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

Interzonal

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
31/03/2021	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 RMS PL
03/2023	Amended zRMS version after comments.

Table of Contents

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 indoor zone for strawberries, fruiting vegetables (tomatoes, eggplant, pepper), cucumber, lettuce and similar, A list of all intended uses within the indoor zone is given in Part B, Section 0.

Overall conclusion

Although the applicant states that "trials used for the calculations (resulted in an unrounded MRL exceeding the existing MRL of 5 mg/kg) are identical to those evaluated under Art. 12 of regulation (EC) No. 396/2005 (EFSA, 2018), in which an MRL of 15 mg/kg is proposed for strawberries" and that "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)", the simple fact is that the MRLs currently in force according to the results of the trials can be expected to be exceeded. Pepper shows a similar issue. Thus, these uses until the MRL change cannot be approved.
For tomatoes (eggplants) (DAR 2007) ~~and peppers~~ trials results were below the relevant MRLs (5 mg/kg). No cucumber and courgettes in the DAR 2007, however the existing relevant residue data are unprotected as submitted in EU in 2011 on the renewal and available then in the RAR (reference EFSA 2018 in table 7.2-3 is misleading; see RAR 2016 for CA 6.3.5-01-02, Kreke N., 2011, see References here). Thus, the approval can be granted. Also, the trials submitted here for lettuce are sufficient. An exceedance of the current MRL of Copper as laid down in Reg. (EU) 396/2005 for lettuces etc. and Cucurbitaceae is not expected.

The necessary for the evaluation excerpts from the DAR 2007 are presented below.
B.7.6.1.3 Field grown crops for processing (industrial tomatoes)
A total of 17 trials in industrial **tomatoes** were carried out in southern France, Spain and Italy over five seasons (1997, 1998, 1999, 2001 and 2002).

B.7.6.1.4 Field grown crops for fresh consumption
A total of 10 trials in **field grown tomatoes** for fresh consumption were carried out in southern France, Spain, and Italy over two seasons (2001 and 2002).

B.7.6.1.5 Indoor protected grown crops for fresh consumption
A total of 10 trials in **indoor** protected grown **tomatoes** for fresh consumption were carried out in southern France, Spain, and Italy over two seasons (2001 and 2002). Two forms of copper were applied at each site. There were six or eight applications at all sites. Six applications are recommended according to the GAP. However, an increase in the number of applications from six to eight (+ 33%) although slightly more than the + 25% considered to give comparable residues according to Commission Directive 7525/VI/95 rev 5,

is not likely to affect residue levels. Application rates were equal to the maximum recommended rate according to the GAP for each copper form or higher at each site. At some sites the application rate for tribasic copper sulphate, Bordeaux Mixture, copper hydroxide or copper oxychloride varied at the different timings (i.e. sites AF/6549/CU1, 4 and 5). In these trials, the last four of the six applications were applied according to the GAP rate. Thus, the trials are considered to conform to the GAP since according to Commission Directive 7525/VI/95 rev 5, it is generally the last application prior to harvest that is crucial to residue behaviour in the treated crop.
Residue decline was measured at five sites (10 observations). Residues of copper were 1.7 to 3.9 mg/kg immediately after the final spray and changed little with time after application, ranging from 1.6 to 4.2mg/kg after 3 days. Residues at all sites at PHI 3 days (20 observations) were 0.92 to 4.2 mg/kg.
Applications were made according to the GAP rate for copper oxide at four sites, for tribasic copper sulphate and copper hydroxide at two sites, and for Bordeaux Mixture and copper oxychloride at one site each. At these sites (10 observations) residues at harvest (PHI 3 days) were 0.92 to 2.7mg/kg.
In four trials in 2002 where the two copper forms were applied according to the GAP (sites AF/6549/CU1, 3, 4 and 5), residue levels following both forms were very similar. Copper was present in untreated crops in the range 0.34 to 0.81mg/kg. The results are presented in Table 7.6.1.5-1 (decline studies) and Table 7.6.1.5-2 (harvest studies).

Table 7.6.1.5-1. Residues of copper in indoor protected tomatoes grown for fresh consumption in southern EU following applications of copper formulations: decline 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				
Spain; 2001 AF/5988/CU1	WP; 500 g/kg; hydroxide	8	1.91-2.07	0.20	fruit	0- 0+ 3	2.0 2.2 2.1	Brereton 2002 (2 mg/kg)
	WP; 200 g/kg; Bordeaux mixture	8	1.90-2.06	0.20	fruit	0- 0+ 3	<2 (1.0) 2.0 2.4	
Spain; 2001 AF/5988/CU2	WP; 750 g/kg; oxide	8	1.01-1.19	0.11	fruit	0- 0+ 3	2.2 <2 (1.7) <2 (1.6)	
	WP; 200 g/kg; Bordeaux mixture	8	2.00-2.15	0.20	fruit	0- 0+ 3	<2 (1.5) <2 (1.9) 2.0	
Italy; 2001 AF/5988/CU3	WP; 750 g/kg; oxide	8	1.13-1.14	0.11	fruit	0- 0+ 3	3.0 3.4 2.7	
	WP; 500 g/kg; oxychloride	8	2.01-2.09	0.20	fruit	0- 0+ 3	<2 (1.5) 3.9 4.2	

Italy; 2001 AF/5988/CU4	SC;189 g/L; tribasic copper sulphate	8	1.56- 1.71	0.16	fruit	0- 0+ 3	4.8 3.9 3.4	
	WP; 500 g/kg; oxychloride	8	2.01- 2.09	0.19- 0.21	fruit	0- 0+ 3	<2 (1.5) <2 (1.8) 4.0	
S.France; 2001 AF/5988/CU5	WP; 500 g/kg; hydroxide	8	1.89- 2.10	0.20	fruit	0- 0+ 3	<2 (1.2) 2.7 2.1	
	SC;189 g/L; tribasic copper sulphate	8	1.51- 1.76	0.16	fruit	0- 0+ 3	3.7 2.9 3.2	

Copper was present in untreated crops at all sampling times in the range 0.34 to 0.81 mg/kg.

Table 7.6.1.1.5-2. Residues of copper in indoor protected tomatoes grown for fresh consumption in southern 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				
S.France; 2002 AF/6549/CU1	WP; 750 g/kg; oxide	6	1.11-1.19	0.11-0.23	fruit	3	<2 (1.0)	Martin 2003c (2 mg/kg)
	SC;189 g/L; tribasic copper sulphate	6	0.80-1.62 (0.80*)	0.11-0.27	fruit	3	<2 (1.0)	
Italy; 2002 AF/6549/CU2	WP; 200 g/kg; Bordeaux mixture	8	1.99-2.07	0.20	fruit	3	2.5	
	WP; 500 g/kg; oxychloride	8	2.00-2.06	0.20	fruit	3	<2 (1.6)	
Italy; 2002 AF/6549/CU3	WP; 500 g/kg; hydroxide	6	1.23-1.37	0.25	fruit	3	<2 (0.92)	
	WP; 750 g/kg; oxide	6	1.03-1.17	0.22-0.23	fruit	3	<2 (1.0)	
Spain; 2002 AF/6549/CU4	WP; 500 g/kg; oxychloride	6	1.24-2.03 (1.24-1.29*)	0.20-0.25	fruit	3	2.0	
	WP; 500 g/kg; hydroxide	6	1.17-2.08 (1.17 - 1.28*)	0.20-0.25	fruit	3	2.0	
Spain; 2002 AF/6549/CU5	SC;189 g/L; tribasic copper sulphate	6	0.74-1.62 (0.72-0.78*)	0.16	fruit	3	<2 (1.6)	
	WP; 200 g/kg; Bordeaux mixture	6	1.17-2.00 (1.16-1.25*)	0.20-0.25	fruit	3	2.0	

* Application rate at last four application timings at sites where variable application rates were applied.
Copper was present in untreated crops at all sampling times in the range 0.47 to 0.70 mg/kg.

