFSA PRIMo*	Not required
NTMDI (% ADI) **	Not required
NEDI (% ADI)**	Not required
NESTI (% ARfD) **	Not required

* include raw and processed commodities if both values are required for PRIMo
** if national model is available

The calculations were made in EFSA PRIMo rev. 3.1. The proposed uses of Copper in the formulation Miedzian 50 WP do not represent unacceptable chronic risks for the consumer. The calculation for acute risk assessment are not required, because ARfD are not established.

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

France, 2007. Draft Assessment Report (DAR). Copper. Residues in or on treated products, food and feed, Volume 3, Annex B7.

France, 2017. Draft Renewal Assessment Report (RAR). Copper Compounds. Residue and Metabolism, Volume 3, Annex B7 (AS).

EFSA (European Food Safety Authority), 2008. Conclusion regarding the peer review of the pesticide risk assessment of the active substance. Copper (I), copper (II) variants namely copper hydroxide, copper oxychloride, tribasic copper sulfate, copper (I) oxide, Bordeaux mixture. EFSA Scientific Report 2008; 187: 1 – 101.

EFSA (European Food Safety Authority), 2018a. Peer review of the pesticide risk assessment of the active substance copper compounds copper (I), copper (II) variants namely copper hydroxide, copper ox-

ychloride, tribasic copper sulfate, copper (I) oxide, Bordeaux mixture. EFSA Journal 2018; 16(1): 5152.

EFSA (European Food Safety Authority), 2018b. Review of the existing maximum residue levels for copper compounds according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(3): 5212

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
KCA 6.3. 7.2.3.	Rakowska M., Naubart K., Kowalska A., Borzym R.	2007	Badanie dynamiki zanikania pozostałości miedzi w materiale roślinnym po stosowaniu Miedzianu 50 WP i Miedzianu Extra 350 SC. (In Polish) Company Report No BA-06/07-2 Instytut Przemysłu Organicznego, Poland GLP Unpublished	N	Synthos Agro Sp. z o.o. (Evaluated at the 1st approval of PPP)
KCA 6.3. 7.2.3.	Peda T.	2020	Magnitude of the residue of copper oxychloride in Apple Raw Agricultural Commodity after four applications of Miedzian 50 WP – four harvest trials and two decline curve trials in Poland 2019. Company Report No 19SGS15 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCA 6.3. 7.2.3.	Peda T.	2020	Magnitude of the residue of copper oxychloride in cherry (Raw Agricultural Commodity) after three applications of Miedzian 50 WP – two harvest trials and two decline curve trials in Poland 2019. Company Report No 19SGS16 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCA 6.3. 7.2.3.	Peda T.	2020	Magnitude of the residue of copper oxychloride in cucumber (openfield) Raw Agricultural Commodity after three applications of Miedzian 50 WP – two harvest trials and two decline curve trials in Poland 2019. Company Report No 19SGS17 GLP	N	Synthos Agro Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCA 6.3. 7.2.3.	Peda T.	2020	Magnitude of the residue of copper oxychloride in tomato (openfield) Raw Agricultural Commodity after three applications of Miedzian 50 WP – two harvest trials in Poland 2019. Company Report No 19SGS18 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCA 6.3. 7.2.3.	Peda T.	2020	Magnitude of the residue of copper oxychloride in French bean (openfield) Raw Agricultural Commodity after two applications of Miedzian 50 WP – two harvest trials in Poland 2019. Company Report No 19SGS19 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCA 6.3. 7.2.3.	Peda T.	2020	Magnitude of the residue of copper oxychloride in black currant (Raw Agricultural Commodity) after two applications of Miedzian 50 WP – two harvest trials in Poland 2019. Company Report No 19SGS20 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCA 6.3. 7.2.3.	Peda T.	2021	Magnitude of the residue of Copper oxychloride in cherry (Raw Agricultural Commodity) after three applications of Miedzian 50 WP – two harvest study trials and two decline curve study trials in Poland – 2021. Company Report No 21SGS89 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCA 6.3. 7.2.3.	Peda T.	2021	Magnitude of the residue of Copper oxychloride in apple (Raw Agricultural Commodity) after four applications of Miedzian 50 WP – two decline curve study trials in Poland – 2021. Company Report No 21SGS90 GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCA 6.3. 7.2.3.	Peda T.	2021	Magnitude of the residue of Copper oxychloride in string-bean (Raw Agricultural Commodity) after two applications of Miedzian 50 WP –two decline curve study trials in Poland – 2021. Company Report No 21SGS92	N	Synthos Agro Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCA 6.3. 7.2.3.	Wojtaniec K.	2020	Determination of residues of cymoxanil and copper in tomato at harvest under open field conditions following three applications of Curzate Cu 49,5 WP in Poland 2019. (Field phase) Company Report No 451SRPL19R01 Trial number: SRPL19-303-451FR GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCA 6.3. 7.2.3.	Dąbrowski G.	2020	Determination of residues of cymoxanil and copper in tomato at harvest under open field conditions following three applications of Curzate Cu 49,5 WP in Poland 2019. (Field phase) Company Report No 451SRPL19R01 Trial number: SRPL19-304-451FR GLP Unpublished	N	Synthos Agro Sp. z o.o.
KCA 6.3. 7.2.3.	Paszek G.	2020	Determination of residues of cymoxanil and copper in tomato at harvest under open field conditions following three applications of Curzate Cu 49,5 WP in Poland 2019. (Analytical phase) Company Report No 451SRPL19R01 Analytical phase code: DPL/84/2020 GLP Unpublished	N	Synthos Agro Sp. z o.o.

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
KCA 6.3.	Columb P.	1999	Generation of wine grape fruits and processed samples, suitable for residue analysis of copper, cymoxanil	N	EuCuT F

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
7.2.3; KCA 6.5.2-6.5.3			and folpet. Report No 9801AGT Viti R&D, GLP Unpublished		(In DAR, 2007)
KCA 6.3. 7.2.3	Brereton R.	2003a	Copper: Residue levels in wine grape and processed fractions from trials conducted in northern France and Germany during 2001. Report No AF/5991/CU. Agrisearch GLP Unpublished.	N	EuCuT F (In DAR, 2007)
KCA 6.3. 7.2.3	Martin C.	2003	Copper: Residue levels in wine grapes from trials conducted in Northern France and Germany during 2002. Report No AF/6890/CU Agrisearch GLP Unpublished.	N	EuCuT F (In DAR, 2007)
KCA 6.3. 7.2.3	Brereton R.	2003b	Copper: Residue levels in wine grapes from a single trial conducted in northern France during 2002. Report No AF/6842/CU. Agrisearch GLP Unpublished.	N	EuCuT F (In DAR, 2007)
KCA 6.3. 7.2.3	Kreke N.	2009a	Determination of residues of copper in cucumber (RAC fruit) following four treatments with different copper formulations under open field conditions in northern and southern Europe in 2009. Report No C 48132 Harlan laboratory GLP Unpublished.	N	EuCuT F
KCA 6.3. 7.2.3	Kreke N.	2010a	Determination of residues of copper in cucumber (RAC fruit) following four treatments with different copper formulations under open field conditions in northern and southern Europe in 2010. Report No C 91095 Harlan laboratory GLP Unpublished.	N	EuCuT F
KCA 6.3. 7.2.3	Kreke N.	2011	Determination of residues of copper in cucumber (RAC fruit) following four treatments with different copper formulations under open field conditions in northern Europe in 2011.	N	EuCuT F

