FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: SHA 9100 A

Product name(s): HYCOP

Chemical active substances:

Copper Hydroxide, 500 g/kg (as Cu)

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: May 2019

MS Finalisation date: 12/2020 08/2021

Version history

When	What
November 2020	Applicant update
December 2020	Assessment finalised by RMS
August 2021	Final version of the RR after commenting period

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

A letter of access to protected data for copper compound allowing the renewal of approval is submitted by applicant to support the application for HYCOP.

Storage stability

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

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

Metabolism in plant and animal

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

The residue definitions agreed for monitoring and risk assessment:

Copper compounds (copper)

No further data are required.

Magnitude of residues in plants

Grapevine

Proposed GAP: BBCH 15-85, 4 applications, interval between applications: 7-12 days, 1.0 kg (as copper), PHI: 21 days

GAP on which MRL/EU a.s. assessment is based: 4 x 2 kg as/ha, BBCH: 15-91, PHI 21d (wine grape, *EFSA Journal 2018;16(3):5212*)

Representative uses: 3 x 1.25 kg as/ha, BBCH: 12-89, PHI 21d (*SANTE/10506/2018Rev. 5, 27November 2018*)

The number of trials is sufficient as to support the use of Copper hydroxide in grapevines according to the proposed GAP in Central Zone (see DAR; trials also reported in RAR).

The residues arising from the proposed use will not exceed the MRLs for wine grape set at 50 mg/kg (Reg. (EU) 149/2008). Extrapolation to table grapes is possible (SANCO 7525/VI/95_rev 10.3).

Pome fruit (apple, pear, quince)

Proposed GAP: BBCH 15-85, 5 applications, interval between applications: 10-14 days, 0.575-1.2 kg (as copper), PHI: 14 days

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

Trials GAP: 3 x 1.2 kg as/ha, interval – 10 days, BBCH 83, PHI 21 days

Four trials were conducted in Hungary in 2019. Two harvest trials and two decline curve trials were set up on apples in Poland in 2019.

Results: 4 x <1.0 (LOQ), 1.2, 1.4, 1.5, 2,9 mg/kg.

GAP of trials is different than proposed. The residues arising from the trials are below MRL.

There is no agreement on the proposed use because the studies are not in line with it.

It is possible to accept the application in line with the provided new trials. GAP corrections were made in accordance with the GAP of this field new trials.

Extrapolation to pear and quince is possible (SANCO 7525/VI/95_rev 10.3).

Potato

Proposed GAP: BBCH 15-85, 4 applications, interval between applications: 7-12 days, 1.0-1.2 kg (as copper), PHI: 14 days

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. Four trials were conducted in Hungary in 2019. Two harvest trials and two decline curve trials were set up on potatoes in Poland in 2019.

Trials GAP: 4 x 1.2 kg as/ha, interval – 7 days, BBCH 85

Results: 8 x < 3.7 (LOQ)

The number of trials is sufficient as to support the use of Copper hydroxide in potato according to the proposed GAP in Central Zone.

The residues arising from the proposed use will not exceed the MRLs for potatoes set at 5.0 mg/kg (Reg. (EU) 149/2008).

Solanaceous fruits (Tomato, aubergine)

Proposed GAP: BBCH 15-85, 3 applications, interval between applications: 7-10 days, 0.75-1.2 kg (as copper), PHI: 14 days

The EU data (EFSA, 2008; EFSA Journal 2018;16(1):5152) are sufficient to cover proposed uses in SEU and protected uses in NEU and SEU. There is no sufficient data to cover proposed uses in outdoor NEU.

Uses are not accepted.

Magnitude of residues in livestock

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

Industrial Processing and/or Household Preparation

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

Magnitude of residues in representative succeeding crops

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

No additional studies are required.

Consumer risk assessment

The proposed uses of copper in the formulation SHA 9100A do not represent unacceptable acute and chronic risks for the consumer.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation product code are presented in Table 7.1-1. They have been selected from the individual GAPs in the zone/EU for crop 1. A list of all intended uses within the zone/EU is given in Part B, Section 0.

Note: A list of all uses within the EU should only be presented if the application refers to the whole EU (seed treatment, indoor application).

Add a justification for the selection of the critical GAP, if appropriate.

Justification for the selection of the critical GAP

Overall conclusion

State whether or not the available data are sufficient for evaluation, if a risk for consumers has been detected for any European Member State and if a new MRL is required prior to authorization. Data gaps and conditions for registration should be listed (if appropriate).