The necessary for the evaluation Cucurbitaceae data after the DAR 2007, from years 2006-2011, reported in the RAR 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

MRLs currently in force:

Code	Products to which MRLs apply	Copper compounds (Copper) Reg. (EC) No 149/2008 applicable
152000	(b) strawberries	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
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 uses consistently with the GAP in table 7.1-1.
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		
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
4	PL	Strawberry	G	*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	MRL exceedance: 5.46, 6.12
5	PL	Tomato Eggplant ~~Pepper~~	G	*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	
7	PL	Lettuce Scarole	G	*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~~ 7	
8	PL	Cucumber Courgettes	G	*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	

* 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 - Greenhouse

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	Strawberry	Yes	Yes (8x)	Yes	Yes	No***	No	No
2	Tomato, eggplant	Yes	Yes** (4x EU + 9x NEU + 5x SEU)	Yes	Yes	~~No~~*** Yes		No
2	Pepper	Yes	Yes (9x pepper)	Yes	Yes	No***		No
3	Lettuce and similars	Yes	Yes (8x lettuce)	Yes	Yes	~~No~~*** Yes		
4	Cucurbits (edible peel)	Yes	Yes (4 x cucumber, 8x courgettes)	Yes	Yes	Yes		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, 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 Copper compound	PHI for Nordox 75 WG proposed by zRMS	zRMS Comments (if different PHI proposed)
Strawberry	3	Yes		
Tomato, eggplant	10	Yes		
Tomato processing	10	Yes		
Pepper	10	Yes		
Lettuce and similars	3 (-7)	Yes	7	supported
Cucumber	3	Yes		

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

Table 7.1-5: Waiting periods before planting succeeding crops

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.

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

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).

Base 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 be not 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 (Appendix D1) 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

No new study on the magnitude of residue has been submitted by the applicant in the framework of this application. However, summary tables of crops which are not already EU evaluated are presented in Appendix 2.
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
Strawberry (0152000)	EFSA 2018 (Art. 12)	EU	**GAP: 4x 0.8 kg a.i./ha, 7day interval, BBCH 13-85, PHI 3** E/RA (HR): 0.54, 1.39, 1.58, 1.63, 2.95, 3.81, 5.46, 6.12	0.14 – 1.23	N/A				
	Overall supporting data for cGAP	EU	**GAP: 4x0.75 kg a.i./ha, 7day interval, BBCH 13-85, PHI 3** E/RA (HR): 0.54, 1.39, 1.58, 1.63, 2.95, 3.81, 5.46, 6.12	--	2.29	6.12	11.069	5 (Art. 12 proposed 15)	No
~~Tomato~~ ** ~~(0231010)~~	~~DAR 2007 EFSA 2018 (Art. 12)~~	~~EU~~	~~**GAP: 6x 1.25 kg a.i./ha, 7day interval, BBCH 13-85, PHI 3**~~ ~~E/RA (HR): 1.0, 1.0, 2.0, 2.0~~	--	N/A				
		~~N-EU~~	~~**GAP: 6x 1.25 kg a.i./ha, 7day interval, BBCH 13-85, PHI 3**~~ ~~E/RA (HR): 0.70, 1.50, 1.60, 1.60, 1.70, 1.70, 2.20, 4.30, 6.60~~	--					

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
		S-EU	**GAP: 6x 1.25 kg a.i./ha, 7day interval, BBCH 13-85, PHI 3** E/RA (HR): 1.70, 2.30, 2.50, 2.90, 3.70	--					
~~→ extrapolated to Tomato (0231010) and eggplant (0211030)~~	~~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
		~~S+N-EU~~ ~~EU (indoor)~~	~~**GAP: 5x1.0 kg a.i./ha, 7day interval, BBCH 15-89, PHI 3**~~ ~~E/RA (HR): 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	6.60	7.907	5 (Art. 12 proposed 10)	No
Pepper (0231020)	EFSA 2018 (Art. 12)	EU	**GAP: 4x 0.8 kg a.i./ha, Interval 7 days, BBCH 15-89, PHI 3 days** EU: 1.08, 1.38, 1.52, 1.53, 2.04, 2.94, 3.79, 3.91, 3.92	0.14 – 0.81	N/A				
	Overall supporting data for cGAP	EU	**GAP: 4x0.75 kg a.i/ha, 7day interval, BBCH 15-89, PHI 3** E/RA (HR): 1.08, 1.38, 1.52, 1.53, 2.04, 2.94, 3.79, 3.91, 3.92	--	2.04	3.92	7.343	5 (Art. 12 proposed 20)	No
Cucumber (0232010)	EFSA 2018 (Art. 12)	EU	**GAP: 5x1.0 kg a.i/ha, 7day interval, BBCH 15-89, PHI 3** E/RA (HR): < 2.0, < 2.0, < 2.0, < 2.0		N/A				
Courgettes (0232030)			**GAP: 5x1.0 kg a.i/ha, 7day interval, BBCH 15-89, PHI 3** E/RA (HR): 0.70, 0.78, 1.10, 1.70, 2.20, 2.50, 2.60, 3.30	0.21 – 0.58	N/A				
→ extrapolated to cucurbits with edible peel (0232000)	Overall supporting data for cGAP	EU	**GAP: 4x1.0 kg a.i/ha, 7day interval, BBCH 15-89, PHI 3** E/RA (HR): 0.70, 0.78, 1.10, 1.70, < 2.0, < 2.0, < 2.0, < 2.0, 2.20, 2.50, 2.60, 3.30	--	2.00	3.30	4.937	5	Yes
		S-EU EU (indoor)	E/RA: 0.81, 0.85, 0.98, 2x 1.20, 1.30, 1.40, 1.70 4x <2.0, 0.70, 0.78, 1.10, 1.70, 2.20, 2.50, 2.60, 3.30		1.55	3.3	4.44		
Lettuce	EFSA 2018	EU	**GAP: 4x0.8 kg a.i/ha, 7day interval, BBCH 12-49,**	--	N/A				

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**
(0251020)	(Art. 12)		**PHI 7** E/RA (HR): 23.0, open leaf varieties: 22.9, 28.3, 34.4, 34.7, 36.8, 43.9, 83						
→ extrapolated to lettuces and salad plants (0251000)	Overall supporting data for cGAP	EU	**GAP: 3x0.75 kg a.i./ha, 7day interval, BBCH 12-499, PHI7** 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	100 (Art. 12 proposed 150)	No

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

** see to overall conclusion for data

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses for all crops are considered acceptable for indoor uses.

Strawberry
Strawberry is major crop for the Indoor zone.
During the Art. 12 evaluation eight trials for strawberry under protected conditions are available (submitted and evaluated in France 2016)
The GAP used for these trials is in line with the intended uses on strawberry in greenhouses.

In accordance to EU guidelines (SANTE/2019/12752) a total of 8 trials is sufficient for the calculation of MRL.
Calculations resulted in an unrounded MRL of 11.069 mg/kg, exceeding the existing MRL of 5 mg/kg. However, trials used for the calculations are identical to those evaluated under Art. 12 of regulation (EC) No. 396/2005 (EFSA, 2018), in which a MRL of 15 mg/kg is proposed for strawberries.
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). Because of that the risk assessments were conducted with the overall calculated STMR und HR (S+N-EU & EU (indoor).

Tomato, Eggplants
Tomatoes are major crop for the Indoor zone.
During the Art. 12 evaluation eighteen trials for tomato under protected (4x) and field (NEU: 8x, SEU: 5x) conditions are available (evaluated in the DAR 2007).
The GAP used for these trials is in line with the intended uses on tomato in greenhouses.

In accordance to EU guidelines (SANTE/2019/12752) a total of 8 trials would be sufficient for the calculation of MRL. Since the intended uses are the same for the use in greenhouse and under field conditions, the trials conducted under unprotected conditions will be taken into account for the calculation of the MRL.
Calculations resulted in an unrounded MRL of 7.907 mg/kg, exceeding the existing MRL of 5 mg/kg. However, trials used for the calculations are identical to those evaluated under Art. 12 of regulation (EC) No. 396/2005 (EFSA, 2018), in which a MRL of 10 mg/kg is proposed for the use in tomato.
Accordance to SANTE/2019/12752, results, determined for the residues in tomato can be extrapolated to eggplants/aubergine.

Pepper
Peppers are major crop for the Indoor zone.
During the Art. 12 evaluation nine trials for pepper under protected conditions are available (evaluated in France 2016)
The GAP used for these trials is in line with the intended uses on pepper in greenhouses.
In accordance to EU guidelines (SANTE/2019/12752) a total of 8 trials would be sufficient for the calculation of MRL.
Calculations resulted in an unrounded MRL of 7.343 mg/kg, exceeding the existing MRL of 5 mg/kg. However, trials used for the calculations are identical to those evaluated under Art. 12 of regulation (EC) No. 396/2005 (EFSA, 2018), in which a MRL of 8 mg/kg is proposed for the use in pepper (indoor).