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
			Report No D35555 Harlan laboratories GLP Unpublished.		
KCA 6.3. 7.2.3	Kreke N.	2009b	Determination of residues of copper in greenhouse cucumber (RAC fruit) following four treatments with different copper formulations in northern and southern Europe in 2009. Report No C48121 Harlan laboratories GLP Unpublished.	N	EuCuT F
KCA 6.3. 7.2.3	Kreke N.	2010b	Determination of residues of copper in greenhouse cucumber (RAC fruit) following four treatments with different copper formulations in greenhouse in northern and southern Europe in 2010. Report No C91084 Harlan laboratories GLP Unpublished.	N	EuCuT F
KCA 6.3. 7.2.3	Foster AC.	2006	Magnitude of residues of copper and cymoxanil in protected melons (fruiting vegetables) following applications of metallic copper (as copper oxychloride)/c ymoxanil (DPX-KK807) 44WG (9.5:1) under maximum label rates – southern europe, 2004. Report No DuPont 14536 DuPont GLP Unpublished.	N	EuCuT F
KCA 6.3. 7.2.3	Hansford RJ.	2008	Magnitude of residues of copper in protected melons (curcurbits – inedible peel) following applications of metallic copper (as copper oxychloride) / cymoxanil (DPX-KK807) 44WP (9.5:1) – Southern Europe, season 2007. Report No DuPont 22564 DuPont GLP Unpublished.	N	EuCuT F
KCA 6.5.2-6.5.3	Perny A.	1999	Determination of copper residues in grape raw agricultural commodity, and in must and wine following treatments with the preparation Bouillie Bordelaise RSR under field conditions in France in 1998. Report No R 8031 GLP, Unpublished.	N	UPL (In DAR, 2007)

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 Copper oxychloride

A 2.1.1 Stability of residues

Stability of residues studies are not required. Copper is an element and is inherently stable as it cannot be transformed into any other material.

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

A 2.1.3 Nature of residue in plants

Studies are not required. Copper is a mono-atomic charged element and inherently stable. It cannot be transformed into related degradation products or metabolites in plants.

A 2.1.4 Nature of residues in livestock

Studies are not required. Copper is a mono-atomic charged element and inherently stable. It cannot be transformed into related degradation products or metabolites.

A 2.1.5 Magnitude of residues in plants

A 2.1.5.1 Apple

Table A 1: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (Art. 12, EFSA, 2018b)	8	0.375 kg as/ha	14 days	-	14
Intended cGAP (Report 19SGS15) Report 21SGS90)	4	0.750 kg as/ha	7-10 days	BBCH 77 - 85	~~7~~ 14

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

A 2.1.5.1.1 Study 1

Comments of zRMS:	Study is accepted

Reference:	Report 19SGS15
Report	Magnitude of the residue of copper oxychloride in apple Raw Agricultural Commodity after four applications of Miedzian 50 WP – four harvest trials and two decline curve trials in Poland – 2019. Peda Tomasz, 2020. Final Report, Study number: 19SGS15
Guideline(s):	SANCO/3029/99 rev. 4; SANCO/825/00rev. 8.1; OECD (2009), Test No. 509.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Six residue trials on apples were carried out in Poland in 2019 (4 harvest and 2 decline curve studies). Product MIEDZIAN 50 WP was applied four times at a rate of 750 g of copper. During the application period the apple trees were at the growth stage BBCH 77-85. Fruits were sampling during commercial harvest (14 DALA) in 19SGS15-01, 19SGS15-02, 19SGS15-03, 19SGS15-04, and in decline curve studies 19SGS15-05, 19SGS15-06: 0, 7, 10, 14 and 21 DALA.
Fruits were collected from the central parts of the plots, selectively from all parts of the tree. Samples were frozen within 5 hours from sampling. The frozen test items were stored at the temperature below -18°C for approx. 3-4 month months.
Specimen extraction and determination of residues of total copper were performed according to the microwave mineralization with concentrated nitric acid and inductively coupled plasma – mass spectrometry (ICP/MS) method. Final extracts were employed for ICP/MS analysis directly after completion of the mineralization procedure (on the same day). The analysis was performed using Rh as internal standard.
The method for determination copper in apples was validated according EC Guidance Documents SANCO/3029/99 rev. 4 and SANCO/825/00 rev. 8.1.

The method for determination of total copper in apples was the same as for cherries (results of validation method are presented in Appendix B of Final Report 19SGS16). According to this EU guidelines a reduced validation data set may be considered where two or more very similar matrices are to be analysed. Reduced validation data for sample matrices within the same crop group (as defined in SANCO/825/00) are acceptable. Cherries and apples belongs to the same matrix group – commodities with high water content.

The range of linearity of the analytical graph of total copper varied from 0.001 to 0.2 mg/l (0.1 to 20.0 mg/kg sample), $R^2 \geq 0.99$. The recovery of the method was estimated for two fortification levels LOQ and 10x LOQ, e.i. 0.5 and 5.0 mg/kg. The mean extraction recovery levels in samples for total copper were: 97.40% and 97%, respectively. All recovery values at fortification level of 0.5 mg/kg and 5 mg/kg comply with the standard acceptance criteria of the guidelines SANCO/3029/99 rev. 4 and SANCO/825/00 rev. 8.1. The precision was 5.15% for LOQ level and 3.58% for 10 x LOQ level.

To confirm the accuracy of the cherry validation method for apple for each analytical set the method applicability in terms of accuracy was assessed by fortification of untreated test portion of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. The recoveries for 0.5 mg/kg level were between 96.6% and 102.0%, and for 5.0 mg/kg level were between 96.1% and 96.6%.

The limit of quantification (LOQ) for total copper was 0.5 mg/kg and the limit of detection was 0.15 mg/kg.

Table A 2: Summary of the study 1 trials

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				Total copper		
	(a)	(b)				(c)				(d)	(e)
19SGS15-01/ Poland (Kozłowo)	Apple/Szampion Reno	Planting date: 10.2016 Harvest: 02.09.2019	0.750 g as/ha	500 L/ha	0.150 g as/hl	4 treatments: 24.07.2019 02.08.2019 11.08.2019 19.08.2019	BBCH 87	Fruits, min 2 kg	2.50	14	
19SGS15-02/ Poland (Sadki)	Apple/Gala	Planting date: 1998 Harvest: 27.09.2019	0.750 g as/ha	500 L/ha	0.150 g as/hl	4 treatments: 20.08.2019 28.08.2019 05.09.2019 13.09.2019	BBCH 81	Fruits, min 2 kg	0.96	14	
19SGS15-03/ Poland (Droszów)	Apple/Lobo	Planting date: 25.10.2009 Harvest: 13.09.2019	0.750 g as/ha	500 L/ha	0.150 g as/hl	4 treatments: 09.08.20019 16.08.2019 23.08.2019 30.08.2019	BBCH 78	Fruits, min 2 kg	0.88	14	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant-ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat-ment or no. of treatments and last date	Growth stage at last treatment or date	Portion ana-lyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Total copper		
	(a)	(b)				(c)				(d)	(e)
19SGS15-04/ Poland (Dębe)	Apple/Jonagored	Planting date: 03.2011 Harvest: 03.10.2019	0.750 g as/ha	500 L/ha	0.150 g as/hl	4 treatments: 26.08.2019 03.09.2019 11.09.2019 19.09.2019	BBCH 85	Fruits, min 2 kg	1.72	14	
19SGS15-05/ Poland (Gać)	Apple/Gala Royal	Planting date: 25.10.2010 Harvest: 13.09.2019	0.750 g as/ha	500 L/ha	0.150 g as/hl	4 treatments: 09.08.2019 16.08.2019 23.08.2019 30.08.2019	BBCH 81	Fruits, min 2 kg	2.40 1.23 1.15 1.73 1.04	0 DALA 7 DALA 10 DALA 14 DALA 21 DALA	
19SGS15-06/ Poland (Miastowice)	Apple/Alwa	Planting date: 1994 Harvest: 27.09.2019	0.750 g as/ha	500 L/ha	0.150 g as/hl	4 treatments: 20.08.2019 28.08.2019 05.09.2019 13.09.2019	BBCH 81	Fruits, min 2 kg	1.71 1.39 1.55 1.18 1.71	0 DALA 7 DALA 10 DALA 14 DALA 21 DALA	

