REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: **Nordox 75 WG**

Chemical active substance:

Copper (I) oxide (Cu_2O), 750 g/kg

NATIONAL ASSESSMENT

Poland

(Authorization in accordance to Art. 43)

Applicant: Nordox AS

Submission date: 31/01/2022

Evaluation date: December 2022

MS Finalisation date: March 2023

Version history

When	What
31/01/2022	Original version from the applicant Nordox AS for Art. 43 submission. All new data and information are marked in yellow.
12/2022	Version evaluated by zRMS PL
15/02/2023	New data submitted (tomato residue trials), according the RMS comments. All new data and information are marked in green.
03/2023	Version amended by zRMS PL after comments.

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Submission and Evaluation of Copper compounds under Art.43 of 1107/2009

General observation: Deviation from standard Guidance Documents and EFSA conclusion is necessary and unavoidable for Copper.

The RMS and EFSA are held to assess plant protection products according to the existing methodology described in a series of guidance documents (GDs). Those have been developed for synthetic, organic molecules, and are in most cases not applicable to minerals and Copper. This has led to an EFSA conclusion that indicated a number of critical concerns, or assessments that could not be finalized, which do not reflect any realistic risk, but rather illustrate the inappropriateness of the current GDs for the assessment of Copper. This can easily be seen in a number of endpoints that suggest a high risk exists at concentrations below natural background of this essential micronutrient. **This has been recognized by EFSA, the RMS and several MS (see comments from DE and IT in the Peer review Report), and the EU Commission has mandated EFSA with the development with a Copper specific guidance (Mandate No. 2019-0036).**
Art.43 submissions and their evaluation by MS are unfortunately due before this GD will be available. The current EFSA conclusion and list of endpoints could at best be considered as a first tier, and applicants as well as MS are required to deviate from the standard procedures described in the GD for the following reasons:

- The current GD do not consider bio-availability; for an essential, ubiquitous micronutrient that is a metal it is indispensable to provide assessment methodologies that consider the bioavailability and the potentially toxic fraction in each real-world exposure scenario. Total concentrations do not result in any meaningful outcome.
- Data normalisation to enable comparison of toxicological lab and field data as well as data obtained with different bioavailable fractions is a pre-requisite to allow a realistic assessment of potential risk. Simplistic worst-case scenarios will always indicate a high risk already at naturally occurring concentrations.
- For a homeostatically tight controlled essential element the application of assessment factors is meaningless. The question whether an excess exposure or deficiency leads to an adverse disruption of the homeostatic control cannot be approached in this way. Further, the exceptional data richness of the Copper dossier and more than 100 years of experience with the use as fungicide make safety factors unnecessary.

These unique features of Copper are already considered in the assessment of Copper under separate legislation (REACH, BPD). While COM directed EFSA in their mandate to take advantage of those methodologies, TF members have to anticipate their use and in their proposed assessments of the critical areas of concern identified in the EFSA conclusion. This should be reviewed once the new GD is available and no use should be cancelled until then.

Submission and Evaluation of Copper compounds under Art.43 of 1107/2009

General observation: Copper compounds should not be considered as Candidate for Substitution (CfS).

The implementing Regulation (EU) 2018/1981 is renewing the approval of the active substance Copper compounds as candidate for substitution (CfS), in accordance with Regulation (EC) 1107/2009. Whereas (12) considers that Copper compounds are persistent and toxic in accordance with points 3.7.2.1 and 3.7.2.3 of Annex II to Regulation (EC) 1107/2009 (PBT assessment), and fulfil the condition set in the second indent of point 4 of Annex II to Regulation (EC) 1107/2009.

The EUCuTF disagrees with the approval as CfS. The conditions in Annex to Regulation (EC) 1107/2009 lack the exemption of inorganic compounds like Copper minerals from the PBT assessment as it has been established under other chemical legislations like REACh and BPD. As laid down in those legislations, the term persistence is meaningless for an element or mineral, due to its natural occurrence. Persistence per se is therefore not a relevant parameter and consequently a PBT assessment is not carried out for inorganic compounds under REACh and BPD. The recent mandate from COM to EFSA directs the development of a guidance towards methods and procedures available under those legislations better adapted for the assessment of inorganic compounds, where the relevant parameter is their bioavailability. This should include an exempt statement regarding the PBT assessment to harmonize the assessment of the same compounds under different legislations.

It should be noted that persistence of minerals is considered not relevant for being categorized as low-risk active substance according to Regulation (EU) 2017/1432. This is clearly not compatible with the same parameter leading to a classification as CfS under the same Regulation (EC) 1107/2009.

The EUCuTF is of the opinion that Copper compounds should not be considered CfS, and have lodged an action for annulment against Regulation (EU) 2018/1981 and renewing the approval of the active substance Copper compounds as candidate for substitution (case number T-153/19 European Union Task Force v. European Commission).

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

It should be noted that the applicant's dRR was not rewritten by the ZRMS and the RR resulted from the evaluation was prepared by an insertion into the dRR of the ZRMS' comments/corrections on the grey background.

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 Nordox 75 WG are presented in Table 7.1-1. They have been selected from the individual GAPs in the northern one for pome fruits (apples, pear, quince), grapes, strawberries, fruiting vegetables (tomatoes, eggplant, pepper), bulb vegetables (onion, garlic, shallots), lettuce and similar, cucurbits (edible and inedible peel) and ornamentals.
A list of all intended uses within the northern zone is given in Part B, Section 0.

Overall conclusion

The existing relevant residue data of cucurbits with edible peel for extrapolation of cucumber and courgettes are unprotected as submitted in EU in 2011 on the renewal and available then in the RAR 2016 (see Kreke, N. (2009, 2010). For pome fruits submitted NEU data is enough for permissible extrapolation. For grapes, strawberries, shallots, onion, and garlic the residue data are consistent with the requirements. Thus, the approval for these uses can be granted.
For tomatoes (eggplants) and peppers in DAR 2007 are not enough NEU data for registration. ~~In later, protected data (France 2016) for tomato the MRL is exceeded.~~
The sufficient number of NEU tomato trials - already evaluated within the MRL Review – with the relevant LoA were submitted by the applicant during the comments period. However, there was an exceedance of MRL. The data cannot be a basis for the approval of the use in tomato.

For field lettuce, scarole, pumpkin and melon no NEU data at all.

The applicant provided LoAs for residue data until 2011. However, these do not change the range of the applicable unprotected data. The data after 2011, on the other hand, do not contain results that change the range of the approval.

An exceedance of the current MRLs of Copper as laid down in Reg. (EU) 396/2005 for the intended uses for which the approval can be done is not expected.

The necessary for the evaluation Cucurbitaceae data after the DAR 2007, from years 2006-2011, reported in the RAR 2016 and presented below:

Table 2.7.4-2: Summary of residues data from the supervised residue trials

Crop	Region/ Indoor (a)	Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
Cucurbits with edible peel	NEU	0.92; 1.03; 1.09; 1.28; 1.35; 1.43; 1.72; 1.81	Total annual rate was considered for the cGAP (*i.e.* 6 kg a.s/ha/year). Proportionality concept was applied.	4	1.81	1.315
	SEU	0.79; 1.11; 1.34; 1.46; 1.97; 2.48; 2.80	Total annual rate was considered for the cGAP (*i.e.* 6 kg a.s./ha/year). Proportionality concept was applied. One trial is required in post-approval.	6	2.80	1.46
	Indoor	0.89; 1.04; 1.08; 1.20; 1.25; 1.77; 2.57; 4.04	Total annual rate was considered for the cGAP (*i.e.* 6 kg a.s./ha/year). Proportionality concept was applied.	6	4.04	1.225
Cucurbits with inedible peel	NEU	No data	-	-	-	-
	SEU	0.34; 0.69; 1.60; 2x <2.0; 2.60; <2.71; <3.02; 2 x <5.0; 4x <10	Total annual rate was considered for the cGAP (*i.e.* 6 kg a.s./ha/year).	20	<10	2.863
	Indoor	<1.97; 2x <2.0; 2x <2.1; 5.0	2 trials in are required post-approval.	8	5.0	2.05

The necessary for the evaluation excerpts from the DAR 2007 are presented below.

B.7.6.2.3.3 Wine grapes in northern EU

A total of 12 trials in wine grapes were carried out in northern France, Germany over four seasons (1992, 1998, 2001 and 2002). In the 1998, 2001 and 2002 trials, two forms of copper were applied. There were two to 12 applications at each site. Application rates were within ±25% of the maximum recommended rate according to the GAP for each copper form at each site, or higher. (7 other trials were not taken into account for the evaluation because the documents submitted by the notifier were in German and the English summary in Tiers I-LII didn't provide enough information to check the validity of the data) Residue decline was measured at 10 sites (13 observations). Residue decline was variable between and within sites and was not consistently related to rainfall after application. Overall, residues of copper in fruit were 2.8 to 40 mg/kg immediately after the final spray, 4.3 to 35 mg/kg after 7 days, 4.1 to 38 mg/kg after 14 days and 4.1 to 56 mg/kg after 21/22 days.

In two sites in 2001 (AF/5991/CU1 and AF/5991/CU2) copper oxide was applied four times at rates within ±25% of the maximum recommended rate according to the GAP. At all sites in 2002, the different copper forms were applied four times at rates within ±25% of the maximum recommended rate according to the GAP. At the 2002 sites, residues at PHI 21 days (13 observations) varied considerably between sites ranging from 4.1 to 56 mg/kg. At the sites in Germany (AF/6890/CU4 and AF/6890/CU5) residues were 20 to 56 mg/kg whereas in northern France residues were 4.1 to 12 mg/kg. The difference between the residues was not related to rainfall, which was similar in Germany to northern France. The difference is thought to be related to the practice of defoliation of the vines, 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. The growers at sites AF/6890/CU4 and AF/6890/CU5 confirmed that their crops were pruned every three weeks according to their commercial practice. No details of the extent of the pruning were recorded in the studies and no measurements or records of leaf cover of the grape bunches were made at the sites in Germany or other sites at application. Removing the leaves would allow more spray to reach the fruit and lead to higher residue levels. In other trials where the rates applied were more than 25% above the GAP rate, a similar difference between countries in residue levels at harvest was observed. In 2001 four applications were made of copper hydroxide, copper oxychloride or Bordeaux Mixture at 2.74 to 3.84 kg/ha (137 to 192% of the GAP rate) or tribasic copper sulphate at 2.39 to 2.54 kg/ha (159 to 169% of the GAP rate). At the sites in Germany (AF/5991/CU4 and 5) residues at harvest (PHI 21 days) were 9.2 to 27 mg/kg (four observations). In contrast, at the sites in northern France (AF/5991/CU1, 2 and 3) residues at harvest (PHI 21 days) were lower, 5.8 to 8.7 mg/kg (four observations).

At other sites the rates applied were within + 25% of the GAP rate but there were fewer or more applications. For example, in northern France in 1998 (9801AGT/V/001), following 12 applications of copper hydroxide or Bordeaux mixture at 2.06 and 1.50 kg/ha, respectively, residues at harvest (PHI 22 days) were 7.1 and 10.0 mg/kg. In the 2002 trials where two copper forms were compared in each trial (each applied according to the GAP rate, PHI 21 days), residue levels following both forms were very similar. Copper was present in untreated crops in the range 0.54 to 4.8 mg/kg. The results are presented in Table 7.6.2.3.3-1 and Table 7.6.2.3.3-2 (decline studies) and Table 7.6.2.3.3.3 (harvest studies).

Table 7.6.2.3.3-2. Residues of copper in wine grapes in northern EU following applications of copper formulations: decline studies 2001 and 2002

Location; Year; Trial	Application				Portion analysed	PHI (days)	Residue (mg/kg)	Ref. (LOQ)
	Formulation type; content and form	No.	kg a.s./ha	kg a.s./hL				
N.France; 2001 AF/5991/CU1	WP; 750 g/kg; oxide	4	1.09-1.55 (1.15*)	0.09-0.12	fruit	0- 0+ 7 14 21	6.1 2.8 5.2 9.8 <u>4.1</u>	Brereton 2003 (5 mg/kg)
	WP; 500 g/kg; hydroxide	4	2.84-3.84	0.19-0.24	fruit	0- 0+ 7 14 21	6.5 6.9 7.8 9.2 5.8	
Germany; 2001 AF/5991/CU4	WP; 500 g/kg; oxychloride	4	2.74-3.04	0.19	fruit	0- 0+ 7 14 21	27 20 17 20 9.2	
	WP; 500 g/kg; hydroxide	4	2.88-3.19	0.19	fruit	0- 0+ 7 14 21	18 20 17 23 19	
N.France; 2002 AF/6842/CU1	WP; 750 g/kg; oxide	4	1.45-1.59	0.12	fruit	0- 0+ 7 14 21	2.7 4.8 4.3 4.1 <u>4.2</u>	Brereton 2003 (5 mg/kg)
N.France; 2002 AF/6890/CU1	WP; 750 g/kg; oxide	4	1.43-1.57	0.10	fruit	0- 0+ 7 14 21	4.2 5.6 11 17 <u>4.3</u>	Martin 2003 (5 mg/kg)
	WP; 500 g/kg; hydroxide	4	1.99-2.07	0.13-0.14	fruit	0- 0+ 7 14 21	4.8 11 12 12 <u>6.9</u>	
Germany; 2002 AF/6890/CU4	WP; 500 g/kg; oxychloride	4	2.01-2.10	0.15	fruit	0- 0+ 7 14 21	21 33 35 38 <u>56</u>	
	WP; 500 g/kg; hydroxide	4	1.97-2.09	0.15	fruit	0- 0+ 7 14 21	22 40 31 25 <u>20</u>	

* Application rate at last application timings at sites where variable application rates were applied. Copper was present in untreated crops in the range 1.1 to 1.5 mg/kg

Table 7.6.2.3.3-3. Residues of copper in wine grapes in northern EU following applications of copper formulations: harvest studies

Location; Year; Trial	Application				Portion analysed	PHI (days)	Residue (mg/kg)	Ref. (LOQ)
	Formulation type; copper content; copper form	No.	kg a.s./ha	kg a.s./hL				
N.France; 1998 9801AGT/V/001	WG; 375 g/kg; hydroxide	12	2.06	0.69	fruit	22	7.1	Coulomb 1999 6.3.11 (0.4 mg/kg)
	WP; 200 g/kg; Bordeaux mix.[a]	12	1.50	0.50	fruit	22	10	
N.France; 2001 AF/5991/CU2	WP; 750 g/kg; oxide	4	1.30-1.57	0.09-0.12	fruit	21	<u>5.2</u>	Brereton 2003 6.3/19 (5 mg/kg)
	SC; 189 g/L; tribasic copper sulphate	4	2.39-2.51	0.15-0.19	fruit	21	8.7	
N.France; 2001 AF/5991/CU3	WP; 500 g/kg; oxychloride	4	2.84-2.99	0.19	fruit	21	8.0	
	WP; 200 g/kg; Bordeaux mix.	4	2.85-3.13	0.19	fruit	21	7.2	
Germany; 2001 AF/5991/CU5	WP; 200 g/kg; Bordeaux mix.	4	2.90-3.12	0.19	fruit	21	27	
	SC;189 g/L; tribasic copper sulphate	4	2.40-2.54	0.15	fruit	21	26	
N.France; 2002 AF/6890/CU2	WP; 750 g/kg; oxide	4	1.53-1.62	0.12	fruit	21	<u>6.8</u>	Martin 2003 6.3/23 (5 mg/kg)
	SC;189 g/L; tribasic copper sulphate	4	1.42-1.59	0.12	fruit	21	<u>12</u>	
N.France; 2002 AF/6890/CU3	WP; 500 g/kg; oxychloride	4	2.02-2.11	0.16	fruit	21	<u>7.5</u>	
	WP; 200 g/kg; Bordeaux mix.	4	1.98-2.05	0.16	fruit	21	<u>9.9</u>	
Germany; 2002 AF/6890/CU5	WP; 200 g/kg; Bordeaux mix.	4	1.93-2.11	0.15	fruit	21	<u>45</u>	
	SC;189 g/L; tribasic copper sulphate	4	1.41-1.51	0.12	fruit	21	<u>30</u>	

Copper was present in untreated crops in the range 0.8 to 3.2 mg/kg.
Results of studies conducted according to the GAP are underlined.
[a] Called copper sulphate in the report.

B.7.6.2.4 Overall assessment of copper residues in grapes

A total of 35 trials were carried out in grapes in France, Spain, Italy, Germany and over four seasons. Trials covered wine and table grapes. In most trials, two forms of copper were applied, and applications were made according to the GAP for each form or at higher rates.

Samples of fruit were taken at normal harvest (PHI 14 or 21 days). Samples were also taken at other timings to assess decline. Residue levels of copper declined slowly after application. (-)

In northern EU, residues of copper at harvest (PHI 21 days) following applications according to the GAP varied according to the location of the trials. In northern France, residues ranged from 4.1 to 12 mg/kg whereas in Germany residues ranged from 20 to 56 mg/kg. The higher residue levels in trials in Germany are thought to be due to the practice of defoliation of the vines, i.e. removing leaves around the grape

bunches prior to application of copper.
Copper was present in untreated crops in the range 0.54 to 4.8 mg/kg.
In five trials in northern EU in 2002, two copper forms were applied, each according to the GAP, and residues were measured at PHI 21 days.

MRLs currently in force:

Code	Products to which MRLs apply	Copper compounds (Copper) Reg. (EC) No 149/2008 applicable
130010	Apples	5
130020	Pears	5
130030	Quinces	5
130040	Medlars	5
151010	Table grapes	50
151020	Wine grapes	50
152000	(b) strawberries	5
220010	Garlic	5
220020	Onions	5
220030	Shallots	5
231010	Tomatoes	5
231020	Sweet peppers/bell peppers	5
231030	Aubergines/eggplants	5
231040	Okra/lady's fingers	5
232010	Cucumbers	5
232020	Gherkins	5
232030	Courgettes	5
233010	Melons	5
233020	Pumpkins	5
233030	Watermelons	5
251020	Lettuces	100
251030	Escaroles/broad-leaved endives	100

The data available are considered sufficient for risk assessment.
The chronic and the short-term intakes of Copper residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended **field uses: apples, pears, quinces, cucumber, courgettes, grapes, strawberries, shallots, onion, and garlic.**

Ornamentals are not the subject of the evaluation. The use is accepted.

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

Data gaps

Noticed data gaps are: none

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

Only the critical and residue relevant uses are stated below. For further information regarding the whole intended uses please refer to Part B0, Appendix 1.

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [(e)]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha[(f)]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	kg a.i./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL	Apple	F	*Venturia inaequalis*	Foliar spray	BBCH 03-BBCH 53	a) 2 b) 2	14	a) 1.0 b) 2.0	a) 0.75 b) 1.50	500-750	144	Extrapolation from pome and stone fruits
2	PL	Pear, quince	F	*Venturia pyrina* *Venturia inaequalis* Bacteriosis: *Pseudomonas syringae* *Ervinia amylovora* *Nectria galligena*	Foliar spay	From the beginning of dormancy period (autumn - BBCH 99) and before BBCH 54 (spring)	a) 2 b) 2	14	a) 1.67 b) 3.34	a) 1.25 b) 2.50	500-1000	144	Extrapolation from pome and stone fruits
3	PL	Vine	F	*Plasmopara viticola*	Foliar spray	BBCH 15-BBCH 81 & BBCH 91	a) 2 b) 2	7	a) 1.60 b) 3.20	a) 1.20 b) 2.40	200-400	21	
4	PL	Strawberry	F	*Marssonina fragariae, Zythia fragariae Mycosphaerella, bacterial disease, Colletotrichum sp.*	Foliar spray	BBCH 13 - BBCH 85	a) 3 b) 3	7	a) 1.33 b) 3.99	a) 1,0 b) 3.0	200 - 800	3	

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [(e)]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha[(f)]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	kg a.i./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
~~5a~~	~~PL~~	~~Tomato Eggplant~~	~~F~~	~~*Phytophtora spp., Alternaria, Colletotrichum, Bacterial disease (Pseudomonas spp., Xanthomonas spp.).*~~	~~Foliar spray~~	~~BBCH 15 - BBCH 51~~	~~a) 3 b) 3~~	~~7~~	~~a) 1.33 b) 3.99~~	~~a) 1.0 b) 3.0~~	~~200-1000~~	~~10~~	MRL exceedance
~~5b~~	~~PL~~	~~Pepper~~	~~F~~	~~*Phytophtora spp., Alternaria, Colletotrichum, Bacterial disease (Pseudomonas spp., Xanthomonas spp.).*~~	~~Foliar spray~~	~~BBCH 15 - BBCH 51~~	~~a) 3 b) 3~~	~~7~~	~~a) 1.33 b) 3.99~~	~~a) 1.0 b) 3.0~~	~~200-1000~~	~~10~~	Not enough NEU data
6	PL	Shallots Onion Garlic	F	*Alternaria, Antracnosis, Bacterial disease, Peronospora destructor, Stemphyllum*	Foliar spray	BBCH 14 - BBCH 47	a) 3 b) 3	7	a) 1.33 b) 3.99	a) 1.0 b) 3.0	200-1000	3	
~~7~~	~~PL~~	~~Lettuce Scarole~~	~~F~~	~~*Alternaria, Bremia lactucae Bacterial disease: Erwinia spp., Pseudomonas spp. Xanthomonas spp.*~~	~~Foliar spray~~	~~BBCH12 - BBCH49~~	~~a) 3 b) 3~~	~~7~~	~~a) 1.33 b) 3.99~~	~~a) 1.0 b) 3.0~~	~~300-1000~~	~~3~~	No NEU data
8	PL	Cucumber Courgettes	F	*Alternaria, Antracnosis, Phytophtora spp.,*	Foliar spray	BBCH 15 - BBCH 89	a) 3 b) 3	7	a) 1.33 b) 3.99	a) 1.0 b) 3.0	200-1000	3	Based on unprotected data reported in 2016 RAR
~~9~~	~~PL~~	~~Pumpkin, Melon~~	~~F~~	~~*Alternaria, Antracnosis, Phytophtora spp.,*~~	~~Foliar spray~~	~~BBCH 15 - BBCH 89~~	~~a) 3 b) 3~~	~~7~~	~~a) 1.33 b) 3.99~~	~~a) 1.0 b) 3.0~~	~~200-1000~~	~~3~~	No NEU data

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	kg a.i./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
10	PL	Ornamental plants	F	*Alternaria, Antracnosis, Phytophtora spp.,*	Foliar spray	Spring - until the beginning of flowering	a) 3 b) 3	7	a) 1.33 b) 3.99	a) 1.0 b) 3.0	200-1000	-	

* 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 Nordox 75 WG is composed of Copper.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of Copper

Reference value	Source	Year	Value	Study relied upon	Safety factor
Active substance – Copper					
ADI	EFSA	2018	0.15 mg/kg bw/day	Based on human data (WHO value of 0.15 mg Cu/kg bw/day for children)	No SF for human data
ARfD	EFSA	2018	Not allocated/not necessary	-	-

7.1.2.1 Summary for Copper compounds

Table 7.1-3: Summary for Copper compounds - Outdoor

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?
1-2	Apple, pear, quince (Pre-flowering)	Yes	Yes (7x NEU & 12x SEU on apple, plum, cherry, pear)	Yes	Yes	Yes	No	No
3	Grapes	Yes	Yes (15x table grapes (N/SEU), 15x wine grapes (N/SEU))	Yes	Yes	~~No~~** Yes	No	No
4	Strawberry	Yes	Yes* (8x NEU)	Yes	Yes	~~No~~** Yes	No	No
5	Tomato, eggplants	Yes	Yes* (9x NEU)	Yes	Yes	No**	No	No
5	Pepper	Yes	~~Yes*~~ No (4x NEU 8x SEU)	~~Yes~~ ~~No~~	Yes	No**	No	No
6	Bulb vegetables (onion garlic, shallots)	Yes	Yes* (4x SEU, 8x NEU)	Yes	Yes	Yes	No	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?
7	Lettuce and similar	No	~~Yes~~*No (7x lettuce (SEU)+8x indoor)	~~Yes~~ No	Yes	No*	No	No
8	Cucurbits edible peel (cucumber)	Yes	Yes* (8 x (SEU & 8x indoor)	Yes	Yes	Yes	No	No
9	Cucurbits inedible peel (Watermelon, pumpkin)	Yes	~~Yes~~* No (8x EUS & 6x indoor)	~~Yes~~ No	Yes	No**	No	No

\# Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
*Because of identical GAPs and comparable results for indoor (worst case), north and south trials overall calculations and conclusion were done and used for consumer risk assessments.
**During the EFSA MRL review (Art. 12, EFSA 2018) new tentative MRLs were proposed. All calculated MRLs are below the new tentative proposed MRLs by EFSA.

The effects of processing on the nature of Copper compound residues have been investigated. Data on effects of processing on the amount of residue have been submitted.
These data were not considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

7.1.2.2 Summary for Nordox 75 WG

Table 7.1-4: Information on Nordox 75 WG (KCA 6.8)

Crop	PHI for Nordox 75 WG proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for Nordox 75 WG proposed by zRMS	zRMS Comments (if different PHI proposed)
		Copper compound		
Apples, pear, quince (Pre-flowering)	144	Yes	No comments.	
Grapes	21	Yes		
Strawberry	3	Yes		
Tomato, eggplants	10	Yes		
Tomato, processing	10	Yes		
Pepper	10	Yes		

Crop	PHI for Nordox 75 WG proposed by applicant	PHI/ Withholding period* sufficiently supported for Copper compound	PHI for Nordox 75 WG proposed by zRMS	zRMS Comments (if different PHI proposed)
Bulb vegetables (onion garlic, shallots)	3	Yes	No comments.	
Lettuce	(3-)7	Yes		
Cucumber	3	Yes		
Melon	(3-)7	Yes		
Courgettes	(3-)7	Yes		
Pumpkin	(3-)7	Yes		

NR: not relevant
* Purpose of withholding period to be specified

Table 7.1-5: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for Nordox 75 WG
Crop group	**Led by Copper compounds**	
Leafy vegetables	NR	Not necessary, please refer to 7.2.2.2
Root vegetables	NR	
…		

NR: not relevant

7.2 Copper compounds

General data on Copper compounds are summarized in the table below (last updated 2018/11/27 (final renewal report).

Table 7.2-1: General information on Copper compound

Active substance (ISO Common Name)	Cuprous oxide
IUPAC	Copper (I) oxide or cuprous oxide
Chemical structure	Cu_2O
Molecular formula	Cu_2O
Molar mass	141.3 g/mol
Chemical group	Inorganic salt of coper
Mode of action (if available)	Fungicidal and bactericidal
Systemic	No
Company (ies)	EU Copper Task Force
Rapporteur Member State (RMS)	France
Approval status	01.01.2019 (Regulation (EU) 2018/1981)
Restriction	Only for use as a fungicide/bactericide
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	EFSA, 2018 – see list of references
EFSA Journal: Conclusion on the peer review	EFSA Journal 2018;16(1):5152
EFSA Journal: conclusion on article 12	No
Current MRL applications on intended uses	EFSA-Q-2010-00183 (FRANCE) Status: Evaluation complete

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.

Conclusion on stability of residues during storage

Copper is an element and is inherently stable as it cannot be chemically (or bio-) degraded. 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.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

No new data submitted in the framework of this application.

Conclusion on stability of residues in sample extracts

Procedural recoveries 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. There is a wealth of published information on the uptake of Copper by plants and its role in plant physiology. Information relevant to the use of Copper as a plant protection product is summarized below.

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 such as tomato, grapes and cucurbits, Copper is necessary for a wide range of metabolic processes such as respiration and photosynthesis[1].

Used according to Good Agricultural Practice, Copper is applied as a fungicidal spray post-emergence to the foliage and fruit of grapes, cucurbits and tomatoes. Copper is a non-systemic like fungicide. Formulations used commercially contain components to ensure that the Copper remains on the foliage or fruit to exert its fungicidal activity.

Copper as the mono-atomic charged element and is 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 and are not required. The critical issue is the magnitude of residues of Copper in the edible portions of grapes, cucurbits and tomatoes following applications of Copper as a plant protection product. Supervised trials to address this issue are summarised in Chapter 7.2.3.

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[1] Linder, M. C. (1991) Biochemistry of Copper, Section 10.4. Plenum Press. See Reference list 'Published papers submitted but not summarised'.

Conclusion on metabolism in primary crops

Sufficient data have been provided to acknowledge the metabolism of Copper in/on grapes, cucurbits and tomatoes.

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

Copper occurs naturally in soils and levels of approximately 6 to 30 mg total Copper/kg in the soil are essential for normal plant growth and development. Concentrations of total Copper in soil found in two surveys were 6 to 24 mg Copper/kg (in a range of EU agricultural soils) and 3 to 194 mg/kg, mean 21 mg/kg, (in 504 soils in France)[2].
Furthermore, since Copper is naturally present in the soil at levels of circa 32 mg/kg (EFSA, 2010 and EFSA, 2013), all crops grown in such soils are expected to contain residues of Copper.

A review of monitoring programs for copper in soil was carried out in 2018 and was used to identify 'background levels' of copper present in soil from natural or anthropogenic sources other than the regulated use for use in soil exposure assessments. The results taken from the LoEP (Appendix A EFSA Journal 2018; 16(1):5152,119 pp doi:10.2903/j.efsa.2018.5152) are summarised in the table below. The EUCuTF stated in their monitoring report that these values are most likely biased towards the higher end as they are mainly based on published literature, which focusses mainly on contaminated sites.

Recently published data from the EU LUCAS program confirms the assumption for this bias and provides lower average values for vineyards, and also shows there is no measurable accumulation for field crops:

[2] Cetois, A., Quesnoit, M. and Hinsinger, P (2003) Soil Copper mobility and bioavailability – a review.

Soil	Soil concentration (mg Cu/kg soil DM)	
Background level	**11.5**	
Vineyards[a]	28 66.4 160 73	Overall median 10th percentile value Overall median value Overall median 90th percentile value Overall mean value
Vineyards	29.5 26.09 128.0 49.26	Overall median 10th percentile value LUCAS data[c] Overall median value LUCAS data Overall median 90th percentile value LUCAS data[d] Overall mean value LUCAS data
Arable fields[b]	7 13.2 26 15	Overall median 10th percentile value Overall median value Overall median 90th percentile value Overall mean value
Orchards[b]	- 39.8 58 23	Overall median 10th percentile value Overall median value Overall median 90th percentile value Overall mean value
Olive groves	24.7 74.5 33.5	Overall median value LUCAS data Overall median 90th percentile value LUCAS data Overall mean value LUCAS data

[a] Recently published data from the EU LUCAS program [Copper distribution in European Topsoils: An assessment based on LUCUS soil survey, Ballabio et al., Science of the Total Environment 636 (2018) 282-298] confirms the assumption that the data for vineyards in the LOEP values are biased towards the higher end as they are mainly based on published literature, which focusses mainly on contaminated sites.
[b] Includes new data from the EU LUCAS program.
[c] Calculated from the standard deviation of the set of data in the paper described in [a].
[d] Calculated from the standard deviation of the set of data in the paper described in [a].