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of xxx mg/kg for active substance as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of active substance residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, authority, zRMS agrees with the authorization of the intended use(s).

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

Or

According to available data, the following specific mitigation measures are recommended: ...

Data gaps

Data gaps should be listed in the summary to give an overview (especially for cMS).

Noticed data gaps are:

- Residue trials for field tomato to cover uses in central zone

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

1	2	3	4	5	6	7	8	9	10	11	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: developmen-tal stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [(f)]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	CEU	**Grapevine**	F	Downy mildew *(Plasmo-para viticola)*	Foliar Spray	BBCH 15-85	a) 4 b) 4	7-12	a) 2.0 b) 8.0	a) 1.0* b) 4.0*	800-1000	21	* Expressed as Cu A
2	CEU	**Potato**	F	Late blight *(Phytophtora infestans)*	Foliar Spray	BBCH 15-85	a) 4 b) 4	7-12	a) 2.0-2.4 b) 7.2- 8.0	a) 1.0-1.2* b) 3.6-4.0*	500-1000	14	* Expressed as Cu 3 applications for dose of 2.4 kg/ha, 4 applica-tions for dose of 2.0 kg/ha A
3	CEU	**Solanaceous fruits (Tomato, aubergine)**	F	Late blight *(Phytophtora infestans)*	Foliar Spray	BBCH 15-85	a) 3 b) 3	7-10	a) 1.5-2.4 b) 4.5-7.2	a) 0.75-1.2* b) 2.25-3.6*	500-1000	3	* Expressed as Cu N
4	CEU	**Pome fruit (apple, pear, quince)**	F	Scab (*Venturia spp.*)	Foliar Spray	BBCH 15-85	~~a) 5~~ 3 ~~b) 5~~ 3	~~10-14~~ 10	a) 1.15-2.4 b) 5.75- 7.2	a) 0.575-1.2* b) 2.875-3.6*	800-1000	~~14~~ 21	* Expressed as Cu 3 applications for dose of 2.4 kg/ha (product) ~~5 applications for dose of 1.15 kg/ha~~ R

* 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 SHA 9100 A is composed of Copper Hydroxide.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Copper (Copper Hydroxide)					
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 Hydroxide

Table 7.1-3: Summary for Copper Hydroxide

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	**Grapevine**	Yes	Yes	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
~~2~~	~~**Solanaceous (tomato, eggplant)**~~	~~Yes~~	~~Yes~~	~~Yes/No~~	Yes~~/No~~	~~Yes/No~~		Yes/No
3	**Potato**	Yes	Yes	Yes/No	Yes/No	Yes/No		Yes/No
4	**Pome fruit (apple, pear, quince)**	Yes	Yes	Yes/No	Yes/No	Yes/No		Yes/No

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

Information that cannot be presented in the table and/or needs to be explained may be presented here.

If needed:

For crop 1, additional data are required in post-registration to confirm that a "no-residue" situation occurs in the worst case application: X application of X g/ha at growth stage BBCH X.

As residues of active substance do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Or

The effects of processing on the nature of active substance 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.

Or:

MRLs in following crops/ following mitigation measures have been proposed: to be specified.

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

~~An acute risk has been identified for crop. The use of product code on crop is therefore not acceptable.~~

7.1.2.2 Summary for SHA 9100 A

Table 7.1-4: Information on SHA 9100 A (KCA 6.8)

Crop	PHI for Copper hydroxide 50% WP proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for Copper hydroxide 50% WP proposed by zRMS	zRMS Comments (if different PHI proposed)
		Copper hydroxide		
Grapevine	21 days	Yes		
Potato	14 days	Yes		
~~Solanaceae fruits (Tomato, aubergine)~~	~~3 days~~	~~Yes~~		
Pome fruit (apple, pear, quince)	14 days	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).

The following table should be filled in if required:

Table 7.1-5: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for SHA 9100 A
Crop group	**Led by HYCOP**	
Leafy vegetables	NR	
Root vegetables	NR	

Grapevine	NR	
Pome fruits (apple, pear, quince)	NR	

NR: not relevant

Assessment

Note: A referral by applicant to an MRL compilation dossier or EFSA Reasoned Opinion is a referral to a summary of studies, and the underpinning studies require an evaluation according to Uniform Principles before they can be relied upon for authorization. Therefore, applicant needs to provide the studies and indicate where they have been previously evaluated to support authorization within the EU (as part of a Uniform Principles assessment).