(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 include

A 2.1.5.1.1 Study 2

Comments of zRMS:	Study is accepted

Reference:	Report 21SGS90
Report	Magnitude of the residue of copper oxychloride in apple (Raw Agricultural Commodity) after four applications of Miedzian 50 WP – two decline curve trials in Poland – 2021. Peda Tomasz, 2021. Final Report, Study number: 21SGS90
Guideline(s):	SANCO/3029/99 rev. 4; SANCO/825/00rev. 8.1; SANTE/2020/12830 rev.1, 24/02/2021; OECD (2009 and 2021), Test No. 509; Commission Working Document 7029/VI/95 Rev. 5.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Two residue trials on apples were carried out in Poland in 2021 (2 decline curve studies). Product MIEDZIAN 50 WP was applied four times at a rate of 750 g of copper. During the application period the apple trees were at the growth stage BBCH 78-88. Fruits were sampling during 0, 7, 10, 14 and 21 days after last application.
Fruits were collected from the central parts of the plots, selectively from all parts of the tree. Samples were frozen within 5 hours from sampling. The frozen test items were stored at the temperature below -18°C for approx. one month.
Specimen extraction and determination of residues of total copper were performed according to the microwave mineralization with concentrated nitric acid and inductively coupled plasma – mass spectrometry (ICP/MS) method. Final extracts were employed for ICP/MS analysis directly after completion of the mineralization procedure (on the same day). The analysis was performed using Rh as internal standard.
The method for determination copper in apples was validated according EC Guidance Documents SANCO/3029/99 rev. 4 and SANCO/825/00 rev. 8.1. Guidance documents SANCO/3029/99 rev. 4 and SANCO/825/00 rev. 8.1 were superseded by SANTE/2020/12830 rev.1 on 24.02.2021. Nevertheless, method validation that was performed within study 19SGS15 (DPL/133/2019) meets the criteria of SANTE/2020/12830 rev.1
The method for determination of total copper in apples was the same as for cherries (results of validation method are presented in Appendix B of Final Report 19SGS16). According to this EU guidelines a reduced validation data set may be considered where two or more very similar matrices are to be analysed. Reduced validation data for sample matrices within the same crop group (as defined in SANTE/2020/12830 rev.1) are acceptable. Cherries and apples belongs to the same matrix group – commodities with high water content.
The range of linearity of the analytical graph of total copper varied from 0.001 to 0.2 mg/l (0.1 to 20.0 mg/kg sample), $R^2 \geq 0.99$. The recovery of the method was estimated for two fortification levels LOQ and 10x LOQ, e.i. 0.5 and 5.0 mg/kg. The mean extraction recovery levels in samples for total copper were: 97.40% and 97%, respectively. All recovery values at fortification level of 0.5 mg/kg and 5 mg/kg comply with the standard acceptance criteria of the guidelines SANTE/2020/12830 rev.1. The precision was 5.15% for LOQ level and 3.58% for 10 x LOQ level.
To confirm the accuracy of the cherry validation method for apple for each analytical set the method applicability in terms of accuracy was assessed by fortification of untreated test portion of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. The recoveries for 0.5 mg/kg level were between 96.4% and 91.2%, and for 5.0 mg/kg level were between 92.4% and 91.9%.
The limit of quantification (LOQ) for total copper was 0.5 mg/kg and the limit of detection was 0.15 mg/kg

Table A 3: Summary of the study 2 trials

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				Total copper		
	(a)	(b)				(c)				(d)	(e)
21SGS90-01/ Poland (Cebulki)	Apple/Janoprince	Planting date: 12016 Harvest: 13/10/2021 – 20/10/2021	0.750 g as/ha	500 L/ha	0.150 g as/hl	4 treatments	BBCH 85	Fruits, min 2 kg	< LOQ 4.80 4.63 4.62 4.60 < LOQ	control 0 DALA 7 DALA 14 DALA 21 DALA control	
21SGS90-02/ Poland (Niemirowice)	Apple/Szampion	Planting date: 15/03/2012 Harvest: 10/10/2021 – 25/10/2021	0.750 g as/ha	500 L/ha	0.150 g as/hl	4 treatments	BBCH 88	Fruits, min 2 kg	< LOQ 5.24 4.97 4.73 4.70 < LOQ	control 0 DALA 7 DALA 14 DALA 21 DALA control	

A 2.1.5.2 Cherry

Table A 4: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (Art. 12, EFSA, 2018b)	3	800 g a.s./ha	14	BBCH 73-85	21
Intended cGAP (Report 19SGS16) Report 21SGS89	3	A1, A2 – 1500 g a.s./ha; A3 – 750 g a.s./ha	7-10 days	BBCH 73-85	14

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

A 2.1.5.2.1 Study 1

Comments of zRMS:	Study is accepted

Reference:	Report 19SGS16
Report	Magnitude of the residue of copper oxychloride in cherry (Raw Agricultural Commodity) after three applications of Miedzian 50 WP – two harvest trials and two decline curve trials in Poland – 2019. Peda Tomasz, 2020. Final Report, Study number: 19SGS16.
Guideline(s):	SANCO/3029/99 rev. 4; SANCO/825/00rev. 8.1; OECD (2009), Test No. 509.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Four residue trials on cherries were carried out in Poland in 2019 (2 harvest and 2 decline curve studies). Three typical fungicide application of Miedzian 50 WP were performed in each trial. At application A1 and A2 target dose rate of Miedzian 50 WP was 1500 g a.s./ha of copper. At application A3 target dose rate of Miedzian 50 WP was 750 g a.s./ha of copper as copper oxychloride. During the application period the cherry trees were at the growth stage BBCH 73-85. Fruits were sampling during commercial harvest (14 DALA) in 19SGS16-01, 19SGS16-02, and in decline curve studies 19SGS16-03, 19SGS16-04: 0, 7, 10, 14 and 21 DALA.
Fruits were collected from the central parts of the plots, selectively from all parts of the tree. Samples were frozen within 5 hours from sampling. The frozen test items were stored at the temperature below -18°C for approx. 3-4 month months.
Specimen extraction and determination of residues of total copper were performed according to the microwave mineralization with concentrated nitric acid and inductively coupled plasma – mass spectrometry (ICP/MS) method. Final extracts were employed for ICP/MS analysis directly after completion of the mineralization procedure (on the same day). The analysis was performed using Rh as internal standard.
The method for determination copper in apples was validated according EC Guidance Documents SANCO/3029/99 rev. 4 and SANCO/825/00 rev. 8.1.
The range of linearity of the analytical graph of total copper varied from 0.001 to 0.2 mg/l (0.1 to 20.0 mg/kg sample), $R^2 \geq 0.99$. The recovery of the method was estimated for two fortification levels LOQ and

10x LOQ, e.i. 0.5 and 5.0 mg/kg. The mean extraction recovery levels in samples for total copper were: 97.40% and 97%, respectively. All recovery values at fortification level of 0.5 mg/kg and 5 mg/kg comply with the standard acceptance criteria of the guidelines SANCO/3029/99 rev. 4 and SANCO/825/00 rev. 8.1. The precision was 5.15% for LOQ level and 3.58% for 10 x LOQ level.
The limit of quantification (LOQ) for total copper was 0.5 mg/kg and the limit of detection was 0.15 mg/kg.