It should be noted that elevated Copper levels were observed in a proportion of vineyard soils and a much lesser extent in some orchard soils.

Due to the ubiquitous property of Copper, which naturally present in planta as an essential micronutrient, field trials on rotational crops according to the current OECD recommendations would not be helpful to assess residues in rotational crops. These studies are therefore not required (EFSA, 2018).

Based on several scientific publications reported by the RMS, bioavailable Copper is taken up by the crops according to the plant's needs. Therefore, independently from the Copper contamination in soil, plants are not expected to absorb more than the essential nutritional amount. It is highlighted that an excess of Copper absorption by plant may cause phytotoxic effects. Consequently, it is assumed that Copper uptake in succeeding crop is naturally auto regulated by the crop. Considering this, it is concluded that Copper can be present in succeeding crops (annual and permanent) as an endogenous compound, following natural soil absorption as a micronutrient (EFSA, 2018).

Conclusion on metabolism in rotational crops

No study conducted. The natural background levels in soil are very much greater than the Copper added by the use as an agricultural fungicide. Therefore, it would not be possible to distinguish between the Copper derived from fungicides and the Copper derived from the Copper naturally present in the soil. The metabolism of Copper in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.

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

Copper is an element and is inherently stable as it cannot be transformed into any other substance. 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 is known to be inherently stable and cannot degrade into any other material and 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 the residue are not required.

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	Copper is an element and therefore cannot be metabolised or broken down
Rotational crops covered	Copper is an element and therefore cannot be metabolised or broken down
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Copper is an element and therefore cannot be metabolised or broken down
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes, Copper is an element and therefore cannot be metabolised or broken down
Plant residue definition for monitoring	Total Copper, EFSA(2008) 187, EFSA, 2018;16(3):5212 and Reg. (EC) 149/2008
Plant residue definition for risk assessment	Total Copper, EFSA(2008) 187, EFSA, 2018;16(3):5212 and Reg. (EC) 149/2008
Conversion factor from enforcement to RA	Not applicable (EFSA, 2008 and 2018)

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 animal metabolism studies reported in the EU

Copper is a monoatomic element which cannot be degraded and thus, no metabolites are expected.
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 poultry along with other minerals and vitamins. Copper absorption, metabolism and excretion are similar in most species of mammals and birds the processes are described in the toxicological part B6.

Copper compounds are authorized for pesticide use on many crops that might be fed to livestock such as citrus fruits, apples, potatoes, head cabbages and several root crops. Furthermore, many major feed items which are not treated with Copper as a fungicide (e.g. cereals and oilseeds) may also contribute to the livestock dietary burdens. Therefore, the dietary burdens were calculated not only considering residues from the authorized uses, but also including the background residue levels and monitoring data (EFSA, 2018). The dietary burdens calculated for all groups of livestock were found to highly exceed the trigger value of 0.004 mg/kg bw/d.

Copper is an essential micronutrient for animals and some specific Copper compounds can also be used as a feed additive in animal nutrition, when needed. For that purpose, maximum contents of Copper in feedstuffs are currently in place in the framework of different Feed Regulations. The maximum contents of Copper in feedstuffs defined in these Regulations are reported in the table below (Regulation (EU) 2018/1039[3]):

Currently authorized maximum Copper contents in feed in the European Union

Livestock group	**Maximum Copper content (mg/kg complete feed)** [(a)]
Bovines	
Bovines before the start of rumination	15
Other bovines	30
Ovines	15
Caprines	35
Piglets	
suckling and weaned up to 4 weeks after weaning	150
from 5th week after weaning up to 8 weeks after weaning	100
Crustaceans	50
Other Animals	25

[(a)] according to current Feed Regulation (Regulation (EU) 2018/1039)

A comparison between the maximum dietary burdens calculated with the currently authorized maximum Copper contents in feed is reported in the table below:

[3] Regulation (EU) 2018/1039; OJ 268, 18.10.2003, p. 29.

Comparison of the maximum dietary burdens with maximum Copper contents to be authorized in complete feed:

	Cattle		Sheep		Swine		Poultry		
	beef	**dairy**	**Ram/Ewe**	**Lamb**	**Breeding**	**Finishing**	**Broiler**	**Layer**	**Turkey**
Feed intake (kg dw/day)	12	25	2.5	1.7	6	3	0.12	0.13	0.5
Feed intake kg fresh weight /day)	13.636	28.409	2.841	1.932	6.818	3.409	0.136	0.148	0.568
Bodyweight (kg)	500	650	75	40	260	100	1.7	1.9	7
Animal Dietary Burden Calculation									
Maximum intake Cu (mg/kg bw/day)	**4.829**	**6.908**	**6.746**	**5.182**	**2.456**	**0.893**	**1.806**	**1.997**	**0.863**
Supplemented Feed									
Cu permitted in Complete feed (mg/kg feed)[a,b]	30	30	15	15	100	100	25	25	25
Total Cu intake mg/kg bw day	**0.818**	**1.311**	**0.568**	**0.724**	**2.622**	**3.409**	**2.005**	**1.944**	**2.029**

[a] Complete feed containing a moisture content of 12%
[b] Regulation (EU) 2018/1039

Conclusion on metabolism in livestock

It can be seen from the comparison of the animal dietary burden consumption intake to the level of Copper permitted in complete animal feed, that the dietary consumption of calculated maximum dietary burden arising from pesticide residues is greater than that from currently allowed maximum level of Copper in complete feed for cattle and sheep. In practice, results from monitoring programmes of complete animal feed in the EU (EFSA FEEDAP Panel, 2015), demonstrate that this may not often occur. It is highlighted, that the maximum levels of Copper in complete feed are legal limits which are therefore expected to be monitored by feed business operators when completing the feed diets. Consequently, the maximum Copper content in complete feed reported in the Feed Regulations should guarantee that the Copper animal intake remains under these levels. In addition, it should also be noted that the theoretical maximal dietary burdens are not expected to occur in practice because they would anyways not be tolerated by most of the animal species (see also EFSA FEEDAP Panel, 2015). Therefore, specific studies to evaluate the metabolism, distribution and expression of the residue in livestock are not required.

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

Copper is an element and will not be metabolized. The chemical fate of Copper in mammals is well documents and no new information will be produced by conducting metabolism studies in livestock, consequently none have been conducted.

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 pre-flowering studies were conducted in cherry (1x) in 2019/20 and finalised in 2020/21.
Data for grapes, tomato, cucumber and melons were already submitted and evaluated in the DAR 2007.

In the framework of the evaluation Report (France 2016) several data to different crops were submitted in France 2016. The already submitted trials were re-evaluated if necessary. Trials conducted in the same area per season were seen as replicates according to EFSA 2015 and SANTE/2019/12752. Highest residues and mean values are calculated and used for the MRL calculations presented in the following table. However, according to EFSA 2015 the mean residue values should be considered for replicate field trial values where each value might be considered as a repetition of the same experimental condition. In contrast, when the experiment conditions differ (different formulation types or products) the highest value only should be collected, which is the case here in most trials (different formulation types of copper). Furthermore, if application rates in the trials showed > 25 % difference to the intended dose rate, the application rate and the residue results were scaled to the application rate of the intended critical GAP.

For summary tables of crops which are not already EU evaluated and further details (selected values) please refer to the summaries presented in Appendix 2.

In several crops the current MRL (EU MRL: Reg. (EC) No: 149/2008 (01/09/2008)) is exceeded. In the framework of the Art. 12 MRL review new MRLs were already proposed (based on the data submitted to France 2016), however some MRLs are only tentative because of the absence of relevant residue data.
The following evaluation is based on data submitted to France. Please note that according to SANTE/2019/12752, Annex II, for France a different data set is required than for other countries/zones. However, data were adjusted to the polish cGAP, respectively the northern zone.

Please note, because of identical GAPs and comparable results for indoor (worst case), north and south trials overall calculations and conclusion were done and used for consumer risk assessments.

Table 7.2-3: Summary of EU reported and new data supporting the intended uses of Nordox 75 WG 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	Control residue in trials (mg/kg)	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Pre-flowering Cherries (0140020-006) and plums (0140040) Apple (0130010)	EFSA 2018 (Art. 12)	S-EU	**GAP: 3 kg a.i./ha, Interval --, BBCH 1-7, PHI –** Fruit E/RA (HR): 0.786, 0.613, 0.617, 0.993, 1.129, 0.878						
	France 2016 (ER)	N-EU	**cGAP; 3x 1.2 kg a.i/ha, BBCH <63, PHI--** Plum, Cherry Fruit: E/RA (HR): 0.667, 0.572 E/RA (Mean): 0.628, 0.488 Pulp: E/RA (HR): 0.760, 0.572 E/RA (Mean): 0.738, 0.54						
			Apple **GAP: 3x 2.0-2.5 kg a.i./ha, Interval --, BBCH <69, PHI --** E/RA (HR): 0.56, 0.57, 1.52, 1.65, 1.09 E/RA (Mean): 0.56, 0.535, 1.21, 0.585, 1.085						
		S-EU	Cherry Fruit: E/RA (HR): 0.786, 0.613, 0.617, 0.993, 1.129, 0.878 E/RA (Mean): 0.672, 1.061, 1.059 Pulp: E/RA (HR): 0.847, 0.686, 0.665, 1.070, 1.330 E/RA (Mean): 0.733, 0.665, 1.2						
			Apple, pear **Intended cGAP: 3x 0.5(-2.5) kg a.i./ha, Interval --, BBCH <69, PHI --**						

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	Control residue in trials (mg/kg)	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
			E/RA (HR): 0.8, 0.99, 0.86, 0.66, 1.14 E/RA (Mean): 0.765, 0.975, 0.765, 0.635, 1.1						
	New trial	S-EU	Cherry: **Intended cGAP; 3x 1.2 kg a.i/ha, BBCH <63, PH--** Whole fruit: <LOQ (0.937)*	1.24**					
→ extrapolated to whole group of pome fruits (0130000) and stone fruits (0140000)	Overall supporting data for cGAP	S-EU N-EU	Fruit E/RA (HR): 0.786, 0.613, 0.617, 0.993, 1.129, 0.878 0.8, 0.99, 0.86, 0.66, 1.14, 0.937 0.667, 0.572, 0.56, 0.57, 1.52, 1.65, 1.09	--	0.860	1.650	2.689	5	Yes
			Pulp E/RA (HR): 0.847, 0.686, 0.665, 1.070, 1.330 0.8, 0.99, 0.86, 0.66, 1.14, 0.760, 0.572, 0.56, 0.57, 1.52, 1.65, 1.09	--	0.847	1.650	2.783	--	--
Grape, table[2] (0151010)	DAR 2007 EFSA 2018 (Art. 12)	S-EU N-EU (FR)	**GAP: 4x 2 kg a.i./ha, Interval 7 days, BBCH 15-81 91, PHI 21 days** N-EU: 4.00, 4.20,4.30, 6.90, 8.70, 9.90, 12, 45, 56 S-EU: 3.7, 6.1, 17						
Table & wine grapes extrapolated to subgroup grapes (0151000)	Overall supporting data for cGAP	N+ S-EU	**Intended cGAP 4x 1.5 g a.i./ha, BBCH 75-89, PHI 21** 37.5, 4.1, 5.2, 5.6, 38, 9.4, 8.7, 4.2, 9.05, 9.75, 6.9, 7.05, 4.85, 2.2, 4.1	-	0.28 (STMR (6.9) wine grapes N/SE * Transfer factor (0.04))	38	55.691	50 (Art. 12 proposed 100)	No

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	Control residue in trials (mg/kg)	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Strawberry[2] (0632010)	EFSA 2018 (Art. 12)	N-EU S-EU	**GAP: 4x 0.8 kg a.i./ha, Interval 7 days, BBCH 13-85, PHI 3 days** N-EU E/RA (HR): 0.51, 0.72, 0.87, 0.98, 0.99, 1.06, 2.08, 3.44 S-EU: E/RA (HR): 0.68, 1.10, 1.44, 1.77, 3.09, 3.31, 3.55	--					
	France 2016 (ER)	N-EU	E/RA (HR): 0.51, 0.72, 0.87, 0.98, 0.99, 1.06, 2.08, 3.44 E/RA (mean): 0.47, 0.97, 0.70, 0.955, 1.755, 0.945, 3.12, 0.815	0.14 – 0.38					
		S-EU	**cGAP: 4x0.75 kg a.i./ha, 7day interval, BBCH 13-85, PHI 3** E/RA (HR): 0.68, 1.10, 1.44, 1.77, 3.09, 3.31, 3.55 E/RA (mean): 2.935, 3.275, 1.745, 1.435, 2.17, 3.275, 0.61	0.26 – 0.6					
	Overall supporting data for cGAP	N-EU	/RA (HR): 0.51, 0.72, 0.87, 0.98, 0.99, 1.06, 2.08, 3.44	--	0.985	3.44	5.210	5 (Art. 12 proposed 15)	No
		N+S-EU	E/RA (HR): 0.51, 0.72, 0.87, 0.98, 0.99, 1.06, 2.08, 3.44 0.68, 1.10, 1.44, 1.77, 3.09, 3.31, 3.55	--	1.10	3.55	6.125		

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	Control residue in trials (mg/kg)	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
~~Tomato (0231010)~~	~~DAR 2007 EFSA 2018 (Art. 12) France 2016 (ER)~~	~~N-EU S-EU (FR)~~	~~**GAP: 6x 1.25 kg a.i./ha, Interval 7 days, BBCH 15-89, PHI 3 days**~~ ~~NEU: 0.70, 1.50, 2x 1.60, 2x 1.70, 2.20, 4.30, 6.60~~ ~~SEU: 1.70, 2.30, 2.50, 2.90, 3.70~~ ~~EU: 2x 1.0, 2x 2.0~~						
		~~Outdoor and EU (Indoor)~~	~~PHI3: 1.8, 2.0, 2.9, 1.7, 1.5, 2.2, 1.5, 1.9, 2.4, 1.0, 1.0, 0.92, 1.0, 2.0, 2.0, 1.6, 2.0~~ ~~PHI10 (Processing): 2.4, 2.2, 1.8, 1.5, 2.0, 2.3, 2.2, 1.4, 3.7, 2,2, 2.0, 2.2, 2.4, 1.4, 1.6, 1.7, 2.2, 2.1, 2.1~~						
	Overall supporting data for cGAP	N-EU	0.70, 1.50, 2x 1.60, 2x 1.70, 2.20, 4.30, 6.60		1.70	6.6	9.814	5 (Art. 12 proposed 10)	No
Pepper (0231020)	EFSA 2018 (Art. 12)	S-EU N-EU (FR)	**GAP: 4x 0.8 kg a.i./ha, Interval 7 days, BBCH 15-89, PHI 3 days** NEU: E/RA (HR): 1.38, 1.64, 2.34, 3.32 SEU: E/RA (HR): 1.92, 2.70, 3.13, 3.32, 3.57, 4.13, 4.79, 13.4 EU: 1.08, 1.38, 1.52, 1.53, 2.04, 2.94, 3.79, 3.91, 3.92						
	France 2016 (ER)	N-EU S-EU	**cGAP: 4x 0.75 kg a.i./ha, Interval 7 days, BBCH 15-89, PHI 3 days** NEU: E/RA (HR): 1.38, 1.64, 2.34, 3.32 E/RA (Mean): 1.25, 1.62, 2.25, 3.07 SEU:	0.14 – 0.81					

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	Control residue in trials (mg/kg)	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
			E/RA (HR): 1.92, 2.70, 3.13, 3.32, 3.57, 4.13, 4.79, 13.4 E/RA (Mean): 1.58, 2.22, 2.97, 3.075, 3.28, 3.37, 4.68, 13.2,						
	Overall supporting data for cGAP	N+S-EU	E/RA (HR): 1.38, 1.64, 2.34, 3.32 1.92, 2.70, 3.13, 3.32, 3.57, 4.13, 4.79, 13.4		3.225	13.4	16.545	5 (Art. 12 proposed 20)	No
Onion[4] (0220020)	EFSA 2018 (Art. 12)	S-EU N-EU (FR)	**GAP: 4x 0.8 kg a.i./ha, Interval 7 days, BBCH 14-47, PHI 3 days** NEU: E/RA (HR): 0.46, 0.48, 0.54, 0.57, 0.62, 0.63, 0.64, 0.75 SEU: E/RA (HR): 0.39, 0.49, 0.66, 0.83						
	France 2016 (ER)	N-EU	**cGAP: 4x 0.75 kg a.i./ha, Interval 7 days, BBCH 14-47, PHI 3 days** E/RA (HR): 0.46, 0.48, 0.54, 0.57, 0.62, 0.63, 0.64, 0.75 E/RA (Mean): 0.455, 0.465, 2x 0.545, 0.585, 0.61, 0.625, 0.74	0.37 – 0.80					
		S-EU	E/RA (HR): 0.39, 0.49, 0.66, 0.83 E/RA (Mean): 0.37, 0.49, 0.615, 0.81						
→ extrapolated to garlic (0220010) and	Overall supporting data for cGAP	N-EU	E/RA (HR): 0.46, 0.48, 0.54, 0.57, 0.62, 0.63, 0.64, 0.75	--	0.595	0.75	1.759	5	Yes

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	Control residue in trials (mg/kg)	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
shallots (0220030)									
Lettuce[3, 4] (0251020)	EFSA 2018 (Art. 12)	N-EU S-EU EU	**GAP: 4x 0.8 kg a.i./ha, Interval 7 days, BBCH 12-49, PHI 7 days** NEU: no data SEU: 2.03, 3.22, 9.08, 11.7 Open leaf varieties: 29.0, 47.4, 66.0 EU (indoor): 23 Open leaf varieties: 22.9, 28.3, 34.4, 34.7, 36.8, 43.9, 83.0						
	France 2016 (ER)	S-EU	**cGAP: 4x 0.75 kg a.i./ha, Interval 7 days, BBCH 12-49, PHI 7 days** E/RA (HR): 2.03, 3.22, 9.08, 11.7, 22.4, 36.5, 66.0 E/RA (Mean): 2.03, 3.22, 11.3, 14.18, 20.2, 31.05, 48.58						
	Overall supporting data for cGAP	S-EU	E/RA (HR): 2.03, 3.22, 9.08, 11.7, 22.4, 36.5, 66.0	--	11.7	66.0	113.497	100 (Art. 12 proposed 150)	No
		EU	E/RA (HR): 21.9, 22.9, 23.0, 28.3, 34.3, 35.5, 36.8, 70.9,	--	31.30	70.90	102.600		
Courgettes[4] (0232030) and/or cucumbers (0232010)	DAR 2007 EFSA 2018 (Art. 12)	S-EU EU (indoor)	**GAP: 5x 1 kg a.i./ha, Interval 7 days, BBCH 15-89, PHI 3 days** E/RA: 0.81, 0.85, 0.98, 2x 1.20, 1.30, 1.40, 1.70 Courgettes:	0.21 – 0.58					

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	Control residue in trials (mg/kg)	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
			E/RA: 0.70, 0.78, 1.10, 1.70, 2.20, 2.50, 2.60, 3.30 Cucumbers: E/RA: 4x <2.0						
→ extrapolated to cucurbits with edible peel (0230000)	Overall supporting data for cGAP	EU (indoor)	E/RA: 0.70, 0.78, 1.10, 1.70, 2.20, 2.50, 2.60, 3.30, 4x <2.0	--	2.0	3.3	4.94	5	Yes
		S-EU	E/RA: 0.81, 0.85, 0.98, 2x 1.20, 1.30, 1.40, 1.70	--	1.2	1.7	3.531		Yes
Melon[2] (0233010)	DAR 2007 EFSA 2018 (Art. 12)	S-EU EU (indoor)	**GAP: 4x 0.9 kg a.i./ha, Interval 7 days, BBCH 15-89, PHI 7 days** E/RA: 2x <5.0, 3x <10.0 E/RA: <1.97, 2x <2.0, 2x <2.1, 5.0						
	France 2016 (ER)	S-EU	***Scaled to the intended French dose rate of 1.2 (±25%)*** *Whole fruit:* *E/RA: 0.34, 0.53, 0.69, 1.6, 1.9, 2.15, 2x 2.6* *Pulp:* *E/RA: 0.29, 0.31, 0.39, 0.41, 0.5, 0.6, 0.73, 0.73*						
→ extrapolated to cucurbits with inedible peel (023300)		S-EU	Whole fruit: E/RA: 0.34, 0.53, 0.69, 1.6, 1.9, 2.15, 2x 2.6		1.75	2.6	5.234	5 (Art. 12 proposed 10)	No

* Source of EU MRL: Reg. (EC) No: 149/2008 (01/09/2008)

France (SANTE/2019/12752) :

1 N: Crops essentially cultivated in Northern France
2 S: Crops essentially cultivated in Southern France
3 N+S: Crops spread out throughout the entire territory
4 N or S: residue data accepted from south and/or north zone

7.2.3.2 Conclusion on the magnitude of residues in plants

Pre-flowering –Stone fruits, Pome fruits

According to SANTE/2019/12752 an extrapolation is possible for the whole group of pome fruit (pre-flowering – before the edible part is formed) if four trials on apples and ~~four~~ trials on stone fruit are available what is the case here. Even the intended GAP is only for apple, pear and quince data for stone fruits are presented as well.

Pre-flowering trials were submitted in the framework of the submission in France (France 2016, ER).
Five pre-flowering trials on apple and pear are available for the northern and five for the southern zone.
Apples were treated 3 times (with an interval of 14-15 days in SEU or 119-124 days and 13-14 days in NEU) at a rate between 800 and 2600 g a.s./ha per application. Fruits were sampled between 144 and 202 days after last application. All results were below <1.5 mg/kg of copper.
Pears were treated 3 times (with an interval of 14-15 days in SEU or 117-174 days and 14 days in NEU) at a rate between 1.60 and 2.62 kg a.s./ha per application. Fruits were sampled between 113 and 169 days after last application. All results were below <1.5 mg/kg of copper, except for one trial on pear where residue in fruits was 1.52 mg/kg of copper.

Two trials on plum, cherry are available for the northern and six trials for the southern zone. One new trial in cherry is available for the southern zone.
Cherries were treated 3 times (with an interval of 11-16 days) at a rate between 1.17 and 1.23 kg a.s./ha per application. Fruits were sampled between 74 and 105 days after last application. Results in fruits ranged between 0.596 and 1.129 mg/kg of copper.
Plums were treated 3 times (with an interval of 15 days) at rates of 1.19 or 1.21 kg a.s./ha per application. Fruits were sampled 129 days after last application. Results in fruits ranged between 0.458 and 0.518 mg/kg (0.488 mg/kg) of copper.

Considering the similar GAP and residue results for both zones, the risk assessments were calculated with the values measured in north and south trials.
Even there are some variabilities within the trial application rates the residue trials can be considered as worst case use compare to the intendend cGAP for Poland.

As copper will be applied at vegetative growth stage of fruits and as copper is a contact fungicide, no residues linked to treatment are awaited in fruits.

Grapes
Grapes (wine) are major crops in the northern zone. Among the residue trials available in the DAR, 7 Northern trials performed on grapes are considered suitable to support the intended uses. Furthermore 2 Northern trials and 3 Southern trials on grapes performed according to the respective GAP have been submitted to France (France 2016, ER).
In all trials the grapes were treated 4 times (with an interval of 7±1 days) at a rate between 1.50 and 2.51 kg a.s./ha per application. Fruits were sampled 21 days after last application. Results in fruits ranged between 3.7 and 56 mg/kg of copper.

The northern residue data were compliant with the data requirements for this crop.
Considering the similar GAP and residue results for both zones, the risk assessments were calculated with the values measured in north and south trials.

The intended cGAP for Poland can be considered as less critical compare to the application data from the trials.

Strawberry

Strawberries are major crops in the northern zone. Overall, 8 northern trials, 7 southern trials and 8 indoor trials on strawberries are available and submitted to France (France 2016). Strawberries were treated 4 times (with an interval of 7±1 days) at a rate between 721 and 921 g a.s./ha per application. Fruits were sampled 3 days after last application, except for one trial in NEU, one trial in SEU and one trial in indoor where samplings were carried out 5 or 7 days after last application. Results in fruits ranged between 0.51 and 6.12 mg/kg of copper.

The calculated unrounded MRL is 6.125 mg/kg for fruits. Thus, the current MRL of 5 is exceeded. However, in the Art. 12 MRL review of copper a tentative MRL of 7 mg/kg was proposed for N+S-EU.

For the for the northern zone the dataset is complete, for the southern zone one trial is missing, however the results from North and South zone (same GAP) are comparable. Thus, an overall evaluation is possible and the risk assessments were calculated with the overall values measured in north and south trials.
Please consider, EU Indoor is the worst-case zone with higher residue values on the same GAP (proposed MRL 15) compare to the outdoor data (N+S-EU).

Even there are parameter deviations between the trial GAP and the intended GAP for Poland the field trial uses can be considered as worst case (4 instead of 3 application, application rate <25%).

Tomato

Tomatoes are major crops in the northern zone and are part of the subgroup Solanaceae (fruiting vegetables).
Among the residue trials available in the DAR 2007, 5 Southern trials and 4 indoor trials performed on tomatoes are considered suitable to support the intended uses.
Furthermore, 9 Northern trials on tomatoes performed according to the GAP have been submitted to France (France 2016).
Tomatoes were treated 6 times (with an interval of 7 days) at a rate between 1.17 and 1.31 kg a.s./ha per application. Fruits were sampled 3 days after last application, except for 3 trials where samplings were carried out 7 or 10 days after last application. Results in fruits ranged between 0.7 and 6.6 mg/kg (STMR 1.7).
The unrounded calculated MRL for the northern zone is 9.814 and exceeds the current MRL of 5. During the MRL review (Art. 12 EFSA 2018) a tentative MRL of 10 was proposed.

According to the EU Guideline on comparability, extrapolation, group tolerance and data requirements for setting MRLs (SANTE/2019/12752), extrapolation is possible from tomatoes to aubergines is a whole data set is available.

Even there are parameter deviations between the trial GAP and the intended GAP for Poland the field trial uses can be considered as worst case (3 instead of 6 application, application rate <25%, BBCH 15-51 instead of 15-89, PHI 10 instead of 3).
The data are already evaluated within the MRL review (Art. 12 EFSA 2018) and summarized in Appendix 2.1.

Pepper

Peppers are major crops in the northern zone and are part of the subgroup Solanaceae (fruiting vegetables). 8 Southern trials, 4 Northern trials and 9 indoor trials are available and submitted to France in 2016 (France 2016).
Peppers were treated 4 times at a rate between 756 and 967 g a.s./ha per application (with an interval of 7 days). Fruits were sampled 3 days after last application, except for 4 trials where samplings were carried

out 5 days after last application. Results in fruits ranged between 1.92 and 13.4 mg/kg of copper in S-EU.

Because of a comparable GAP and results for N+S-EU an overall evaluation was done.
Results in fruits of both zones ranged between 1.38 and 13.4 mg/kg (STMR 3.225).
The unrounded calculated MRL is 16.545 and exceeded the MRL of 5. During the MRL review (Art. 12 EFSA 2018) a tentative MRL of 20 was proposed.

Even there are parameter deviations between the trial GAP and the intended GAP for Poland the field trial uses can be considered as worst case (3 instead of 4 application, application rate <25%, BBCH 15-51 instead of 15-89, PHI 10 instead of 3).

Onion
Onions are major crops in the northern zone and part of the group bulb vegetables.
Eight GAP-compliant trials for EUN and further four GAP-compliant trials for EUS are available.
In all trials onions were treated 4 times (with an interval of 7 days) instead of 3 at a rate between 781 and 857 g a.s./ha (within the 25% rule) per application. Bulbs were sampled 3 days after last application, except for 4 trials where samplings were carried out between 5 and 8 days after last application. Results in bulbs ranged between 0.46 and 0.75 mg/kg of copper (STMR 0.595).
The unrounded calculated MRL was 1.759 and is below the current MRL of 5.

Even there are parameter deviations between the trial GAP and the intended polish GAP the field trial uses can be considered as worst case.

According to the EU Guideline on comparability, extrapolation, group tolerance and data requirements for setting MRLs (SANTE/2019/12752), extrapolation from onions to garlic and shallots is possible if a whole data set is available.

Lettuce
Lettuce are major crops in the northern zone. No trials are available for the northern zone.
However, 7 southern and 8 indoor trials on lettuce are available. Lettuce was treated 4 times (with an interval of 7±2 days) at a rate between 608 and 888 g a.s./ha per application. Lettuce was sampled between 5 and 8 days after last application. S-EU results ranged between 2.03 and 66.0 mg/kg of copper (STMR 11.7).
The calculated MRL for SEU and Indoor was 113.5 and 102.6 mg/kg respectively. For both cases the current MRL of 100 was exceeded. During the MRL review (Art. 12, EFSA 2018) a new MRL of 150 was proposed. It is very unlikely that new trials conducted in the northern zone and a similar GAP occur to higher residue or an MRL above 150 mg/kg.

Even there are parameter deviations (3 instead of 4 applications, application rate <25%) between the trial GAP and the intended GAP the field trial uses can be considered as worst case.

However, the number of residue trials supporting the northern cGAP is not compliant with the data requirements for this crop. Therefore, risk assessment values are only tentative.

According to the EU Guideline on comparability, extrapolation, group tolerance and data requirements for setting MRLs (SANTE/2019/12752), extrapolations from lettuce to “whole lettuce and other salad plants groups” are possible.

Cucurbits with edible peel (cucumber, courgettes)
Cucumbers are major and courgettes are minor crops in the northern zone. 8 trials on courgettes in southern Europe (and 8 indoor on courgettes and 4 indoor trials on cucumbers) are available (DAR 2007). No trials

for the northern zone are available. However, the earlier data reported in RAR 2016 (see overall conclusion) could be used.
Courgettes were treated 5 times (with an interval of 5-6 days) at a rate at 1.2 kg a.s./ha per application. Fruits were sampled 3 days after last application.
Results in fruits from the southern zone ranged between 0.70 and 3.3 mg/kg of copper (STMR 2.0).
The calculated unrounded MRL for indoor was with 4.94 mg/kg below the current MRL of 5. The calculated S-EU MRL was 3.531 mg/kg. Therefore, it is very unlikely that new trials conducted in the northern zone with a similar GAP occur to higher residue or an MRL above 5 mg/kg.