Lettuce
Lettuce is major crop for the Indoor zone.
During the Art. 12 evaluation eight trials for lettuce under protected conditions are available (evaluated in

France 2016)
The GAP used for these trials is in line with the intended uses on lettuce and salad plants in greenhouses.
In accordance to EU guidelines (SANTE/2019/12752) a total of 8 trials is sufficient for the calculation of MRL. Furthermore, in accordance to the guideline, results determined for the residues in lettuce can be extrapolated to the whole subgroup "lettuce and salad plants".
Calculations resulted in an unrounded MRL of 102.6 mg/kg, exceeding the existing MRL of 100 mg/kg. However, trials used for the calculations are identical to those evaluated under Art. 12 of regulation (EC) No. 396/2005 (EFSA, 2018), in which a MRL of 150 mg/kg is proposed for the use in lettuce.

Cucurbits (edible peel): Cucumber, courgettes
Cucumber and courgettes are major crops for the Indoor zone.
During the Art. 12 evaluation twelve trials for cucumber (4x) and courgettes (8x) under protected conditions are available (~~evaluated in the DAR 2007~~; no cucumber and courgettes in the DAR 2007 (see the DAR), the data were submitted and evaluated after the DAR, however, are unprotected).
The GAP used for these trials is in line with the intended uses on cucurbits with edible peel in greenhouses. Both crops are part of the group "cucurbits with edible peel". In accordance to Appendix D of EU guideline (SANTE/2019/12752), results determined for the residues in these crops can be extrapolated to the whole subgroup "cucurbits with edible peel".
Calculations resulted in an unrounded MRL of 4.937 mg/kg, not exceeding the existing MRL of 5 mg/kg.

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)
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)

Feed Commodity	**Median dietary burden**		**Maximum dietary burden**	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
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)
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)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
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	-	none	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			
Wine grapes, wet pomace	6	1.20			
Wine grapes, must	14	0.85			
Wine grapes, red wine	20[c]	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[c]			

Processed commodity	Number of studies[a]	Median PF *	Median CF **	Comments	Reference
Olives for oil production, press cake	10	0.71		none	
Hopes, beer	8	<0.10[d]			
Indicative processing faactors (limited dataset)					
Oranges, wet pomaace	1	2.12		none	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		none	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).

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)
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
4	Cherries							1.02	0.77	2.69	STMR
4	Peaches							1.02	0.89	2.35	STMR
4	Plums							1.02	0.62	1.15	STMR
4	Other stone 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
2	**Berries & small fruits**										
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

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	Currants (red, black, white)	3						1.4	0.78	1.00	STMR raspberries/currant
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)

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	Other misc. fruits (edible peel)							0.86	-	0.86	Background data (EFSA, 2018)
3	Miscellaneous fruit (inedible peel, small)	20									
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)

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	Bread fruit							0.96	-	0.96	Background data (EFSA, 2018)
4	Durian							0.96	-	0.96	Background data (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)

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	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
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		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 NEU+SEU+GH
	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 NEU+SEU+GH

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	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
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 NEU+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	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	2.0	5		0.42	0.47	2.0	STMR SEU+GH Pulp
			GH	< 1.97, < 2.0, < 2.0, < 2.1, < 2.1, 5.0							
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									

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
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
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	21.9, 22.9, 23.0, 28.3, 34.3, 35.5, 36.8, 70.9,	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)
			SEU	2.03, 3.22, 9.08, 11.7, 22.4, 36.5, 66.0							

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	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: 23.0 Tier II: 2.57	Extrapolation lettuce
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

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	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**									
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)

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	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)
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)

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	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)
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**									

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	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)
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**									

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	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)
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)

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						0.3		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)
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)

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	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**									
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)

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**
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 127% of ADI. For this diet, the highest contributor is natural Copper background in maize with 12% 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 G11" with 85% of ADI where soybean is the major contributor with 30% 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 96% of ADI. For this diet, the highest contributor is natural Copper background in maize with 12% 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. If a revision of the inputs into the PRIMo model is made, this reduces the TMDI for copper in the "NL Toddler" diet to 81% of ADI and wheat becomes the major contributor with 11% of the ADI.

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 v.3.1) 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 10.2kg toddler. For the next highest dietary intake group, "GEMS/Food G11" with 73% of ADI, for a 60kg 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

[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 (2015). Scientific Opinion on Dietary Reference Values for Copper. EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). EFSA Journal 2015: 13(10):4253

Copper intake levels.
Therefore, it can be concluded that the risk to consumers from the use of Copper as a plant protection 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,

[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*

representing 11% of ADI for both. It should be noted that the biggest contributors (cereal) are not supported uses for Copper compounds.

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 rev. 3.1
** 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

EFSA (European Food Safety Authority), 2013. Conclusion on pesticide peer review. Conclusion on the peer review of the pesticide risk assessment of confirmatory data submitted for the active substance Copper (I), Copper (II) variants namely Copper hydroxide, Copper oxychloride, tribasic Copper sulfate, Copper (I) oxide, Bordeaux mixture. EFSA Scientific Report (2013) 11(6), 3235.

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Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
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	N	EuCu Task Force
KCA 6.3.12/02	Grall, E.	2011	Funguran-OH 50 WP, Bordeaux Mixture RSR Disperss, Copper Oxychloride 37.5 NC WG, Cuproxat flüssig: Determination of residues of Copper in strawberry (RAC fruit) following four treatments with different Copper formulations under protected greenhouse conditions in northern and southern Europe in 2010. Company Report No: C91297 Harlan Laboratories Ltd., Itingen, Switzerland GLP Unpublished	N	EuCu Task Force
KCA 6.3.12/03	Grall, E.	2011	Copper oxychloride 50% WP, Flowbrix SC (Copper oxychloride SC), Bordoflow New, Copper hydroxide 25% DF, Cuproxat flüssig, Bordeaux Mixture 20 NC WG, CA2491 (Champion 50 WG) Determination of residues of Copper in strawberry (RAC fruit) following four treatments with different Copper formulations under protected greenhouse conditions in northern and southern Europe in 2009 Company Report No: C48290 Harlan Laboratories Ltd., Itingen, Switzerland GLP Unpublished	N	EuCu Task Force
KCA 6.3.19/01	Kreke, N.	2012	Bordeaux Mixture RSR Disperss, Copper Oxychloride 50% WP, Copper hydroxide 25% DF, Bordoflow New, Flowbrix SC (Copper oxychloride SC), Bordeaux Mixture 20 NC WG: Determination of residues of Copper in peppers (RAC fruit) following four treatments with different Copper formulations under	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	Vertebrate study Y/N	Owner
			greenhouse conditions in northern and southern Europe in 2010 Company Report No: C91051 Harlan Laboratories Ltd. Itingen, Switzerland GLP Unpublished		
KCA 6.3.19/02	Kreke, N.	2011	Bordeaux Mixture RSR Disperss, Copper Oxychloride 50% WP, Funguran-OH 50 WP, Cuproxat Flüssig Determination of residues of Copper in peppers (RAC fruit) following four treatments with different Copper formulations under greenhouse conditions in northern and southern Europe in 2009 Company Report No: C48097 Harlan Laboratories Ltd. Itingen, Switzerland GLP Unpublished	N	EuCu Task Force
KCA 6.3.19/03	Kreke, N.	2011	Kreke, N. (2011) Copper hydroxide 25% DF, Bordoflow New Determination of residues of Copper in peppers (RAC fruit) following four treatments with different Copper formulations under greenhouse conditions in northern Europe in 2011, Company Report No. D35590 Harlan Laboratories Ltd. Itingen, Switzerland GLP Unpublished	N	EuCu Task Force
KCA 6.3.21/01	Kreke, N.	2011	Bordeaux Mixture 20% WG, Copper hydroxide 25% DF, Flowbrix SC (Copper oxychloride SC), Cuproxat flüssig Determination of residues of Copper in lettuce (RAC whole plant without roots) following four treatments with different Copper formulations under greenhouse conditions in northern and southern Europe in 2009 Company Report No: C48053 Harlan Laboratories Ltd. Itingen, Switzerland GLP Unpublished	N	EuCu Task Force
KCA 6.3.21/02	Kreke, N.	2012	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	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	Vertebrate study Y/N	Owner
			treatments with different Copper formulations under greenhouse conditions in northern and southern Europe in 2010 Company Report No: C91038 Harlan Laboratories Ltd. Itingen, Switzerland GLP 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 6.3.3-01	Brereton, R.	2002	Copper: Residue levels in tomato (protected) from trials conducted in France, Spain and Italy during 2001. AF/5988/CU. Agrisearch, Y N	N	EuCuTF
CA 6.3.3-02	Martin, C.	2003f	Copper: Residue levels in tomato (protected) from trials conducted in France, Spain and Italy during 2002. AF/6549/CU. Agrisearch, Y N	N	EuCuTF
CA 6.3.5-01	Kreke, N.	~~2009b~~ 2011	Determination of residues of Copper in greenhouse cucumber (RAC fruit) following four treatments with different Copper formulations in northern and southern Europe in 2009 C48121 Harlan laboratories Yes No	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 6.3.5-02	Kreke, N.	~~2010b~~ 2011	Determination of residues of Copper in greenhouse cucumber (RAC fruit) following four treatments with different Copper formulations in greenhouse in northern and southern Europe in 2010 C91084 Harlan laboratories Yes No	N	EuCuTF*
CA 6.3.7-01	Foster, AC	2006c	Magnitude of residues of Copper and cymoxanil in protected 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 14536 DuPont Y N	N	EuCuTF*
CA 6.3.7-02	Hansford, R.J.	2008b	Magnitude of residues of Copper in protected melons (curcurbits – inedible peel) following applications of metallic Copper (as Copper oxychloride) / cymoxanil (DPX-KK807) 44WP (9.5:1) – Southern Europe, season 2007 DuPont 22564, DuPont Y N	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 Tomato, indoor (CA 6.3.3)