Table A 5: Summary of the study 1 trials

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 treat-ments 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				Total copper		
	(a)	(b)				(c)				(d)	(e)
19SGS16-01/Poland (Miastowice)	Cherry/Pandy	Planting date: 10.1999 Harvest: 08.07.2019	A1, A2 – 1500 g a.s./ha; A3 – 750 g a.s./ha	500 – 750 l/ha	150 – 200 g a.s./hl	3 treatments: 07.06.2019 15.06.2019 24.06.2019	BBCH 81	Fruits, min 2 kg	2.09	14	
19SGS16-02/Poland (Nowy Kawęczyn)	Cherry/Sabina	Planting date: 04.2013	A1, A2 – 1500 g a.s./ha; A3 – 750 g a.s./ha	500 – 750 l/ha	150 – 200 g a.s./hl	3 treatments: 04.06.2019 11.06.2019 21.06.2019	BBCH 85	Fruits, min 2 kg	2.20	14	
19SGS16-03/Poland (Jankowice Małe)	Cherry/Łutówka	Planting date: 22.10.2008 Harvest: 16.07.2019	A1, A2 – 1500 g a.s./ha; A3 – 750 g a.s./ha	500 – 750 l/ha	150 – 200 g a.s./hl	3 treatments: 17.06.2019 26.06.2019 03.07.2019	BBCH 81	Fruits, min 2 kg	5.62 2.87 2.23 <u>2.62</u> 2.56	0 DALA 7 DALA 10 DALA 14 DALA 21 DALA	
19SGS16-04/Poland (Izbica)	Cherry/Łutówka	Planting date: 04.2004 Harvest: 11.07.2019	A1, A2 – 1500 g a.s./ha; A3 – 750 g a.s./ha	500 – 750 l/ha	150 – 200 g a.s./hl	3 treatments: 13.06.2019 21.06.2019 28.06.2019	BBCH 81/85	Fruits, min 2 kg	5.49 3.55 4.36 <u>3.84</u> 3.33	0 DALA 7 DALA 10 DALA 14 DALA 21 DALA	

(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 include

A 2.1.5.2.1 Study 2

Comments of zRMS:	Study is accepted

Reference:	Report 21SGS89
Report	Magnitude of the residue of copper oxychloride in cherry (Raw Agricultural Commodity) after three applications of Miedzian 50 WP – two harvest trials and two decline curve trials in Poland – 2021. Peda Tomasz, 2021. Final Report, Study number: 21SGS89.
Guideline(s):	SANCO/3029/99 rev. 4; SANCO/825/00rev. 8.1; SANTE/2020/12830 rev.1, 24/02/2021; OECD (2009), Test No. 509; Commission Working Document 7029/VI/95 Rev. 5.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Four residue trials on cherries were carried out in Poland in 2021 (2 harvest and 2 decline curve studies).
Three typical fungicide application of Miedzian 50 WP were performed in each trial. At application A1 and A2 target dose rate of Miedzian 50 WP was 1500 g a.s./ha of copper. At application A3 target dose rate of Miedzian 50 WP was 750 g a.s./ha of copper as copper oxychloride. During the application period the cherry trees were at the growth stage BBCH 73-81. Fruits were sampling during commercial harvest (14 DALA) in 21SGS89-01, 21SGS89-02, and in decline curve studies 21SGS89-03, 21SGS89-04: 0, 7, 10, 14 and 21 DALA.
Fruits were collected from the central parts of the plots, selectively from all parts of the tree. Samples were frozen within 2 - 5 hours from sampling. The frozen test items were stored at the temperature below -18°C for approx. 4 months.
Specimen extraction and determination of residues of total copper were performed according to the microwave mineralization with concentrated nitric acid and inductively coupled plasma – mass spectrometry (ICP/MS) method. Final extracts were employed for ICP/MS analysis directly after completion of the mineralization procedure (on the same day). The analysis was performed using Rh as internal standard.
The method for determination copper in apples was validated according EC Guidance Documents SANCO/3029/99 rev. 4 and SANCO/825/00 rev. 8.1. Guidance documents SANCO/3029/99 and SANCO/825/00 were superseded by SANTE/2020/12830, Rev.1 on 24.02.2021. Nevertheless, method validation that was performed within study DPL/133/2019 (mentioned above) meets the criteria of SANTE/2020/12830, Rev. 1.
The range of linearity of the analytical graph of total copper varied from 0.001 to 0.2 mg/l (0.1 to 20.0 mg/kg sample), $R^2 \geq 0.99$. The recovery of the method was estimated for two fortification levels LOQ and 10x LOQ, e.i. 0.5 and 5.0 mg/kg. The mean extraction recovery levels in samples for total copper were: 97.40% and 97%, respectively. All recovery values at fortification level of 0.5 mg/kg and 5 mg/kg comply with the standard acceptance criteria of the guidelines SANCO/3029/99 rev. 4, SANCO/825/00 rev. 8.1 and SANTE/2020/12830, Rev.1. The precision was 5.15% for LOQ level and 3.58% for 10 x LOQ level.
To confirm the accuracy of the cherry validation method in Report 21SGS89 (2021) for each analytical set the method applicability in terms of accuracy was assessed by fortification of untreated test portion of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. The recoveries for 0.5 mg/kg level were between 87.7% and 100%, and for 5.0 mg/kg level were between 99.4% and 100%.
The limit of quantification (LOQ) for total copper was 0.5 mg/kg and the limit of detection was 0.15 mg/kg.

Table A 6: Summary of the study 2 trials

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 treat-ments and last date	Growth stage at last treatment or date	Portion ana-lyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Total copper		
	(a)	(b)				(c)				(d)	(e)
21SGS89-01/Poland (Jankowice Małe)	Cherry/Łutówka	Planting date: 2001 Harvest: 14.07.2021 – 22.07.2021	A1, A2 – 1500 g a.s./ha; A3 – 750 g a.s./ha	500 – 750 l/ha	150 – 200 g a.s./hl	3 treatments: 14.06.2021 23.06.2021 30.06.2021	BBCH 81	Fruits, min 2 kg	1.88	14	
21SGS89-02/Poland (Niemirowice)	Cherry/Łutówka	Planting date: 04/2010 Harvest: 13.07.2021 – 15.07.2021	A1, A2 – 1500 g a.s./ha; A3 – 750 g a.s./ha	500 – 750 l/ha	150 – 200 g a.s./hl	3 treatments: 16.06.2021 23.06.2021 30.06.2021	BBCH 77	Fruits, min 2 kg	2.15	14	
21SGS89-03/Poland (Stare Olszyny)	Cherry/Łutówka	Planting date: 2017 Harvest: 20.07.2021 – 25.07.2021	A1, A2 – 1500 g a.s./ha; A3 – 750 g a.s./ha	500 – 750 l/ha	150 – 200 g a.s./hl	3 treatments: 17.06.2021 25.06.2021 02.07.2021	BBCH 78	Fruits, min 2 kg	9.54 4.57 2.12 1.19 1.12	0 DALA 7 DALA 10 DALA 14 DALA 21 DALA	
21SGS89-04/Poland (Miastowice)	Cherry/Groniasta	Planting date: 04/2010 Harvest: 23.07.2021 – 30.07.2021	A1, A2 – 1500 g a.s./ha; A3 – 750 g a.s./ha	500 – 750 l/ha	150 – 200 g a.s./hl	3 treatments: 24.06.2021 02.07.2021 09.07.2021	BBCH 81	Fruits, min 2 kg	7.32 3.32 2.75 1.28 1.43	0 DALA 7 DALA 10 DALA 14 DALA 21 DALA	