7.2 Copper Hydroxide

General data on Copper Hydroxide (Copper) are summarized in the table below.

Table 7.2-1: General information on Copper (as Copper Hydroxide)

Active substance (ISO Common Name)	Copper as Copper Hydroxide
IUPAC	copper(II) hydroxide or cupric hydroxide
Chemical structure	Cu(OH)2
Molecular formula	CuH2O2
Molar mass	97.6
Chemical group	Inorganic salt of copper
Mode of action (if available)	Fungicidal and bactericidal
Systemic	No
Company (ies)	EUCuTF *
Rapporteur Member State (RMS)	FR
Approval status	Approved Date of (01/12/2009) and reference to decision (COMMISSION DIRECTIVE 2009/37/EC – COMMISSION IMPLEMENTING REGULATION (EU) No 540/2011) Renewal Date of (01/01/2019) and reference to decision Commission Implementing Regulation (EU 2018/1981)
Restriction	Only uses as bactericide and fungicide may be authorised
Review Report	SANCO/150/08 –10/10/2014 SANTE/10506/2018 Rev. 5 27 November 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	Yes: EFSA 2008 and EFSA 2013 (confirmatory data) and EFSA 2018 (Conclusion on Peer Review)
EFSA Journal: conclusion on article 12	No
Current MRL applications on intended uses	EFSA-Q-2010-00183

	Status: Evaluation complete

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

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

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 a monoatomic element and inherently stable. Therefore, it does not metabolize or form degradation products. All the methods used to generate residue data for both tomato and grapes include mineralization of the samples by acid digestion. In this condition, all forms of Copper present in the plant are converted to Cu^{2+}. Residue definition for risk assessment and monitoring is **total Copper.**

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 summarised 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 grapevine, solanaceous, potato, and pome fruits, 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 grapevine, solanaceous, potato, and pome fruits. 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 grapevine, cucurbits, solanaceous, potato, leafy vegetables and artichoke following applications of copper as a plant protection product. Supervised trials to address this issue are summarised in Chapter 7.2.3.

Conclusion on metabolism in primary crops

Additional plant metabolism studies were not required and not relevant. Residue definition for risk assessment and monitoring is **total Copper.**

Sufficient data have been provided to acknowledge the metabolism of copper in/on grapevine, solanaceous, potato, and pome fruits.

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 is naturally present in soil and is essential for normal plant growth and development, thus all soil-grown crops contain Copper. It has been estimated that concentrations of Copper hitting the ground during application were found insignificant compared to the concentration of Copper naturally present in soil. Residue definition for risk assessment and monitoring is **total Copper.**

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

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

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.

Soil	**Soil concentration (mg Cu/kg soil DM)**	
Background level	**11.5**	
Vineyards	29.5	Overall median 10th percentile value LUCAS data[c]
	26.09	Overall median value LUCAS data
	128.0	Overall median 90th percentile value LUCAS data[d]
	49.26	Overall mean value LUCAS data
Arable fields[b]	7	Overall median 10th percentile value
	13.2	Overall median value
	26	Overall median 90th percentile value
	15	Overall mean value
Orchards[b]	-	Overall median 10th percentile value
	39.8	Overall median value
	58	Overall median 90th percentile value
	23	Overall mean value
Olive groves	24.7	Overall median value LUCAS data
	74.5	Overall median 90th percentile value LUCAS data
	33.5	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. The EUCuTF have therefore used the LUCAS data for their PEC soil calculations.
[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.

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

Due to the ubiquitous property of copper, which naturally present in plants 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 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.

Plant metabolism studies for rotational crops were not required and not relevant. Residue definition for risk assessment and monitoring is **total Copper.**

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	Yes

in primary crops?	
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.

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

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

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:

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)	**3.021**	**4.669**	**4.209**	**3.582**	**1.534**	**0.715**	**1.098**	**1.518**	**0.782**
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 calculated under Section 7.2.4.1 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)

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

	Endpoints
Animals covered	No study, not required
Time needed to reach a plateau concentration	Not applicable
Animal residue definition for monitoring	Total Copper (EFSA, 2008)
Animal residue definition for risk assessment	Total Copper (EFSA, 2008)
Conversion factor	None (EFSA, 2008)
Metabolism in rat and ruminant similar	Not applicable
Fat soluble residue	No

Copper is an element and will not be metabolised. 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