Even there are parameter deviations (5 instead of 3 application) between the trial GAP and the intended GAP the field trial uses can be considered as worst case.

According to the EU Guideline on comparability, extrapolation, group tolerance and data requirements for setting MRLs (SANTE/2019/12752), extrapolation is possible with cucumbers or courgettes trials (if courgettes alone 8 trials) to the whole group of "cucurbits with edible peel".

Cucurbits with inedible peel (Melon, pumpkin)
Melons and pumpkins are minor crops in the northern zone.
Eight southern are available on melons submitted with the DAR 2007. Melons were treated 6 times (interval of 7 days) with an overdosed rate of 3.0 kg a.s./ha per application. The results were scaled to the intended dose rate (French submission).

Fruits were sampled 7 days after last application. All scaled trials were carried out according to the intended French GAP. Scaled results in fruits ranged between 0.34 and 2.6 mg/kg of copper (STMR 1.75). The calculated unrounded MRL was 5.234 mg/kg and exceeded the current MRL of 5.
However, during the MRL review (EFSA 2018, Art. 12) a MRL of 10 was proposed.

The number of residue trials supporting the northern cGAP is not compliant with the data requirements for this crop. Therefore, risk assessment values are only tentative.
Even there are parameter deviations (3 instead of 4 application) between the trial GAP and the intended GAP the field trial uses can be considered as worst case.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

The input values for the dietary burden calculations are presented in the following table.

Table 7.2-4: 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
Copper				
Beet sugar, tops	40.70	STMR	40.70	STMR
Cabbage heads, leaves	0.26	Monitoring data (EFSA,2018)	0.26	Monitoring data (EFSA,2018)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Kale leaves	1.24	Monitoring data (EFSA,2018)	1.24	Monitoring data (EFSA,2018)
Carrot, culls	0.92	STMR	0.92	STMR
Potato, culls	2.43	STMR	2.43	STMR
Swede	0.95	Background data (EFSA,2018)	0.95	Background data (EFSA,2018)
Turnip	0.95	Background data (EFSA,2018)	0.95	Background data (EFSA,2018)
Barley, grain	4.09	Monitoring data (EFSA,2018)	4.09	Monitoring data (EFSA,2018)
Bean, seed	7.21	Monitoring data (EFSA,2018)	7.21	Monitoring data (EFSA,2018)
Corn, field, grain	2.40	Background data (EFSA,2018)	2.40	Background data (EFSA,2018)
Cotton, delinted seed	12.0	Background data (EFSA,2018)	12.0	Background data (EFSA,2018)
Lupin, seed	7.30	Background data (EFSA,2018)	7.30	Background data (EFSA,2018)
Millet, grain	4.15	Background data (EFSA,2018)	4.15	Background data (EFSA,2018)
Oat, grain	4.15	Background data (EFSA,2018)	4.15	Background data (EFSA,2018)
Rye, grain	3.57	Monitoring data (EFSA,2018)	3.57	Monitoring data (EFSA,2018)
Sorghum, grain	4.15	Background data (EFSA,2018)	4.15	Background data (EFSA,2018)
Soybean, seed	12.0	Background data (EFSA,2018)	12.0	Background data (EFSA,2018)
Wheat, grain	4.13	Monitoring data (EFSA,2018)	4.13	Monitoring data (EFSA,2018)
Apple, pomace, wet	1.41	STMR	1.41	STMR
Beet, sugar	1.24	STMR	1.24	STMR
Citrus	3.5	STMR (oranges)	3.5	STMR (oranges)
Flaxseed, linseed, meal	12.96	Monitoring data (EFSA,2018)	12.96	Monitoring data (EFSA,2018)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Palm, kernel meal	0.65	Background data (EFSA,2018)	0.65	Background data (EFSA,2018)
Peanut, meal	12	Background data (EFSA,2018)	12	Background data (EFSA,2018)
Rape, meal	1.20	Background data (EFSA,2018)	1.20	Background data (EFSA,2018)
Rice, bran/pollard	2.54	Monitoring data (EFSA,2018)	2.54	Monitoring data (EFSA,2018)
Safflower, meal	12.0	Background data (EFSA,2018)	12.0	Background data (EFSA,2018)
Sunflower, meal	18.41	Monitoring data (EFSA,2018)	18.41	Monitoring data (EFSA,2018)

Table 7.2-5: Results of the dietary burden calculation

Animal species	Median dietary burden	Maximum dietary burden	Median dietary burden	Maximum dietary burden	Highest contributing commodity	Trigger exceeded (Y/N)
	(mg/kg bw/d)		(mg/kg DM)			
Cattle (all diets)	6.908	6.908	201.19	201.19	Potato, process waste	Y
Cattle (dairy only)	6.908	6.908	179.60	179.60	Potato, process waste	Y
Sheep (all diets)	6.746	6.746	202.38	202.38	Potato, process waste	Y
Sheep (ewe only)	6.746	6.746	202.38	202.38	Potato, process waste	Y
Swine (all diets)	2.456	2.456	106.41	106.41	Potato, process waste	Y
Poultry (all diets)	1.997	1.997	29.18	29.18	Beet, sugar tops	Y
Poultry (layer only)	1.997	1.997	29.18	29.18	Beet, sugar tops	Y

In all animal species the trigger is exceeded. Livestock feeding data are required. Please refer to the conclusion under 7.2.4.2.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Copper is used as feed additive for all livestock species. The EFSA Scientific Opinion on the safety and efficacy of Copper compounds (E4) as feed additives for all animal species (EFSA Journal 2016; 14(8):4563) proposed the maximum acceptable levels of Copper in feed as a dietary supplement as summarized in the table below.

Livestock group	**Maximum Copper content (mg/kg complete feed)** $^{(a)}$	**Maximum Copper content (mg/kg complete feed DM basis)** $^{(b)}$
Bovines		
Bovines before the start of rumination	15	13.2
Other bovines	30	26.4
Ovines	15	13.2
Caprines	35	30.8
Piglets		
suckling and weaned up to 4 weeks after weaning	150	132
from 5th week after weaning up to 8 weeks after weaning	100	88
Crustaceans	50	44
Other Animals	25	22

[a] Complete feed containing a moisture content of 12%
[b] Regulation (EU) 2018/1039

A comparison of the results of the maximum intake of Copper resulting from the animal dietary burden calculation compared to that arising from supplemented feed is shown in the table below.

Comparison of the maximum dietary burdens with maximum Copper contents to be authorized in complete feed:

	Cattle		**Sheep**		**Swine**		**Poultry**		
	beef	**dairy**	**Ram/Ewe**	**Lamb**	**Breeding**	**Finishing**	**Broiler**	**Layer**	**Turkey**
Feed intake (kg dw/day)	12	25	2.5	1.7	6	3	0.12	0.13	0.5
Feed intake kg fresh weight /day)	13.636	28.409	2.841	1.932	6.818	3.409	0.136	0.148	0.568
Bodyweight (kg)	500	650	75	40	260	100	1.7	1.9	7
Animal Dietary Burden Calculation									
Maximum intake Cu (mg/kg bw/day)	**4.829**	**6.908**	**6.746**	**5.182**	**2.456**	**0.893**	**1.806**	**1.997**	**0.863**
Supplemented Feed									
Cu permitted in Complete feed (mg/kg feed)$^{(a,b)}$	30	30	15	15	100	100	25	25	25
Total Cu intake mg/kg bw day	**0.818**	**1.311**	**0.568**	**0.724**	**2.622**	**3.409**	**2.005**	**1.944**	**2.029**

[a] Complete feed containing a moisture content of 12%
[b] Regulation (EU) 2018/1039

It can be seen from the comparison of the animal dietary burden consumption intake to the level of Copper permitted in complete animal feed, that the dietary consumption of calculated maximum dietary burden arising from pesticide residues is greater than that from currently allowed maximum level of Copper in complete feed for cattle and sheep. In practice, results from monitoring programmes of complete animal feed in the EU (EFSA FEEDAP Panel, 2015), demonstrate that this may not often occur. It is highlighted, that the maximum levels of Copper in complete feed are legal limits which are therefore expected to be monitored by feed business operators when completing the feed diets. Consequently, the maximum Copper content in complete feed reported in the Feed Regulations should guarantee that the Copper animal intake remain under these levels. In addition, it should also be noted that the theoretical maximal dietary burdens are not expected to occur in practice because they would anyways not be tolerated by most of the animal species (see also EFSA FEEDAP Panel, 2015).

Although these dietary intake levels do not include Copper derived from drinking water, the level of Copper intake is already much greater than the trigger value of 0.004 mg/kg bw /day set by Regulation (EC) 1107/2009 for the conduction of livestock feeding studies on the grounds that there may be risks to consumers through consumption of Copper residues in food of animal origin.

In addition, the EFSA Scientific Opinion on the safety and efficacy of Copper compounds (E4) as feed additives for all animal species (EFSA, 2009), 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. Nevertheless, the use of Copper as a plant protection product can be considered acceptable.

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

Data/information on processing studies was reviewed during the approval of active substance and were considered acceptable. No further studies have been performed.
According to EFSA 2018 (Art. 12) several processing studies are available but no further processing studies are required.

7.2.5.1 Available data for all crops under consideration

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

Table 7.2-6: Overview of the available processing studies

Processed commodity	Number of studies[(a)]	Median PF *	Median CF **	Comments	Reference
EU data					
Copper					
Oranges, peeled	11	0.31	-	No comments	EFSA, 2018
Mandarins, peeled	12	0.30			
Oranges, juice	5	0.94			
Oranges, marmalde	5	0.53			
Cherries, canned	8[(b)]	0.36			
Peaches, canned	8[(b)]	0.19			
Plums, dried (prunes)	8	3.62			
Table grapes, dried (raisins)	9	2.60			
Wine grapes, juice	9	0.39			

Processed commodity	Number of studies[a]	Median PF *	Median CF **	Comments	Reference
Wine grapes, wet pomace	6	1.20			
Wine grapes, must	14	0.85			
Wine grapes, red wine	20[I]	0.04			
Wine grapes, white wine					
Strawberries, jam	8	0.85			
Kiwi fruits, peeled	5	0.42			
Melons, peeled	5	0.42			
Peas (without pods), cooked	8	0.96			
Peas (without pods), canned	8	0.66			
Olives for oil production, virgin oil after cold press	10	<0.10[I]			
Olives for oil production, press cake	10	0.71			
Hopes, beer	8	<0.10[d]			
Indicative processing faactors (limited dataset)					
Oranges, wet pomaace	1	2.12		No comments.	EFSA, 2018
Oranges, dry pomace	1	8.61			
Apples, wet pomace	2	0.73			
Olives for oil production, refined oil after warm press	1	<0.10[d]			
Applicant data, used in risk assessment (previously assessed at EU level)					
Tomatoes, washed fruit	10	0.6		No comments.	DAR, 2007 RAR 2017
Tomatoes, canned	10	0.5			
Tomatoes, juiced	10	1.9			
Tomatoes, puree	10	2.0			

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

a) Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur)
b) Processing factor calculated for canned unstoned cherry/peach (-pulp)
c) PF for wine is derived from a combined dataset of red and white wine studies
d) Residues <LOQ in all processed samples of virgin, refined oil and beer

7.2.5.2 Conclusion on processing studies

Tomatoes:
A total of 10 trials were carried out in industrial tomatoes in southern France, Spain and Italy over two seasons. Applications were made according to the GAP for each Copper form or at higher rates.
Samples of treated and untreated fruit were taken at normal harvest (PHI 10 days) and processed into fractions following the production of juice, puree and canned fruit.
In one study, residues of Copper were determined in all processed fractions including the water used for washing or blanching. In other studies, residues were determined in the relevant edible commodities only (i.e. pasteurised juice, puree and canned fruit) and transfer factors were determined.

Residues of Copper in treated fruit were reduced by washing with a mean transfer factor of 0.6 compared to the unwashed values.
Residues in the treated juice and puree were higher than in the corresponding unprocessed fruit and the mean transfer factors for these two commodities were 1.9 and 2.0, respectively. However, Copper levels in the untreated juice and puree were also higher than in the untreated unprocessed fruit, and for untreated fruit the mean transfer factors for juice and puree were 4.2 and 2.5, respectively. Thus, Copper levels in untreated puree and untreated juice concentrated more than in the treated puree and treated juice. Actual Copper levels in the juice from untreated and treated fruit were similar (mean 3.4 mg/kg in treated juice; mean 3.2 mg/kg in untreated juice).
Residues of Copper in treated canned fruit were lower than in the corresponding unprocessed fruit and the mean transfer factor was 0.5 mg/kg. Levels of Copper in untreated canned fruit were variable but overall similar to the corresponding untreated unprocessed fruit.
For detailed information please refer to studies already EU evaluated (CA 6.5.3).

Grapes:
A total of 24 trials were carried out in wine and table grapes in southern and northern EU countries over four seasons.
Samples of treated and untreated fruit were taken at normal harvest (PHI 21 days or later) and processed into fractions following the production of juice, wine and raisins.
In balance studies, residues of Copper were determined in all processed fractions including the by-products and waster products. In follow-up studies, residues were determined in by-products and edible commodities only (i.e. must, juice, wine, wet pomace and raisins) and transfer factors were determined.
In wine grapes, residues of Copper in the treated must and pomace were higher than in the corresponding unprocessed fruit and the mean transfer factors for these two commodities were 1.9 and 2.8, respectively. Residues of Copper in treated juice and wine were lower than in the corresponding unprocessed fruit and the mean transfer factors for these two commodities were 0.4 and 0.07, respectively. The mean residue for Copper in wine was 0.4 mg/kg.
Levels of Copper in untreated commodities were higher than the untreated unprocessed fruit in juice (transfer factor 1.5), wet pomace (transfer factor 3.5) and lower than untreated fruit in must (transfer factor 0.7) and wine (transfer factor 0.11).
In table grapes, residues of Copper in the treated raisins were higher than in the corresponding unprocessed fruit (mean transfer factor 2.7). Levels of Copper in the untreated raisins were also higher than in the corresponding unprocessed fruit (mean transfer factor 4.7).
For detailed information please refer to studies already EU evaluated (CA 6.5.3).

Cucurbits:
Other than washing and/or peeling cucurbits are not normally processed. Therefore, no study is required

7.2.6 Magnitude of residues in representative succeeding crops

See Chapter 7.2.2.2.

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

The available data for the active substance sufficiently addresses aspects of the residue situation that might arise from the use of Nordox 75 WG. Therefore, other special studies are not needed.

Copper is non-systemic therefore it is not likely that residues would be found in pollen or honey.
A survey of recent peer-reviewed literature revealed that levels of Copper broadly vary between 0.10-15.5 mg/kg, as presented in the table below.

Cu in honey or pollen	**Comment**	**Reference**
Mean 0.50 mg/100 g	Content of Copper in honey in Ireland	G. Downey et al. (2005) Preliminary contribution to the characterization of artisanal honey produced on the island of Ireland by palynological and physic-chemical data/ Food Chemistry 91 347–354
Mean: 3.22 mg/kg Range: 0.37-15.5 mg/kg	Trace and minor elements in Slovenian honey	T. Golob et al. Determination of trace and minor elements in Slovenian honey by total reflection X-ray fluorescence spectroscopy / Food Chemistry 91 (2005) 593–600
Mean: 0.37 mg/kg Range: 0.10-1.73	Metals found in honey from Canary Islands and non-Canary (range)	O.M. Hernandez et al. (2005) Characterization of honey from the Canary Islands: determination of the mineral content by atomic absorption spectrophotometry/ Food Chemistry 93 449–458
Mean: 0.42 mg/kg Range: 0.11-0.88	Honey in Czech Republic	J. Lachman et al. (2007) Analysis of minority honey components: Possible use for the evaluation of honey quality/ Food Chemistry 101 973–979
Range: 0.23-2.41 mg/kg	Honey from different geographic regions of Turkey	M. Tuzen et al. (2007) Trace element levels in honeys from different regions of Turkey. Food Chemistry 103 (2007) 325–330
Mean: 1.07 mg/kg	Honey in Croatia	Bilandzic N et al (2011) Determination of grace elements in Croatina floral honey originating from different regions. Food Chemistry 128 (2011): 1160-1164.
Range: 1.77-2.99 mg/kg	Honey from various floral origin	Özcan M et al (2012). Mineral and heavy metal contents of different honeys produced in Turkey. Journal of Apicultural Research 51(4): 353-358 (2012)
Mean: 0.31 mg/kg	Honey from different botanical origin in Italy	Conti M E (2000). Lazio region (central Italy) honeys: a survey of mineral content and typical quality parameters. Food Control 11 (2000) 459-463
Range: 0.67-1.94 mg/kg	Honey from Marche Region in Italy, different floral origin.	Conti et al (2007). Characterization of Italian honeys (Marche Region) on the basis of their mineral content and some typical quality parameters. *Chemistry Central Journal* 2007, **1**:14

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

7.2.8.1 Input values for the consumer risk assessment

In order to evaluate the potential chronic exposure to Copper residues through the diet, the Theoretical Maximum Dietary Intakes (TMDI) were estimated using the EFSA PRIMo model (revision 3.1). For the evaluation of the chronic exposure the model uses 5 WHO diets relevant to the EU and 22 national diets from 13 different EU Member States.
The calculation of the TMDI was performed by taking into account all the crops to which Copper may be

applied as well as natural background or monitoring values in other crops and livestock matrices. Table 7.2-7 and Table 7.2-9 show the input values for inclusion in the PRIMO model.

The values used in the PRIMo are shown below. They represent the residue levels present in the edible parts of the RAC and differ from those values in Table 6.3-1 which represent the residues present in the RAC as harvested. Where replicate trials have been conducted on different formulations, the average of the two independent plots has been taken. It has been demonstrated that the formulation type and form of copper present in the formulation has no effect on the level of the residues in the crops and there is no acute consumer dietary risk calculation, so this approach is considered justified. The residue present at the designated PHI for the crop is also taken, regardless of whether higher residues are present at later time points. Again, the chronic nature of the risk assessment being undertaken justifies this approach.

A two tier approach has been used to refine the input to the PRIMO model. Residues present in the edible portion of the RAC from the supervised field trials have been used where available. In addition to this, to take into account the presence of copper in the environment, background and monitoring data has been sought and input to give a fair representation of the total intake of copper in the diet. Monitoring data has only been used where a significant number of samples (number of samples noted in the table below). The refinement steps taken have been designated as Tier II inputs in Table 7.2-7.

Table 7.2-7: Input values for the consumer risk assessment (all crops)

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 2)	Back-ground mg/kg 1)	Monitoring mg/kg 1)	PRIMo Input mg/kg	Comment / Reference EFSA 2018
1	**FRUIT (FRESH OR FROZEN)**										
	Citrus fruit	**20**			**3.93**	**7.59**					
	Grapefruit							0.44	0.49	1.22	STMR (tentative x PF (peeling) (EFSA, 2018)
4	Oranges							0.44	0.51	1.22	
4	Lemons							0.44	0.53	1.18	
4	Limes							0.44		1.18	
4	Mandarins							0.44	0.59	1.18	
4	Other citrus fruits										
2	**Tree nuts (shelled or unshelled)**	30			11.7	15.2	7.27-18.3	4.5-13.3	12.64-18.92	11.7	STMR Almond/walnut
	Almonds							10.7	-	11.7	STMR Almond/walnut
	Brazil nuts							10.7	18.92	11.7	Extrapolation from Almond/walnut (STMR)
	Cashew nuts							13.3	-	13.3	Background data (EFSA, 2018)
	Chestnuts							10.7	-	11.7	Extrapolation from Almond/walnut (STMR)
	Coconuts							4.5	-	4.5	Background data (EFSA, 2018)
	Hazelnuts/cobnuts							10.7	15.13	11.7	Extrapolation from Almond/walnut (STMR)
	Macadamia							10.7	-	11.7	Extrapolation from Almond/walnut (STMR)
	Pecans							10.7	-	11.7	Extrapolation from Almond/walnut (STMR)
	Pine nut kernels							13.3	15.96 (n=103)	15.96	Monitoring data (EFSA, 2018)

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 2)	Back-ground mg/kg 1)	Monitoring mg/kg 1)	PRIMo Input mg/kg	Comment / Reference EFSA 2018
	Pistachios							13.3	-	11.7	Extrapolation from Almond/walnut (STMR)
	Walnuts							10.7	12.64	11.7	Extrapolation from Almond/walnut (STMR)
	Other tree nuts									11.7	Extrapolation from Almond/walnut (STMR)
2	**Pome fruit**	**5**		(Post-flowering data as worst case)							
	Apples				1.41	3.37	0.39 – 0.67	0.77	0.5 (n=128)	Tier I: 1.41 Tier II: 0.5	Tier I: STMR Apples Tier II: Monitoring data (EFSA, 2018)
4	Pears							0.77	0.8	1.41	STMR Apples (post-flowering)
4	Quinces							0.77	<2	1.41	STMR Apples (post-flowering)
4	Medlar							0.77	-	1.41	STMR Apples (post-flowering)
	Loquat							0.77	-	1.41	STMR Apples (post-flowering)
4	Other pome fruits									1.41	STMR Apples (post-flowering)
2	**Stone fruit**	**5**		(Post-flowering data as worst case) – supplement information needed for extrapolation (pre-harvest use)							
	Apricots							1.02	0.76	1.50	STMR (EFSA 2018
4	Cherries							1.02	0.77	2.69	STMR (EFSA 2018
4	Peaches							1.02	0.89	2.35	STMR (EFSA 2018
4	Plums							1.02	0.62	1.15	STMR (EFSA 2018
4	Other stone fruits										
2	**Berries & small fruits**										

Level	**RAC**	**tMRL**	**Region**	**Individual trial results mg/kg**	**Median STMR mg/kg**	**Highest residue mg/kg**	**Control mg/kg** 2)	**Back-ground mg/kg** 1)	**Monitoring mg/kg** 1)	**PRIMo Input mg/kg**	**Comment / Reference EFSA 2018**
3	Table and wine grapes	50									
4	Table grapes		SEU	See DAR	7.15	12		1.20	1.28 (n=258)	Tier I: 7.15 Tier II: 1.28	Tier I: STMR all regions Tier II: Monitoring data (EFSA, 2018)
4	Wine grapes		N/SEU	37.5, 4.1, 5.2, 5.6, 38, 9.4, 8.7, 4.2, 9.05, 9.75, 6.9, 7.05, 4.85, 2.2, 4.1	6.9	56		1.20	0.26	0.28	(STMR (6.9) wine grapes N/SE * Transfer factor (0.04))
3	Strawberry	5	N/SEU Indoor	0.51, 0.72, 0.87, 0.98, 0.99, 1.06, 2.08, 3.44 0.68, 1.10, 1.44, 1.77, 3.09, 3.31, 3.55, 0.54, 1.39, 1.58, 1.63, 2.95, 3.81, 5.46, 6.12	1.580	6.12	0.14 – 1.23	0.43	0.37 (n=193)	Tier I: 1.58 Tier II: 0.37	Tier I: STMR all regions Tier II: Monitoring data (EFSA, 2018)
4	Blackberries							1.4	0.95	1.00	Extrapolation raspberries/currant STMR
4	Dewberries							1.4	0.79	1.00	Extrapolation raspberries/currant STMR
4	Raspberries	3						1.4	0.61	1.00	STMR raspberries/currant
4	Other Cane fruits									1.00	Extrapolation raspberries/currant STMR
3	Other small fruits & berries	5									
4	Blueberries							1.4	0.6	1.00	Extrapolation raspberries/currant STMR
4	Cranberries							1.4	<2	1.00	Extrapolation raspberries/currant STMR
4	Currants (red, black, white)	3						1.4	0.78	1.00	STMR raspberries/currant

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 2)	Back-ground mg/kg 1)	Monitoring mg/kg 1)	PRIMo Input mg/kg	Comment / Reference EFSA 2018
4	Gooseberries							1.4	0.77	1.00	Extrapolation raspberries/currant STMR
4	Rose hips							1.4	-	1.00	Extrapolation raspberries/currant STMR
4	Mulberries							1.4	-	1.00	Extrapolation raspberries/currant STMR
4	Azarole							1.4	-	1.00	Extrapolation raspberries/currant STMR
4	Elderberries							1.4	-	1.00	Extrapolation raspberries/currant STMR
4	Other small fruits & berries								-	1.00	Extrapolation raspberries/currant STMR
2	**Miscellaneous fruit**										
3	Miscellaneous fruit (edible peel)	20									
4	Dates							0.86	1.73	0.86	Background data (EFSA, 2018)
4	Figs							0.86	7.85	7.85	Monitoring data (EFSA, 2018)
4	Table olives							2.28	2.95	6.23	STMR olive
4	Kumquats							0.86	<2	0.86	Background data (EFSA, 2018)
4	Carambola							0.86	-	0.86	Background data (EFSA, 2018)
4	Persimmon							0.86	0.22	0.86	Background data (EFSA, 2018)
4	Jambolan (java plum)							0.86	-	0.86	Background data (EFSA, 2018)
4	Other misc. fruits (edible peel)							0.86	-	0.86	Background data (EFSA, 2018)
3	Miscellaneous fruit (inedible peel, small)	20									

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 2)	Back-ground mg/kg 1)	Monitoring mg/kg 1)	PRIMo Input mg/kg	Comment / Reference EFSA 2018
4	Kiwi							1.48	1.54	6.94	STMR Kiwi (whole fruit)
4	Lychee (Litchi)							1.48	2.72	1.48	Background data (EFSA, 2018)
4	Passion Fruit							1.48	3.55	1.48	Background data (EFSA, 2018)
4	Prickly pear (cactus fruit)							1.48	-	1.48	Background data (EFSA, 2018)
4	Star apple							1.48	-	1.48	Background data (EFSA, 2018)
4	American persimmon							1.48	-	1.48	Background data (EFSA, 2018)
4	Other misc. fruit (inedible peel, small										
3	Miscellaneous fruit (inedible peel, large)										
4	Avocados							0.96	2.9	0.96	Background data (EFSA, 2018)
4	Bananas							0.96	1.08	0.96	Background data (EFSA, 2018)
4	Mangoes							0.96	0.6	0.96	Background data (EFSA, 2018)
4	Papaya							0.96	0.39	0.96	Background data (EFSA, 2018)
4	Pomegranate							0.96	1.44	0.96	Background data (EFSA, 2018)
4	Cherimoya							0.96	-	0.96	Background data (EFSA, 2018)
4	Guava							0.96	0.74	0.96	Background data (EFSA, 2018)
4	Pineapple							0.96	0.88	0.96	Background data (EFSA, 2018)
4	Bread fruit							0.96	-	0.96	Background data (EFSA, 2018)
4	Durian							0.96	-	0.96	Background data (EFSA, 2018)

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 2)	Back-ground mg/kg 1)	Monitoring mg/kg 1)	PRIMo Input mg/kg	Comment / Reference EFSA 2018
4	Soursop							0.96	-	0.96	Background data (EFSA, 2018)
4	Other misc. fruit (inedible peel, small									0.96	Background data (EFSA, 2018)
1	**VEGETABLES (FRESH OR FROZEN)**										
	Root and tuber vegetables incl. potatoes	5									
3	Potatoes	5						1.06	0.86 (n=572)	0.86	Monitoring data (EFSA, 2018)
3	Tropical root and tuber vegetables										
4	Cassava							1.51	-	1.51	Background data (EFSA, 2018)
4	Sweet potatoes							1.51	0.68	1.51	Background data (EFSA, 2018)
4	Yams							1.51	-	1.51	Background data (EFSA, 2018)
4	Arrowroot							1.51	-	1.51	Background data (EFSA, 2018)
4	Other tropical root and tuber vegetables							1.51	-	1.51	Background data (EFSA, 2018)
4	Beetroot							0.95	0.77	0.95	Background data (EFSA, 2018)
4	Carrots	3						0.95	0.46 (n=125)	0.46	Monitoring data (EFSA, 2018)
4	Celeriac							0.95	1.16	1.16	Monitoring data (EFSA, 2018)
4	Horseradish							0.95	-	0.95	Background data (EFSA, 2018)
4	Jerusalem artichokes							0.95	-	0.95	Background data (EFSA, 2018)
4	Parsnips							0.95	1.02	0.95	Background data (EFSA, 2018)
4	Parsley root							0.95	1.46	0.95	Background data (EFSA, 2018)
4	Radishes							0.95	0.17 (n=76)	0.17	Monitoring data (EFSA, 2018

Level	**RAC**	**tMRL**	**Region**	**Individual trial results mg/kg**	**Median STMR mg/kg**	**Highest residue mg/kg**	**Control mg/kg** [2)]	**Back-ground mg/kg** [1)]	**Monitoring mg/kg** [1)]	**PRIMo Input mg/kg**	**Comment / Reference EFSA 2018**
4	Salsify							0.95	1.3	0.95	Background data (EFSA, 2018)
4	Swedes							0.95	<2	0.95	Background data (EFSA, 2018)
4	Turnips							0.95	-	0.95	Background data (EFSA, 2018)
4	Other root and tuber vegetables							0.95	-	0.95	Background data (EFSA, 2018)
2	**Bulb vegetables**	**5**									
4	Garlic							2.24	1.93 (n=56)	1.93	Monitoring data (EFSA, 2018)
4	Onions		NEU SEU	0.46, 0.48, 0.54, 0.57, 0.62, 0.63, 0.64, 0.75, 0.39, 0.49, 0.66, 0.83	0.595	0.83	0.37-0.8	0.56	0.55	0.595	STMR Onion NEU+SEU
4	Shallots									0.595	STMR onion
	Spring onions							0.83	0.51	0.83	Background data (EFSA, 2018)
4	Other bulb vegetables									0.83	Background data (EFSA, 2018)
2	**Fruiting vegetables**										
3	Solanacea	5									
4	Tomatoes		NEU SEU GH	0.70, 1.00, 1.00, 1.50, 1.60, 1.60, 1.70, 1.70, 1.70, 2.00, 2.00, 2.20, 2.30, 2.50, 2.90, 3.70, 4.30, 6.60	1.85	6.6	0.47-1.2	0.75	0.37	1.85	STMR
	Peppers		NEU SEU GH	1.38, 1.64, 2.34, 3.32 1.92, 2.70, 3.13, 3.32, 3.57, 4.13, 4.79, 13.4 1.00, 1.38, 1.52, 1.53, 2.04, 2.94, 3.79, 3.91, 3.92	2.94	13.	0.14-0.81	0.75	0.56	2.94	STMR
4	Aubergines (eggplant)									1.85	Extrapolation from Tomato (STMR)
4	Okra, lady's fingers							0.94	-	0.94	Background data (EFSA, 2018)
4	Other solanacea								-	0.94	Extrapolation from Okra