(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 include

A 2.1.5.3 Cucumber

Table A 7: 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)
France, 2017 (outdoor uses)	7	850 g a.s./ha	7 days	BBCH 10-89	3
France, 2017 (indoor uses)	1 + 4	1000 + 1250 g a.s./ha	7 days	BBCH 10-89	3
cGAP EU (Art. 12, EFSA, 2018b)	5	1000 g a.s./ha	7 days	BBCH 15-89	3
Intended cGAP (Report 19SGS17)	3	1250 g a.s./ha	7-10 days	BBCH 61-89	3

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

A 2.1.5.3.1 Study 1

Comments of zRMS:	Study is accepted

Reference:	Report 19SGS17
Report	Magnitude of the residue of copper oxychloride in cucumber (openfield) Raw Agricultural Commodity after three applications of Miedzian 50 WP – two harvest trials and two decline curve trials in Poland – 2019. Peda Tomasz, 2020. Final Report, Study number: 19SGS17.
Guideline(s):	SANCO/3029/99 rev. 4; SANCO/825/00rev. 8.1; OECD (2009), Test No. 509.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Four residue trials on cucumbers in openfield conditions were carried out in Poland in 2019 (2 harvest and 2 decline curve studies).
Three typical fungicide application of Miedzian 50 WP were performed in each trial at the target dose rate was 1250 g a.s./ha of copper. During the application period the cucumber plants were at the growth stage BBCH 61-89. Fruits were sampling during commercial harvest (7 DALA) in 19SGS17-01, 19SGS17-02, and in decline curve studies 19SGS17-03, 19SGS17-04: 0, 3, 7, 10 and 14 DALA.
Fruits were collected from the central parts of the plots. Samples were frozen within 5 hours from sampling. The frozen test items were stored at the temperature below -18°C for approx. 3-4 month months.
Specimen extraction and determination of residues of total copper were performed according to the microwave mineralization with concentrated nitric acid and inductively coupled plasma – mass spectrometry (ICP/MS) method. Final extracts were employed for ICP/MS analysis directly after completion of the mineralization procedure (on the same day). The analysis was performed using Rh as internal standard.

The method for determination of total copper in cucumbers was the same as for cherries (results of validation method are presented in Appendix B of Final Report 19SGS16). According to this EU guidelines a reduced validation data set may be considered where two or more very similar matrices are to be analysed. Reduced validation data for sample matrices within the same crop group (as defined in SANCO/825/00) are acceptable. Cherries and cucumbers belongs to the same matrix group – commodities with high water content.

The range of linearity of the analytical graph of total copper varied from 0.001 to 0.2 mg/l (0.1 to 20.0 mg/kg sample), $R^2 \geq 0.99$. The recovery of the method was estimated for two fortification levels LOQ and 10x LOQ, e.i. 0.5 and 5.0 mg/kg. The mean extraction recovery levels in samples for total copper were: 97.40% and 97%, respectively. All recovery values at fortification level of 0.5 mg/kg and 5 mg/kg comply with the standard acceptance criteria of the guidelines SANCO/3029/99 rev. 4 and SANCO/825/00 rev. 8.1. The precision was 5.15% for LOQ level and 3.58% for 10 x LOQ level.

To confirm the accuracy of the cherry validation method for cucumbers for each analytical set the method applicability in terms of accuracy was assessed by fortification of untreated test portion of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. The recoveries for 0.5 mg/kg level were between 95.7% and 101.0%, and for 5.0 mg/kg level were between 97.7% and 98.8%.

The limit of quantification (LOQ) for total copper was 0.5 mg/kg and the limit of detection was 0.15 mg/kg.

Table A 8: Summary of the study 1 trials

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 treat-ments 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				Total copper		
	(a)	(b)				(c)				(d)	(e)
19SGS17-01/Poland (Kamień Krajeński)	Cucumber/ Tomasz F1	Sowing date: 22.05.2019 Harvest: 14.08.2019	1250 g a.s./ha	700 l/ha	178.6 g a.s./hl	3 treatments: 23.07.2019 31.07.2019 07.08.2019	BBCH 73	Fruits, min 2 kg	< LOQ	7	
19SGS17-02/Poland (Kaczkowo)	Cucumber/ Gwidon	Sowing date: 17.05.2019 Harvest: 14.09.2019	1250 g a.s./ha	700 l/ha	178.6 g a.s./hl	3 treatments: 23.07.2019 30.07.2019 07.08.2019	BBCH 89	Fruits, min 2 kg	0.99	7	
19SGS17-03/Poland (Przylesie)	Cucumber/ Izyd F1	Sowing date: 01.08.2019 Harvest: 11.10.2019	1250 g a.s./ha	700 l/ha	178.6 g a.s./hl	3 treatments: 18.09.2019 26.09.2019 04.10.2019	BBCH 72	Fruits, min 2 kg	0.68 0.63 0.56 0.59 0.60	0 DALA 3 DALA 7 DALA 10 DALA 14 DALA	
19SGS17-04/Poland (Piskrzówek)	Cucumber/ Anya	Sowing date: 20.06.2019 Harvest: 15.08.2019	1250 g a.s./ha	700 l/ha	178.6 g a.s./hl	3 treatments: 23.07.2019 01.08.2019 08.08.2019	BBCH 71	Fruits, min 2 kg	2.17 1.32 0.60 0.59 0.56	0 DALA 3 DALA 7 DALA 10 DALA 14 DALA	

(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 include

A 2.1.5.4 Tomato

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)
France, 2017 (outdoor uses)	7	850 g a.s./ha	7 days	BBCH 12-89	3 (fresh), 10 (industrial)
France, 2017 (indoor uses)	1 + 4	1000 + 1250 g a.s./ha	7 days	BBCH 12-89	3 (fresh), 10 (industrial)
cGAP EU (Art. 12, EFSA, 2018b)	6	1250 g a.s./ha	7 days	BBCH 15-89	3
Intended cGAP (Report 19SGS18)	3	1250 g a.s./ha	7 days	BBCH 71 -85	7

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

A 2.1.5.4.1 Study 1

Comments of zRMS:	Study is accepted

Reference:	Report 19SGS18
Report	Magnitude of the residue of copper oxychloride in tomato (openfield) Raw Agricultural Commodity after three applications of Miedzian 50 WP – two harvest trials in Poland – 2019. Peda Tomasz, 2020. Final Report, Study number: 19SGS18.
Guideline(s):	SANCO/3029/99 rev. 4; SANCO/825/00rev. 8.1; OECD (2009), Test No. 509.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Two harvest residue trials on tomato in openfield conditions were carried out in Poland in 2019.
Three typical fungicide application of Miedzian 50 WP were performed in each trial at the target dose rate was 1250 g a.s./ha of copper. During the application period the tomato plants were at the growth stage BBCH 71-85. Fruits were sampling during commercial harvest (7 DALA).
Fruits were collected from the central parts of the plots. Samples were frozen within 5 hours from sampling. The frozen test items were stored at the temperature below -18°C for approx. 3-4 month months.
Specimen extraction and determination of residues of total copper were performed according to the microwave mineralization with concentrated nitric acid and inductively coupled plasma – mass spectrometry (ICP/MS) method. Final extracts were employed for ICP/MS analysis directly after completion of the mineralization procedure (on the same day). The analysis was performed using Rh as internal standard.
The method for determination of total copper in tomato was the same as for cherries (results of validation method are presented in Appendix B of Final Report 19SGS16). According to this EU guidelines a re-

duced validation data set may be considered where two or more very similar matrices are to be analysed. Reduced validation data for sample matrices within the same crop group (as defined in SANCO/825/00) are acceptable. Cherries and tomatoes belongs to the same matrix group – commodities with high water content.