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)	6	1.25	7	All stages	10 (indus trial) 3 (fresh)
cGAP EU (RAR, 2017)	8	1.25	7	BBCH 12-89	3
cGAP EU (Art. 12, 2018)	6	1.25	7	BBCH 15-89	3
Intended cGAP (2*)	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

No new studies are submitted. 19 trials were already evaluated at EU peer review.

A 2.1.3.2 Cucumber, indoor (CA 6.3.5)

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 (RAR 2017)	8	1.25	7	BBCH 10-89	3
cGAP EU (Art. 12, 2018)	5	1.0	7	BBCH 15-89	3
Intended cGAP (Use 4*)	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. 8 trials were already evaluated at EU peer review.

A 2.1.3.3 Strawberry, indoor

Table A 3: Comparison of intended and critical EU GAPs - Indoor

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 (1*)	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

For supplement information regarding processing one outdoor study is presented below (KCA 6.3.12/01)

A 2.1.3.3.1 KCA 6.3.12 (Strawberry, outdoor EUS/EUN)

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

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
GLP:	Yes
Acceptability:	Yes

Table A 4: Summary of the copper studies in strawberries

PPP (product name/code):	**Copper oxide WG** Copper oxychloride WG Copper oxychloride SC Copper hydroxide WG Copper hydroxide DF Bordeaux mixture SC	Conc. of as 1:	**75%** 37.5% 380 g/L 40% 25% 1.24 kg/L
Crop group:	Strawberry	Other a.i. in formulation:	None
Indoor/outdoor:	Outdoor (2009)	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 analysed**	**Residues [mg/kg]**	**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**		
A/GE/F/09/92 Field Germany 2009	Copper Oxychloride 37.5 N WG	Strawberry Florence	1)16.04.08 2) 25.04.09 to 28.05.09	0.813 0.756 0.838 0.914		0.267	25.06.2009	81 85 86 86		Fruit	0.57 0.51	0 3	HR: 0.51 Mean: 0.47
A/GE/F/09/92 Field Germany 2009	Nordox 75WG	Strawberry Florence	1)16.04.08 2) 25.04.09 to 28.05.09	0.845 0.749 0.800 0.788		0.267	25.06.2009	81 85 86 86		Fruit	0.65 0.43	0 3	
A/GE/F/09/94 Field Germany 2009	Copper hydroxide 25% DF	Strawberry Symphonie	1) 10.05 to 14.05.08 2) 07.05.09 to 10.06.09	0.791 0.818 0.827 0.845		0.267	29.06.2009	81 82 84 87		Fruit Jam	0.95 0.96 0.61	0 3 3	Fruit: HR: 0.98 Mean: 0.97
A/GE/F/09/94 Field Germany 2009	Bordoflow New	Strawberry Symphonie	1) 10.05 to 14.05.08 2) 07.05.09 to 10.06.09	0.728 0.768 0.818 0.791		0.267	29.06.2009	81 82 84 87		Fruit Jam	1.06 0.98 0.59	0 3 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 analysed	Residues [mg/kg]	PHI [days]	Selected values
				kg a.s./ ha	Water [l/ha]	kg a.s./hl					Copper		
A/NF/F/09/96 Field North France 2009	Copper Oxychloride 37.5 N WG	Strawberry Sonata	1) 07.05.08 2) 02.06.09 to 17.06.09	0.808 0.839 0.839 0.781		0.267	26.06.2009	61 81 85 85		Fruit	0.80 0.78 0.72 0.61 0.59	0 1 3 5 7	HR: 0.72 Mean: 0.70
A/NF/F/09/96 Field North France 2009	Nordox 75WG	Strawberry Sonata	1) 07.05.08 2) 02.06.09 to 17.06.09	0.764 0.773 0.813 0.768		0.267	26.06.2009	61 81 85 85		Fruit	0.73 0.76 0.68 0.60 0.57	0 1 3 5 7	
A/GE/F/09/97 Field Germany 2009	Flowbrix SC	Strawberry Yamaska	1) 26.05.08 2) 01.06.09 to 18.06.09	0.845 0.801 0.809 0.774		0.267	26.06.2009	78-80 81 85 86		Fruit	1.03 0.83 0.84 0.92 0.88	0 1 3 5 7	HR: 0.99 Mean: 0.96
A/GE/F/09/97 Field Germany 2009	Copper hydroxide 40% WG	Strawberry Yamaska	1) 26.05.08 2) 01.06.09 to 18.06.09	0.791 0.809 0.800 0.844		0.267	26.06.2009	78-80 81 85 86		Fruit	1.11 0.84 0.89 0.90 0.99	0 1 3 5 7	
A/UK/F/09/98 Field United Kingdom 2009	Copper hydroxide 25% 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	81 81 85 87		Fruit Jam	2.38 2.01 2.08 1.69 1.48 1.93	0 1 3 7 9 3	Fruit: HR: 2.08 Mean: 1.76
A/UK/F/09/98 Field United Kingdom 2009	Bordoflow New	Strawberry Symphony	1) May 2007 2) Beg. to end May 2009	0.772 0.809 0.782 0.773		0.267	29.06.2009	81 81 85 87		Fruit Jam	1.99 1.71 1.43 0.86 1.03 1.89	0 1 3 7 9 3	

PPP (product name/code):	**Copper oxide WG** Copper oxychloride WG Copper oxychloride SC Copper hydroxide WG Copper hydroxide DF Bordeaux mixture SC	Conc. of as 1:	**75%** 37.5% 380 g/L 40% 25% 1.24 kg/L
Crop group:	Strawberry	Other a.i. in formulation:	None
Indoor/outdoor:	Outdoor (2009)	Residues calculated as:	Copper
Applicant:	EU Copper Taskforce		
Zone(s):	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 analysed**	**Residues [mg/kg]**	**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**		
A/SP/F/09/95 Field Spain 2009	Copper Oxychloride 37.5 N WG	Strawberry Gaviota	1) Mid Sept. 2008 2) End February to end July 2009	0.756 0.778 0.809 0.769		0.267	26.06.2009	87 87 87-89 87-89		Fruit Jam Washed fruit	4.48 3.09 2.28 2.26	0 3 3 3	Fruit: HR: 3.09 Mean: 2.94
A/SP/F/09/95 Field Spain 2009	Nordox 75WG	Strawberry Gaviota	1) Mid Sept. 2008 2) End February to end July 2009	0.765 0.785 0.796 0.782		0.267	26.06.2009	87 87 87-89 87-89		Fruit Jam Washed fruit	3.57 2.78 2.62 2.16	0 3 3 3	
A/SP/F/09/99 Field Spain 2009	Flowbrix SC	Strawberry Albion	1) End March 2009 2) Mid. to end May 2009	0.802 0.823 0.771 0.786		0.267	11.09.09	81-85		Fruit	4.60 3.78 3.00 2.99 1.82	0 1 3 5 7	HR: 3.55 Mean: 3.28
A/SP/F/09/99 Field Spain 2009	Copper hydroxide 40% WG	Strawberry Albion	1) End March 2009 2) Mid. to end May 2009	0.791 0.836 0.787 0.782		0.267	11.09.09	81-85		Fruit	5.77 4.08 3.55 2.71 2.01	0 1 3 5 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 analysed**	**Residues [mg/kg]**	**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**		
A/IT/F/09/100 Field Italy 2009	Copper hydroxide 25% DF	Strawberry Aromas	1) 28.04.09 2) Mid. June to mid. August 2009	0.782 0.773 0.773 0.782		0.267	01.08.2009	73 75 81 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: 1.75
A/IT/F/09/100 Field Italy 2009	Bordoflow New	Strawberry Aromas	1) 28.04.09 2) Mid. June to mid. August 2009	0.752 0.744 0.728 0.736		0.267	01.08.2009	73 75 81 85		Fruit Jam	1.80 1.37 1.72 1.44 1.60 1.34	0 1 3 5 7 3	