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 2)	Back-ground mg/kg 1)	Monitoring mg/kg 1)	PRIMo Input mg/kg	Comment / Reference EFSA 2018
3	Cucurbits (edible peel)	5									
4	Cucumbers		SEU GH	0.81, 0.85, 0.98, 2x 1.20, 1.30, 1.40, 1.70, 0.70, 0.78, 1.10, 1.70, < 2.0, < 2.0, < 2.0, < 2.0, 2.20, 2.50, 2.60, 3.30	1.55	3.3	0.21-0.58	0.37	0.31	1.55	STMR SEU+GH
4	Gherkins									1.55	Extrapolation from cucumber (STMR)
4	Courgettes									1.55	Extrapolation from cucumber (STMR)
4	Other cucurbits (edible peel)									1.55	Extrapolation from cucumber (STMR)
3	Cucurbits (inedible peel)	5									
4	Melon		SEU GH	Whole fruit: 0.34, 0.53, 0.69, 1.6, 1.9, 2.15, 2.6, 2.6 Pulp: 0.29, 0.31, 0.39, 0.41, 0.5, 0.6, 0.73, 0.73 < 1.97, < 2.0, < 2.0, < 2.1, < 2.1, 5.0	2.0	5		0.42	0.47	2.0	STMR SEU+GH Pulp
4	Pumpkin									2.0	Extrapolation from melon (STMR Pulp)
4	Watermelon									2.0	Extrapolation from melon (STMR Pulp)
4	Other cucurbits (inedible peel)									2.0	Extrapolation from melon (STMR Pulp)
3	Sweet corn	10						0.48	0.88 (n=84)	0.88	Monitoring data (EFSA, 2018)
3	Other fruiting vegetables	5									
2	**Brassica vegetables**	**20**									
3	Flowering brassica										
4	Broccoli							0.41	0.52 (n=31)	0.52	Monitoring data (EFSA, 2018)
4	Cauliflower							0.41	0.28 (n=47)	0.28	Monitoring data (EFSA, 2018)
4	Other fl. Brassica									1.01	STMR

Level	**RAC**	**tMRL**	**Region**	**Individual trial results mg/kg**	**Median STMR mg/kg**	**Highest residue mg/kg**	**Control mg/kg 2)**	**Back-ground mg/kg 1)**	**Monitoring mg/kg 1)**	**PRIMo Input mg/kg**	**Comment / Reference EFSA 2018**
3	Head brassica										
4	Brussels sprout							0.41	0.42 (n=162)	0.42	Monitoring data (EFSA, 2018)
4	Head cabbage							0.41	0.26 (n=81)	0.26	Monitoring data (EFSA, 2018)
4	Other head brassica									0.42	Monitoring data (EFSA, 2018)
3	Leafy brassica										
4	Chinese cabbage							0.56	0.37	0.56	Background data (EFSA, 2018)
4	Kale							0.56	1.24 (n=127)	1.24	Monitoring data (EFSA, 2018)
4	Other leafy brassica									1.24	Monitoring data (EFSA, 2018)
3	Kohlrabi							0.56	0.28	0.25	Monitoring data (EFSA, 2018)
2	**Leaf vegetables & fresh herbs**										
3	Lettuce and other salad plants incl. Brassicacea	100									
4	Lamb's lettuce							0.83	-	Tier I: 22.75 Tier II: 2.57	Extrapolation lettuce
4	Lettuce		GH SEU	21.9, 22.9, 23.0, 28.3, 34.3, 35.5, 36.8, 70.9, 2.03, 3.22, 9.08, 11.7, 22.4, 36.5, 66.0	23.0	70.9		0.83	2.57 (n=166)	Tier I: 23.0 Tier II: 2.57	Tier I: STMR GH+SEU Tier II: Monitoring data (EFSA, 2018)
4	Escarole (broad-leave endive)							0.56	0.44	Tier I: 23.0 Tier II: 2.57	Extrapolation lettuce
4	Cress							0.83	-	Tier I: 23.0 Tier II: 2.57	Extrapolation lettuce
4	Land cress							0.83	-	Tier I:	Extrapolation lettuce

Level	**RAC**	**tMRL**	**Region**	**Individual trial results mg/kg**	**Median STMR mg/kg**	**Highest residue mg/kg**	**Control mg/kg** [2)]	**Back-ground mg/kg** [1)]	**Monitoring mg/kg** [1)]	**PRIMo Input mg/kg**	**Comment / Reference EFSA 2018**
										23.0 Tier II: 2.57	
4	Rocket, Rucola							0.83	0.81 (n=61)	0.81	Monitoring data (EFSA, 2018)
4	Red mustard							0.83	-	Tier I: 23.0 Tier II: 2.57	Extrapolation lettuce
4	Leaves and sprouts of Brassica spp							0.56	-	Tier I: 23.0 Tier II: 2.57	Extrapolation lettuce
4	Other lettuce and other salad plants									Tier I: 23.0 Tier II: 2.57	Extrapolation lettuce
2	**Leaf vegetables & fresh herbs**										
3	Spinach & similar (leaves)	20									
4	Spinach							0.83	1.59	Tier I: 23.0 Tier II: 2.57	Extrapolation lettuce
4	Purslane							0.83	-	0.83	Extrapolation lettuce
4	Beet leaves							0.83	<2	0.83	Extrapolation lettuce
4	Other spinach and similar						1.1	0.83	-	0.83	Extrapolation lettuce
3	Vine leaves (grape leaves)	20					4.2	4.15	64	4.15	Background data (EFSA, 2018)
3	Water cress	20					0.8	0.1	1.25	0.1	Background data (EFSA, 2018)
3	Witloof	20					0.5	0.51	0.51	0.5	Background data (EFSA, 2018)
3	Herbs						4.2	1.20	1.85 (n=530)	1.85	Monitoring data (EFSA, 2018)
2	**Legume vegetables (fresh)**	**20**									

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 2)	Back-ground mg/kg 1)	Monitoring mg/kg 1)	PRIMo Input mg/kg	Comment / Reference EFSA 2018
4	Beans (whole pods)							0.48	0.78	0.48	Background data (EFSA, 2018)
	Beans (without pods)							3.18	-	3.18	Background data (EFSA, 2018)
4	Peas (with pods)							1.34	1.14	1.34	Background data (EFSA, 2018)
	Peas (without pods)							1.76	1.42	1.76	
4	Lentils (fresh)									3.18	Background data (EFSA, 2018)
4	Other legume vegetables (fresh)									3.18	Background data (EFSA, 2018)
2	**Stem veg. (fresh)**										
4	Asparagus	5						0.65	0.79 (n=73)	0.79	Monitoring data (EFSA, 2018)
4	Cardoons	20						0.65	-	0.65	Background data (EFSA, 2018)
4	Celery	20						0.65	0.24	0.65	Background data (EFSA, 2018)
4	Fennel	20						0.65	0.7	0.65	Background data (EFSA, 2018)
4	Globe artichokes	20						0.65	-	0.65	Background data (EFSA, 2018)
4	Leek	20						0.65	0.38	0.65	Background data (EFSA, 2018)
4	Rhubarb	20						0.65	0.35	0.65	Background data (EFSA, 2018)
4	Bamboo shoots	20						0.65	-	0.65	Background data (EFSA, 2018)
4	Palm hearts	20						0.65	-	0.65	Background data (EFSA, 2018)
4	Other stem veg.	20								6.49	Extrapolation from Globe artichoke
2	**Fungi**	**20**									
4	Cultivated fungi							2.86	2.2 (n=229)	2.2	Monitoring data (EFSA, 2018)

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg [2]	Back-ground mg/kg [1]	Monitoring mg/kg [1]	PRIMo Input mg/kg	Comment / Reference EFSA 2018
4	Wild fungi							2.86	5.39	2.86	Background data (EFSA, 2018)
4	Other fungi							2.86		2.86	Background data (EFSA, 2018)
2	Seaweeds									1.8	Background HR
1	**PULSES, DRY**	**20**									
4	Beans							7.3	7.21 (n=100)	7.21	Monitoring data (EFSA, 2018)
4	Lentils							7.3	9.19 (n=211)	9.19	Monitoring data (EFSA, 2018)
4	Peas							7.3	6.11 (n=117)	6.11	Monitoring data (EFSA, 2018)
4	Lupins							7.3	-	7.3	Background data (EFSA, 2018)
4	Other pulses, dry									9.19	Monitoring data (EFSA, 2018)
1	**OILSEEDS AND OILFRUITS**										
2	**Oilseeds**										
4	Linseeds	30						12.0	12.96 (n=96)	12.96	Monitoring data (EFSA, 2018)
4	Peanuts	30						12.0	-	12	Background data (EFSA, 2018)
4	Poppy seeds	30						12.0	16.05 (n=80)	16.05	Monitoring data (EFSA, 2018)
4	Sesame seed	30						12.0	16.11	12	Background data (EFSA, 2018)
4	Sunflower seed	40						12.0	18.41 (n=101)	18.41	Monitoring data (EFSA, 2018)
4	Rape seed	30						12.0	-	1.2	12.0 (x PF oil)
4	Soya bean	40						12.0	-	12	Background data (EFSA, 2018)
4	Mustard seed	30						12.0	6.17	12	Background data (EFSA, 2018)
4	Cotton seed	30						12.0	-	12	Background data (EFSA, 2018)
4	Pumpkin seed	30						12.0	11.35	12	Background data (EFSA, 2018)

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 2)	Back-ground mg/kg 1)	Monitoring mg/kg 1)	PRIMo Input mg/kg	Comment / Reference EFSA 2018
4	Safflower	30						12.0	-	12	Background data (EFSA, 2018)
4	Borage	30								12	Extrapolated from Linseed
4	Gold of pleasure	30								12	Extrapolated from Linseed
4	Hemp seed	30								12	Extrapolated from Linseed
4	Castor bean	30								12	Extrapolated from Linseed
4	Other oilseeds	30								12	Extrapolated from Linseed
2	**Oil fruits**	**30**									
4	Olives for oil production							2.28	-	2.28	Background data (EFSA, 2018)
1	Palm nuts (palmoil kernels)	30								4.54	From literature 3)
4	Palmfruit	30								3.34	From literature 4)
4	Kapok	30								4.54	Extrapolation from Palm nuts
4	Other oil fruits									4.54	Extrapolation from Palm nuts
1	**CEREALS**	**10**									
4	Barley							4.15	4.09 (n=83)	4.09	Monitoring data (EFSA, 2018)
4	Buckwheat							8.42	6.68	8.42	Background data (EFSA, 2018)
4	Maize							4.15	2.4	2.4	Median monitoring data (EFSA, 2018)
4	Millet							4.15	6.73	4.15	Background data (EFSA, 2018)
4	Oats							4.15	5.09	4.15	Background data (EFSA, 2018)
4	Rice							4.15	2.54 (n=264)	2.54	Monitoring data (EFSA, 2018)
4	Rye							4.15	3.57 (n=157)	3.57	Monitoring data (EFSA, 2018)

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 2)	Back-ground mg/kg 1)	Monitoring mg/kg 1)	PRIMo Input mg/kg	Comment / Reference EFSA 2018
4	Sorghum							4.15	-	4.15	Background data (EFSA, 2018
4	Wheat							4.15	4.13 (n=351)	4.13	Monitoring data (EFSA, 2018)
4	Other cereals									4.15	Extrapolation from cereals
1	**TEA, COFFEE, HERBAL INFUSIONS AND COCOA**										
2	**Tea, dry leaves and stalks**	40						0.25	2.46 (n=176)	2.46	Monitoring data (EFSA, 2018)
4	Tea										
2	**Coffee beans**	50						16.3	14.03 (n=115)	14.03	Monitoring data (EFSA, 2018)
2	**Herbal infusions**	100						0.3	0.17 (n=74)	0.17	Monitoring data (EFSA, 2018)
2	**Cocoa (fermented beans)**	50						1.5	-	1.5	Background data (EFSA, 2018)
2	**Carob (St. John's bread)**	20						5.71	-	5.71	Background data (EFSA, 2018)
1	**HOPS (dried cone)**	1000						-	149.8 (n=8)	149.8	Monitoring data (EFSA, 2018)
1	**SPICES**	40								11.3	Background Ref. 4)
1	**SUGAR PLANTS**	**5**									
4	Sugar beet (root)							1.25	-	1.25	Background data (EFSA, 2018)
4	Sugar cane							0.69	-	0.69	Background data (EFSA, 2018)
4	Chicory roots							1.09	-	1.09	Background data (EFSA, 2018)
4	Other sugar plants									1.24	Extrapolation from Sugar beet
1	**PRODUCT OF ANIMAL ORIGIN**										
2	**MEAT, etc.**										
3	SWINE										
4	Meat	5						0.88	0.68	0.88	Background data (EFSA, 2018)

Level	**RAC**	**tMRL**	**Region**	**Individual trial results mg/kg**	**Median STMR mg/kg**	**Highest residue mg/kg**	**Control mg/kg** [2)]	**Back-ground mg/kg** [1)]	**Monitoring mg/kg** [1)]	**PRIMo Input mg/kg**	**Comment / Reference EFSA 2018**
4	Fat	5						0.41		0.41	Background data (EFSA, 2018)
4	Liver	30						11.6	9.71	11.6	Background data (EFSA, 2018)
4	Kidney	30						7.28		7.28	Background data (EFSA, 2018)
4	Edible offal	30								-	
4	Other products	5								-	
3	BOVINE										
4	Meat	5						0.9	2.03	0.9	Background data (EFSA, 2018)
4	Fat	5						0.39		0.39	Background data (EFSA, 2018)
4	Liver	30						64.3	86.68 (n=206)	86.7	Monitoring data (EFSA, 2018)
4	Kidney	30						4.61	3.45	4.61	Background data (EFSA, 2018)
4	Edible offal	30								-	
4	Other products	5								-	
3	**SHEEP**										
4	Meat	5						1.25	1.03	1.25	Background data (EFSA, 2018)
4	Fat	5						0.3		0.3	Background data (EFSA, 2018)
4	Liver	30						90		90	Background data (EFSA, 2018)
4	Kidney	30						3.85		3.85	Background data (EFSA, 2018)
4	Edible offal	30						-		-	
4	Other products	5						-		-	
3	**GOAT**										
4	Meat	5						1.25	1.03	1.25	Background data (EFSA, 2018)
4	Fat	5						0.3		0.3	Background data (EFSA, 2018)
4	Liver	30						90		90	Background data (EFSA, 2018)

Level	**RAC**	**tMRL**	**Region**	**Individual trial results mg/kg**	**Median STMR mg/kg**	**Highest residue mg/kg**	**Control mg/kg** [2]	**Back-ground mg/kg** [1]	**Monitoring mg/kg** [1]	**PRIMo Input mg/kg**	**Comment / Reference EFSA 2018**
4	Kidney	30						3.85		3.85	Background data (EFSA, 2018)
4	Edible offal	30								-	
4	Other products	5								-	
3	HORSES, ASSES, MULES. HINNIES										
4	Meat	5						0.9	2.1	0.9	Background data (EFSA, 2018)
4	Fat	5						0.39		0.39	Background data (EFSA, 2018)
4	Liver	30						64.3		64.3	Background data (EFSA, 2018)
4	Kidney	30						4.61		4.61	Background data (EFSA, 2018)
4	Edible offal	30								-	
4	Other products	5								-	
3	POULTRY										
4	Meat	5						0.65	3.47 (n=144)	3.47	Monitoring data (EFSA, 2018)
4	Fat	5						0	3.2	0	Background data (EFSA, 2018)
4	Liver	30						6.9	-	6.9	Background data (EFSA, 2018)
4	Kidney	30								-	
4	Edible offal	30								-	
4	Other products	5								-	
3	OTHER FARM ANIMALS										
4	Meat	5							1.84 (n=392)	1.84	Monitoring data (EFSA, 2018)
4	Fat	5									
4	Liver	30									
4	Kidney	30									
4	Edible offal	30									
4	Other products	5									
2	**MILK AND CREAM**	**2**									

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg [2)]	Back-ground mg/kg [1)]	Monitoring mg/kg [1)]	PRIMo Input mg/kg	Comment / Reference EFSA 2018
4	Cattle							0.1	0.24 (n=433)	0.24	Monitoring data (EFSA, 2018)
4	Sheep							0.1	0.24 (n=433)	0.24	Monitoring data (EFSA, 2018)
4	Goat							0.1	0.24 (n=433)	0.24	Monitoring data (EFSA, 2018)
4	Horse							0.1	0.24 (n=433)	0.24	Monitoring data (EFSA, 2018)
4	Other products							0.1	0.24 (n=433)	0.24	Monitoring data (EFSA, 2018)
2	**BIRDS EGGS**	**2**									
4	Chicken							0.62	0.58 (n=145)	0.58	Monitoring data (EFSA, 2018)
4	Duck							0.62	0.58 (n=145)	0.58	Monitoring data (EFSA, 2018)
4	Goose							0.62	0.58 (n=145)	0.58	Monitoring data (EFSA, 2018)
4	Qual							0.62	0.58 (n=145)	0.58	Monitoring data (EFSA, 2018)
4	Other eggs							0.62	0.58 (n=145)	0.58	Monitoring data (EFSA, 2018)
2	**Honey**									0.53	ANSES background values
2	**Amphibian and Rep.**									2.5	ANSES background values
2	**Other terr.**									4.00	ANSES background values
	Wild terrestrial animal							-	1.72 (n=184)	1.72	Monitoring data (EFSA, 2018)

References
Ref. 1 Control samples from Magnitude of Residue trials
Ref. 2 EFSA Journal 2018;16(3):5212
Ref. 3 Izah *et al.*, EC Nutrition 11.6 (2017): 244-252
Ref. 4 Akpakpan *et al.*, International Journal of Modern Chemistry, 2012, 2(1):20-27

TIER I

If all crops for which a defined MRL under 396/2005 are included, the diet with the highest TMDI for Copper is the “NL Toddler” with 119% of ADI. For this diet, the highest contributor is natural Copper background in maize with 11% of ADI. It should be noted that the biggest contributor (cereal) is not a supported use for Copper compounds. The second highest TMDI for Copper is the “GEMS/Food G10” with 79% of ADI where soyabean is the major contributor with 26% of the ADI.

TIER II (including monitoring data)

Refinement of the inputs into the PRIMo model were made to take into account data generated by background monitoring of Copper in crops throughout the UK, and also monitoring results (France, 2016). Using this refined Tier II input, the diet with the highest TMDI for Copper is the “NL Toddler” with 93% of ADI. For this diet, the highest contributor is natural Copper background in maize with 11% of ADI.

In private communication with EFSA[4], the input values for maize consumption in the “NL Toddler” diet in the PRIMo model have been queried. The chronic input figure for this diet indicates a much higher consumption than any other diet. EFSA assume that an error has been made and that maize oil consumption has been recalculated to whole maize. In fact, the consumption of maize oil should have been reported as a processed product. It can be assumed that using an oil content of maize of 4%, that the figure for maize consumption is overestimated by a factor of 25. EFSA say that they will investigate this finding with the data provider for the NL Toddler diet and will hopefully incorporate any solution into a future version of the model.

Copper levels in drinking water[5,] were determined from monitoring studies conducted in Sweden, Germany, France, The Netherlands, Greece and Ireland. Median daily intake of Copper from drinking water in children aged 9–21 months was estimated to be 0.46 mg in Uppsala and 0.26 mg in Malmö. In Berlin (Germany), Copper concentration in random daytime samples of tap water ranged between > 0.01 and 3.0 mg/L, with a median of 0.03 mg/L. The typical concentrations reported in the VRAR were 0.11 mg/L. Typical drinking water concentrations in flushed tap water range from 0.01 to 0.5 mg/L, which on an average would contribute to the ADI to less than 5%. It is therefore determined that the exceedance of the ADI of Copper to be unlikely.

For all further information please refer to Appendix 3.

Dietary surveys

Model calculations as estimated above, based on STMR residue values are typically worst-case as they assume that all of the food commodity contains residues. Even with this assumption, the intakes of Copper found on treated commodities are within the ADI of 0.15 mg/kg bw/day. The standard model (PRIMo) estimates that the highest dietary intake for Copper is for the “NL Toddler” at 93% of the ADI, i.e an intake of 1.41 mg/day for a 10.2 kg toddler. For the next highest dietary intake group, “GEMS/Food G11” with 72% of ADI, for a 60 kg adult, this equates to an intake level of 6.57 mg/day.
In addition, several dietary surveys [6] were conducted and the results summarised Table 7.2-8 below. These surveys indicate that the European median intakes of Copper via the diet are in fact in the range of 0.39 – 1.46 mg/day across different age groups for both males and females. This is a more realistic estimate of Copper intake levels.
Therefore, it can be concluded that the risk to consumers from the use of Copper as a plant protection

[4] Private communication with Hermine Reich, EFSA contact for PRIMo model, 25/02/2019
[5] EFSA (2009). Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on Copper(II) oxide as a source of Copper added for nutritional purposes to food supplements following a request from the European Commission. The EFSA Journal 1089, 1-15
[6] EFSA (2015a). Scientific Opinion on Dietary Reference Values for Copper. EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). EFSA Journal 2015: 13(10):4253

product is acceptable.

Table 7.2-8: Results of European Surveys on the European dietary intake of Copper (Germany, Finland, UK, Italy, France, Netherlands, Latvia, Sweden)

Age class	Sex	Number of individuals surveyed	Range of median intake levels (mg Cu/day)	Overall median intake level (mg Cu/day)
Infant	Male	1039	0.39–0.49	0.39
	Female	1005	0.34–0.49	0.38
1 to <3	Male	1209	0.62–0.84	0.67
	Female	1174	0.54–0.81	0.63
3 to <10	Male	1843	0.95–1.41	0.95
	Female	1808	0.78–1.27	0.89
10 to <18	Male	1796	1.12–1.48	1.26
	Female	1943	0.96–1.39	1.10
18 to <65	Male	5429	13.7–1.59	1.46
	Female	7472	1.11–1.37	1.25
65 to <75	Male	601	1.29–1.48	1.46
	Female	763	1.12–1.27	1.23
≥75	Male	241	1.07–1.40	1.30
	Female	359	1.02–1.27	1.14

Chambers *et al* [7] concluded that the optimal intake of Copper is 2.6 mg/day. This means that from the results of the surveys, in the main, adults are more likely to be deficient in their normal dietary intake of Copper rather than under threat from excess Copper in the diet.
EFSA derived adequate intakes for Copper to 1.6 mg/day for men and 1.3 mg/day for woman. The diet with the lowest TMDI for Copper is not providing sufficient Copper for the PL, DK, UK and UK vegetarian adults.
A position paper has been prepared on behalf of the EUCuTF examining the effect of copper intake from natural sources as well as fungicide use. Copper is not a typical pesticide; it is an essential micronutrient required in many biochemical processes. Copper deficiency or excess can lead to adverse effects, and therefore the human body has an efficient homeostatic mechanism that tightly controls bioavailable copper concentrations to the required normal levels. Copper excess is rare and is seen mainly in genetic diseases such as Wilson's disease, idiopathic copper toxicosis and childhood cirrhosis.
The impact of the increased risk from fungicide use of this essential micronutrient is assessed against the variability of natural copper background levels and shown that the non-systemic nature of copper compounds does not lead to any increase of the copper content in many crops (e.g. root and tuber crops, fruit and vegetables with non-edible peel, etc.). The natural variability found in copper consumed in food is managed by all populations by adapting the absorption rate and the homeostatic control. (Long, E. and Weidenauer, M., 2019, Document Reference KCA 6.9/01).

7.2.8.2 Conclusion on consumer risk assessment

The TMDI estimates for the various diets were found 93-6% of ADI. The highest TMDI was calculated for the NL Toddler. For this diet, maize and wheat were the highest contributors to the residue intake, representing 11% of ADI for both. It should be noted that the biggest contributors (cereal) are not supported uses for Copper compounds.

[7] Chambers, A., Krewski, D., Birkett, N., Plunkett., Hertzberg, R., Danzeisen, R., Aggett, PJ., Starr, TB., Baker, S., Dourson., PJ., Keen, CL., Meek, R and Slob, W. (2010). An exposure-response curve for Copper excess and deficiency. *J. Toxicol. and Envrion. Health, Part B* ***13****: 546–578*

The NESTI was not calculated as no ArfD was set.

Table 7.2-9: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo rev. 3.1	Tier I **119%** (NL Toddler) Tier II 93% (NL Toddler)
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	Not calculated, not necessary
NEDI (% ADI)**	--
IESTI (% ArfD) according to EFSA PRIMo rev. 3.1*	Not calculated
NESTI (% ArfD) **	--

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

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

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

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U.S. Department of Agriculture, Agricultural Research Service (2002). USDA National Nutrient Database for Standard Reference, Release 15 Nutrient Data Laboratory Home Page, http://www.ars.usda.gov/nuteintdata

US Department of Health (2002) Draft toxicological profile for Copper. September 2002

European Commission (2003). Opinion of the Scientific Committee on Food on Tolerable Upper Intake Level of Copper (expressed on 5 March 2003). SCF/CS/NUT/UPPLEV/57 Final, 27 March 2003

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	Protection	Vertebrate study Y/N	Owner
KCA 6.3.2/07	Forster A.C.	2009	Magnitude of residues of copper in tomatoes (*solanaceae* -fruiting vegetables) following application of metallic copper (as copper hydroxyde) (DPC-GFJ52) 35WG – Northern Europe, Season 2007-2008 Company Report No: DuPont 22566 Charles River Laboratories (UK) GLP Unpublished *Also submitted under KCP 5.1.2/03*	Y	N	European Union Copper Task Force (LoA available)
KCA 6.3.10/03	Brereton, R.	2003	Copper: Residue levels in pome fruit from trials conducted in France, Spain and Italy during 2001/2002 Company Report No: AF/6150/CU Agrisearch UK GLP Unpublished	Y	N	EuCu Task Force
KCA 6.3.10/04	Brereton, R.	2004	Copper: Residue levels in pome fruit from trials conducted in the UK, France and Germany du ring 2001 /2002 Company Report No: AF-6151-CU Agrisearch UK GLP Unpublished	y	N	EuCu Task Force
KCA 6.3.11/08	Grall, E.	2011	Bordoflow New, Copper oxychloride 50 WP (SU), Copper hydroxide 25% DF, Nordox 75 WG, Cuproxat flüssig, Bordeaux Mixture 20% WG, Copper Oxychloride 37.5 NC WG, CA2111 (CHAMP DP), ATOFAP17: Determination of residues of Copper in stone fruit (RAC fruit) following three treatments with different Copper formulations under open field conditions in northern and southern Europe in 2010	y	N	EuCu Task Force

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Protection	Vertebrate study Y/N	Owner
			Company Report No: C48222 Harlan Laboratories Ltd., Itingen, Switzerland GLP Unpublished			
KCA 6.3.11/09	North, L.	2021	Determination of residues of copper after one application of copper in cherry (outdoor) at 1 site in Southern Europe 2020 Company Report No: S20-01045 Eurofins AgroScience, Germany GLP Unpublished *Also submitted under KCP 5.1.2/02*	y	N	Nordox AS
KCA 6.3.12/01	Grall, E.	2011	Nordox 75 WG , Copper Oxychloride 37.5 NC WG, Flowbrix SC, Copper hydroxide 40% WG, Copper hydroxide 25% DF, Bordoflow New Determination of residues of Copper in strawberry (RAC fruit) following four treatments with different Copper formulations under open field conditions in northern and southern Europe in 2009 Company Report No: C48301 Harlan Laboratories Ltd., Itingen, Switzerland GLP Unpublished	y	N	EuCu Task Force
KCA 6.3.12/02	Grall, E.	2011	Flowbrix SC (Copper oxychloride SC), Copper hydroxide 40% WG, Bordeaux Mixture RSR Disperss, Nordox 75 WG, Copper Oxychloride 50% WP, Copper oxychloride 50 WP (SU), Cuproxat flüssig, Copper hydroxide 25% DF: Determination of residues of Copper in strawberry (RAC fruit) following four treatments with different Copper formulations under open field conditions in northern and southern Europe in 2010 Company Report No: C91308 Harlan Laboratories Ltd., Itingen, Switzerland GLP Unpublished	y	N	EuCu Task Force

Data point	**Author(s)**	**Year**	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Protection**	**Vertebrate study Y/N**	**Owner**
KCA 6.3.18/01	Kreke, N.	2011	Nordox 75 WG, Bordeaux Mixture 20 NC WG, Funguran-OH 50 WP. Determination of residues of Copper in onion (RAC bulb) following four treatments with different Copper formulations under open field conditions in northern Europe in 2010 Company Report No: C91073 Harlan Laboratories Ltd. Itingen, Switzerland GLP Unpublished	y	N	EuCu Task Force
KCA 6.3.18/02	Kreke, N.	2011	Bordeaux Mixture 20 NC WG, Nordox 75 WG, Copper oxychloride 37.5 NC WG, COC 35 DF, CA2111 (Champ DP), Copper oxychloride 50 WP (SU), Funguran-OH 50 WP, ATOFAP17, Bordeaux Mixture 20% WG, Flowbrix SC (Copper oxychloride SC). Determination of residues of Copper in onion (RAC bulb) following four treatments with different Copper formulations under open field conditions in northern and southern Europe in 2009 Company Report No: C48110 Harlan Laboratories Ltd. Itingen, Switzerland GLP Unpublished	y	N	EuCu Task Force
KCA 6.3.19/01	Kreke, N.	2011	Bordeaux Mixture 20 NC WG, Flowbrix SC (Copper oxychloride SC), Funguran-OH 50 WP, Nordox 75 WG, Cuproxat flüssig, Bordeaux Mixture RSR Disperss, Copper Oxychloride 50% WP, Copper hydroxide 25% DF Determination of residues of Copper in peppers (RAC fruit) following four treatments with different Copper formulations under open field conditions in northern and southern Europe in 2009 Company Report No: C48108 Harlan Laboratories Ltd. Itingen, Switzerland GLP Unpublished	y	N	EuCu Task Force
KCA 6.3.19/02	Kreke, N.	2011	Copper oxychloride 50 WP (SU), CA2112 (CHAMP FLO), Flowbrix SC (Copper oxychloride SC), Bordoflow New, ATOFAP17: Determination of residues of Copper in peppers (RAC fruit) following four treatments with different Copper formulations under open field conditions in northern and southern Europe in 2010 Company Report No: C91062	y	N	EuCu Task Force