The range of linearity of the analytical graph of total copper varied from 0.001 to 0.2 mg/l (0.1 to 20.0 mg/kg sample), $R^2 \geq 0.99$. The recovery of the method was estimated for two fortification levels LOQ and 10x LOQ, e.i. 0.5 and 5.0 mg/kg. The mean extraction recovery levels in samples for total copper were: 97.40% and 97%, respectively. All recovery values at fortification level of 0.5 mg/kg and 5 mg/kg comply with the standard acceptance criteria of the guidelines SANCO/3029/99 rev. 4 and SANCO/825/00 rev. 8.1. The precision was 5.15% for LOQ level and 3.58% for 10 x LOQ level.

To confirm the accuracy of the cherry validation method for tomatoes for each analytical set the method applicability in terms of accuracy was assessed by fortification of untreated test portion of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. The recoveries for 0.5 mg/kg level were between 91.5% and 97.4%, and for 5.0 mg/kg level were between 97.5% and 98.7%.

The limit of quantification (LOQ) for total copper was 0.5 mg/kg and the limit of detection was 0.15 mg/kg.

Table A 10: Summary of the study 1 trials

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 treat-ments and last date	Growth stage at last treatment or date	Portion ana-lyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Total copper		
	(a)	(b)				(c)				(d)	(e)
19SGS18-01/Poland (Kaczkowo)	Tomato/Asterix	Planting date: 30.05.2019 Harvest: 29.08.2019	1250 g a.s./ha	700 l/ha	178.6 g a.s./hl	3 treatments: 06.08.2019 18.08.2019 22.08.2019	BBCH 85	Fruits, min 2 kg	1.89	7	
19SGS18-02/Poland (Kamień Krajeński)	Tomato/Pocet	Planting date: 29.05.2019 Harvest: 21.08.2019	1250 g a.s./ha	700 l/ha	178.6 g a.s./hl	3 treatments: 30.07.2019 06.08.2019 14.08.2019	BBCH 81	Fruits, min 2 kg	1.62	7	

(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 include

Study 2

Comments of zRMS:	Study is accepted

Reference:	Report 451SRPL19R1
Report	Determination of residues of cymoxanil and copper in tomato at harvest under open field conditions following three application of Curzate Cu 49,5 WP in Poland 2019. Field Phase: Study number 451SRPL19R1, Wojtaniec K., Dąbrowski G., 2020. Analytical Phase Code: DPL/84/2020, Paszek G., 2020.
Guideline(s):	SANCO/3029/99 rev. 4; SANCO/825/00rev. 8.1; OECD (2009), Test No. 509.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Two harvest residue trials on tomato in openfield conditions were carried out in Poland in 2019.
Three typical fungicide application of Curzate Cu 49,5 WP were performed in each trial at the target dose rate was 1125 g a.s./ha of copper. During the application period the tomato plants were at the growth stage BBCH 71-85 in trial SRPL19-303-451FR and BBCH 81-87 in trial SRPL19-304-451FR. Fruits were sampling during commercial harvest (7 DALA).
Samples were collected by hand using disposable gloves from entire plot except the edges from all parts of plants: as well protected as exposed. Only marketable fruits were collected (with no damages or scratches) from 24 plants for each sample. During transport and storage, control and treated samples were stored separately. Samples were put in freezer within 6 hours after sampling. Samples were deep frozen (min. -30.3°C, max -23.3°C).
Specimen extraction and determination of residues of total copper were performed according to the microwave mineralization with concentrated nitric acid and inductively coupled plasma – mass spectrometry (ICP/MS) method. Final extracts were employed for ICP/MS analysis directly after completion of the mineralization procedure (on the same day). The analysis was performed using Rh as internal standard.
The method for determination of total copper in tomato was the same as for cherries (results of validation method are presented in Appendix B of Final Report 19SGS16). According to this EU guidelines a reduced validation data set may be considered where two or more very similar matrices are to be analysed. Reduced validation data for sample matrices within the same crop group (as defined in SANCO/825/00) are acceptable. Cherries and tomatoes belongs to the same matrix group – commodities with high water content.
The range of linearity of the analytical graph of total copper varied from 0.001 to 0.2 mg/l (0.1 to 20.0 mg/kg sample), $R^2 \geq 0.99$. The recovery of the method was estimated for two fortification levels LOQ and 10x LOQ, e.i. 0.5 and 5.0 mg/kg. The mean extraction recovery levels in samples for total copper were: 97.4% and 97.0%, respectively. All recovery values at fortification level of 0.5 mg/kg and 5 mg/kg comply with the standard acceptance criteria of the guidelines SANCO/3029/99 rev. 4 and SANCO/825/00 rev. 8.1. The precision was 5.15% for LOQ level and 3.58% for 10 x LOQ level.
To confirm the accuracy of the cherry validation method for tomatoes for each analytical set the method applicability in terms of accuracy was assessed by fortification of untreated test portion of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. The recoveries for 0.5 mg/kg level were 100%, and for 5.0 mg/kg level were between 96.2% and 99.5%.
The limit of quantification (LOQ) for total copper was 0.5 mg/kg and the limit of detection was 0.15 mg/kg.

Table A 11: Summary of the study 1 trials

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				Total copper		
	(a)	(b)				(c)				(d)	(e)
SRPL19-303-451FR/Poland (Feliksów)	Tomato/Chelse F1	Planting date: 11.06.2019 Harvest: 19.09.2019	1125 g a.s./ha	700 l/ha	160.7 g a.s./hl	3 treatments: 30.08.2019 05.09.2019 12.09.2019	BBCH 71-85	Fruits, min 2 kg	1.47	7	
SRPL19-304-451FR/Poland (Murczyn)	Tomato/Miceno F1)	Planting date: 03.06.2019 Harvest: 13.09.2019	1125 g a.s./ha	700 l/ha	160.7 g a.s./hl	3 treatments: 24.08.2019 30.08.2019 06.09.2019	BBCH 81-87	Fruits, min 2 kg	1.02	7	

(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 include

A 2.1.5.5 French Bean

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)
Bean (with pods) cGAP EU (Art. 12, EFSA, 2018b)	4	800 g a.s./ha	7 days	BBCH 61-78	3
Intended cGAP (Report 19SGS18) Report 21SGS92	2	1500 g a.s./ha	7 days	BBCH 69-81	7

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

A 2.1.5.5.1 Study 1

Comments of zRMS:	Study is accepted

Reference:	Report 19SGS19
Report	Magnitude of the residue of copper oxychloride in French (openfield) Raw Agricultural Commodity after three applications of Miedzian 50 WP – two harvest trials in Poland – 2019. Peda Tomasz, 2020. Final Report, Study number: 19SGS19.
Guideline(s):	SANCO/3029/99 rev. 4; SANCO/825/00rev. 8.1; OECD (2009), Test No. 509.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Two harvest residue trials on French bean in openfield conditions were carried out in Poland in 2019.
Two typical fungicide application of Miedzian 50 WP were performed in each trial at the target dose rate was 1500 g a.s./ha of copper. During the application period the beans plants were at the growth stage BBCH 69-81. Fruits were sampling during commercial harvest (7 DALA).
RAC specimens were collected from the central parts of the plots. Samples were frozen within 5 hours from sampling. The frozen test items were stored at the temperature below -18°C for approx. 3-4 month months.
Specimen extraction and determination of residues of total copper were performed according to the microwave mineralization with concentrated nitric acid and inductively coupled plasma – mass spectrometry (ICP/MS) method. Final extracts were employed for ICP/MS analysis directly after completion of the mineralization procedure (on the same day). The analysis was performed using Rh as internal standard.
The method for determination copper in French bean was validated according EC Guidance Documents SANCO/3029/99 rev. 4 and SANCO/825/00 rev. 8.1.
The range of linearity of the analytical graph of total copper varied from 0.001 to 0.2 mg/l (0.1 to 20.0 mg/kg sample), $R^2 \geq 0.99$. The recovery of the method was estimated for two fortification levels LOQ and 10x LOQ, e.i. 1.0 and 10.0 mg/kg. The mean extraction recovery levels in samples for total copper were: 96.7% and 94.4%, respectively. All recovery values at fortification level of 1 mg/kg and 10 mg/kg com-

ply with the standard acceptance criteria of the guidelines SANCO/3029/99 rev. 4 and SANCO/825/00 rev. 8.1. The precision was 8.8% for LOQ level and 12.8% for 10 x LOQ level.
The limit of quantification (LOQ) for total copper was 1.0 mg/kg and the limit of detection was 0.3 mg/kg.