A 2.1.3.3.2 KCA 6.3.12 (Strawberry, Indoor)

Comments of zRMS:	Studies are acceptable. They were conducted according to acceptable guidelines. and have been used in evaluation. The purpose of first study was to obtain residue data from greenhouse strawberry (RAC fruit) treated with different copper formulations under protected conditions. The trials were performed during the 2010 growing season at two field sites in northern and southern Europe. The procedural recovery was carried out during sample analysis to check the performance of the method at LOQ level of 0.2 mg/kg. At least one procedural recovery every ten sample was carried out during the sample analysis. The procedural recovery was within the 70-110% limits and accounted for 89.8 %. The purpose of second study was to obtain residue data from crops of greenhouse strawberry (RAC fruit) treated with different copper formulations. The trials were performed during the 2009 growing season in six greenhouses in northern and southern Europe. (Exception: trial A/SF/F/09/79 in Spain was delayed and done at the beginning of 2010 season). The method has been fully validated at RA high acid content Raw Agricultural Commodities (RAC) (GLP study No. RA.09.23). The limit of detection (LOD) and the limit of quantification (LOQ) were 0.04 mg/kg and 0.2 mg/kg, respectively. Moreover, the linearity and accuracy of instrumental response and procedural recovery tests have been checked during the present analytical phase. Residues of copper are determined from homogenised samples by acidic digestion and microwave heating. The solution is filtered and analysed by reading of its absorbance at 324.8 nm, after calibration of the Flame Atomic Absorption Spectrometer (FAAS) with standard solutions. 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 82.7%.

Reference:	**KCA 6.3.12/02**
Report:	Grall, E., 2011 Funguran-OH 50 WP, Bordeaux Mixture RSR Disperss, Copper Oxychloride 37.5 NC WG, Cuproxat flüssig: Determination of residues of Copper in strawberry (RAC fruit) following four treatments with different Copper formulations under protected greenhouse conditions in northern and southern Europe in 2010. Report No: C91297
Guideline(s):	Yes EU Directive 96/68/EC Commission Working Document 7029/VI/95 rev. 5
Deviations:	No
GLP:	Yes
Acceptability:	Yes

And

Reference:	**KCA 6.3.12/03**
Report:	Grall, E., 2011

	Copper oxychloride 50% WP, Flowbrix SC (Copper oxychloride SC), Bordoflow New, Copper hydroxide 25% DF, Cuproxat flüssig, Bordeaux Mixture 20 NC WG, CA2491 (Champion 50 WG), Report No: C48290
Guideline(s):	Yes EU Directive 96/68/EC Commission Working Document 7029/VI/95 rev. 5
Deviations:	No
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 a.i./kg.

PPP (product name/code):	Copper hydroxide WG Copper hydroxide WP Copper hydroxide DF Copper oxychloride WG Copper oxychloride WP Copper oxychloride SC Bordeaux mixture WG Bordeaux mixture SC Tribasic copper sulfate SC	Conc. of as 1:	50% 50% 25% 37.5% 50% 380 g/L 20% 1240 g/L 190 g/L
Crop group:	Strawberry	Other a.i. in formulation:	None
Indoor/outdoor:	Indoor (2009, 2010)	Residues calculated as:	Copper
Applicant:	EU Copper Taskforce		
Zone(s):	EU (Germany, Italy, Spain, 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 analysed**	**Residues [mg/kg]**	**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**		
A/UK/F/10/83 Plot 1 United Kingdom Herefordshire HR8 2JH Ledbury 2010	Bordeaux Mixture RSR Dispersss	Strawberry/Jubilee	1) 06.02.10 2) May to October 2010	0.862 0.800 0.791 0.862		0.267	02.07.2010	65-85		Fruit	4.79 5.77	0 3	HR: 6.12 Mean: 5.94
A/UK/F/10/83 Plot 2 United Kingdom Herefordshire HR8 2JH Ledbury 2010	Fungaran-OH 50 WP	Strawberry/Jubilee	1) 06.02.10 2) May to October 2010	0.898 0.827 0.871 0.773		0.267	02.07.2010	65-85		Fruit	7.89 6.12	0 3	
A/IT/F/10/84 Plot 1 Italy Sicilia, 95036 Randazzo 2010	Copper oxychloride 37.5 NC WG	Strawberry/Elsinore	1) 25.01.10 2) May to June 2010	0.800 0.769 0.790 0.769		0.267	15.06.2010	43-85		Fruit	9.32 5.46	0 3	HR: 5.46 Mean: 5.17
A/IT/F/10/84 Plot 2 Italy Sicilia, 95036 Randazzo 2010	Cuproxat flüssig	Strawberry/Elsinore	1) 25.01.10 2) May to June 2010	0.759 0.821 0.749 0.769		0.267	15.06.2010	43-85		Fruit	10.9 4.87	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 analysed**	**Residues [mg/kg]**	**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**		
A/UK/F/09/75 Plot 1 Herefordshire HR8 2JH, Ledbury United Kingdom 2009	Bordeaux Mixture 20 NC WG	Strawberry/Jubilee	1) 2007 2) May to mid July 2009	0.844 0.853 0.844 0.924		0.267	03.08.2009	55-85		Fruit	2.55 2.95	0 3	HR: 2.95 Mean: 2.69
A/UK/F/09/75 Plot 2 Herefordshire HR8 2JH, Ledbury United Kingdom 2009	Cuproxat flüssig	Strawberry/Jubilee	1) 2007 2) May to mid July 2009	0.836 0.818 0.845 0.827		0.267	03.08.2009	55-85		Fruit	2.56 2.42	0 3	
A/IT/F/09/76 Plot 1 Sicilia, 95036 Randazzo Italy 2009	Copper hydroxide 25% DF	Strawberry/Annabelle	1) March 2008 2) April to August 2009	0.816 0.748 0.782 0.816		0.267	20.07.2009	65-85		Fruit	1.87 1.04 1.13 1.23 0.64	0 1 3 5 8	HR: 1.58 Mean: 1.41
A/IT/F/09/76 Plot 2 Sicilia, 95036 Randazzo Italy 2009	Copper oxychloride 50% WP	Strawberry/Annabelle	1) March 2008 2) April to August 2009	0.850 0.816 0.816 0.816		0.267	20.07.2009	65-85		Fruit	1.62 1.42 1.58 1.17 1.17	0 1 3 5 8	
A/GE/F/09/77 Plot 1 Sachsen, 01640 Coswig Germany 2009	Copper oxychloride 50% WP	Strawberry/Sonata	1) 25.07.09 2) 02.08.09 to 28.08.09	0.853 0.871 0.853 0.853		0.267	13.09.2009	86-87		Fruit	0.45 0.57 0.54 0.51 0.41	0 1 3 5 7	HR: 0.54 Mean: 0.47
A/GE/F/09/77 Plot 2 Sachsen 01640 Coswig Germany 2009	Copper hydroxide 25% DF	Strawberry/Sonata	1) 25.07.09 2) 02.08.09 to 28.08.09	0.782 0.818 0.764 0.773		0.267	13.09.2009	86-87		Fruit	0.42 0.41 0.40 0.44 0.41	0 1 3 5 7	
A/UK/F/09/78 Plot 1 Worcestershire WR6 6LP Little Witley United Kingdom 2009	Flowbrix SC (Copper oxychloride SC)	Strawberry/Albion	1) March 2007 2) June to September 2009	0.844 0.809 0.835 0.782		0.267	03.08.2009	55-85		Fruit	1.56 1.63 1.26 1.06 1.39	0 1 3 5 7	HR: 1.39 Mean: 1.26
A/UK/F/09/78 Plot 2 Worcestershire WR6 6LP Little Witley United Kingdom,	Bordoflow New	Strawberry/Albion	1) March 2007 2) June to September 2009	0.836 0.773 0.782 0.773		0.267	03.08.2009	55-85		Fruit	1.23 1.32 1.11 1.00	0 1 3 5	