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Protection	Vertebrate study Y/N	Owner
			Harlan Laboratories Ltd. Itingen, Switzerland GLP Unpublished			
KCA 6.3.21/01	Kreke, N.	2011	ATOFAP17, CA2112 (CHAMP FLO), Copper oxychloride 50 WP (SU), Bordoflow New Determination of residues of Copper in lettuce (RAC whole plant without roots) following four treatments with different Copper formulations under open field conditions in southern Europe in 2009 Company Report No: C48064 Harlan Laboratories Ltd. Itingen, Switzerland GLP Unpublished	y	N	EuCu Task Force
KCA 6.3.21/02	Kreke, N.	2012	Bordeaux Mixture 20 NC WG, Copper hydroxide 25% DF, Flowbrix SC (Copper oxychloride SC), Copper hydroxide 40% WG: Determination of residues of Copper in lettuce (RAC whole plant without roots) following four treatments with different Copper formulations under open field conditions in southern Europe in 2010 Company Report No: C91040 Harlan Laboratories Ltd. Itingen, Switzerland GLP Unpublished	y	N	EuCu Task Force
KCA 6.3.21/03	Sicbaldi, F.	2005	Copper residue levels on lettuce (open field) after four applications of copper oxychloride 37.5 WG. A decline study in Northern Italy in 2005 Company Report No: RA.05.14 GLP Unpublished	y	N	EuCu Task Force
KCA 6.3.21/04	Sicbaldi, F.	2005	Copper residue levels on lettuce (open field) after four applications of copper oxychloride 37.5 WG. A decline study in Southern Italy in 2005 Company Report No: RA.05.15 GLP	y	N	EuCu Task Force

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

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

Please note that all data mentioned as part of Monograph, DAR, RAR, or EFSA journals are considered as 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
CA 6.3.1-01	Coulomb, P.	1999	Generation of wine grape fruits and processed samples, suitable for residue analysis of Copper, cymoxanil and folpet. 9801AGT Viti R&D, Y N	N	EuCuTF*
CA 6.3.1-02	Brereton, R.	2003a	Copper: Residue levels in wine grape and processed fractions from trials conducted in France, Spain and Italy during 2001. AF/5989/CU. Agrisearch Y N	N	EuCuTF
CA 6.3.1-03	Martin, C.	2003a	Copper: Residue levels in wine grapes from trials conducted in southern France, Italy and southern Spain during 2002., AF/6891/CU. Agrisearch Y N	N	EuCuTF

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
CA 6.3.1-04	Brereton, R.	2003b	Copper: Residue levels in wine grape and processed fractions from trials conducted in northern France and Germany during 2001 AF/5991/CU. Agrisearch GLP, Unpublished.	N	EuCuTF
K-CA 6.3.1-05	Martin, C.	2003b	Copper: Residue levels in wine grapes from trials conducted in Northern France and Germany during 2002 AF/6890/CU Agrisearch Y N	N	EuCuTF
K-CA 6.3.1-06	Brereton, R.	2003c	Copper: Residue levels in wine grapes from a single trial conducted in northern France during 2002. AF/6842/CU. Agrisearch Y N	N	EuCuTF
K-CA 6.3.1-07	Collina, A	1998a	Determinazione dei residui di rame in uva a seguito di trattamenti per la difes della vite con I formulate pasta caffaro e cuprocaffaro 255 CER/RES (11/98) Industrie Chimiche Caffaro Y N	N	EuCuTF*
K-CA 6.3.1-08	Malet & Allard	1999a	Mesure du niveau de résidus de cuivre de l'hydroxyde de cuivre sur vigne. Ministère de l'agriculture et de la pêche, RVVIXX198/43 Y N	N	EuCuTF*
K-CA 6.3.1-09	Collina, A	1998b	Determinazione dei residui di rame in uva e vino 252 CER/RES (8/98)	N	EuCuTF*

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
			Industrie Chimiche Caffaro, Y N		
CA 6.3.1-10	Brereton, R	2003d	Copper: Residue levels in table grape and processed fractions from trials conducted in Spain and Italy during 2001. AF/5990/CU Agrisearch, Y N	N	EuCuTF
CA 6.3.1-11	Brereton, R	2003e	Copper: Residue levels in table grape from a single trial conducted in Spain during 2002. AF/6550/CU. Agrisearch Y N	N	EuCuTF
KCA 6.3.1/12	Forster, A.C.	2009	Magnitude of Residues of Copper in Grapes (Berries and Small Fruit) Following Applications of Metallic Copper (as Copper Hydroxide) (DPX-GFJ52) 35WG – Europe, Season 2008 Report No. DuPont-24354 GLP Unpublished	N	EuCuTF
CA 6.3.2-01	Martin, C	2003c	Copper: Residue levels in tomato (outdoor - industrial for processing) from trials conducted in France, Spain and Italy during 2002. AF/6548/CU. Agrisearch Y N	N	EuCuTF
CA 6.3.2-02	Malet, J C & Allard, L	1999b	*n.b. This reference is comprised of three separate reports in one pdf document…* 1. Mesure du niveau de résidus de cuivre sur tomate. RLTOXX197/30 Ministère de l'agriculture et de la pêche	N	EuCuTF*

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
			Y N 2. Mesure du niveau de résidus de cuivre de l'hydroxyde de cuivre sur tomate RLTOXX198/42 Ministère de l'agriculture et de la pêche Y N 3. Mesure du niveau de résidus de cuivre de l'hydroxyde de cuivre sur tomate RLTOXX199/43 Ministère de l'agriculture et de la pêche Y N		
CA 6.3.2-03	Brereton, R	2003f	Copper: Residue levels in tomato (outdoor - industrial for processing) from trials conducted in France, Spain and Italy during 2001. AF/5987/CU. Agrisearch, Y N	N	EuCuTF
CA 6.3.2-04	Martin, C.	2003d	Copper: Residue levels in tomato (outdoor - for fresh consumption) from trials conducted in France, Spain and Italy during 2002. AF/6547/CU Agrisearch, Y N	N	EuCuTF
CA 6.3.2-05	Brereton, R.	2003g	Copper: Residue levels in tomato (outdoor - for fresh consumption) from trials conducted in France, Spain and Italy during 2001. AF/5986/CU. Agrisearch Y N	N	EuCuTF

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
CA 6.3.2-06	Martin, C.	2003e	Copper: Residue levels in tomato (outdoor - for fresh consumption) from trials conducted in France, Spain and Italy during 2002. AF/6547/CU Agrisearch, Y N	N	EuCuTF
CA 6.3.4-01	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 C 48132 Harlan laboratories Y N	N	EuCuTF*
CA 6.3.4-02	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 C 91095 Harlan laboratories Y N	N	EuCuTF*
CA 6.3.4-03	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 D35555 Harlan laboratories Y N	N	EuCuTF*
CA 6.3.6-01	Foster, A.C.	2006a	Magnitude of residues of Copper and cymoxanil in field melons (fruiting vegetables) following applications of metallic Copper (as Copper oxychloride)/cymoxanil (DPX-KK807) 44WG (9.5:1) under maximum label rates - southern Europe, 2004 DuPont-14542, Revision No. 1 Charles River Laboratories (UK) Y N	N	EuCuTF*

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
CA 6.3.6-02	Foster, A.C.	2006b	Magnitude of residues of Copper and cymoxanil in field melons (fruiting vegetables) following applications of metallic Copper (as Copper oxychloride)/cymoxanil (DPX-KK807) 44WG (9.5:1) under maximum label rates - southern Europe, season 2005 DuPont-16970 Charles River Laboratories (UK) Y N	N	EuCuTF*
CA 6.3.6-03	Hansford, R.J.	2008a	Magnitude of residues of Copper in field melons (cucurbits-inedible peel) following applications of metallic Copper (as Copper oxychloride)/Cymoxanil (DPX-KK807) 44WP (9.5:1)-southern Europe, season 2007 DuPont-22565 Charles River Laboratories (UK) Y N	N	EuCuTF*
CA 6.3.6-04	Goebel, O	2005	Residue determination of Copper in melon after 6 applications of ATOFAP02 (WG 20%) or ATOFAP17NC (WG 40%) B_05RFLME01 Staphyt Yes No	N	EuCuTF*
CA 6.3.6-05	Goebel, O	2006	Residue determination of Copper in melon after 6 applications of ATOFAP02 (Copper - 20% WG) or ATOFAP17NC (Copper - 40% WG) B_06RFLME01 Y N	N	EuCuTF*
CA 6.5.3/01:	Brereton, R.	2003h	Copper: Residue levels in tomato (outdoor - industrial for processing) from trials conducted in France, Spain and Italy during 2001 AF/5987/CU Agrisearch Y N	N	EuCuTF

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
CA 6.5.3/02:	Martin, C.	2003g	Copper: Residue levels in tomato (outdoor - industrial for processing) from trials conducted in France, Spain and Italy during 2002. AF/6548/CU Agrisearch Y N	N	EuCuTF
CA 6.5.3/03	Coulomb, P.	1999	Generation of wine grape fruits and processed samples, suitable for residue analysis of Copper, cymoxanil and folpet 9801AGT, Processing phase 9801ATV. Viti R&D Y N	N	EuCuTF*
CA 6.5.3/03	Saint-Joly, C.	1999a	Analyses de résidus de cuivre sur raisin, vin, marc et mout. 981218 Lara Laboratoire Y N	N	EuCuTF*
CA 6.5.3/03	Saint-Joly, C.	2003a	Analyses de résidus de cuivre et cymoxanil sur raisin, vin. 981219. Lara Laboratoire Y N	N	EuCuTF*
CA 6.5.3/03	Saint-Joly, C.	2003b	Analyses de résidus de cuivre, cymoxanil et folpel sur raisin et vin. 981220. Lara Laboratoire Y N	N	EuCuTF*
CA 6.5.3/03	Saint-Joly, C.	1999b	Analyses de résidus de cuivre sur raisin. Lara Laboratoire, 990723.	N	EuCuTF*

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
			Y N		
CA 6.5.3/04:	Collina, A.	1998b	Determinazione dei residui di rame in uva e vino 252 CER/RES (8/98) Industrie Chimiche Caffaro, Y N	N	EuCuTF*
CA 6.5.3/05:	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. R 8031	N	UPL
CA 6.5.3/06:	Brereton, R..	2003i	Copper: Residue levels in wine grape and processed fractions from trials conducted in France, Spain and Italy during 2001. AF/5989/CU	N	EuCuTF
CA 6.5.3/07	Brereton, R.	2003j	Copper: Residue levels in wine grape and processed fractions from trials conducted in northern France and Germany during 2001 AF/5991/CU	N	EuCuTF
CA 6.5.3/08	Brereton, R.	2003k	Copper: Residue levels in table grape and processed fractions from trials conducted in Spain and Italy during 2001. AF/5990/CU. Agrisearch Y N	N	EuCuTF
CA 6.5.3/09	Anon	1992	Cuprasol (49.9% Copper as Copper oxychloride) SPI 12827	N	EuCuTF
CA 6.5.3/10	Anon	1992	Wacker 83 v (24.8% Copper as Copper oxychloride) SPI 12828	N	EuCuTF
CA 6.5.3/11	Anon	1992	Fitoran grün (42.8% Copper as Copper oxychloride) SPI 12828	N	EuCuTF

* Owned by some members of the Task Force

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Copper compounds

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

Not relevant. No new study is submitted for the evaluation of this new product.

A 2.1.1.1.2 Storage stability of residues in animal products

Not relevant. No new study is submitted for the evaluation of this new product.

A 2.1.1.1.3 Storage stability of residues in sample extracts

Not relevant. No new study is submitted for the evaluation of this new product.

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

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

Not relevant. No new study is submitted for the evaluation of this new product.

A 2.1.2.1.2 Nature of residue in rotational crops

Not relevant. No new study is submitted for the evaluation of this new product.

A 2.1.2.1.3 Nature of residues in processed commodities

Not relevant. No new study is submitted for the evaluation of this new product.

A 2.1.2.2 Nature of residues in livestock

Not relevant. No new study is submitted for the evaluation of this new product.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Grape (CA 6.3.1)

Table A 1: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (kg a.i./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, 2007)	4	1.6	7	BBCH 71-89	21
cGAP EU (RAR, 2017)	8	1.25	7	BBCH 12-89	21
cGAP EU (Art. 12, 2018)	4	2	7	BBCH 15-81 & 91	21
Intended cGAP (Use 3*)	2	1.2	7	BBCH 15-81 & 91	21

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

7 +8 trials for table grapes and 15 trials for wine grapes in EUN/EUS were already evaluated at EU peer review.

A 2.1.3.2 Tomato, outdoor (CA 6.3.2)

Table A 2: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (kg a.i./ha)	Interval between application	Growth stage at last application	PHI (days)
~~cGAP EU (DAR, 2007)~~	~~6~~	~~1.25~~	~~7~~	~~All stages~~	~~10 (indus trial)~~ ~~3 (fresh)~~
~~cGAP EU (RAR, 2017)~~	~~8~~	~~0.85~~	~~7~~	~~BBCH 12-89~~	~~3~~
cGAP EU (Art. 12, 2018)	6	1.25	7	BBCH 15-89	3
Intended cGAP (5*)	3	1.0	7	BBCH 15-51	10
SL	5	0.75	7	BBCH 89	3
HU	4	0.60	7	BBCH 89	7

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

~~No new studies are submitted.~~ 17 trials were already evaluated at EU peer review, but no trials from the Northern zone. However, nine new trials are available and already evaluated within the MRL Review (Art. 12, 2018).

A 2.1.3.2.1 KCA 6.3.2 (Tomato, EUN)

Comments of zRMS:	.

Reference:	**KCA 6.3.2/07**
Report	Forster A.C. 2009 Magnitude of residues of copper in tomatoes (Solanaceae-Fruiting vegetables) following applications of metallic copper (as copper hydroxide) (DPX-GFJ52) 35WG – Northern Europe, Season 2007-2008 Report No: DuPont-22566AF/6150/CU, 69163
Guideline(s):	Yes SANCO 7029/VI/95/Rev. 5/1997/Appendix B
Deviations:	No
Already evaluated:	Yes, evaluated in Art. 12 (EFSA 2018) and submitted France 2016 (Evaluation Report, Art. 12.1)
GLP:	Yes
Acceptability:	

All trials were presented below. Please note that some trials are in duplicate. Nine trials were conducted in Hungary, Germany, Czech Republic, and N-France. All trials were conducted with 6 x 1.2 kg a.i./ha and an interval of 7 d at BBCH 89 (last treatment).
For further details please refer to EFSA review of the Art. 12 (EFSA 2018) and the Evaluation Report (EFSA 2016) respectively.

The LOQ is 0.7 mg/kg. For further analytical data please refer to Section 5 (KCP 5.1.2/03)

Table A 3: Summary of the copper studies in tomato (EU-N)

PPP (product name/code):	Copper hydroxide WG	Conc. of as 1:	**350 g/kg**
Crop group:	Tomato	Other a.i. in formulation:	None
Indoor/outdoor:	Outdoor (2007-2008)	Residues calculated as:	Copper
Applicant:	EU Copper Taskforce		
Zone(s):	N-EU (Hungary, Germany, Czech Republic, N-France)		

1	2	3	4			5	6	7	8	9	10
Report No. Location including Postal Code	**Commodity / Variety (a)**	**Date of: Sowing or Planting Flowering Harvest (b)**	**Application rate per treatment (A1, A2, A3, A4, A5 + A6)**			**Dates of treatment(s) or no. of treatment(s) and last date (A1, A2, A3, A4, A5 + A6) (c)**	**Growth stage at Application A1 – A6 and at Sampling**	**Portion Analyzed (a)**	**Residues (mg/kg)[4]**	**PHI (days) (d)**	**Remarks (f)**
			g a.s./ha	**water(L/ha)**	**g a.s./hL**						
DuPont- 22566, Douai, Nord, 59500, France	Tomato / Montfauet	05 Jul 07 NR 30 Sep 07	-	-	-	Untreated	BBCH -, -, -, -, -, -,81/82-89	Fruit	0.4 (nq)	-	None WG – copper hydroxide LOQ : 0.7 mg/kg
			1217.58 1231.78 1216.12 1205.57 1216.12 1235.42	696 704 695 689 695 706	174.94 174.97 174.98 174.97 174.98 174.99	A1 = 21 Aug 07 A2 = 28 Aug 07 A3 = 04 Sep 07 A4 = 12 Sep 07 A5 = 19 Sep 07 A6 = 27 Sep 07	BBCH 60-70, 60-70, 60-70, 60-70, 81-82, 81-82		4.3	3	
DuPont-22566, Dolni Bojanovice, Moravia 69617 Czech Republic	Tomato / Marienka F1	13 Apr 07 NR 10 Aug 07	-	-	-	Untreated	BBCH -, -, -, -, -, -, 89	Fruit	0.78	-	None WG – copper hydroxide LOQ : 0.7 mg/kg
			1196.00 1178.00 1260.00 1207.00 1219.00 1178.00	683 673 720 690 697 673	175.11 175.04 175.00 174.93 174.89 175.04	A1 = 03 Jul 07 A2 = 11 Jul 07 A3 = 17 Jul 07 A4 = 24 Jul 07 A5 = 31 Jul 07 A6 = 07 Aug 07	BBCH 69-71, 71-73,73, 75-81, 78-82, 87-88, 89		1.6	3	

DuPont-22566, Gerichshain Saxony 04827 Germany	Tomato / Rendita	07 Jun 07 NR 27 Aug 07	-	-	-	Untreated	BBCH -, -, -, -, -, -, 89	Fruit	0.5 (nq)	-	None WG – copper hydroxide LOQ : 0.7 mg/kg
			1264.00 1289.00 1325.00 1216.00 1246.00 1277.00	695 708 728 668 685 702	181.87 182.06 182.01 182.04 181.90 181.91	A1 = 20 Jul 07 A2 = 27 Jul 07 A3 = 03 Aug 07 A4 = 10 Aug 07 A5 = 17 Aug 07 A6 = 24 Aug 07	BBCH 71, 73, 79, 83, 86, 89, 89		2.2	3	
DuPont- 22566, Prušànky 69621 Moravia Czech Republic	Tomato / Šejk F1	10 Apr 07 NR 10 Aug 07	-	-	-	Untreated	BBCH -, -, -, -, -, -, 89	Fruit	0.76	-	1.7 mg/kg is the average of duplicate analysis (1.7 mg/kg and 1.7 mg/kg) WG – copper hydroxide LOQ : 0.7 mg/kg
			1178.00 1237.00 1172.00 1237.00 1231.00 1196.00	673 707 670 707 703 683	174.94 174.97 174.98 174.97 174.98 174.99	A1 = 03 Jul 07 A2 = 11 Jul 07 A3 = 17 Jul 07 A4 = 24 Jul 07 A5 = 31 Jul 07 A6 = 07 Aug 07	BBCH 69-71, 71-73, 73-75, 75-83, 78-83, 87, 89		1.7**	3	
DuPont-22566, Székesfehérvár-Csala, H-8000, Fejér County, Hungary	Tomato / Mobil	20 Apr 07 NR 24 Aug 07	-	-	-	Untreated	BBCH -, -, -, -, -, -, 89	Fruit	0.6 (nq)	-	None WG – copper hydroxide LOQ : 0.7 mg/kg
			1233.55 1228.50 1248.72 1238.61 1248.72 1253.77	677.77 675.00 686.11 680.55 686.11 690.27	182.00 182.00 182.00 182.00 182.00 181.63	A1 = 16 Jul 07 A2 = 23 Jul 07 A3 = 30 Jul 07 A4 = 06 Aug 07 A5 = 13 Aug 07 A6 = 20 Aug 07	BBCH 56, 62, 75, 82, 82, 89		1.6	3	
DuPont-22566, Douai,	Tomato / Coeur de	05 Jun 08 NR	-	-	-	Untreated	BBCH -, -, -, -, -, -, 89	Fruit	0.6 (nq)	-	None WG – copper hydroxide

59500, Nord Pas-de- Calais, France	Boeuf	13 Sep 08	1238.69 1231.78 1244.15 1228.14 1247.43 1212.48	708 704 711 702 713 693	174.96 174.97 174.99 174.95 174.96 174.96	A1 = 06 Aug 08 A2 = 14 Aug 08 A3 = 20 Aug 08 A4 = 27 Aug 08 A5 = 03 Sep 08 A6 = 10 Sep 08	BBCH 70-80, 70-80, 81, 81-82, 83-84, 85, 89		6.6	3	LOQ : 0.7 mg/kg
DuPont-22566, Mikulčice, Moravia, 69 619, Czech Republic	Tomato / ZKI 04-11	31 Mar 08 NR 15 Aug 08	-	-	-	Untreated	BBCH -, -, -, -, -, -, 89	Fruit	0.5 (nq)	-	None WG – copper hydroxide LOQ : 0.7 mg/kg
			1184 1172 1213 1167 1248 1190	677 670 693 667 713 680	174.89 174.93 175.04 174.96 175.04 175.00	A1 = 08 Jul 08 A2 = 15 Jul 08 A3 = 22 Jul 08 A4 = 29 Jul 08 A5 = 05 Aug 08 A6 = 12 Aug 08	BBCH 63, 64, 67, 71, 71, 83, 89		0.7	3	
DuPont-22566, Motterwitz, Saxony, 04668, Germany	Tomato / Rendita	1 May 08 NR 09 Aug 09	-	-	-	Untreated	BBCH -, -, -, -, -, -, 89	Fruit	0.4 (nq)	-	None WG – copper hydroxide LOQ : 0.7 mg/kg
			1312.98 1288.72 1264.42 1276.59 1306.91 1252.33	721.67 708.33 695.00 701.67 718.33 688.33	181.94 181.94 181.93 181.94 181.94 181.94	A1 = 02 Jul 08 A2 = 09 Jul 08 A3 = 16 Jul 08 A4 = 23 Jul 08 A5 = 30 Jul 08 A6 = 06 Aug 08	BBCH 71, 72, 73, 74, 75, 87, 89		1.5	3	
DuPont-22566, Kápolnásnyék, H-2481, Fejér County Hungary	Tomato / Kecskeméti fürtös	04 Jul 08 NR 22 Sep 08	-	-	-	Untreated	BBCH -, -, -, -, -, -, 89	Fruit	0.5 (nq)	-	1.7 mg/kg is the average of duplicate analysis (1.6 mg/kg and 1.7 mg/kg) WG – copper hydroxide LOQ : 0.7 mg/kg
			1226.68 1241.24 1212.12 1219.40 1193.92 1212.12	702.77 711.11 694.44 697.22 683.33 694.44	174.55 174.55 174.55 181.40 174.72 174.55	A1 = 15 Aug 08 A2 = 22 Aug 08 A3 = 29 Aug 08 A4 = 05 Sep 08 A5 = 12 Sep 08 A6 = 19 Sep 08	BBCH 71, 76, 80, 82, 85, 87, 89		1.7**	3	

A 2.1.3.3 Cucumber, outdoor (CA 6.3.4)

Table A 4: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (kg a.i./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (RAR 2017)	8	0.85	7	BBCH 10-89	3
cGAP EU (Art. 12, 2018)	5	1.0	7	BBCH 15-89	3
Intended cGAP (Use 8*)	3	1.0	7	BBCH 15-89	3

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

No new studies are submitted. 16 trials in EUN/EUS were already evaluated at EU peer review.

A 2.1.3.4 Melons, outdoor (CA 6.3.6)

Table A 5: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (kg a.i./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (RAR 2017)	8	0.85	7	BBCH 10-89	7
cGAP EU (Art. 12, 2018)	4	0.9	7	BBCH 15-89	7
Intended cGAP Curcubits inedible peel (Use 9*)	3	1.0	7	BBCH 15-89	3

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

No new studies are submitted. 23 trials in EUN/EUS for whole fruit and pulps were already evaluated at EU peer review.

A 2.1.3.5 Pome fruits (pre-flowering)

Table A 6: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (kg a.i./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, RMS, year)	--	--	--	--	--
cGAP EU (Art. 12, 2018) EUN/EUS	--	--	--	--	--
Intended cGAP (Use 1*)	2	0.75	14	BBCH 03-53	144

Type of GAP	Number of applications	Application rate per treatment (kg a.i./ha)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (Use 2*)	2	1.25	14	BBCH 00-54 (autumn to spring)	144

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

A 2.1.3.5.1 KCA 6.3.10 (Pre-Flowering: Apple, Pear)

Comments of zRMS:	Studies are acceptable. They were conducted according to acceptable guidelines and have been used in evaluation. **1.** Five residue trials were conducted on pome fruit in SEU during 2001-2002. Three applications of various combinations of BORDEAUX MIXTURE, TRIBASIC COPPER SULPHATE, COPPER HYDROXIDE, COPPER OXYCHLORIDE and COPPER OXIDE were applied at various rates, diluted with water immediately to prior to application to; target spray volume of 500l/ha. Specimens of crop from the untreated and treated plots were at taken by hand at normal commercial harvest. Crop specimens were analysed for residues of copper using the method MR029/RES. Determination of copper residues by atomic absorption spectrometry. The method consists of acidic sample digestion by the closed vessels microwave technique. Total copper is then determined by flame atomic absorption spectrometry by reading its absorbance at 324.8 nm. The analytical method was validated on pome fruit in study No. 00245 ('Analytical method validation for the determination of copper in / on pome fruit). For 2 fortification levels recoveries were within the required range. **2.** Five residue trials were conducted on pome fruit in NEU during 2001-2003. Three applications of various combinations of BORDEAUX MIXTURE, TRIBASIC COPPER SULPHATE, COPPER HYDROXIDE, COPPER OXYCHLORIDE and COPPER OXIDE were applied at various rates, diluted with water immediately to prior to application to; target spray volume of 500l/ha. Specimens of crop from the untreated and treated plots were at taken by hand at normal commercial harvest. Crop specimens were analysed for residues of copper using the method MR029/RES. Determination of copper residues by atomic absorption spectrometry. The method consists of acidic sample digestion by the closed vessels microwave technique. Total copper is then determined by flame atomic absorption spectrometry by reading its absorbance at 324.8 nm. The analytical method was validated on pome fruit in study No. 00245 ('Analytical method validation for the determination of copper in / on pome fruit). The recoveries were within the required range.

Reference:	**KCA 6.3.10/03**
Report	Brereton, R., 2003 Copper: Residue levels in pome fruit from trials conducted in France, Spain and Italy during 2001/2002 Report No: AF/6150/CU
Guideline(s):	Yes Commission Directive 96/68/EC (amending Council Directive 91/414/EC)
Deviations:	No
Already evaluated:	Yes, evaluated in Art. 12 (EFSA 2018) and submitted France 2016 (Evaluation Report, Art. 12.1)

GLP:	Yes
Acceptability:	

And

Reference:	**KCA 6.3.10/04**
Report	Brereton, R., 2004 Copper: Residue levels in pome fruit from trials conducted in UK, France, and Germany during 2001/2002 Report No: AF/6151/CU
Guideline(s):	Yes Commission Directive 96/68/EC (amending Council Directive 91/414/EC)
Already evaluated:	Yes, evaluated in Art. 12 (EFSA 2018) and submitted France 2016 (Evaluation Report, Art. 12.1)
Deviations:	Yes
GLP:	Yes
Acceptability:	

For a better overview both trials were presented together in a single summary table presented below. Please note that some trials are in duplicate. Only trials with the most critical level of copper are taken into account. For further details please refer to EFSA review of the Art. 12 (EFSA 2018) and the Evaluation Report (EFSA 2016) respectively.

The LOQ is 1.5 mg/kg.