Table A 13: Summary of the study 1 trials

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 treat-ments and last date	Growth stage at last treatment or date	Portion ana-lyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Total copper		
	(a)	(b)				(c)				(d)	(e)
19SGS19-01/Poland (Kaczkowo)	French bean/Jagusia	Sowing date: 14.06.2019 Harvest: 27.08.2019	1500 g a.s./ha	600 l/ha	250 g a.s./hl	2 treatments: 13.08.2019 20.08.2019	BBCH 73	Fruits, min. 2 kg	8.05	7	
19SGS19-02/Poland (Kamień Krajeński)	French bean/Jagusia	Sowing date: 06.05.2019 Harvest: 29.07.2019	1500 g a.s./ha	600 l/ha	250 g a.s./hl	2 treatments: 15.07.2019 22.07.2019	BBCH 81	Fruits, min. 2 kg	7.13	7	

(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 include

A 2.1.5.5.1 Study 2

Comments of zRMS:	Study is accepted

Reference:	Report 21SGS92
Report	Magnitude of the residue of copper oxychloride in string-bean (Raw Agricultural Commodity) after two applications of Miedzian 50 WP – two decline curve study trials in Poland – 2021. Peda Tomasz, 2021. Final Report, Study number: 19SGS19.
Guideline(s):	SANCO/3029/99 rev. 4; SANCO/825/00rev. 8.1; SANTE/2020/12830 rev.1, 24/02/2021; OECD (2009), Test No. 509; Commission Working Document 7029/VI/95 Rev. 5.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Two decline curve study trials on string bean in openfield conditions were carried out in Poland in 2021. Two typical fungicide application of Miedzian 50 WP were performed in each trial at the target dose rate was 1500 g a.s./ha of copper. During the application period the beans plants were at the growth stage BBCH 71-74. Fruits were sampling 0, 3, 7, 14 and 21 days after last application (DALA).

RAC specimens were collected from the central parts of the plots. Samples were frozen within 1-3 hours from sampling. The frozen test items were stored at the temperature below -18°C for approx. 3 months.
Specimen extraction and determination of residues of total copper were performed according to the microwave mineralization with concentrated nitric acid and inductively coupled plasma – mass spectrometry (ICP/MS) method. Final extracts were employed for ICP/MS analysis directly after completion of the mineralization procedure (on the same day). The analysis was performed using Rh as internal standard.
The method for determination copper in string bean was validated according EC Guidance Documents SANCO/3029/99 rev. 4 and SANCO/825/00 rev. 8.1. Guidance documents SANCO/3029/99 and SANCO/825/00 were superseded by SANTE/2020/12830, Rev.1 on 24.02.2021. Nevertheless, method validation that was performed within study DPL/133/2019 (mentioned above) meets the criteria of SANTE/2020/12830, Rev.1.
The range of linearity of the analytical graph of total copper varied from 0.001 to 0.2 mg/l (0.1 to 20.0 mg/kg sample), $R^2 \geq 0.99$. The recovery of the method was estimated for two fortification levels LOQ and 10x LOQ, e.i. 1.0 and 10.0 mg/kg. The mean extraction recovery levels in samples for total copper were: 96.7% and 94.4%, respectively. All recovery values at fortification level of 1 mg/kg and 10 mg/kg comply with the standard acceptance criteria of the guidelines SANCO/3029/99 rev. 4, SANCO/825/00 rev. 8.1. and SANTE/2020/12830, Rev.1. The precision was 8.8% for LOQ level and 12.8% for 10 x LOQ level.
To confirm the accuracy of the French bean validation method in Report 21SGS92 (2021) for each analytical set the method applicability in terms of accuracy was assessed by fortification of untreated test portion of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. The recoveries for 1 mg/kg level were between 99.5% and 94.4%, and for 10.0 mg/kg level were between 98.4% and 94.7%.

The limit of quantification (LOQ) for total copper was 1.0 mg/kg and the limit of detection was 0.3 mg/kg.

Table A 14: Summary of the study 2 trials

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 treat-ments and last date	Growth stage at last treatment or date	Portion ana-lyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Total copper		
	(a)	(b)				(c)				(d)	(e)
21SGS92-01/Poland (Kaczkowo)	String bean/Złota Saxa	Sowing date: 15.05.2021 Harvest: 30.07.2021 – 06.08.2021	1500 g a.s./ha	600 l/ha	250 g a.s./hl	2 treatments: 15.07.2021 23.07.2021	BBCH 73	Fruits	3.35 2.87 1.68 1.55 1.37	0 DALA 3 DALA 7 DALA 10 DALA 14 DALA	
19SGS19-02/Poland (Cebulki)	Stringbean/Sonesta	Sowing date: 02.06.2021 Harvest: 17.08.2021	1500 g a.s./ha	600 l/ha	250 g a.s./hl	2 treatments: 28.07.2021 03.08.2021	BBCH 74	Fruits	3.53 2.37 1.54 1.38 1.33	0 DALA 3 DALA 7 DALA 10 DALA 14 DALA	

(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 include

A 2.1.5.6 Black currant

Table A 15: 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 (Art. 12, EFSA, 2018b)	2	1200 g a.s./ha	7	BBCH 13-57	n.a.
Intended cGAP	2	1200 g a.s./ha	10 days	BBCH 81-85	7

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

A 2.1.5.6.1 Study 1

Comments of zRMS:	Study is accepted

Reference:	Report 19SGS20
Report	Magnitude of the residue of copper oxychloride in black currant (Raw Agricultural Commodity) after two applications of Miedzian 50 WP – two harvest trials in Poland – 2019. Peda Tomasz, 2020. Final Report, Study number: 19SGS20.
Guideline(s):	SANCO/3029/99 rev. 4; SANCO/825/00rev. 8.1; OECD (2009), Test No. 509.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Two harvest residue trials on black currant carried out in Poland in 2019. Two typical fungicide application of Miedzian 50 WP were performed in each trial at the target dose rate was 1500 g a.s./ha of copper. During the application period the currant plants were at the growth stage BBCH 81-85. Fruits were sampling during commercial harvest (7 DALA).
Fruits were collected from the central parts of the plots. Samples were frozen within 5 hours from sampling. The frozen test items were stored at the temperature below -18°C for approx. 3-4 month months.
Specimen extraction and determination of residues of total copper were performed according to the microwave mineralization with concentrated nitric acid and inductively coupled plasma – mass spectrometry (ICP/MS) method. Final extracts were employed for ICP/MS analysis directly after completion of the mineralization procedure (on the same day). The analysis was performed using Rh as internal standard.
The method for determination copper in black currant was validated according EC Guidance Documents SANCO/3029/99 rev. 4 and SANCO/825/00 rev. 8.1.
The method for determination of total copper in tomato was the same as for cherries (results of validation method are presented in Appendix B of Final Report 19SGS16). According to this EU guidelines a reduced validation data set may be considered where two or more very similar matrices are to be analysed. Reduced validation data for sample matrices within the same crop group (as defined in SANCO/825/00) are acceptable. Cherries and black currants belongs to the same matrix group – commodities with high water content.