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 analysed**	**Residues [mg/kg]**	**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**		
2009											1.12	7	
A/SP/F/09/79 Plot 1 Communidad Valenciana 46837, Quatretonda Spain 2010	Bordoflow New	Strawberry/Camarosa	1) 05.10.09 2) End Nov 2009 to end Dec 2009	0.765 0.769 0.784 0.791		0.267	18.03.2010	82		Fruit	3.70 3.99 3.33 2.86 2.77	0 1 3 5 7	HR: 3.81 Mean: 3.57
A/SP/F/09/79 Plot 2 Communidad Valenciana 46837 Quatretonda Spain 2010	Flowbrix SC (Copper oxychloride SC)	Strawberry/Camarosa	1) 05.10.09 2) End Nov 2009 to end Dec 2009	0.767 0.760 0.789 0.787		0.267	18.03.2010	82		Fruit	4.97 5.33 3.81 3.66 3.06	0 1 3 5 7	
A/IT/F/09/80 Plot 1 Sicilia 95036 Randazzo Italy 2009	Cuproxat flüssig	Strawberry/Elsinore	1) 20.02.09 2) April to August 2009	0.847 0.762 0.762 0.794		0.267	28.07.2009	65-85		Fruit	1.77 1.63	0 3	HR: 1.63 Mean: 1.43
A/IT/F/09/80 Plot 2 Sicilia 95036 Randazzo Italy 2009	CA2491 (CHAMPION 50 WG)	Strawberry/Elsinore	1) 20.02.09 2) April to August 2009	0.847 0.772 0.762 0.847		0.267	28.07.2009	65-85		Fruit	1.69 1.23	0 3	

A 2.1.3.4 Pepper

Table A 5: Comparison of intended and critical EU GAPs - Indoor

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 (Use 8, 9*)	4	0.75	7	BBCH 15-89	3

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

A 2.1.3.4.1 KCA 6.3.19 (Pepper, Indoor)

Comments of zRMS:	Studies are acceptable. They were conducted according to acceptable guidelines and have been used in evaluation. The purpose of first study was to obtain residue data from peppers (RAC fruit) treated with different copper formulations under protected greenhouse conditions. The trials were performed during the 2010 growing season at three greenhouse sites in northern and southern Europe. The recoveries, obtained from the fortification experiments with copper nitrate solution, were all in the range of 70-110% with a mean recovery of 94.9%. The purpose of second study was to obtain residue data from pepper (RAC fruit) treated with different copper formulations under protected greenhouse conditions. The trials were performed during the 2009 growing season at five sites in northern and southern Europe. 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 90.2%. The purpose of third study was to obtain residue data from pepper (RAC fruit) treated with different copper formulations under protected greenhouse conditions. The trial was performed during the 2011 growing season at one field site in northern Europe. The recoveries, obtained from the fortification experiments with copper nitrate solution, were all in the range of 70-110% with a mean recovery of 107.6%.

Reference:	**KCA 6.3.19/01**
Report:	Kreke, N. (2011) Bordeaux Mixture RSR Disperss, Copper Oxychloride 50% WP, Copper hydroxide 25% DF, Bordoflow New, Flowbrix SC (Copper oxychloride SC), Bordeaux Mixture 20 NC WG: Determination of residues of Copper in peppers (RAC fruit) following four treatments with different Copper formulations under greenhouse conditions in northern and southern Europe in 2010, Report No. C91051
Guideline(s):	Yes, EU Directive 96/68/EC Commission Working Document 7029/VI/95 rev. 5
Deviations:	No
GLP:	Yes
Acceptability:	Yes

And

Reference:	**KCA 6.3.19/02**
Report:	Kreke, N. (2011) Bordeaux Mixture RSR Disperss, Copper Oxychloride 50% WP, Funguran-OH 50 WP, Cuproxat Flüssig Determination of residues of Copper in peppers (RAC fruit) following four treatments with different Copper formulations under greenhouse conditions in northern and southern Europe in 2009, Report No. C48097
Guideline(s):	Yes, EU Directive 96/68/EC Commission Working Document 7029/VI/95 rev. 5
Deviations:	No
GLP:	Yes
Acceptability:	Yes

And

Reference:	**KCA 6.3.19/03**
Report:	Kreke, N. (2011) Copper hydroxide 25% DF, Bordoflow New Determination of residues of Copper in peppers (RAC fruit) following four treatments with different Copper formulations under greenhouse conditions in northern Europe in 2011, Report No. D35590
Guideline(s):	Yes, EU Directive 96/68/EC Commission Working Document 7029/VI/95 rev. 5 OECD Guidelines for the Testing of Chemicals
Deviations:	No
GLP:	Yes
Acceptability:	Yes

For a better overview all trials of the three 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 a.i./kg.

PPP (product name/code):	Copper oxychloride WP Copper oxychloride SC Copper hydroxide WP Copper hydroxide DF Bordeaux mixture WG Bordeaux mixture SC Tribasic copper sulfate	Conc. of as 1:	50% 380 g/L 50% 25% 20% 10% 190 g/L
Crop group:	Pepper	Other a.i. in formulation:	None
Indoor/outdoor:	Indoor (2009, 2010)	Residues calculated as:	Copper
Applicant:	EU Copper Taskforce		
Zone(s):	EU (Germany, France, Italy, 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 analysed**	**Residues [mg/kg]**	**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**		
A/NF/F/10/115 Plot 1 Glasshouse 51110 Auménancourt le Grand, France - North 2010	Bordeaux Mixture RSR Dispersss	Pepper/Lamuyo	1) 01.06.10 2) 15.06-15.09.10 3) 12.09.10	0.844 0.844 0.804 0.826		0.267	20.08.2010 26.08.2010 03.09.2010 09.09.2010	A1-A4: 74-76 S1 76 S3 76	7±1 day	Fruit Fruit washed	1.82 1.11 1.14	0 3 3	Fruit: HR: 1.52 Mean: 1.32
A/NF/F/10/115 Plot 2 Glasshouse 51110 Auménancourt le Grand France - North 2010	Copper oxychloride 50% WP	Pepper/Lamuyo	1) 01.06.10 2) 15.06-15.09.10 3) 12.09.10	0.827 0.818 0.811 0.821		0.267	20.08.2010 26.08.2010 03.09.2010 09.09.2010	A1-A4: 74-76 S1 76 S3 76	7±1 day	Fruit Fruit washed	1.68 1.52 1.80	0 3 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 analysed**	**Residues [mg/kg]**	**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**		
A/GE/F/10/116 Plot 1 Glasshouse 04420 Markranstädt Germany 2010	Copper hydroxide 25% DF	Pepper Bossanova RZ (~50%) Century F1 (~50%)	1) 20.04.10 2) 10.05-21.07.10 3) 13.08.10	1.033 1.089 1.067 0.967		0.267	21.07.2010 29.07.2010 05.08.2010 12.08.2010	A1-A4: 73-82 S1 82 S2 82 S3 84 S4 84 S5 87	7±1 day	Fruit Fruit washed	3.07 2.98 3.79 2.03 1.80 1.46	0 1 3 5 7 3	Fruit: HR: 3.79 Mean: 3.18
A/GE/F/10/116 Plot 2 Glasshouse 04420 Markranstädt Germany 2010	Bordoflow New	Pepper Bossanova RZ (~50%) Century F1 (~50%)	1) 20.04.10 2) 10.05-21.07.10 3) 13.08.10	1.011 1.027 1.083 1.044		0.267	21.07.2010 29.07.2010 05.08.2010 12.08.2010	A1-A4: 73-82 S1 82 S2 82 S3 84 S4 84 S5 87	7±1 day	Fruit Fruit washed	2.51 2.15 2.56 2.01 1.64 0.98	0 1 3 5 7 3	
A/IT/F/10/117 Plot 1 Glasshouse 97019 Vittoria Italy 2010	Flowbrix SC (Copper oxychloride SC)	Pepper/Asideo	1) 22.02.10 2) start 25.03.10 3) 30.09.10	0.757 0.794 0.776 0.831		0.267	06.09.2010 13.09.2010 20.09.2010 27.09.2010	A1-A4: 69-81 S1 81 S3 84	7 days	Fruit	6.84 3.91	0 3	HR: 3.91 Mean: 2.90
A/IT/F/10/117 Plot 2 Glasshouse 97019 Vittoria Italy 2010	Bordeaux Mixture 20 NC WG	Pepper/Asideo	1) 22.02.10 2) start 25.03.10 3) 30.09.10	0.778 0.852 0.815 0.833		0.267	06.09.2010 13.09.2010 20.09.2010 27.09.2010	A1-A4: 69-81 S1 81 S3 84	7 days	Fruit	3.29 2.90	0 3	
A/NF/F/09/168 Plot 1 Glasshouse 51110 Auménancourt France - North 2009	Bordeaux Mixture RSR Dispers	Pepper/M 7.5	1) 09.06.2009 2) 03.07-19.08.2009 3) 05.09.09 (3DALA)	0.815 0.803 0.801 0.799		0.133		A1-A4: 74-76 S1 76 S2 76 S3 76 S4 77 S5 77		Fruits	0.85 1.16 1.38 1.17 1.07	0 1 3 5 8	HR: 1.38 Mean: 1.27
A/NF/F/09/168 Plot 2 Glasshouse 51110 Auménancourt France - North 2009	Copper oxychloride 50% WP	Pepper/M 7.5	1) 09.06.2009 2) 03.07-19.08.2009 3) 05.09.09 (3DALA)	0.822 0.824 0.859 0.804		0.133		A1-A4: 74-76 S1 76 S2 76 S3 76 S4 77 S5 77		Fruits	0.80 1.03 1.16 1.03 0.77	0 1 3 5 8	