Table A 7: Summary of the copper studies in apple and pear: Pre-flowering (EU-S)

PPP (product name/code):	**Copper oxide WP** Copper oxychloride WP Bordeaux mixture WP Copper hydroxide WP Tribasic copper sulphate SC	Conc. of as 1:	**75%** **50%** **20%** **50%** **189 g/L**
Crop group:	Pome fruit /Apple, pear	Other a.i. in formulation:	None
Indoor/outdoor:	Outdoor (2001/2002)	Residues calculated as:	Copper
Applicant:	EU Copper Taskforce		
Zone(s):	S-EU (France, Spain, Italy)		

Trial No./ Location/ EU zone/ Year	**Formulation**	**Commodity/ Variety**	**Date of 1.Sowing or planting 2.Flowering 3. Harvest**	**Application rate**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Interval between applications**	**Portion analyzed**	**Residues [mg/kg]**		**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**			
AF/6150/CU/1 Plot 1 Calatorao Aragon Spain 2001	Bordeaux mixture WP	Apple/Reineta	1) Dec 1996 2) N/A 3) 14/08/02	2.64 2.61 2.56)	527 522 512	N/A	13.12.2001 28.02.2002 14.03.2002	BBCH 55	14-77 days	Fruit	0.73 (< LOQ)		153	**HR: 0.8 (<LOQ)** (Mean: 0.765 (<LOQ)
AF/6150/CU/1 Plot 2 Calatorao Aragon Spain 2001	Tribasic copper sulphate SC	Apple/Reineta	1) Dec 1996 2) N/A 3) 14/08/02	0.76 0.78 0.81	474 490 506	N/A	13.12.2001 28.02.2002 14.03.2002	BBCH 55	14-77 days	Fruit	0.8 (< LOQ)		153	
AF/6150/CU/2 Plot 1 82100 Castelsarrasin Tarn et Garonne France 2001	Copper oxide WP	Apple/Granny	1) 1988 2) N/D 3) 02/10/02	1.48 1.52 1.52	493 507 507	N/A	18.12.2001 28.02.2002 14.03.2002	BBCH 54	14-72 days	Fruit	0.99 (< LOQ)		202	**HR: 0.99 (<LOQ)** (Mean: 0.975 <LOQ)
AF/6150/CU/2 Plot 2 82100 Castelsarrasin	Copper-oxychloride WP	Apple/Granny	1) 1988 2) N/D 3) 02/10/02	2.45 2.65 2.54	490 530 507	N/A	18.12.2001 28.02.2002 14.03.2002	BBCH 54	14-72 days	Fruit	0.96 (< LOQ)		202	

Trial No./ Location/ EU zone/ Year	**Formulation**	**Commodity/ Variety**	**Date of 1.Sowing or planting 2.Flowering 3. Harvest**	**Application rate**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Interval between applications**	**Portion analyzed**	**Residues [mg/kg]**		**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**			
Tarn et Garonne France 2001														
AF/6150/CU/3 Plot 1 82290 Meauzac Tarn et Garonne France 2001	Copper-oxychloride WP	Pear/Williams	1) 1990 2) N/D 3) 12/08/02	2.48 2.40 2.62	2.48 2.40 2.62	N/A	07.12.2001 06.03.2002 20.03.2002	BBCH 55	14-89 days	Fruit	0.86 (< LOQ)		145	**HR: 0.86 (<LOQ** (Mean:0.765 <LOQ)
AF/6150/CU/3 Plot 2 82290 Meauzac Tarn et Garonne France 2001	Copper hydroxide WP	Pear/Williams	1) 1990 2) N/D 3) 12/08/02	2.46 2.60 2.62	491 520 523	N/A	07.12.2001 06.03.2002 20.03.2002	BBCH 55	14-89 days	Fruit	0.67 (< LOQ)		145	
AF/6150/CU/4 Plot 1 Poggetto Bologna Emilia Romagna Italy 2001	Tribasic copper sulphate SC	Apple/Red chief	1) N/D 2) N/D 3) 03/09/02	0.8 0.8 0.8	489 481 516	N/A	04.12.2001 27.03.2002 11.04.2002	BBCH 61	13-115 days	Fruit	0.66 (< LOQ)		145	**HR: 0.66 (<LOQ** (Mean:0.635 <LOQ)
AF/6150/CU/4 Plot 2 Poggetto Bologna Emilia Romagna Italy 2001	Copper hydroxide WP	Apple/Red chief	1) N/D 2) N/D 3) 03/09/02	2.5 2.6 2.6	493 524 520	N/A	04.12.2001 27.03.2002 11.04.2002	BBCH 61	13-115 days	Fruit	0.61 (< LOQ)		145	

Trial No./ Location/ EU zone/ Year	**Formulation**	**Commodity/ Variety**	**Date of 1.Sowing or planting 2.Flowering 3. Harvest**	**Application rate**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Interval between applications**	**Portion analyzed**	**Residues [mg/kg]**		**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**			
AF/6150/CU/5 Plot 1 Poggetto Bologna Emilia Romagna Italy 2001	Copper oxide WP	Pear/William	1) N/D 2) N/D 3) 02/08/02	1.6 1.5 1.6	518 506 519	N/A	04.12.2001 27.03.2002 11-04.2002	BBCH 69	13-115 days	Fruit	1.14 (< LOQ)		113	**HR: 1.14 <LOQ** (Mean: 1.1 <LOQ)
AF/6150/CU/5 Plot 2 Poggetto Bologna Emilia Romagna Italy 2001	Bordeaux mixture WP	Pear/William	1) N/D 2) N/D 3) 02/08/02	2.5 2.4 2.5	490 481 506	N/A	04.12.2001 27.03.2002 11-04.2002	BBCH 69	13-115 days	Fruit	1.06 (< LOQ)		113	

(a) According to CODEX Classification / Guide, (b) Only if relevant, (c) Year must be indicated, (d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
Underlined values presented in Art. 12 evaluation

Table A 8: Summary of the copper studies in apple: Pre-flowering (EU-N)

PPP (product name/code):	**Copper oxide WP** Copper oxychloride WP Bordeaux mixture WP Copper hydroxide WP Tribasic copper sulphate SC	Conc. of as 1:	**75%** **50%** **20%** **50%** **189 g/L**
Crop group:	Pome fruit /Apple, pear	Other a.i. in formulation:	None
Indoor/outdoor:	Outdoor (2001/2002)	Residues calculated as:	Copper
Applicant:	EU Copper Taskforce		
Zone(s):	N-EU (Germany, France, UK)		

Trial No./ Location/ EU zone/ Year	Formulation	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Interval between applications	Portion analyzed	Residues [mg/kg]		PHI [days]	Selected values
				kg a.s./ ha	Water [l/ha]	kg a.s./hl					Copper	-		
AF/6151/CU/1 69168 Baiertal, Germany Plot 1 2001	Bordeaux mixture WP	Apple/Jonica	1) 1988 2) N/D 3) 17 Sep 02	2.6 2.6 2.6	524 527 521	N/A	09.11.2001 13.03.2002 26.03.2002	BBCH 53-55	13-124 days	Fruit	0.56 (< LOQ)		175	**HR: 0.56 (<LOQ** (Mean: <LOQ)
AF/6151/CU/1 69168 Baiertal, Germany Plot 2 2001	Tribasic copper sulphate SC	Apple/Jonica	1) 1988 2) N/D 3) 17 Sep 02	2.0 2.0 1.9	534 521 498	N/A	09.11.2001 13.03.2002 26.03.2002	BBCH 53-55	13-124 days	Fruit	0.55 (< LOQ)		175	
AF/6151/CU/2 Sigloy, 45110, Northern France Plot 1 2001	Tribasic copper sulphate SC	Apple/Gala	1) 1991 2) N/D 3) 20 Aug 02	2.0 2.0 1.8	519 531 475	N/A	14.11.2001 15.03.2002 29.03.2002	BBCH 56-47	14-121 days	Fruit	0.57(< LOQ)		144	**HR: 0.57 (<LOQ** (Mean: 0.535 (<LOQ)
AF/6151/CU/2 Sigloy, 45110, Northern France Plot 2 2001	Copper-hydroxide WP	Apple/Gala	1) 1991 2) N/D 3) 20 Aug 02	2.6 2.6 2.6	522 525 525	N/A	14.11.2001 15.03.2002 29.03.2002	BBCH 56-47	14-121 days	Fruit	0.50 (< LOQ)		144	

AF/6151/CU/3 Sigloy, 45110, Northern France Plot 1 2001	Copper oxychloride WP	Pear/Williams	1) 1991 2) N/D 3) 06 Aug 02	2.6 2.6 2.5	516 524 508	N/A	14.11.2001 11.03.2002 25.03.2001	BBCH 63	14-117 days	Fruit	0.90 (< LOQ)		134	**HR: 1.52** (Mean: 1.21 (<LOQ)
AF/6151/CU/3 Sigloy, 45110, Northern France Plot 2 2001	Copper oxychloride WP	Pear/Williams	1) 1991 2) N/D 3) 06 Aug 02	2.6 2.5 2.6	520 508 516	N/A	14.11.2001 11.03.2002 25.03.2001	BBCH 63	14-117 days	Fruit	1.52		134	
AF/6151/CU/6 Sherif's Lench, Hereford & Worchester, UK Plot 1 2002	Copper oxide WP	Apple/Bramley	1) 1982 2) N/D 3) 16 Sep 03	1.5 1.5 1.5	513 513 502	N/A	18.11.2002 17.03.2003 31.03.2003	BBCH 53	14-119 days	Fruit	0.52 (< LOQ)		169	**HR: 0.65 (<LOQ** (Mean: 0.585 (<LOQ)
AF/6151/CU/6 Sherif's Lench, Hereford & Worchester, UK Plot 2 2002	Copper oxychloride WP	Apple/Bramley	1) 1982 2) N/D 3) 16 Sep 03	2.5 2.5 2.5	502 497 508	N/A	18.11.2002 17.03.2003 31.03.2003	BBCH 53	14-119 days	Fruit	0.65 (< LOQ)		169	
AF/6151/CU/7 Sherif's Lench, Hereford & Worchester, UK Plot 1 2002	Copper oxide WP	Pear/Conference	1) 1987 2) N/D 3) 16 Sep 03	1.5 1.6 1.6	506 528 521	N/A	24.10.2002 17.03.2003 31.03.2003	BBCH 55	14-144 days	Fruit	1.09 (< LOQ)		169	**HR: 1.09 (<LOQ** (Mean: 1.085 <LOQ)
AF/6151/CU/7 Sherif's Lench, Hereford & Worchester, UK Plot 2 2002	Copper oxide WP	Pear/Conference	1) 1987 2) N/D 3) 16 Sep 03	2.5 2.6 2.6	503 528 528	N/A	24.10.2002 17.03.2003 31.03.2003	BBCH 55	14-144 days	Fruit	1.08 (< LOQ)		169	

(a) According to CODEX Classification / Guide, (b) Only if relevant, (c) Year must be indicated, (d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
Underlined values presented in Art. 12 evaluation

A 2.1.3.6 Stone fruits (Pre-flowering)

Table A 9: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (kg a.i./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, RMS, year)	-	-	-	-	-
cGAP EU (Art. 12, 2018) EUN	1-7	3	14	BBCH 00-53	n.a.
Intended cGAP (1+2**)	--	--	--	--	--

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0
** only for supplement information – extrapolation, refer to GAP pome fruits under A 2.1.3.5

A 2.1.3.6.1 KCA 6.3.11 (Pre-flowering: Cherry, plum, EUN/EUS)

Comments of zRMS:	Study is acceptable. It was conducted according to acceptable guidelines. It has been used in evaluation. The purpose of this study was to obtain residue data from stone fruit (RAC fruit), cherry and plum, treated with different copper formulations under open field conditions. The trials were performed during the 2010 growing season at four field sites in northern and southern Europe. The recovery, obtained from the fortification experiment with copper nitrate solution, is in the range of 70-110% and accounts for 96.9%.

Reference:	**KCA 6.3.11/08**
Report:	Grall, E., 2011 Bordoflow New, Copper oxychloride 50 WP (SU), Copper hydroxide 25% DF, Nordox 75 WG, Cuproxat flüssig, Bordeaux Mixture 20% WG, Copper Oxychloride 37.5 NC WG, CA2111 (CHAMP DP), ATOFAP17: Determination of residues of Copper in stone fruit (RAC fruit) following three treatments with different Copper formulations under open field conditions in northern and southern Europe in 2010 Report No: C48222
Guideline(s):	Yes, EU Directive 96/68/EC Commission Working Document 7029/VI/95 rev. 5
Deviations:	No
Already evaluated:	Yes, evaluated in Art. 12 (EFSA 2018) and submitted France 2016 (Evaluation Report, Art. 12.1)
GLP:	Yes
Acceptability:	Yes

And

Comments of zRMS:	Study is acceptable. It was conducted according to acceptable guidelines.

Reference:	**KCA 6.3.11/09**
Report	L. North, 2020 Nordox 75 WG Determination of residues of Copper after one application of Copper in cherry (outdoor) at 1 site in Southern Europe 2020 Report No: S20-01045 [Analytical phase report included: D. Iffland 2020, Report No.: S20-01045-L1]
Guideline(s):	Yes Reg. (EC) 1107/2009; OECD (2009) No. 64 & 32; OECD 509 OECD (2016) ENV/JM/MONO(2011)50/REV1, No. 164 & 66 EC (1997) 7029/VI/95 rev. 5 EU SANCO 7525/VI/95 rev. 10.3 EU SANCO/3029/99 rev. 4 EU SANCO/825/00 rev. 8.1
Already evaluated:	No, new study
Deviations:	Yes
GLP:	Yes
Acceptability:	Yes

The objective of the new study was to determine residue levels of copper in the raw agricultural commodity cherry.
One residue trial was conducted on cherry during 2020, in France (S20-01045-01). Three applications of NORDOX 75 WG (750 g/kg, copper was applied nominally at 1.0 kg ai/ha, diluted with water immediately prior to application to a spray volume of 1000 L/ha.
Cherry samples were analysed for residues of copper using a method validated within the analytical phase of the study. The method involved the addition of nitric acid and hydrogen peroxide followed by digestion in a microwave oven. Ultra-pure water was added to the sample prior to analysis using ICP-MS.
The duration from sampling (03.06.2020) to the end of analysis (24.07.2020) was 51 days.
The study S20-01045 (North L. 2020) has not been previously evaluated in the EU, therefore some analytical information might be required. These are presented in the following:

Study:	S20-01045 (KCP 6.3.11/09)
Year:	2020
Author:	North, L.
Test product	Nordox 75 WG (75 % Copper oxide, WG)
LOQ:	0.970 mg/kg
LOD:	0.0417 mg/kg
Analytical method:	ICP-MS
Storage of samples:	-18 °C
Storage duration:	51 days

For further details on analytical methods, please refer to Part B Section 5, of this submission (KCP 5.1.2/02).
For a better overview both trials were presented together in a single summary table presented below. Please note that some trials are in duplicate. Only trials with the most critical level of copper are taken into account. For further details please refer to EFSA review of the Art. 12 (EFSA 2018) and the Evaluation Report (EFSA 2016) respectively.
The LOQ of the fruit is 0.97 mg/kg in pulp it is 0.2 mg/kg.

Table A 10: Summary of the copper studies in cherries: Pre-Flowering

PPP (product name/code):	**Copper oxide WG** Copper oxychloride WG Copper oxychloride WP Copper hydroxide DF Copper hydroxide WG Bordeaux mixture WG Bordeaux mixture SC Tribasic copper sulfate WG Tribasic copper sulfate SC	Conc. of as 1:	**75%** **37.5%** **50%** **25%** **37.5%** **20%** **10%** **40%** **190 g/L**
Crop group:	Stone fruit /Cherry	Other a.i. in formulation:	None
Indoor/outdoor:	Outdoor (2010, 2020)	Residues calculated as:	Copper
Applicant:	EU Copper Taskforce		
Zone(s):	S-EU (France, Spain)		

Trial No./ Location/ EU zone/ Year	**Formulation**	**Commodity/ Variety**	**Date of 1.Sowing or planting 2.Flowering 3. Harvest**	**Application rate**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Interval between applications**	**Portion analyzed**	**Residues [mg/kg]**		**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**	**-**		
A/SF/F/10/3 Plot 1 69440 St Laurent d'Agny France 2010	Bordeaux micture WG	Cherry/Duroni	1) 1997 2) 15/04/10 – 25/04/10 3) 19/06/10	1.216 1.233 1.193	617 597 588	N/A	11.03.2010 22.03.2010 02.04.2010	BBCH 54	11 days	Pulp Fruit	0.847 0.786 (<LOQ)	Fruit (mean): 0.672 Pulp (mean: 0.733)	78	**Fruit 0.786** **Pulp 0.847**
A/SF/F/10/3 Plot 2 69440 St Laurent d'Agny France 2010	copper oxychloride WG	Cherry/Duroni	1) 1997 2) 15/04/10 – 25/04/10 3) 19/06/10	1.189 1.147 1.215	628 610 600	N/A	11.03.2010 22.03.2010 02.04.2010	BBCH 54	11 days	Pulp Fruit	0.686 0.613 (<LOQ)		78	**Fruit 0.613** **Pulp 0.686**

Trial No./ Location/ EU zone/ Year	**Formulation**	**Commodity/ Variety**	**Date of 1.Sowing or planting 2.Flowering 3. Harvest**	**Application rate**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Interval between applications**	**Portion analyzed**	**Residues [mg/kg]**		**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**	**-**		
A/SF/F/10/3 Plot 3 69440 St Laurent d'Agny France 2010	Tribasic copper sulphate WG	Cherry/Duroni	1) 1997 2) 15/04/10 – 25/04/10 3) 19/06/10	1.257 1.219 1.200	628 610 600	N/A	11.03.2010 22.03.2010 02.04.2010	BBCH 54	11 days	Pulp Fruit	0.665 0.617 (<LOQ)		78	**Fruit 0.617** **Pulp 0.665**
A/SP/F/10/4 Plot 1 50313 Aniñón Aragon, Spain 2010	Copper oxide WG	Cherry/Summit	1) before 1990 2) middle/end April 3) 15/07/10	1.244 1.193 1.235	622 597 618	N/A	05.03.2010 16.03.2010 01.04.2010	BBCH 03	11-16 days	Pulp Fruit	1.070 0.993 (<LOQ)		105	**Fruit HR: 1.129** (Mean: 1.061) **Pulp HR 1.330** (Mean: 1.2**)**
A/SP/F/10/4 Plot 2 50313 Aniñón Aragon, Spain 2010	Copper hydroxide WG	Cherry/Summit	1) before 1990 2) middle/end April 3) 15/07/10	1.228 1.224 1.213	614 612 607	N/A	05.03.2010 16.03.2010 01.04.2010	BBCH 03	11-16 days	Pulp Fruit	1.330 1.129		105	
S20-01045-01 47340, Monbalen, Lot-et-Garonne, France 2020	Copper oxide WG	Cherry/Summit	1) 12 Oct 2000 2) 04 to 15 Apr 3) 03 Jun 2020	Control	-	-	-	-	-	Fruit	1.24 Untreated sample contained <1.17 mg/kg copper		NCH	**Fruit HR: 1.24** (Mean: 1.059)
S20-01045-02 47340, Monbalen, Lot-et-Garonne, France 2020	Copper oxide WG	Cherry/Summit	1) 12 Oct 2000 2) 04 to 15 Apr 3) 03 Jun 2020	1.02 0.95 0.99	1049 970 1018	0.10 0.10 0.10	17.03.2020 24.03.2020 31.03.2020	BBCH 59-60	7 days	Fruit calc. to whole fruit	0.878 (<LOQ) 0.937 (<LOQ)		64 NCH	**Pulp HR --** (Mean: --)

(a) According to CODEX Classification / Guide, (b) Only if relevant, (c) Year must be indicated, (d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
Underlined values presented in Art. 12 evaluation

Table A 11: Summary of the copper studies in cherries and plums (pre-flowering)

PPP (product name/code):	**Copper oxide WG** Copper oxychloride WG Copper oxychloride WP Copper hydroxide DF Copper hydroxide WG Bordeaux mixture WG Bordeaux mixture SC Tribasic copper sulfate WG Tribasic copper sulfate SC	Conc. of as 1:	**75%** **37.5%** **50%** **25%** **37.5%** **20%** **10%** **40%** **190 g/L**
Crop group:	Stone fruit /Plum, Cherry	Other a.i. in formulation:	None
Indoor/outdoor:	Outdoor (2010)	Residues calculated as:	Copper
Applicant:	EU Copper Taskforce		
Zone(s):	N-EU (Germany)		

Trial No./ Location/ EU zone/ Year	**Formulation**	**Commodity/ Variety**	**Date of 1.Sowing or planting 2.Flowering 3. Harvest**	**Application rate**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Interval between applications**	**Portion analyzed**	**Residues [mg/kg]**		**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**	**--**		
A/GE/F/10/1 Plot 1 Rheinland-Pfalz 67229 Gerolsheim Germany 2010	Copper oxychloride WP	Cherry/Regina	1) 2003 2) 25/04/10 to 05/05/10 3) 28/06/10	1.170 1.205 1.215	585 603 608	N/A	18.03.2010 31.03.2010 15.04.2010	BBCH 60	13-15 days	Pulp Fruit	0.730 0.596 (<LOQ)		74	**Fruit HR: <LOQ (0.667)** (Mean: <LOQ 0.628) **Pulp HR: 0.760**
A/GE/F/10/1 Plot 2 Rheinland-Pfalz 67229 Gerolsheim Germany 2010	Copper hydroxide DF	Cherry/Regina	1) 2003 2) 25/04/10 to 05/05/10 3) 28/06/10	1.188 1.180 1.180	594 590 590	N/A	18.03.2010 31.03.2010 15.04.2010	BBCH 60	13-15 days	Pulp Fruit	0.723 0.622 (<LOQ)		74	

Trial No./ Location/ EU zone/ Year	Formulation	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Interval between applications	Portion analyzed	Residues [mg/kg]		PHI [days]	Selected values
				kg a.s./ ha	Water [l/ha]	kg a.s./hl					Copper	--		
A/GE/F/10/1 Plot 3 Rheinland-Pfalz 67229 Gerolsheim Germany 2010	Bordeaux mixture SC	Cherry/Regina	1) 2003 2) 25/04/10 to 05/05/10 3) 28/06/10	1.171 1.259 1.176	595 640 597	N/A	18.03.2010 31.03.2010 15.04.2010	BBCH 60	13-15 days	Pulp Fruit	0.760 0.667 (<LOQ)		74	(Mean: 0.738)
A/GE/F/10/2 Plot 1 Rheinland-Pfalz 67229 Gerolsheim Germany 2010	Copper oxide WG	Plum/Präsenta	1) 2006 2) 15/04/10 to 30/04/10 3) 22/08/10	1.205 1.170 1.194	603 585 597	N/A	18.03.2010 31.03.2010 15.04.2010	BBCH 63	13-15 days	Pulp Fruit	0.508 0.458 (<LOQ)		129	**Fruit HR: <LOQ (0.572)** (Mean: <LOQ 0.488) **Pulp HR: 0.572** (Mean: 0.54)
A/GE/F/10/2 Plot 2 Rheinland-Pfalz 67229 Gerolsheim Germany 2010	Tribasic copper sulphate SC	Plum/Präsenta	1) 2006 2) 15/04/10 to 30/04/10 3) 22/08/10	1.194 1.159 1.216	603 585 614	N/A	18.03.2010 31.03.2010 15.04.2010	BBCH 63	13-15 days	Pulp Fruit	0.572 0.518 (<LOQ)		129	

(a) According to CODEX Classification / Guide, (b) Only if relevant, (c) Year must be indicated, (d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
Underlined values presented in Art. 12 evaluation

A 2.1.3.7 Strawberry, outdoor

Table A 12: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (kg a.i./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, RMS, year)	-	-	-	-	-
cGAP EU (Art. 12, 2018)	4	0.8	7	BBCH 13-85	3
Intended cGAP (4*)	3	1.0	7	BBCH 13-85	3

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

A 2.1.3.7.1 KCA 6.3.12 (Strawberry, EUS/EUN)

Comments of zRMS:	Studies are acceptable. They were conducted according to acceptable guidelines and have been used in evaluation. 1. The purpose of this study was to obtain residue data from crops of strawberry (RAC fruit) treated with different copper formulations under open field conditions. The trials were performed during the 2009 growing season at eight field sites in northern and southern Europe. The residues found in the control specimens, in the range of 0.14 to 0.53 mg/kg of copper, are assumed to be the background level, i.e. the natural copper content of strawberries. The limit of quantification (LOQ) for copper in strawberry specimens was 0.2 mg/kg for fruits and 0.4 mg/kg for jam. The average recoveries obtained from the fortification experiments with copper nitrate solution, were all in the range of 70-110 % with a mean recovery of 97 % for fruits and 93.5 % for jam. 2. The purpose of this study was to obtain residue data from strawberry (RAC fruit) treated with different copper formulations under open field conditions. The trials were performed during the 2010 growing season at seven field sites in northern and southern Europe. The levels found in the control specimens, in the range of 0.17 to 0.6 mg/kg of copper are assumed to be the background level, i.e. the natural copper content of strawberries. The limit of quantification (LOQ) for copper in strawberry fruit samples was 0.2 mg/kg. The recovery, obtained from the fortification experiment with copper nitrate solution, is in the range of 70-110% and accounts for 94.2%.

Reference: **KCA 6.3.12/01**

Report: Grall, E., 2009
Determination of residues of Copper in strawberry (RAC fruit) following four treatments with different Copper formulations under open field conditions in northern and southern Europe in 2009
Report No: C48301

Guideline(s): Yes EU Directive 96/68/EC
Commission Working Document 7029/VI/95 rev. 5
Commission Working Document 7035/VI/95 rev.5

Deviations: No

Already evaluated:	Yes, evaluated in Art. 12 (EFSA 2018) and submitted France 2016 (Evaluation Report, Art. 12.1)
GLP:	Yes
Acceptability:	Yes

and

Reference:	**KCA 6.3.12/02**
Report:	Grall, E., 2010 Determination of residues of Copper in strawberry (RAC fruit) following four treatments with different Copper formulations under open field conditions in northern and southern Europe in 2010 Report No: C91308
Guideline(s):	Yes EU Directive 96/68/EC Commission Working Document 7029/VI/95 rev. 5
Deviations:	No
Already evaluated:	Yes, evaluated in Art. 12 (EFSA 2018) and submitted France 2016 (Evaluation Report, Art. 12.1)
GLP:	Yes
Acceptability:	Yes

For a better overview all trials of both reports were presented together in a single summary table presented below. Please note that some trials are in duplicate. Only values with the most critical level of copper are taken into account.
For further details please refer to EFSA review of the Art. 12 (EFSA 2018) and the Evaluation Report (EFSA 2016) respectively.

The LOQ for strawberry is 0.2 mg/kg.

Table A 13: Summary of the copper studies in strawberries

PPP (product name/code):	**Copper oxide WP** Copper oxychloride WP Bordeaux mixture WP Copper hydroxide WP + DS	Conc. of as 1:	**75%** **50%** **20%**
Crop group:	Strawberry	Other a.i. in formulation:	None
Indoor/outdoor:	Outdoor (2009, 2010)	Residues calculated as:	Copper
Applicant:	EU Copper Taskforce		
Zone(s):	N-EU (France, Germany, UK)		

Trial No./ Location/ EU zone/ Year	**Formulation**	**Commodity/ Variety**	**Date of 1.Sowing or planting 2.Flowering 3. Harvest**	**Application rate**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Interval between applications**	**Portion analyzed**	**Residues (mg/kg)**		**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**	**Overall mean residues (trials in duplicate)**		
A/GE/F/09/92 Plot 1 Germany Sachsen 04523 Pegau EUN, 2009	Copper oxychloride WG	Strawberry Florence	1. 16.04.2008 2. 25.04. to 28.05.2009 3. --	0.813 0.756 0.838 0.914		0.267	25.06.2009	BBCH 86	--	Fruit	0.57 0.51	--	0 3	**HR 0.51** (mean 0.47)
A/GE/F/09/92 Plot 2 Germany Sachsen 04523 Pegau EUN, 2009	**Copper oxide WG**	Strawberry Florence	1. 16.04.2008 2. 25.04. to 28.05.2009 3. --	0.845 0.749 0.800 0.788		0.267	25.06.2009	BBCH 86	--	Fruit	0.65 0.43	--	0 3	
A/GE/F/10/91 Plot 1 Germany Sachsen 04523 Pegau EUN, 2010	Bordeaux mixture WG	Strawberry Florence	1. 16.04.2008 2. 20.05. to 21.06.2010 3. --	0.809 0.809 0.844 0.844		0.267	30.06.2010	BBCH 87	--	Fruit	1.16 0.87	--	0 3	**HR 0.87** (mean 0.815)

Trial No./ Location/ EU zone/ Year	Formulation	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Interval between applications	Portion analyzed	Residues (mg/kg)		PHI [days]	Selected values
				kg a.s./ ha	Water [l/ha]	kg a.s./hl					Copper	Overall mean residues (trials in duplicate)		
A/GE/F/10/91 Plot 2 Germany Sachsen 04523 Pegau EUN, 2010	Copper oxychloride WP	Strawberry Florence	1. 16.04.2008 2. 20.05. to 21.06.2010 3. --	0.845 0.836 0.800 0.800		0.267	30.06.2010	BBCH 87	--	Fruit	0.91 0.76	--	0 3	
A/GE/F/09/97 Plot 1 Germany Sachsen 01640 Coswig EUN, 2009	Copper oxychloride SC	Strawberry Yamaska	1. 26.05.2008 2. 01. To 18.06.2009 3. --	0.845 0.801 0.809 0.774		0.267	26.06.2009	BBCH 86	--	Fruit	1.03 0.83 0.84 0.92 0.88	--	0 1 3 5 7	**HR 0.99** (mean 0.955)
A/GE/F/09/97 Plot 2 Germany Sachsen 01640 Coswig EUN, 2009	Copper hydroxide WG	Strawberry Yamaska	1. 26.05.2008 2. 01. To 18.06.2009 3. --	0.791 0.809 0.800 0.844		0.267	29.06.2009	BBCH 87	--	Fruit	1.11 0.84 0.89 0.90 0.99		0 1 3 5 7	
A/GE/F/09/94 Plot 1 Germany Thüringen 04626 Lumpzig EUN, 2009	Copper hydroxide DF	Strawberry Symphonie	1. 10. to 14.05.2008 2. 07.05. to 10.06.2009	0.791 0.818 0.827 0.845		0.267	29.06.2009	BBCH 87	--	Fruit Jam	0.95 0.96 0.61	--	0 3 3	**HR 0.98** (mean 0.97)
A/GE/F/09/94 Plot 2 Germany Thüringen 04626 Lumpzig EUN, 2009	Bordeaux mixture SC	Strawberry Symphonie	1. 10. To 14.05.2008 2. 07.05. to 10.06.2009 3. --	0.728 0.768 0.818 0.791		0.267	29.06.2009	BBCH 87	--	Fruit Jam	1.06 0.98 0.59	--	0 3	
A/GE/F/10/90 Plot 1 Germany, Thüringen 04626 Lumpzig	Copper hydroxide WG	Strawberry Elsanta	1. 2008 2. 18.05. to 06.06.2010 3. --	0.862 0.871 0.871 0.862		0.267	22.06.2010	BBCH 85	--	Fruit	2.36 2.89 3.44 2.70 2.09	--	0 1 3 5 7	**HR 3.44** (mean 3.12)

Trial No./ Location/ EU zone/ Year	**Formulation**	**Commodity/ Variety**	**Date of 1.Sowing or planting 2.Flowering 3. Harvest**	**Application rate**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Interval between applications**	**Portion analyzed**	**Residues (mg/kg)**		**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**	**Overall mean residues (trials in duplicate)**		
EUN, 2010														
A/GE/F/10/90 Plot 2 Germany, Thüringen 04626 Lumpzig EUN, 2010	**Copper oxide**	Strawberry Elsanta	1. 2008 2. 18.05. to 06.06.2010 3. --	0.847 0.830 0.812 0.812		0.267	22.06.2010	BBCH 85	--	Fruit	2.73 2.07 2.80 2.01 2.00	--	0 1 3 5 7	
A/NF/F/09/96 Plot 1 France Champagne-Ardenne 51110 Auménancourt EUN, 2009	Copper oxychloride WG	Strawberry Sonata	1. 07.05.2008 2. 02. To 17.06.2009 3. --	0.808 0.839 0.839 0.781		0.267	26.06.2009	BBCH 85	--	Fruit	0.80 0.78 0.72 0.61 0.52	--	0 1 3 5 7	**HR 0.72** (mean 0.70)
A/NF/F/09/96 Plot 2 France Champagne-Ardenne 51110 Auménancourt EUN, 2009	**Copper oxide WG**	Strawberry Sonata	1. 07.05.2008 2. 02. To 17.06.2009 3. --	0.764 0.773 0.813 0.768		0.267	26.06.2009	BBCH 85	--	Fruit	0.73 0.76 0.68 0.60 0.57	--	0 1 3 5 7	
A/NF/F/10/89 Plot 1 Northern France Champagne-Ardenne 51110 Auménancourt le Grand EUN, 2010	Copper oxychloride SC	Strawberry n.a.	1. 07.05.2008 2. 10.05. to 12.06.2010 3. 18.06.2010	0.832 0.873 0.825 0.804		0.267	15.06.2010	BBCH 87	--	Fruit	0.84 0.83	--	0 3	**HR 1.06** (mean 0.945)
A/NF/F/10/89 Plot 2 Northern France Champagne-Ardenne	Bordeaux mixture WG	Strawberry n.a.	1. 07.05.2008 2. 10.05. to 12.06.2010 3. 18.06.2010	0.783 0.769 0.769 0.762		0.267	15.06.2010	BBCH 87	--	Fruit	1.00 1.06	--	0 3	