The range of linearity of the analytical graph of total copper varied from 0.001 to 0.2 mg/l (0.1 to 20.0 mg/kg sample), $R^2 \geq 0.99$. The recovery of the method was estimated for two fortification levels LOQ and 10x LOQ, e.i. 0.5 and 5.0 mg/kg. The mean extraction recovery levels in samples for total copper were: 97.40% and 97%, respectively. All recovery values at fortification level of 0.5 mg/kg and 5 mg/kg comply with the standard acceptance criteria of the guidelines SANCO/3029/99 rev. 4 and SANCO/825/00 rev. 8.1. The precision was 5.15% for LOQ level and 3.58% for 10 x LOQ level.

To confirm the accuracy of the cherry validation method for black currants for each analytical set the method applicability in terms of accuracy was assessed by fortification of untreated test portion of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. The recoveries for 0.5 mg/kg level were between 92.8% and 93.8%, and for 5.0 mg/kg level were between 94.3% and 94.8%.

The limit of quantification (LOQ) for total copper was 0.5 mg/kg and the limit of detection was 0.15 mg/kg.

Table A 16: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Scaling factor	Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	Result from scaling (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl					Total copper			
	(a)	(b)					(c)					(d)	(e)
19SGS20-01/Poland (Miastowice)	Black currant/Ores	Planting date: 05.09.2014 Harvest: 01.07.2019	1500 g a.s./ha	700 l/ha	214.3 g a.s./hl	0.800	2 treatments: 14.06.2019 24.06.2019	BBCH 81	Fruits, min. 0.5 kg	5.99	4.79	7	
19SGS20-02/Poland (Sadki)	Black currant/Tibem	Planting date: 12.09.2016 Harvest: 04.07.2019	1500 g a.s./ha	700 l/ha	214.3 g a.s./hl	0.800	2 treatments: 17.06.2019 27.06.2019	BBCH 85	Fruits, min. 0.5 kg	4.57	3.66	7	

(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 include

A 2.1.6 Magnitude of residues in representative succeeding crops

Not required.

A 2.1.7 Other/Special Studies

Not required.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Copper oxychloride

LOQs (mg/kg) range from: to:

Input values | Details - chronic risk assessment | Supplementary results - chronic risk assessment | Details - acute risk assessment/children | Details - acute risk assessment/adults

Toxicological reference values

ADI (mg/kg bw/day):	0,15	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARfD:	
Year of evaluation:	2008	Year of evaluation:	

Comments:

Use hyperlir

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
31%	NL toddler	45,76	12%	Apples	9%	Table grapes	4%	Pears		31%
29%	DE child	42,78	14%	Apples	8%	Table grapes	2%	Tomatoes		29%
21%	GEMS/Food G06	32,07	6%	Table grapes	6%	Tomatoes	3%	Watermelons		21%
17%	NL child	25,82	7%	Apples	6%	Table grapes	1%	Pears		17%
12%	RO general	18,19	3%	Tomatoes	3%	Wine grapes	2%	Apples		12%
11%	IE adult	16,08	2%	Melons	2%	Wine grapes	2%	Table grapes		11%
10%	GEMS/Food G15	15,42	2%	Tomatoes	2%	Table grapes	2%	Wine grapes		10%
10%	PT general	14,73	4%	Wine grapes	2%	Table grapes	1%	Tomatoes		10%
10%	GEMS/Food G07	14,70	3%	Wine grapes	2%	Table grapes	2%	Tomatoes		10%
10%	GEMS/Food G08	14,51	2%	Table grapes	2%	Tomatoes	2%	Wine grapes		10%
10%	FR child 3 15 yr	14,50	2%	Table grapes	2%	Apples	1%	Tomatoes		10%
9%	DE women 14-50 yr	13,58	3%	Apples	2%	Table grapes	1%	Wine grapes		9%
9%	GEMS/Food G11	13,42	2%	Table grapes	2%	Apples	2%	Wine grapes		9%
9%	DK child	13,03	3%	Apples	2%	Cucumbers	1%	Table grapes		9%
9%	GEMS/Food G10	12,88	2%	Tomatoes	2%	Table grapes	0,9%	Apples		9%
8%	DE general	12,32	3%	Apples	1%	Table grapes	1%	Wine grapes		8%
8%	FR adult	12,01	4%	Wine grapes	0,9%	Apples	0,8%	Tomatoes		8%
8%	FR toddler 2 3 yr	11,29	4%	Apples	2%	Beans (with pods)	0,8%	Tomatoes		8%
7%	PL general	10,14	2%	Apples	2%	Table grapes	1%	Tomatoes		7%
6%	IT toddler	9,52	2%	Tomatoes	1%	Apples	0,6%	Table grapes		6%
6%	NL general	9,42	2%	Apples	1%	Table grapes	1,0%	Wine grapes		6%
6%	IT adult	9,36	2%	Tomatoes	0,9%	Apples	0,8%	Table grapes		6%
6%	FI 3 yr	8,98	1%	Cucumbers	1%	Table grapes	1%	Apples		6%
6%	DK adult	8,90	2%	Wine grapes	1%	Apples	1%	Table grapes		6%
6%	ES child	8,62	2%	Tomatoes	1%	Apples	0,5%	Watermelons		6%
5%	ES adult	8,25	1%	Tomatoes	0,9%	Apples	0,7%	Wine grapes		5%
5%	UK toddler	7,90	2%	Apples	1%	Table grapes	1,0%	Tomatoes		5%
5%	SE general	7,42	1%	Tomatoes	1%	Apples	0,4%	Cucumbers		5%
5%	FI 6 yr	6,85	1%	Table grapes	0,9%	Cucumbers	0,7%	Tomatoes		5%
5%	FR infant	6,85	2%	Apples	1%	Beans (with pods)	0,6%	Courgettes		5%
4%	UK vegetarian	6,50	1%	Wine grapes	1%	Tomatoes	0,7%	Apples		4%
4%	LT adult	6,23	2%	Apples	1%	Tomatoes	0,5%	Cucumbers		4%
4%	UK adult	5,73	2%	Wine grapes	0,7%	Tomatoes	0,5%	Apples		4%
3%	UK infant	5,02	2%	Apples	0,6%	Tomatoes	0,2%	Pears		3%
3%	FI adult	4,98	0,9%	Tomatoes	0,7%	Apples	0,5%	Wine grapes		3%
1,0%	IE child	1,43	0,4%	Apples	0,3%	Table grapes	0,1%	Tomatoes		1,0%

Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of Copper oxychloride is unlikely to present a public health concern.

DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.2 IEDI calculations

Not required.

A 3.3 IESTI calculations - Raw commodities

Acute risk assessment /children	Acute risk assessment / adults / general population	Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): ---	**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI): ---	**IESTI new Results for children** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---	**IESTI new Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---
IESTI	**IESTI**	IESTI new	IESTI new

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)	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)

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)		**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)**	

A 3.4 IESTI calculations - Processed commodities

Processed commodities	Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
	IESTI				IESTI				IESTI new				IESTI new			
	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)	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)
	Expand/collapse list															

Conclusion:

Appendix 4 Additional information provided by the applicant

Not required.