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 analysed**	**Residues [mg/kg]**	**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**		
A/GE/F/09/169 Plot 1 Glasshouse 04420 Markranstädt-Kulkwitz Germany 2009	Fungaran-OH 50 WP	Pepper Mix of Monte and Bontempi F1	1) 24.04.2009 (planting) 2) 06.05-20.07.2009 3) 16.08.09 (3DALA)	0.800 0.814 0.847 0.860		0.133		A1 71 A2 73 A3 76-78 A4 81-83 S1 81-83 S3 82-84		Fruits	1.76 1.16	0 3	HR: 1.53 Mean:1.35
A/GE/F/09/169 Plot 2 Glasshouse 04420 Markranstädt-Kulkwitz Germany 2009	Cuproxat flüssig	Pepper Mix of Monte and Bontempi F1	1) 24.04.2009 (planting) 2) 06.05-20.07.2009 3) 16.08.09 (3DALA)	0.774 0.820 0.833 0.780		0.133		A1 71 A2 73 A3 76-78 A4 81-83 S1 81-83 S3 82-84		Fruits	1.57 1.53	0 3	
A/SF/F/09/171 Plot 1 Glasshouse 13970 Rognonas France - South 2009	Fungaran-OH 50 WP	Pepper/Relys	1) 01.04.2009 (transplanting) 2) 20.04.2009 till Sept. 3) 25.08.09 (3DALA)	0.810 0.804 0.784 0.839		0.133		A1-A4: 85-85 S1 85 S2 85 S3 85 S4 85 S5 85		Fruits	2.63 2.07 2.04 1.22 0.89	0 1 3 5 7	HR: 2.04 Mean: 1.99
A/SF/F/09/171 Plot 2 Glasshouse 13970 Rognonas France - South 2009	Cuproxat flüssig	Pepper/Relys	1) 01.04.2009 (transplanting) 2) 20.04.2009 till Sept. 3) 25.08.09 (3DALA)	0.783 0.802 0.787 0.824		0.133		A1-A4: 85-85 S1 85 S2 85 S3 85 S4 85 S5 85		Fruits	3.00 1.91 1.93 1.37 1.16	0 1 3 5 7	
A/SP/F/09/172 Plot 1 Glasshouse 04700 El Ejido Spain 2009	Bordeaux Mixture RSR Disperss	Pepper/Soberano	1) 25.07.2009 (transplanting) 2) 3-4 weeks after Transplanting 3) 10-Nov-2009	0.768 0.774 0.762 0.787		0.133		A1-A4: 71-73 S1 72-73 S3 72-73		Fruits	2.47 2.81	0 3	HR: 2.94 Mean: 2.88
A/SP/F/09/172 Plot 2 Glasshouse 04700 El Ejido Spain 2009	Copper oxychloride 50% WP	Pepper/Soberano	1) 25.07.2009 (transplanting) 2) 3-4 weeks after Transplanting 3) 10-Nov-2009	0.754 0.761 0.793 0.805		0.133		A1-A4: 71-73 S1 72-73 S3 72-73		Fruits	2.43 2.94	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 analysed**	**Residues [mg/kg]**	**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**		
A/SP/F/09/173 Plot 1 Glasshouse 46419 Mareny de Barraquetes Sueca Spain 2009	Fungaran-OH 50 WP	Pepper/Lipari	1) mid-February 2) 01.04.2009 till end of crop cycle 3) 12.Aug.2009 (3DALA)	0.777 0.788 0.785 0.836		0.133		A1-A4: 73-77 S1 76-77 S2 77 S3 77 S4 77-78 S5 77-78		Fruits	4.01 4.83 3.24 3.85 3.68	0 1 3 5 7	HR: 3.92 Mean: 3.89
A/SP/F/09/173 Plot 2 Glasshouse 46419 Mareny de Barraquetes Sueca Spain 2009	Cuproxat flüssig	Pepper/Lipari	1) mid-February 2) 01.04.2009 till end of crop cycle 3) 12.Aug.2009 (3DALA)	0.771 0.805 0.781 0.787		0.133		A1-A4: 73-77 S1 76-77 S2 77 S3 77 S4 77-78 S5 77-78		Fruits	4.22 4.05 2.68 3.92 3.12	0 1 3 5 7	
A/GE/F/11/132 Plot 1 Glasshouse Germany 2011	Copper hydroxide 25% DF	Pepper Bossanova (50%), Mazurka (50%)	1) 18.04.11 2) 08.05.11 to 15.08.11 3) 15.08.2011	0.780 0.832 0.865 0.770		0.267	21.07.2011 27.07.2011 04.08.2011 12.08.2011	76 78 81 82	7±1 days	Fruits Fruits washed	0.97 0.88 0.89 0.97 1.00 0.86	0 1 3 5 7 3	Fruit: HR: 1.00 Mean: 0.99
A/GE/F/11/132 Plot 2 Glasshouse Germany 2011	Bordoflow New	Pepper Bossanova (50%), Mazurka (50%)	1) 18.04.11 2) 08.05.11 to 15.08.11 3) 15.08.2011	0.815 0.849 0.830 0.834		0.267	21.07.2011 27.07.2011 04.08.2011 12.08.2011	76 78 81 82	7±1 days	Fruits Fruits washed	1.11 1.20 1.08 0.97 0.95 0.78	0 1 3 5 7 3	

A 2.1.3.5 Lettuce and similar

Table A 6: Comparison of intended and critical EU GAPs - Indoor

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 14-16*)	3	0.75	7	BBCH 12-49 Applications from seedling stage	7

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

A 2.1.3.5.1 KCA 6.3.21 (Lettuce, Indoor)

Comments of zRMS:	Studies are acceptable. They were conducted according to acceptable guidelines and have been used in evaluation. The purpose of first study was to obtain residue data from lettuce (RAC whole plant without roots) treated with different copper formulations under protected greenhouse conditions. The trials were performed during the 2009 growing season at six field sites in northern and southern Europe. 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 86.5%. The purpose of second study was to obtain residue data from lettuce (RAC whole plant without roots) treated with different copper formulations under protected greenhouse conditions. The trials were performed during the 2010 growing season at two field sites in northern and southern Europe. 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 88.0%.

Reference:	**KCA 6.3.21/01**
Report:	Kreke, N. (2011) Bordeaux Mixture 20% WG, Copper hydroxide 25% DF, Flowbrix SC (Copper oxychloride SC), Cuproxat flüssig Determination of residues of Copper in lettuce (RAC whole plant without roots) following four treatments with different Copper formulations under greenhouse conditions in northern and southern Europe in 2009, Report No. C48053
Guideline(s):	Yes, EU Directive 96/68/EC Commission Working Document 7029/VI/95 rev. 5
Deviations:	No
GLP:	Yes
Acceptability:	Yes

And

Reference:	**KCA 6.3.21/02**

Report:	Kreke, N. (2012) 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 greenhouse conditions in northern and southern Europe in 2010, Report No. C91038
Guideline(s):	Yes, EU Directive 96/68/EC Commission Working Document 7029/VI/95 rev. 5
Deviations:	No
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 a.i./kg.