Trial No./ Location/ EU zone/ Year	Formulation	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Interval between applications	Portion analyzed	Residues (mg/kg)		PHI [days]	Selected values
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**	**Overall mean residues (trials in duplicate)**		
51110 Aménancourt le Grand EUN, 2010														
A/UK/F/09/98 Plot 1 United Kingdom Worcestershire Little Witley Worcester WR6 6LP EUN, 2009	Copper hydroxide DF	Strawberry Symphony	1. May 2007 2. Beg to end May 2009	0.876 0.831 0.800 0.805		0.267	29.06.2009	BBCH 87	--	Fruit Jam	2.38 2.01 2.08 1.69 1.48 1.93	--	0 1 3 5 7 3	**HR 2.08** (mean 1.755)
A/UK/F/09/98 Plot 2 United Kingdom Worcestershire Little Witley Worcester WR6 6LP EUN, 2009	Bordeaux mixture SC	Strawberry Symphony	1. May 2007 2. Beg to end May 2009	0.772 0.809 0.782 0.773		0.267	29.06.2009	BBCH 87	--	Fruit Jam	1.99 1.71 1.43 0.86 1.03 1.89	--	0 1 3 5 7 3	

Table A 14: Summary of the copper studies in strawberries

PPP (product name/code):	**Copper oxide WP** Copper oxychloride WP, WG, SC Bordeaux mixture WP, SC, WG Copper hydroxide WP Tribasic copper sulphate SC	Conc. of as 1:	**75%** **50%** **20%** **50%** **15%**
Crop group:	Strawberry	Other a.i. in formulation:	None
Indoor/outdoor:	Outdoor (2009, 2010)	Residues calculated as:	Copper
Applicant:	EU Copper Taskforce		
Zone(s):	S-EU (France, Spain, Italy)		

Trial No./ Location/ EU zone/ Year	**Formulation**	**Commodity/ Variety**	**Date of 1.Sowing or planting 2.Flowering 3. Harvest**	**Application rate**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Interval between applications**	**Portion analyzed**	**Residues (mg/kg)**		**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**	**Overall mean residues (trials in duplicate)**		
A/SP/F/09/95 Plot 1 Spain Valencia 46692 Montesa EUS, 2009	Copper oxychloride WG	Strawberry Gaviota	1. Mid Sept. 2008 2. End Feb. to End July 2009 3. --	0.756 0.778 0.809 769		0.267	26.06.2009	BBCH 87	--	Fruit Jam Washed fruit	4.48 3.09 2.28 2.26	--	0 3 3 3	**HR** **3.09** (mean 2.935)
A/SP/F/09/95 Plot 2 Spain Valencia 6692 Montesa EUS, 2009	**Copper oxide WG**	Strawberry Gaviota	1. Mid Sept. 2008 2. End Feb. to End July 2009 3. --	0.765 0.785 0.796 0.782		0.267	26.06.2009	BBCH 87	--	Fruit Jam Washed fruit	3.57 2.78 2.62 2.16		0 3 3 3	
A/SP/F/09/99 Plot 1 Spain Valencia 46837	Copper oxychloride SC	Strawberry Albion	1. End March 2009 2. Mid to end May 2009 3. --	0.802 0.823 0.771 0.786		0.267	11.09.2009	BBCH 81-85		Fruit	4.60 3.78 3.00 2.99 1.82	--	0 1 3 5 7	**HR** **3.55** (mean 3.275)

Trial No./ Location/ EU zone/ Year	**Formulation**	**Commodity/ Variety**	**Date of 1.Sowing or planting 2.Flowering 3. Harvest**	**Application rate**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Interval between applications**	**Portion analyzed**	**Residues (mg/kg)**		**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**	**Overall mean residues (trials in duplicate)**		
Quatretonda EUS, 2009														
A/SP/F/09/99 Plot 2 Spain Valencia 46837 Quatretonda EUS, 2009	Copper hydroxide WG	Strawberry Albion	1. End March 2009 2. Mid to end May 2009 3. --	0.791 0.836 0.787 0.782		0.267	11.09.2009	BBCH 81-85		Fruit	5.77 4.08 3.55 2.71 2.01	--	0 1 3 5 7	
A/SP/F/10/92 Plot 1 Spain Communidad Valenciana 46837 Quatredonda EUS, 2010	Copper oxychloride SC	Strawberry Camarosa	1. Sept 2009 2. 01.03.2010 to n.a. 3. --	0.820 0.760 0.843 0.788		0.267	02.06.2010	BBCH 87	--	Fruit	1.22 1.11 1.02 1.44 1.38	--	0 1 3 5 7	**HR 1.44** (mean 1.435)
A/SP/F/10/92 Plot 2 Spain Communidad Valenciana 46837 Quatredonda EUS, 2010	Copper oxychloride WP	Strawberry Camarosa	1. Sept 2009 2. 01.03.2010 to n.a. 3. --	0.797 0.850 0.831 0.820		0.267	02.06.2010	BBCH 87	--	Fruit	1.19 1.62 1.37 1.38 1.43	--	0 1 3 5 7	
A/SP/F/10/94 Plot 1 Spain Communidad Valenciana 46692 Montesa	Copper hydroxide WG	Strawberry Pajaro-Gaviota	1. Sept 2009 2. Feb – March 2010 3. --	0.790 0.773 0.808 0.804		0.267	02.06.2010	BBCH 85	--	Fruit	4.53 3.24	--	0 3	**HR 3.31** (mean 3.275)
A/SP/F/10/94 Plot 2 Spain Communidad Valenciana 46692 Montesa	Tribasic copper sulphate SC	Strawberry Pajaro-Gaviota	1. Sept 2009 2. Feb – March 2010 3. --	0.787 0.822 0.788 0.761		0.267	02.06.2010	BBCH 85	--	Fruit	5.55 3.31		0 3	

Trial No./ Location/ EU zone/ Year	**Formulation**	**Commodity/ Variety**	**Date of 1.Sowing or planting 2.Flowering 3. Harvest**	**Application rate**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Interval between applications**	**Portion analyzed**	**Residues (mg/kg)**		**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**	**Overall mean residues (trials in duplicate)**		
EUS, 2010														
A/IT/F/09/100 Plot 1 Italy Lombardia 23010 Albosaggia EUS, 2009	Copper Hydroxide DF	Strawberry Aromas	1. 28.04.2009 2. Mid-June to mid Aug 2009 3. --	0.782 0.773 0.773 0.782		0.267	01.08.2009	BBCH 85		Fruit Jam	2.01 1.54 1.77 1.77 1.12 2.01	--	0 1 3 5 7 3	**HR 1.77** (mean 1.745)
A/IT/F/09/100 Plot 2 Italy Lombardia 23010 Albosaggia EUS, 2009	Bordeaux mixture SC	Strawberry Aromas	1. 28.04.2009 2. Mid-June to mid Aug 2009	0.752 0.744 0.728 0.736		0.267	01.08.2009	BBCH 85	--	Fruit Jam	1.80 1.37 1.72 1.44 1.60 1.34	--	0 1 3 5 7 3	
A/IT/F/10/95 Plot 1 Italy Piemonte 12012 Boves EUS, 2010	Copper hydroxide DF	Strawberry Record	1. March 2010 2. mid-May to mid-June 2010 3. --	0.809 0.773 0.827 0.782		0.267	21.06.2010	BBCH 83	--	Fruit	0.76 1.02 0.50 0.54 0.43		0 1 3 5 7	**HR 0.68** (mean 0.61)
A/IT/F/10/95 Plot 2 Italy Piemonte 12012 Boves EUS, 2010	Tribasic copper sulphate SC	Strawberry Record	1. March 2010 2. mid May to mid-June 2010 3. --	0.836 0.782 0.791 0.809		0.267	21.06.2010	BBCH 83	--	Fruit	0.81 0.40 0.51 0.68 0.48		0 1 3 5	
A/SF/F/10/93 Plot 1 Southern France Languedoc Roussillon 34590 Marsillargues	Copper oxide WG	Strawberry Mara des Bois	1. 06.05.2009 2. May to Oct 2010 3. --	0.840 0.828 0.840 0.852		0..267	08.10.2010	BBCH 89	--	Fruit	1.42 1.10		0 3	**HR 1.10** (mean 2.17)

Trial No./ Location/ EU zone/ Year	Formulation	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Interval between applications	Portion analyzed	Residues (mg/kg)		PHI [days]	Selected values
				kg a.s./ ha	Water [l/ha]	kg a.s./hl					Copper	Overall mean residues (trials in duplicate)		
A/SF/F/10/93 Plot 2 Southern France Languedoc Roussillon 34590 Marsillargues	Bordeaux mixture WG	Strawberry Mara des Bois	1. 06.05.2009 2. May to Oct 2010 3. --	0.825 0.849 0.778 0.861		0..267	08.10.2010	BBCH 89	--	Fruit	4.53 3.24		0 3	

A 2.1.3.8 Onion

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 (DAR, RMS, year)	--	--	--	--	--
cGAP EU (Art. 12, 2018) onion, shallots Spring onion	 4 5	 0.8 kg a.i./ha	 7	 BBCH 14-47 BBCH 17-85	 3
Intended cGAP (Use 6*)	3	1.0	7	BBCH 14-47	3

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

A 2.1.3.8.1 KCA 6.3.18 (Onion, EUN/EUS)

Comments of zRMS:	Studies are acceptable. They were conducted according to acceptable guidelines and have been used in evaluation. 1. The purpose of this study was to obtain residue data from onion (RAC bulb) treated with different copper formulations under open field conditions. The trials were performed during the 2010 growing season at three field sites in northern Europe. The levels found in the control specimens, in the range of 0.40 to 0.62 are assumed to be the background level, i.e. the natural copper content of onions. The limit of quantification (LOQ) for copper in pepper samples was 0.2 mg/kg. The recoveries, obtained from the fortification experiments with copper nitrate solution, were all in the range of 70-110% with a mean recovery of 89.9%. 2. The purpose of this study was to obtain residue data from onions (RAC bulb) treated with different copper formulations under open field conditions. The trials were performed during the 2009 growing season at nine field sites in northern and southern Europe. The residues found in the control specimens, in the range of 0.37 to 0.80 mg/kg of copper, are assumed to be the background level, i.e. the natural copper content of bulb onions. The limit of quantification (LOQ) for copper in onion samples was 0.2 mg/kg. The average recoveries obtained from the fortification experiments with copper nitrate solution, were all in the range of 70-110% with a mean recovery of 97.3%.

Reference:	**KCA 6.3.18/01**
Report:	Kreke, N. (2010) Nordox 75 WG, Bordeaux Mixture 20 NC WG, Funguran-OH 50 WP: Determination of residues of Copper in onion (RAC bulb) following four treatments with different Copper formulations under open field conditions in northern Europe in 2010, Report No. C91073
Guideline(s):	Yes, EU Directive 96/68/EC Commission Working Document 7029/VI/95 rev. 5
Deviations:	No

Already evaluated:	Yes, evaluated in Art. 12 (EFSA 2018) and submitted France 2016 (Evaluation Report, Art. 12.1)
GLP:	Yes
Acceptability:	Yes

and

Reference:	**KCA 6.3.18/02**
Report:	Kreke, N. (2011) Bordeaux Mixture 20 NC WG, Nordox 75 WG, Copper oxychloride 37.5 NC WG, COC 35 DF, CA2111 (Champ DP), Copper oxychloride 50 WP (SU), Funguran-OH 50 WP, ATOFAP17, Bordeaux Mixture 20% WG, Flowbrix SC (Copper oxychloride SC): Determination of residues of Copper in onion (RAC bulb) following four treatments with different Copper formulations under open field conditions in northern and southern Europe in 2009, Report No. C48110
Guideline(s):	Yes, EU Directive 96/68/EC Commission Working Document 7029/VI/95 rev. 5
Deviations:	Yes (refer to EFSA 2016 (ER))
Already evaluated:	Yes, evaluated in Art. 12 (EFSA 2018) and submitted France 2016 (Evaluation Report, Art. 12.1)
GLP:	Yes
Acceptability:	Yes

For a better overview all trials of both reports were presented together in a single summary table. Please note that some trials are in duplicate. Only values with the most critical level of copper are taken into account.
For further details please refer to EFSA review of the Art. 12 (EFSA 2018) and the Evaluation Report (EFSA 2016) respectively.

The LOQ is 0.2 mg/kg.

Table A 16: Summary of the copper studies in onion

PPP (product name/code):	**Copper oxide WP** Copper oxychloride WP Bordeaux mixture WP Copper hydroxide WP Tribasic copper sulphate SC	Conc. of as 1:	**75%** **50%** **20%** **50%** **15%**
Crop group:	Onion	Other a.i. in formulation:	None
Indoor/outdoor:	Outdoor (2009, 2010)	Residues calculated as:	Copper
Applicant:	EU Copper Taskforce		
Zone(s):	N-EU (France; Germany, UK) S-EU (Spain, Italy)		

Trial No./ Location/ EU zone/ Year	**Formulation**	**Commodity/ Variety**	**Date of 1. Sowing or planting 2. Flowering 3. Harvest**	**Application rate**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Interval between applications**	**Portion analyzed**	**Residues [mg/kg]**		**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**	**Overall mean residues (trials in duplicate)**		
A/NF/F/10/123 Field France - North 2010	Nordox 75 WG	Onion Hyfield	1) 17.03.10 2) not applicable	0.830 0.856 0.832 0.866	311 321 312 325	0.267	12.08.2010 20.08.2010 28.08.2010 03.09.2010	47 48 48 49	7±1 days	Bulb peeled	0.41 0.50 0.42 0.57 0.56 0.45		0 1 3 5 7 3	**HR: 0.64** (Mean: 0.61)
A/NF/F/10/123 Field France - North 2010	Bordeaux mixture 20 NC WG	Onion Hyfield	1) 17.03.10 2) not applicable	0.831 0.834 0.816 0.813	316 317 310 309	0.267	12.08.2010 20.08.2010 28.08.2010 03.09.2010	47 48 48 49	7±1 days	Bulb peeled	0.50 0.54 0.56 0.56 0.64 0.61		0 1 3 5 7 3	

Trial No./ Location/ EU zone/ Year	**Formulation**	**Commodity/ Variety**	**Date of 1. Sowing or planting 2. Flowering 3. Harvest**	**Application rate**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Interval between applications**	**Portion analyzed**	**Residues [mg/kg]**		**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**	**Overall mean residues (trials in duplicate)**		
A/GE/F/10/124 Field Germany 2010	Bordeaux mixture 20 NC WG	Onion Hyskin F1	1) 20.04.10 2) not applicable	0.762 0.813 0.794 0.813	178 190 182 190	0.267	16.08.2010 23.08.2010 29.08.2010 06.09.2010	43 44 46 47	7±1 days	Bulb	0.47 0.45		0 3	**HR: 0.46** (Mean: 0.455)
A/GE/F/10/124 Field Germany 2010	Funguran-OH 50 WP	Onion Hyskin F1	1) 20.04.10 2) not applicable	0.737 0.794 0.826 0.857	172 185 193 200	0.267	16.08.2010 23.08.2010 29.08.2010 06.09.2010	43 44 46 47	7±1 days	Bulb	0.47 0.46		0 3	
A/UK/F/10/125 Field United Kingdom 2010	Funguran-OH 50 WP	Onion Wellington	1) 20.04.10 2) not applicable	0.858 0.839 0.828 0.837	178 190 182 190	0.267	16.08.2010 23.08.2010 29.08.2010 06.09.2010	42 42 44 47	7±1 days	Bulb peeled	0.39 0.45 0.53		0 3 3	**HR: 0.48** (Mean: 0.465)
A/UK/F/10/125 Field United Kingdom 2010	Nordox 75 WG	Onion Wellington	1) 20.04.10 2) not applicable	0.843 0.845 0.823 0.838	172 185 193 200	0.267	16.08.2010 23.08.2010 29.08.2010 06.09.2010	42 42 44 47	7±1 days	Bulb peeled	0.49 0.48 0.58		0 3	
A/NF/F/09/82 Field France - North 2009	Bordeaux mixture 20 NC WG	Onion Stardust	1) 23.03.2009 2) not applicable	0.798 0.821 0.824 0.782	299 308 309 293	0.267 0.267 0.267 0.267	30.08.2009 05.09.2009 13.09.2009 19.09.2009	45 46 47 49	7±1 days	Bulb	0.82 0.75		0 3	**HR: 0.75** (Mean: 0.74)
A/NF/F/09/82 Field France - North 2009	Copper oxychloride 50WP (SU)	Onion Stardust	1) 23.03.2009 2) not applicable	0.796 0.815 0.824 0.821	298 305 309 308	0.267 0.267 0.267 0.267	30.08.2009 05.09.2009 13.09.2009 19.09.2009	45 46 47 49	7±1 days	Bulb	0.65 0.73		0 3	
A/NF/F/09/83 Field France - North 2009	Nordox 75WG	Onion Hyfield	1) 18.03.2009 2) not applicable	0.803 0.782 0.766 0.798	301 293 287 299	0.267 0.267 0.267 0.267	29.08.2009 05.09.2009 13.09.2009 19.09.2009	47 48 48 49	7±1 days	Bulb	0.56 0.55 0.53 0.55 0.44		0 1 3 5 6	**HR: 0.62** (Mean: 0.585)

Trial No./ Location/ EU zone/ Year	**Formulation**	**Commodity/ Variety**	**Date of 1. Sowing or planting 2. Flowering 3. Harvest**	**Application rate**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Interval between applications**	**Portion analyzed**	**Residues [mg/kg]**		**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**	**Overall mean residues (trials in duplicate)**		
A/NF/F/09/83 Field France - North 2009	Funguran-OH 50WP	Onion Hyfield	1) 18.03.2009 2) not applicable	0.803 0.819 0.790 0.819	301 307 296 307	0.267 0.267 0.267 0.267	29.08.2009 05.09.2009 13.09.2009 19.09.2009	47 48 48 49	7±1 days	Bulb	0.55 0.64 0.60 0.62 0.58		0 1 3 5 6	
A/GE/F/09/84 Field Germany 2009	Bordeaux mixture 20 NC WG	Onion Sturon	1) 15.03.2009 2) not applicable	0.838 0.794 0.829 0.781	314 298 311 293	0.267 0.267 0.267 0.267	09.07.2009 15.07.2009 22.07.2009 29.07.2009	41-42 43 45 46	7±1 days	Bulb	0.55 0.63		0 3	**HR: 0.63** (Mean: 0.625)
A/GE/F/09/84 Field Germany 2009	Copper oxychloride 50WP (SU)	Onion Sturon	1) 15.03.2009 2) not applicable	0.842 0.810 0.805 0.795	317 324 282 307	0.267 0.267 0.267 0.267	09.07.2009 15.07.2009 22.07.2009 29.07.2009	42 43 45 46	7±1 days	Bulb	0.75 0.62		0 3	
A/GE/F/09/85 Onion Hyskin Field Germany 2009	Copper oxychloride 37.5NC WG	Onion Hyskin	1) 17.04.2009 2) not applicable	0.842 0.810 0.805 0.795	316 304 302 398	0.267 0.267 0.267 0.267	23.08.2009 30.08.2009 07.09.2009 13.09.2009	43-45 45 46 46	7±1 days	Bulb	0.71 0.66 0.54 0.52 0.57		0 1 3 5 8	**HR: 0.57** (Mean: 0.545)
A/GE/F/09/85 Onion Hyskin Field Germany 2009	Nordox 75WG	Onion Hyskin	1) 17.04.2009 2) not applicable	0.827 0.795 0.837 0.816	310 298 314 306	0.267 0.267 0.267 0.267	23.08.2009 30.08.2009 07.09.2009 13.09.2009	43-45 45 46 46	7±1 days	Bulb	0.70 0.75 0.52 0.47 0.50		0 1 3 5 8	
A/UK/F/09/86 Field UK 2009	Copper oxychloride 37.5NC WG	Onion Armstrong	1) 06.03.2009 2) not applicable	0.826 0.771 0.752 0.815	310 290 282 306	0.267 0.267 0.267 0.267	28.07.2009 04.08.2009 11.08.2009 19.08.2009	45 45 45 48	7±1 days	Bulb	0.48 0.50 0.54 0.45 0.48		0 1 3 5 6	**HR: 0.54** (Mean: 0.545)
A/UK/F/09/86 Field UK	Funguran-OH 50WP	Onion Armstrong	1) 06.03.2009 2) not applicable	0.826 0.778 0.798	310 292 296	0.267 0.267 0.267	28.07.2009 04.08.2009 11.08.2009	45 45 45	7±1 days	Bulb	0.47 0.50 0.52		0 1 3	

Trial No./ Location/ EU zone/ Year	**Formulation**	**Commodity/ Variety**	**Date of 1. Sowing or planting 2. Flowering 3. Harvest**	**Application rate**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Interval between applications**	**Portion analyzed**	**Residues [mg/kg]**		**PHI [days]**	**Selected values**
				kg a.s./ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**	**Overall mean residues (trials in duplicate)**		
2009				0.785	294	0.267	19.08.2009	48			0.52 0.48		5 6	
A/IT/F/09/87 Field Italy 2009	Bordeaux mixture 20% WG	Onion Giarratana	1) March 2009 2) not applicable	0.825 0.825 0.762 0.787	310 310 286 295	0.267 0.267 0.267 0.267	30.06.2009 07.07.2009 13.07.2009 21.07.2009	48 48 49 49	7±1 days	Bulb	0.37 0.35		0 3	**HR: 0.39** (Mean: 0.37)
A/IT/F/09/87 Field Italy 2009	Flowbrix SC	Onion Giarratana	1) March 2009 2) not applicable	0.759 0.822 0.759 0.790	286 310 286 298	0.267 0.267 0.267 0.267	30.06.2009 07.07.2009 13.07.2009 21.07.2009	48 48 49 49	7±1 days	Bulb	0.33 0.39		0 3	
A/SP/F/09/88 Field Spain 2009	Bordeaux mixture 20 NC WG	Onion Recas	1) end February 2) not applicable	0.780 0.836 0.804 0.816	293 313 302 306	0.267 0.267 0.267 0.267	06.08.2009 13.08.2009 20.08.2009 27.08.2009	45 45-46 47-48 48-49	7 days	Bulb	0.83 0.83		0 3	**HR: 0.83** (Mean: 0.81)
A/SP/F/09/88 Field Spain 2009	COC 35 DF	Onion Recas	1) end February 2) not applicable	0.769 0.823 0.825 0.820	288 303 309 308	0.267 0.267 0.267 0.267	06.08.2009 13.08.2009 20.08.2009 27.08.2009	45 45-46 47-48 48-49	7 days	Bulb	0.77 0.79		0 3	
A/SP/F/09/89 Field Spain 2009	Funguran-OH 50WP	Onion Rita	1) 20.02.2009 2) not applicable	0.836 0.811 0.791 0.831	313 304 297 312	0.267 0.267 0.267 0.267	10.07.2009 17.07.2009 23.07.2009 30.07.2009	43-45 45-46 45-47 45-48	7±1 days	Bulb	0.49 0.44 0.48 0.43 0.49		0 1 3 5 6	**HR: 0.49** (Mean: 0.49)
A/SP/F/09/89 Field Spain 2009	CA211 (Champ DP)	Onion Rita	1) 20.02.2009 2) not applicable	0.804 0.833 0.822 0.793	302 313 308 298	0.267 0.267 0.267 0.267	10.07.2009 17.07.2009 23.07.2009 30.07.2009	43-45 45-46 45-47 45-48	7±1 days	Bulb	0.46 0.51 0.44 0.48 0.49		0 1 3 5 6	
A/IT/F/09/90 Field Italy 2009	Copper oxychloride 37.5NC WG	Onion Dorata di Parma	1) 11.05.2009 2) not applicable	0.831 0.773 0.791 0.809	312 290 297 303	0.267 0.267 0.267 0.267	13.07.2009 20.07.2009 27.07.2009 03.08.2009	41 43 47 49	7 days	Bulb	0.66 0.45 0.66 0.55 0.53		0 1 3 5 8	**HR: 0.66**

Trial No./ Location/ EU zone/ Year	**Formulation**	**Commodity/ Variety**	**Date of 1. Sowing or planting 2. Flowering 3. Harvest**	**Application rate**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Interval between applications**	**Portion analyzed**	**Residues [mg/kg]**		**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**	**Overall mean residues (trials in duplicate)**		
														(Mean: 0.615)
A/IT/F/09/90 Field Italy 2009	Funguran-OH 50WP	Onion Dorata di Parma	1) 11.05.2009 2) not applicable	0.782 0.773 0.813 0.796	293 290 305 298	0.267 0.267 0.267 0.267	13.07.2009 20.07.2009 27.07.2009 03.08.2009	41 43 47 49	7 days	Bulb	0.65 0.52 0.57 0.54 0.54		0 1 3 5 8	

A 2.1.3.9 Pepper

Table A 17: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (kg a.i./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, RMS, year)	--	--	--	--	--
cGAP EU (Art. 12, 2018)	4	0.8	7	BBCH 15-89	3
Intended cGAP (5*)	3	1.0	7	BBCH 15-51	10

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

A 2.1.3.9.1 KCA 6.3.19 (Pepper, EUN/EUS)

Comments of zRMS:	Studies are acceptable. They were conducted according to acceptable guidelines and have been used in evaluation. 1. The purpose of this study was to obtain residue data from crops of peppers (RAC fruit) treated with different copper formulations. The trials were performed during the 2009 growing season at nine field sites in northern and southern Europe. The residues found in the control specimens, in the range of 0.23 to 0.81 mg/kg of copper, are assumed to be the background level, i.e. the natural copper content of pepper. In chilli peppers (trial A/IT/F/09/181), copper levels in the control specimens were between 3.13 and 3.28 mg/kg. The limit of quantification (LOQ) for copper in pepper samples was 0.2 mg/kg. The average recoveries obtained from the fortification experiments with copper nitrate solution, were all in the range of 70-110% with a mean recovery of 88.8%. 2. The purpose of this study was to obtain residue data from peppers (RAC fruit) treated with different copper formulations under open field conditions. The trials were performed during the 2010 growing season at three field sites in northern and southern Europe. The levels found in the control specimens, in the range of 0.42 to 0.96 mg/kg of copper, are assumed to be the background level, i.e. the natural copper content of pepper. The limit of quantification (LOQ) for copper in pepper samples was 0.2 mg/kg. The recoveries, obtained from the fortification experiments with copper nitrate solution, were all in the range of 70-110% with a mean recovery of 97.8%.

Reference:	**KCA 6.3.19/01**
Report:	Kreke, N. (2011) Bordeaux Mixture 20 NC WG, Flowbrix SC (Copper oxychloride SC), Funguran-OH 50 WP, Nordox 75 WG, Cuproxat flüssig, Bordeaux Mixture RSR Disperss, Copper Oxychloride 50% WP, Copper hydroxide 25% DF Determination of residues of Copper in peppers (RAC fruit) following four treatments with different Copper formulations under open field conditions in northern and southern Europe in 2009, Report No. C48108
Guideline(s):	Yes, EU Directive 96/68/EC Commission Working Document 7029/VI/95 rev. 5
Deviations:	No
Already evaluated:	Yes, evaluated in Art. 12 (EFSA 2018) and submitted France 2016

	(Evaluation Report, Art. 12.1)
GLP:	Yes
Acceptability:	Yes

and

Reference:	**KCA 6.3.19/02**
Report:	Kreke, N. (2011) Copper oxychloride 50 WP (SU), CA2112 (CHAMP FLO), Flowbrix SC (Copper oxychloride SC), Bordoflow New, ATOFAP17: Determination of residues of Copper in peppers (RAC fruit) following four treatments with different Copper formulations under open field conditions in northern and southern Europe in 2010, Report No. C91062
Guideline(s):	Yes, EU Directive 96/68/EC Commission Working Document 7029/VI/95 rev. 5
Deviations:	No
Already evaluated:	Yes, evaluated in Art. 12 (EFSA 2018) and submitted France 2016 (Evaluation Report, Art. 12.1)
GLP:	Yes
Acceptability:	Yes

For a better overview all trials of both reports were presented together in a single summary table. Please note that some trials are in duplicate. Only values with the most critical level of copper are taken into account.
For further details please refer to EFSA review of the Art. 12 (EFSA 2018) and the Evaluation Report (EFSA 2016) respectively.

The LOQ is 0.2 mg/kg.