PPP (product name/code):	Copper oxychloride WP Copper oxychloride SC Copper hydroxide DF Copper hydroxide SC Bordeaux mixture WG Bordeaux mixture SC Tribasic copper sulfate WG Tribasic copper sulfate SC	Conc. of as 1:	50% 380 g/L 25% 360g/L 20% 10% 40% 190 g/L
Crop group:	Lettuce	Other a.i. in formulation:	None
Indoor/outdoor:	Indoor (2009, 2010)	Residues calculated as:	Copper
Applicant:	EU Copper Taskforce		
Zone(s):	EU (Germany, France, Spain, 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 analysed**	**Residues [mg/kg]**	**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**		
A/NF/F/09/161 Plot 1 Champagne-Ardennes 51110 Auménancourt Greenhouse 2009	Bordeaux Mixture 20% WG	Lettuce/Batavia	1) 11.09.09	0.850 0.788 0.792 0.832			09.10.2009 17.10.2009 23.10.2009 31.10.2009	42 43 44 45	7±1 days	Whole plant without roots	42.2 36.8	0 3	HR: 36.8 Mean: 36.0
A/NF/F/09/161 Plot 2 Champagne-Ardennes 51110 Auménancourt Greenhouse 2009	Copper hydroxide 25% DF	Lettuce/Batavia	1) 11.09.09	0.797 0.832 0.819 0.806			09.10.2009 17.10.2009 23.10.2009 31.10.2009	42 43 44 45	7±1 days	Whole plant without roots	47.0 35.1	0 3	
A/GE/F/09/162 Plot 1 Sachsen, 04420 Markranstädt-Kulkwitz Greenhouse 2009	Copper hydroxide 25% DF	Lettuce Mix of Lollo Rosso + Oak Leaf lettuce	1) 17.08.09	0.845 0.863 0.836 0.711			27.08.2009 02.09.2009 10.09.2009 17.09.2009	13-15 33 39 42	7±1 days	Whole plant without roots	46.9 21.1 26.3 21.9 12.5	0 3 5 7 13	HR: 21.9 Mean: 20.2
A/GE/F/09/162 Plot 2 Sachsen, 04420 Markranstädt-Kulkwitz Greenhouse 2009	Flowbrix SC (Copper oxychloride SC)	Lettuce Mix of Lollo Rosso + Oak Leaf lettuce	1) 17.08.09	0.868 0.868 0.850 0.833			27.08.2009 02.09.2009 10.09.2009 17.09.2009	13-15 33 39 42	7±1 days	Whole plant without roots	44.8 22.1 34.7 18.4 13.4	0 3 5 7 13	

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 analysed**	**Residues [mg/kg]**	**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**		
A/UK/F/09/163 Plot 1 United Kingdom Worcestershire Offenham/Evesham WR11 8RE Greenhouse 2009	Bordeaux Mixture 20% WG	Lettuce/Gaugin	1) 18.09.09	0.854 0.818 0.764 0.889			23.09.2009 29.09.2009 05.10.2009 12.10.2009	19 19 19 19	7±1 days	Whole plant without roots	138 94.3 83.0 70.9 40.6	0 3 5 7 14	HR: 70.9 Mean: 64.6
A/UK/F/09/163 Plot 2 United Kingdom Worcestershire Offenham/Evesham WR11 8RE Greenhouse 2009	Cuproxat flüssig	Lettuce/Gaugin	1) 18.09.09	0.846 0.765 0.738 0.809			23.09.2009 29.09.2009 05.10.2009 12.10.2009	19 19 19 19	7±1 days	Whole plant without roots	141.0 88.0 75.5 58.2 27.4	0 3 5 7 14	
A/SF/F/09/164 Plot 1 Provence-Alpes-Côte d'Azur 13160 Chateaurenard Greenhouse 2009	Bordeaux Mixture 20% WG	Lettuce/Batavia blonde	1) Not recorded	0.821 0.847 0.821 0.841			09.11.2009 16.11.2009 23.11.2009 30.11.2009	14 16 18 49	7 days	Whole plant without roots Washed	53.4 48.2 41.3 35.5 31.7 45.2	0 3 5 7 14 7	HR: 35.5 Mean: 35.4
A/SF/F/09/164 Plot 2 Provence-Alpes-Côte d'Azur 13160 Chateaurenard Greenhouse 2009	Flowbrix SC (Copper oxychloride SC)	Lettuce/Batavia blonde	1) Not recorded	0.780 0.818 0.844 0.836			09.11.2009 16.11.2009 23.11.2009 30.11.2009	14 16 18 49	7 days	Whole plant without roots Washed	47.0 45.3 43.9 35.2 25.6 32.1	0 3 5 7 14 7	
A/SP/F/09/165 Plot 1 Spain Valencia 12580 Benicarló Greenhouse	Copper hydroxide 25% DF	Lettuce/Valladolid	1) mid September	0.811 0.825 0.828 0.850			12.10.2009 19.10.2009 27.10.2009 03.11.2009	42-43 43-44 44-46 45-47	7±1 days	Whole plant without roots	14.0 22.9	0 3	HR: 22.9 Mean: 18.5
A/SP/F/09/165 Plot 2 Spain Valencia 12580 Benicarló Greenhouse	Cuproxat flüssig	Lettuce/Valladolid	1) mid September	0.820 0.820 0.814 0.828			12.10.2009 19.10.2009 27.10.2009 03.11.2009	42-43 43-44 44-46 45-47	7±1 days	Whole plant without roots	20.7 12.1	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 analysed**	**Residues [mg/kg]**	**PHI [days]**	**Selected values**
				kg a.s./ ha	**Water [l/ha]**	**kg a.s./hl**					**Copper**		
A/SP/F/09/166 Plot 1 Spain Valencia 12580 Benicarló Greenhouse 2009	Flowbrix SC (Copper oxychloride SC)	Lettuce/Chiquina	1) 17.09.09	0.784 0.793 0.826 0.828			05.10.2009 12.10.2009 19.10.2009 27.10.2009	42 43-44 44-46 45-47	7±1 days	Whole plant without roots	24.5 11.6 17.0 9.61 6.60	0 3 5 7 15	HR: 23.0 Mean: 16.3
A/SP/F/09/166 Plot 2 Spain Valencia 12580 Benicarló Greenhouse 2009	Cuproxat flüssig	Lettuce/Chiquina	1) 17.09.09	0.776 0.811 0.776 0.807			05.10.2009 12.10.2009 19.10.2009 27.10.2009	42 43-44 44-46 45-47		Whole plant without roots	20.0 24.1 14.4 23.0 14.5	0 3 5 7 15	
A/NF/F/10/109 Plot 1 France Champagne-Ardennes 51110 Auménancourt le Grand 2010	Copper oxychloride 50 WP (SU)	Lettuce/Florine	1) 07.09.2010	0.858 0.779 0.805 0.800			05.10.2010 12.10.2010 19.10.2010 26.10.2010	46 47 48 48	7 days	Whole plant without roots Washed	58.9 28.3 24.7	0 7 7	HR: 28.3 Mean: 25.3
A/NF/F/10/109 Plot 2 France Champagne-Ardennes 51110 Auménancourt le Grand 2010	Bordoflow New	Lettuce/Florine	1) 07.09.2010	0.804 0.779 0.784 0.794			05.10.2010 12.10.2010 19.10.2010 26.10.2010	46 47 48 48	7 days	Whole plant without roots Washed	57.3 22.2 29.6	0 7 7	
A/SF/F/10/110 Plot 1 France Provence-Alpes- Côte d'Azur 13160 Châteaurenard 2010	ATOFAP17	Lettuce/Kitonia	1) 10.09.2010 (seeding) 23.09.2010 (transplanting)	0.853 0.853 0.831 0.840			13.10.2010 20.10.2010 27.10.2010 02.11.2010	19 41 47 49	7 days	Whole plant without roots Washed	47.3 34.1 32.5	0 7 7	HR: 34.3 Mean: 34.2
A/SF/F/10/110 Plot 2 France Provence-Alpes-Côte d'Azur 13160 Châteaurenard 2010	CA2112 (CHAMP FLO)	Lettuce/Kitonia	1) 10.09.2010 (seeding) 23.09.2010 (transplanting)	0.792 0.845 0.832 0.818			13.10.2010 20.10.2010 27.10.2010 02.11.2010	19 41 47 49	7 days	Whole plant without roots Washed	55.7 34.3 29.5	0 7 7	

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 rev. 3.1)

A 3.1 TMDI calculations (all crops) – Tier I

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

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:	

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	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	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	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities
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.