Table A 18: Summary of the copper studies in pepper

PPP (product name/code):	**Copper oxide WP** Copper oxychloride WP Bordeaux mixture WP Copper hydroxide WP Tribasic copper sulphate SC	Conc. of as 1:	**75%** **50%** **20%** **50%** **15%**
Crop group:	Pepper	Other a.i. in formulation:	None
Indoor/outdoor:	Outdoor (2009, 2010)	Residues calculated as:	Copper
Applicant:	EU Copper Taskforce		
Zone(s):	N-EU (Hungary, Austria S-EU (France, Spain, Italy)		

Trial No./ Location/ EU zone/ Year	**Formulation**	**Commodity/ Variety**	**Date of 1. Sowing or planting 2. Flowering 3. Harvest**	**Application rate**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Interval between applications**	**Portion analyzed**	**Residues [mg/kg]**		**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					Copper	--		
A/AU/F/09/175 7163 Andau Austria	Bordeaux mixture 20 NC WG	Pepper/Capir	1) 11.05.09 2) From end of June 2009 3) 13.Sep.2009 (3DALA)	0.826 0.796 0.796 0.836		0.133	20.08.09 26.08.09 02.09.09 10.09.09	72 73 81 82	7±1 days	Fruit	2.950 2.360 2.060 1.790 2.160		0 1 3 5 7	**HR: 2.34** (Mean: 2.25)
A/AU/F/09/175 7163 Andau Austria	Flowbrix SC	Pepper/Capir	1) 11.05.09 2) From end of June 2009 3) 13.Sep.2009 (3DALA)	0.812 0.798 0.828 0.824		0.133	20.08.09 26.08.09 02.09.09 10.09.09	72 73 81 82	7±1 days	Fruit	2.860 2.720 2.340 2.030 1.730		0 1 3 5 7	
A/HU/F/09/176 Field Hungary 2009	Funguran-OH 50 WP	Pepper Century	1) 07.05.09 2) From end of June 2009	0.777 0.803 0.764 0.767		0.133	12.08.09 19.08.09 26.08.09 01.09.09	71 72 73 75	7±1 days	Fruit	3.710 3.320		0 3	**HR: 3.32**

Trial No./ Location/ EU zone/ Year	**Formulation**	**Commodity/ Variety**	**Date of 1. Sowing or planting 2. Flowering 3. Harvest**	**Application rate**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Interval between applications**	**Portion analyzed**	**Residues [mg/kg]**		**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					Copper	--		
			3) 04.Sep.2009 (3DALA)											(Mean: 3.07)
A/HU/F/09/176 Field Hungary 2009	Nordox 75WG	Pepper Century	1) 07.05.09 2) From end of June 2009 3) 04.Sep.2009 (3DALA)	0.798 0.835 0.813 0.787		0.133	12.08.09 19.08.09 26.08.09 01.09.09	71 72 73 75	7±1 days	Fruit	3.670 2.820		0 3	
A/HU/F/09/177 Field Hungary 2009	Cuproxat Flüssig	Pepper T 304	1) 20.05.09 2) From end of June 2009 3) 13.Sep.2009 (3DALA)	0.828 0.816 0.819 0.811		0.133	19.08.09 26.08.09 02.09.09 10.09.09	71 73 74-81 81	7±1 days	Fruit	1.200 1.090 1.590 1.410 1.590		0 1 3 5 7	**HR: 1.64** (Mean: 1.62)
A/HU/F/09/177 Field Hungary 2009	Flowbrix SC	Pepper T 304	1) 20.05.09 2) From end of June 2009 3) 13.Sep.2009 (3DALA)	0.828 0.811 0.822 0.838		0.133	19.08.09 26.08.09 02.09.09 10.09.09	71 73 74-81 81	7±1 days	Fruit	1.050 1.440 1.350 1.640 1.630		0 1 3 5 7	
A/HU/F/10/119 Plot 1 9226 Dunasziget Hungary 2010	Copper oxychloride 50 WP (SU)	Pepper/Century	1) 05.05.2010 2) 20.06 to 15. 08.2010 3) 11.Aug.2010	0.805 0.823 0.804 0.837		0.267	16.07.2010 23.07.2010 31.07.2010 08.08.2010	A1-A4: 65; 66; 66; 71 S1: 71 S3: 73	7±1 days	Fruit	1.43 1.12		0 3	**HR: 1.38** (Mean: 1.25)
A.HU.F.10.119 Plot 2 9226 Dunasziget Hungary 2010	CA2112 (CHAMP FLO)	Pepper.Century	1) 05.05.2010 2) 20.06 to 15.08.2010 3) 11.Aug.2010	0.840 0.785 0.785 0.822		0.267	16.07.2010 23.07.2010 31.07.2010 08.08.2010	A1-A4: 65; 66; 66; 71 S1: 71 S3: 73	7±1 days	Fruit	1.64 1.38		0 3	

Trial No./ Location/ EU zone/ Year	**Formulation**	**Commodity/ Variety**	**Date of 1. Sowing or planting 2. Flowering 3. Harvest**	**Application rate**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Interval between applications**	**Portion analyzed**	**Residues [mg/kg]**		**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					Copper	--		
A/SF/F/09/178 Field France-South 2009	Bordeaux mixture RSR Disperss	Pepper Alby	1) 28.04.09 to 02.07.09 2) 20 May to September 2009 3) 03.Sep.2009 (3DALA)	0.820 0.842 0.838 0.809		0.133	10.08.09 17.08.09 24.08.09 31.08.09	62 63 70 71	7±1 days	Fruit	1.780 1.92		0 3	**HR: 1.92** (Mean: 1.58)
A/SF/F/09/178 Field France-South 2009	Copper oxychloride 50% WP	Pepper Alby	1) 28.04.09 to 02.07.09 2) 20 May to September 2009 3) 03.Sep.2009 (3DALA)	0.800 0.829 0.831 0.814		0.133	10.08.09 17.08.09 24.08.09 31.08.09	62 63 70 71	7±1 days	Fruit	1.440 1.240		0 3	
A/SP/F/09/179 Field Spain 2009	Copper hydroxide 25% DF	Pepper Aurelio	1) 24.04.09 2) From middle May 2009 3) 10.Aug.2009 (3DALA)	0.805 0.838 0.825 0.825		0.133	18.07.09 25.07.09 01.08.09 07.08.09	72-73 73-74 74-76 76-78	7±1 days	Fruit	4.430 3.320		0 3	**HR: 3.32** (Mean: 2.97)
A/SP/F/09/179 Field Spain 2009	Nordox 75WG	Pepper Aurelio	1) 24.04.09 2) From middle May 2009 3) 10.Aug.2009 (3DALA)	0.803 0.786 0.838 0.830		0.133	18.07.09 25.07.09 01.08.09 07.08.09	72-73 73-74 74-76 76-78	7±1 days	Fruit	2.790 2.620		0 3	
A/SP/F/09/180 Field Spain 2009	Funguran-OH 50 WP	Pepper Estrada	1) Mid.April 2009 2) From end May 2009	0.780 0.770 0.804 0.785		0.133	16.07.09 24.07.09 31.07.09 07.08.09	72-73 73-74 75 75-77	7±1 days	Fruit	4.590 3.730 2.580 3.020 2.770		0 1 3 5 7	**HR: 3.13** (Mean: 3.075)

Trial No./ Location/ EU zone/ Year	**Formulation**	**Commodity/ Variety**	**Date of 1. Sowing or planting 2. Flowering 3. Harvest**	**Application rate**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Interval between applications**	**Portion analyzed**	**Residues [mg/kg]**		**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					Copper	--		
			3. 10.Aug.2009 (3DALA)											
A/SP/F/09/180 Field Spain 2009	Cuproxat Flüssig	Pepper Estrada	1. Mid.April 2009 2. From end May 2009 3) 10.Aug.2009 (3DALA)	0.813 0.810 0.834 0.793		0.133	16.07.09 24.07.09 31.07.09 07.08.09	72-73 73-74 75 75-77	7±1 days	Fruit	2.760 4.350 3.130 2.620 2.340		0 1 3 5 7	
A/IT/F/09/181 T120060 Mediglia Italy	Bordeaux mixture WG	Chilli pepper Vulcano	1) 30.06.2009 2) End July to end Aug 2009 3) 25.09.2009	0.804 0.798 0.809 0.800			02.09.09 08.09.09 14.09.09 22.09.09	83 85 85 87	7±1 days	Fruit	12.700 13.600 13.000 12.700 5.160		0 1 3 5 7	**HR: 13.4** (Mean: 13.2)
A/IT/F/09/181 T2 20060 Mediglia Italy	Copper oxychloride WP	Chilli pepper Vulcano	1) 30.06.2009 2) End July to end Aug 2009 3) 25.09.2009	0.789 0.805 0.789 0.802			02.09.09 08.09.09 14.09.09 22.09.09	83 85 85 87	7±1 days	Fruit	10.900 11.400 12.600 13.400 8.310		0 1 3 5 7	
A/IT/F/09/182 Field Italy 2009	Copper hydroxide 25% DF	Pepper Ragazzo	1) 21 May 2009 2) From 10 June 2009 3) 27.Aug.2009 (3DALA)	0.806 0.802 0.790 0.821		0.133	03.08.09 10.08.09 17.08.09 24.08.09	73 75 77 81	7±1 days	Fruit	2.650 2.700		0 3	**HR: 2.7** (Mean: 2.22)
A/IT/F/09/182 Field Italy 2009	Nordox 75WG	Pepper Ragazzo	1) 21 May 2009 2) From 10 June 2009 3) 27.Aug.2009 (3DALA)	0.802 0.814 0.802 0.821		0.133	03.08.09 10.08.09 17.08.09 24.08.09	73 75 77 81	7±1 days	Fruit	3.910 1.740		0 3	

Trial No./ Location/ EU zone/ Year	**Formulation**	**Commodity/ Variety**	**Date of 1. Sowing or planting 2. Flowering 3. Harvest**	**Application rate**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Interval between applications**	**Portion analyzed**	**Residues [mg/kg]**		**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					Copper	--		
A/IT/F/09/183 Field Italy 2009	Funguran-OH 50 WP	Pepper Palio	1) 26 May 2009 2) 15 June to September 2009 3) 24.Aug.2009 (3DALA)	0.817 0.795 0.809 0.809		0.133	31.07.09 07.08.09 13.08.09 21.08.09	74 75 78 81	7±1 days	Fruit	2.340 2.800 2.990 2.170 2.120		0 1 3 5 7	**HR: 3.57** (Mean: 3.28)
A/IT/F/09/183 Field Italy 2009	Cuproxat Flüssig	Pepper Palio	1) 26 May 2009 2) 15 June to September 2009 3) 24.Aug.2009 (3DALA)	0.808 0.793 0.767 0.808		0.133	31.07.09 07.08.09 13.08.09 21.08.09	74 75 78 81	7±1 days	Fruit	3.710 4.040 2.180 3.570 2.150		0 1 3 5 7	
A.SP.F.10.120 Plot 1 12580 Benicarló Spain 2010	Flowbrix SC (Copper oxychloride SC)	Pepper.Estrada	1) middle April (transplanting) 2) middle May to end September 3) 02.Aug.2010	0.786 0.764 0.816 0.757		0.267	09.07.2010 15.07.2010 22.07.2010 30.07.2010	A1-A4: 72; 72; 73; 74 S1: 74 S2: 74 S3: 74-75 S4: 74-75 S5: 75	7±1 days	Fruit	2.69 2.95 2.61 2.11 2.18		0 1 3 5 6	**HR: 4.13** (Mean: 3.37)
A.SP.F.10.120 Plot 2 12580 Benicarló Spain 2010	Bordoflow New	Pepper.Estrada	1) middle April (transplanting) 2) middle May to end September 3) 02.Aug.2010	0.804 0.769 0.766 0.756		0.267	09.07.2010 15.07.2010 22.07.2010 30.07.2010	A1-A4: 72; 72; 73; 74 S1: 74 S2: 74 S3: 74-75 S4: 74-75 S5: 75	7±1 days	Fruit	4.11 3.74 4.13 2.10 2.89		0 1 3 5 6	
A.IT.F.10.121 Plot 1 95121 Catania Sicilia	Flowbrix SC (Copper	Pepper.Adina	1) 12.07.2010 2) 01.08.2010 (continuous)	0.744 0.799 0.788 0.799		0.267	31.08.2010 07.09.2010 14.09.2010 21.09.2010	A1-A4: 69; 69; 75; 77 S1: 77-81 S3: 79-85	7 days	Fruit	6.01 4.79		0 3	**HR: 4.79**

Trial No./ Location/ EU zone/ Year	**Formulation**	**Commodity/ Variety**	**Date of 1. Sowing or planting 2. Flowering 3. Harvest**	**Application rate**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Interval between applications**	**Portion analyzed**	**Residues [mg/kg]**		**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					Copper	--		
Italy 2010	oxychloride SC)		3) 24.Sep.2010											(Mean: 4.68)
A.IT.F.10.121 Plot 2 95121 Catania Sicilia Italy 2010	ATOFAP17	Pepper.Adina	1) 12.07.2010 2) 01.08.2010 (continuous) 3) 24.Sep.2010	0.778 0.800 0.789 0.844		0.267	31.08.2010 07.09.2010 14.09.2010 21.09.2010	A1-A4: 69; 69; 75; 77 S1: 77-81 S3: 79-85	7 days	Fruit	6.32 4.57		0 3	

A 2.1.3.10 Lettuce and similar

Table A 19: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (kg a.i./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, RMS, year)	--	--	--	--	--
cGAP EU (Art. 12, 2018)	4	0.8	7	BBCH 12-49	7
Intended cGAP (Use 7*)	3	1.0	7	BBCH 12-49	3

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

A 2.1.3.10.1 KCA 6.3.21 (Lettuce, EUS)

Comments of zRMS:	Studies are acceptable. They were conducted according to acceptable guidelines.

Reference:	**KCA 6.3.21/01**
Report:	Kreke, N. (2011) ATOFAP17, CA2112 (CHAMP FLO), Copper oxychloride 50 WP (SU), Bordoflow New Determination of residues of Copper in lettuce (RAC whole plant without roots) following four treatments with different Copper formulations under open field conditions in southern Europe in 2009, Report No. C48064
Guideline(s):	Yes, EU Directive 96/68/EC Commission Working Document 7029/VI/95 rev. 5
Deviations:	No
Already evaluated:	Yes, evaluated in Art. 12 (EFSA 2018) and submitted France 2016 (Evaluation Report, Art. 12.1)
GLP:	Yes
Acceptability:	Yes

and

Reference:	**KCA 6.3.21/02**
Report:	Kreke, N. (2012) Bordeaux Mixture 20 NC WG, Copper hydroxide 25% DF, Flowbrix SC (Copper oxychloride SC), Copper hydroxide 40% WG: Determination of residues of Copper in lettuce (RAC whole plant without roots) following four treatments with different Copper formulations under open field conditions in southern Europe in 2010, Report No. C91040
Guideline(s):	Yes, EU Directive 96/68/EC Commission Working Document 7029/VI/95 rev. 5

Deviations:	No
Already evaluated:	Yes, evaluated in Art. 12 (EFSA 2018) and submitted France 2016 (Evaluation Report, Art. 12.1)
GLP:	Yes
Acceptability:	Yes

and

Reference:	**KCA 6.3.21/03**
Report:	Sicbaldi, F. (2005) Copper residue levels on lettuce (open field) after four applications of copper oxychloride 37.5 WG. A decline study in Northern Italy in 2005, Report No. RA.05.14
Guideline(s):	Directive 91/414/EEC (Annex II part A, section 6 and Annex III, part A, section 8). Commission of the European Communities, Directorate-General for Agriculture, VI, B II-1 1607/VI/97 rev.2 10/6/1999
Deviations:	Yes (refer to EFSA 2016 (ER)
GLP:	Yes
Acceptability:	Yes

and

Reference:	**KCA 6.3.21/04**
Report:	Sicbaldi, F. (2005) Copper residue levels on lettuce (open field) after four applications of copper oxychloride 37.5 WG. A decline study in Southern Italy in 2005, Report No. RA.05.15
Guideline(s):	Directive 91/414/EEC (Annex II part A, section 6 and Annex III, part A, section 8). Commission of the European Communities, Directorate-General for Agriculture, VI, B II-1 1607/VI/97 rev.2 10/6/1999
Deviations:	Yes (refer to EFSA 2016 (ER)
GLP:	Yes
Acceptability:	Yes

For a better overview all trials of all reports were presented together in a single summary table. Please note that some trials are in duplicate. Only values with the most critical level of copper are taken into account. For further details please refer to EFSA review of the Art. 12 (EFSA 2018) and the Evaluation Report (EFSA 2016) respectively.

The LOQ is 0.2 mg/kg.

Table A 20: Summary of the copper studies in beans (with pods)???

PPP (product name/code):	**Copper oxide WP** Copper oxychloride WP Bordeaux mixture WP Copper hydroxide WP Tribasic copper sulphate SC	Conc. of as 1:	**75%** **50%** **20%** **50%** **15%**
Crop group:	Lettuce	Other a.i. in formulation:	None
Indoor/outdoor:	Outdoor (2009, 2010)	Residues calculated as:	Copper
Applicant:	EU Copper Taskforce		
Zone(s):	S-EU (France, Spain, Italy)		

Trial No./ Location/ EU zone/ Year	**Formulation**	**Commodity/ Variety**	**Date of 1. Sowing or planting 2. Flowering 3. Harvest**	**Application rate**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Interval between applications**	**Portion analyzed**	**Residues [mg/kg]**		**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					Copper	--		
A/SF/F/09/150 Plot 1 PACA 13160 Châteaurenard	Bordoflow new	Lettuce Lollo Rossa (open leaf variety)	1) 01.09.09	0.796 0.838 0.851 0.833			04.11.2009 10.11.2009 18.11.2009 25.11.2009	45 46 47 48	7±1 days	Whole plant without roots Washed	68.9 80.0 42.4 66.0 64.2 37.2		0 3 5 **7** 14 7	**HR: 66.0** (mean: 48.58)
A/SF/F/09/150 Plot 2 PACA 13160 Châteaurenard	Copper oxychloride 50 WP (SU)	Lettuce Lollo Rossa (open leaf variety)	1) 01.09.09	0.827 0.829 0.807 0.814			04.11.2009 10.11.2009 18.11.2009 25.11.2009	45 46 47 48	7±1 days	Whole plant without roots Washed	48.8 65.5 38.9 41.9 40.4 33.2		0 3 5 7 14 7	

Trial No./ Location/ EU zone/ Year	**Formulation**	**Commodity/ Variety**	**Date of 1. Sowing or planting 2. Flowering 3. Harvest**	**Application rate**			**Dates of treatment or no. of treatments and last date**	**Growth stage at last treatment or date**	**Interval between applications**	**Portion analyzed**	**Residues [mg/kg]**		**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					Copper	--		
A/SF/F/09/151 Plot 1 PACA 13160 Châteaurenard	CA2112 (CHAMP FLO)	Lettuce/Feuille de chêne rouge	1) 18.09.09	0.826 0.853 0.774 0.841			04.11.2009 10.11.2009 18.11.2009 25.11.2009	16 18 19 50	7±1 days	Whole plant without roots Washed	41.0 30.1 24.6		0 7 7	
A/SF/F/09/151 Plot 2 PACA 13160 Châteaurenard	ATOFAP17	Lettuce/Feuille de chêne rouge	1) 18.09.09	0.849 0.842 0.804 0.822			04.11.2009 10.11.2009 18.11.2009 25.11.2009	16 18 19 50	7±1 days	Whole plant without roots Washed	62.0 56.3 37.7		0 7 7	
A/SP/F/09/152 Plot 1 Spain Valencia 12580 Benicarló	Bordoflow new	Lettuce/ Cervantes	1) 06.09.09	0.809 0.769 0.776 0.773			22.09.2009 01.10.2009 07.10.2009 14.10.2009	42 43 45-46 47-48	7±1 days	Whole plant without roots	14.3 9.08		0 6	**HR: 9.08** (Mean: 14.18)
A/SP/F/09/152 Plot 2 Spain Valencia 12580 Benicarló	Copper oxychloride 50 WP (SU)	Lettuce/ Cervantes	1) 06.09.09	0.782 0.818 0.822 0.771			22.09.2009 01.10.2009 07.10.2009 14.10.2009	42 43 45-46 47-48	7±1 days	Whole plant without roots	13.4 5.10		0 6	
A/IT/F/09/153 Plot 1 Italy Lombardia 20090 Caleppio di Settala	CA2112 (CHAMP FLO)	Lettuce Gentiuna (open leaf variety)	1) 07.08.09	0.815 0.815 0.824 0.819			13.08.2009 20.08.2009 27.08.2009 02.09.2009	35 37 41 47/79	7±1 days	Whole plant without roots	49.7 41.0 29.0 22.4 2.71		0 3 5 **7** 14	**HR: 22.4** (Mean: 20.2)
A/IT/F/09/153 Plot 2 Italy Lombardia 20090 Caleppio di Settala	ATOFAP17	Lettuce Gentiuna (open leaf variety)	1) 07.08.09	0.836 0.813 0.809 0.791			13.08.2009 20.08.2009 27.08.2009 02.09.2009	35 37 41 47/79	7±1 days	Whole plant without roots	26.0 38.0 22.0 18.0 4.85		0 3 5 7 14	

Trial No./ Location/ EU zone/ Year	Formulation	Commodity/ Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest	Application rate			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Interval between applications	Portion analyzed	Residues [mg/kg]		PHI [days]	Selected values
				kg a.s./ ha	Water [l/ha]	kg a.s./hl					Copper	--		
A/SF/F/10/112 Plot 1 Provence-Alpes-Côte d'Azur, 13160 Châteaurenard	Bordeaux Mixture 20 NC WG	Lettuce Murai (open leaf variety)	1) 30.08.2010 (seeding) 10.09.2010 (transplanting)	0.756 0.820 0.804 0.813			14.10.2010 21.10.2010 27.10.2010 04.11.2010	35 37 46 47	7±1 days	Whole plant without roots	69.1 51.1 47.4 36.5 24.1		0 3 5 **7** 14	**HR: 36.5** (mean: 31.05)
A/SF/F/10/112 Plot 2 Provence-Alpes-Côte d'Azur, 13160 Châteaurenard	Copper hydroxide 25% DF	Lettuce Murai (open leaf variety)	1) 30.08.2010 (seeding) 10.09.2010 (transplanting)	0.756 0.833 0.796 0.785			14.10.2010 21.10.2010 27.10.2010 04.11.2010	35 37 46 47	7±1 days	Whole plant without roots	58.5 42.8 37.5 25.6 13.9		0 3 5 7 14	
A/IT/F/10/113 Plot 1 Italy Lombardia 20060 Bellinzago Lombardo	Flowbrix SC (Copper oxychloride SC)	Lettuce/Canasta	1) 10.09.2010 (transplanting)	784 816 810 790			06.10.2010 13.10.2010 20.10.2010 27.10.2010	42 43 45 47	7±1 days	Whole plant without roots	33.0 11.7		0 7	**HR: 11.7** (mean: 11.3)
A/IT/F/10/113 Plot 2 Italy Lombardia 20060 Bellinzago Lombardo	Copper hydroxide 40% WG	Lettuce/Canasta	1) 10.09.2010 (transplanting)	784 816 810 790			06.10.2010 13.10.2010 20.10.2010 27.10.2010	42 43 45 47	7±1 days	Whole plant without roots	25.4 10.9		0 7	
RA.05.14 1D Lusia (RO)-I-40026 Italy	Copper oxychloride WG	Lettuce Trocadero	1) 23.06.2005 3) 18, to 28.07.2005	594 609 569 625	792 813 758 833		27.06.05 04.07.05 11.07.05 18.07.05	41 42 44 44-46	7±1 days	Head lettuce	21.9 20.35 3.22 <LOQ		0 3 7 10	**3.22**
RA.05.15 1D Siracusa-I-96100 Italy	Copper oxychloride WG	Lettuce Patagonia	1) 12.02.2005 2) 21 to 28.04.2005 & 01.05.2005	604 615 611 608	805 820 815 810		29.03.05 07.04.05 14.04.05 21.04.05	41 43 45 47-48	7±1 days	lettuce	2.45 1.26 2.03 <LOQ		0 3 7 10	**2.03**

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

Not relevant. No new study is submitted for the evaluation of the product.

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

A 2.1.5.1 Distribution of the residue in peel/pulp

Not relevant. No new study is submitted for the evaluation of the product.

A 2.1.5.2 Processing studies on a core set of representative processes

Not relevant. No new study is submitted for the evaluation of the product.

A 2.1.6 Magnitude of residues in representative succeeding crops

Not relevant. No new study is submitted for the evaluation of the product.

A 2.1.7 Other/Special Studies

Not relevant.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations (all crops) – Tier I

efsa
European Food Safety Authority
EFSA PRIMo revision 3.1; 2021/01/06

Copper

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.15	ARfD (mg/kg bw):	insert valid entry
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

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

omments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 1

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exp MRLs the L (in % of
119%	NL toddler	178.12	11%	Maize/corn	11%	Spinaches	11%	Wheat	
79%	GEMS/Food G10	118.78	26%	Soyabeans	11%	Wheat	5%	Lettuces	
78%	GEMS/Food G11	117.28	30%	Soyabeans	10%	Wheat	3%	Coffee beans	
76%	GEMS/Food G06	114.01	20%	Wheat	10%	Soyabeans	5%	Table grapes	
74%	GEMS/Food G07	110.57	14%	Soyabeans	12%	Wheat	8%	Bovine: Liver	
72%	NL child	108.43	11%	Wheat	7%	Sugar beet roots	5%	Apples	
69%	GEMS/Food G08	104.11	16%	Soyabeans	11%	Wheat	6%	Sunflower seeds	
66%	GEMS/Food G15	99.43	14%	Soyabeans	13%	Wheat	7%	Sunflower seeds	
63%	FI adult	95.23	52%	Coffee beans	2%	Lettuces	2%	Rye	
63%	DE child	95.04	12%	Apples	12%	Wheat	7%	Table grapes	
58%	IE adult	87.56	14%	Sheep: Liver	6%	Wheat	4%	Sweet potatoes	
52%	FR child 3 15 yr	78.15	13%	Wheat	4%	Milk: Cattle	3%	Sugar beet roots	
48%	DK child	71.55	13%	Rye	12%	Wheat	2%	Apples	
44%	ES child	66.40	12%	Wheat	6%	Lettuces	3%	Poultry: Muscle/meat	
42%	RO general	63.36	14%	Wheat	8%	Sunflower seeds	2%	Tomatoes	
42%	FR toddler 2 3 yr	62.52	8%	Wheat	5%	Milk: Cattle	3%	Apples	
39%	IT toddler	58.66	18%	Wheat	4%	Lettuces	4%	Other cereals	
37%	NL general	56.03	5%	Wheat	3%	Coffee beans	3%	Sunflower seeds	
37%	UK infant	55.25	7%	Wheat	6%	Milk: Cattle	5%	Bovine: Liver	
37%	UK toddler	55.16	11%	Wheat	4%	Beans	3%	Milk: Cattle	
36%	DE women 14-50 yr	53.40	6%	Wheat	4%	Coffee beans	4%	Sugar beet roots	
35%	DE general	52.37	5%	Wheat	4%	Coffee beans	4%	Sugar beet roots	
34%	PT general	51.47	11%	Wheat	4%	Sunflower seeds	3%	Potatoes	
34%	SE general	50.98	9%	Wheat	6%	Lettuces	3%	Bovine: Muscle/meat	
32%	ES adult	48.55	8%	Lettuces	6%	Wheat	1%	Poultry: Muscle/meat	
31%	IT adult	47.11	11%	Wheat	6%	Lettuces	2%	Other lettuce and other salad plants	
28%	FR adult	41.65	6%	Wheat	4%	Coffee beans	2%	Other lettuce and other salad plants	
22%	FI 3 yr	32.85	3%	Wheat	3%	Potatoes	2%	Oat	
19%	FR infant	28.43	4%	Spinaches	3%	Milk: Cattle	2%	Wheat	
19%	UK vegetarian	28.42	6%	Wheat	2%	Lettuces	2%	Beans	
19%	FI 6 yr	28.00	3%	Wheat	2%	Potatoes	1%	Rye	
18%	LT adult	27.04	3%	Wheat	3%	Rye	2%	Potatoes	
17%	UK adult	25.43	5%	Wheat	2%	Lettuces	1%	Beans	
15%	DK adult	22.95	3%	Wheat	1%	Lettuces	1%	Rye	
10%	PL general	14.30	2%	Potatoes	2%	Apples	2%	Table grapes	
7%	IE child	10.47	3%	Wheat	0.6%	Milk: Cattle	0.5%	Rice	

A 3.2 TMDI calculations (all crops) – Tier II

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Copper

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.15	ARfD (mg/kg bw):	insert valid entry
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details - chronic risk assessment | Supplementa… chronic risk a…

Details - acute risk assessment/children | Details - a… assessme…

mments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities
93%	NL toddler	138.94	11%	Maize/corn	11%	Wheat	10%	Milk: Cattle
72%	GEMS/Food G11	107.26	30%	Soyabeans	10%	Wheat	3%	Coffee beans
71%	GEMS/Food G10	107.11	26%	Soyabeans	11%	Wheat	3%	Poultry: Muscle/meat
69%	GEMS/Food G06	103.31	20%	Wheat	10%	Soyabeans	4%	Tomatoes
68%	GEMS/Food G07	101.34	14%	Soyabeans	12%	Wheat	8%	Bovine: Liver
63%	GEMS/Food G08	94.59	16%	Soyabeans	11%	Wheat	6%	Sunflower seeds
63%	GEMS/Food G15	93.81	14%	Soyabeans	13%	Wheat	7%	Sunflower seeds
61%	FI adult	90.89	52%	Coffee beans	2%	Rye	0.9%	Wheat
59%	NL child	88.12	11%	Wheat	7%	Sugar beet roots	5%	Sunflower seeds
54%	IE adult	80.88	14%	Sheep: Liver	6%	Wheat	4%	Sweet potatoes
46%	FR child 3 15 yr	69.63	13%	Wheat	4%	Milk: Cattle	3%	Sugar beet roots
46%	DE child	68.72	12%	Wheat	4%	Apples	3%	Oranges
44%	DK child	65.31	13%	Rye	12%	Wheat	2%	Milk: Cattle
41%	RO general	60.93	14%	Wheat	8%	Sunflower seeds	2%	Tomatoes
37%	FR toddler 2 3 yr	55.38	8%	Wheat	5%	Milk: Cattle	2%	Bovine: Liver
37%	ES child	54.89	12%	Wheat	3%	Poultry: Muscle/meat	2%	Milk: Cattle
35%	UK infant	53.20	7%	Wheat	6%	Milk: Cattle	5%	Bovine: Liver
34%	UK toddler	50.94	11%	Wheat	4%	Beans	3%	Milk: Cattle
32%	IT toddler	47.48	18%	Wheat	4%	Other cereals	2%	Tomatoes
31%	PT general	46.69	11%	Wheat	4%	Sunflower seeds	3%	Potatoes
31%	NL general	46.06	5%	Wheat	3%	Coffee beans	3%	Sunflower seeds
30%	DE women 14-50 yr	45.31	6%	Wheat	4%	Coffee beans	4%	Sugar beet roots
30%	DE general	45.20	5%	Wheat	4%	Coffee beans	4%	Sugar beet roots
27%	SE general	40.23	9%	Wheat	3%	Bovine: Muscle/meat	2%	Potatoes
24%	FR adult	35.46	6%	Wheat	4%	Coffee beans	1%	Sunflower seeds
23%	ES adult	35.06	6%	Wheat	1%	Poultry: Muscle/meat	1%	Barley
21%	IT adult	32.20	11%	Wheat	2%	Other cereals	1%	Tomatoes
19%	FI 3 yr	28.14	3%	Wheat	3%	Potatoes	2%	Oat
16%	LT adult	23.92	3%	Wheat	3%	Rye	2%	Potatoes
16%	UK vegetarian	23.73	6%	Wheat	2%	Beans	0.8%	Potatoes
16%	FI 6 yr	23.26	3%	Wheat	2%	Potatoes	1%	Rye
15%	UK adult	21.94	5%	Wheat	1%	Beans	1.0%	Poultry: Muscle/meat
14%	FR infant	21.22	3%	Milk: Cattle	2%	Wheat	1%	Sugar beet roots
13%	DK adult	18.90	3%	Wheat	1%	Rye	0.8%	Milk: Cattle
7%	PL general	10.20	2%	Potatoes	1%	Tomatoes	0.7%	Apples
6%	IE child	9.59	3%	Wheat	0.6%	Milk: Cattle	0.5%	Rice

A 3.3 IEDI calculations

Not required as the TMDI does not exceed the ADI

A 3.4 IESTI calculations - Raw commodities

Not required as an ARfD for Copper has not been set

A 3.5 IESTI calculations - Processed commodities

Not required as an ARfD for Copper has not been set

Appendix 4 Additional information provided by the applicant

None.