Table 7.2-4: Summary of EU reported and new data supporting the intended uses of SHA 9100A and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Residue levels (mg/kg)	~~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
Apple		~~S-EU outside~~	~~Whole fruit: 1.09, 1.325, 2.63, 1.235, 1.10, 0.985, 2.235, 1.335~~	~~0.39 – 0.67~~	~~1.28~~	~~2.2~~	-	~~5~~	~~Yes~~
	New trials	CEU outside	~~8 trials on going~~ GAP: 3x1.2 kg as/ha, interval – 10 days, BBCH 83, PHI 21 days ~~0.17 (<LOQ), 0.54 (<LOQ), 0.92 (<LOQ), 1.185, 1.421, 1.54, 2.964~~ 4 x <1.000 (LOQ), ~~1.2~~ 1.15, 1.42 , 1.54, ~~3.0~~ 2.96	-	~~1.0525~~ 1.00	~~2.964~~ 2.96		5	Yes
Grape, table, wine	DAR (also reported in RAR) XXX, P., 1999 XXX, R, 2003a;2003b; 2003c;2003d; 2003e;2003f XXX, C., 2003a;2003b XXX, A., 1998a;1998b	S-EU outside	GAP: 4x2kg as/ha, BBCH 83-89, PHI 14 9.05, 9.75, 6.9, 7.05, 4.85, 2.2, 4.1	-	7.15	9.75	-	~~20~~ 50	Yes
Grape, table, wine		N-EU ~~/ S-EU~~ outside	GAP: 4x2kg as/ha, BBCH 83-89, PHI 21 37.5, 4.1, 5.2, 5.6, 38, 9.4, 8.7, 4.2	-	~~7.15~~ 7.2	38.0	-	50	Yes

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Residue levels (mg/kg)	~~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
Grape, wine	XXX and Alland, 1999a XXX, A., 1999	N-EU / S-EU outside	37.5, 4.1, 5.2, 5.6, 38, 9.4, 8.7, 4.2, 9.05, 9.75, 6.9, 7.05, 4.85, 2.2, 4.1	-	~~0.28 (STMR (6.9) wine grapes N/SE * Transfer factor (0.04))~~ 6.9	38.0	-	50	Yes
Potato		~~N-EU outside~~	~~0.94, 0.54, 1.20, 1.00, 1.10, 1.00, 2.20, 0.90, 1.40, 1.60, 2.00, 2.30, 1.40, 1.10, 1.60, 1.30, 2.40, 3.10~~	~~0.48 – 3.8~~	~~1.30~~	~~4.3~~	-	~~5~~	~~Yes~~
		~~S-EU outside~~	~~1.52, 4.30, 3.10, 1.87, 3.30, 0.75, 1.70, 0.87, 1.00, 1.30, 2.80, 1.30, 1.20, 1.00, 1.80, 0.60, 1.60, 1.10, 1.66, 1.74, 6×<2.00, 1.2~~	~~0.08 – 1.9~~					
	New trials	N-EU	GAP: 4x1.2 kg as/ha, interval – 7 days, BBCH 85, PHI 14 days 7x<LOD (1.1), <LOQ (3.7)					5	Yes

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Residue levels (mg/kg)	Control residue in trials (mg/kg)	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Tomato	DAR (also reported in RAR) XXX, R, 2003f;2003g; 2003h; 2002 XXX, C., 2003c;2003d;2003e;2003f;2003g XXX and Alland, 1999b	Outdoor and In-door EU	PHI3: 1.8, 2.0, 2.9, 1.7, 1.5, 2.2, 1.5, 1.9, 2.4, 1.0, 1.0, 0.92, 1.0, 2.0, 2.0, 1.6, 2.0 PHI10 (PROC): 2.4, 2.2, 1.8, 1.5, 2.0, 2.3, 2.2, 1.4, 3.7, 2,2, 2.0, 2.2, 2.4, 1.4, 1.6, 1.7, 2.2, 2.1, 2.1	0.47 – 1.2	2.0 (STMR SEU PHI 3+10) 1.9	3.7	-	5	Yes
Pepper		N-EU/S-EU out-side	2.20, 3.07, 1.465, 1.25, 1.58, 2.97, 2.855, 2.22, 2.585, 3.37, 4.68	0.14 – 0.81	2.59	4.68	-	10	Yes
		Indoor EU	1.27, 1.345, 1.985, 2.875, 2.96, 0.985, 1.315, 3.175, 3.405						
		IndoorEU	Whole fruits: 0.79, 1.2, 1.8, 2, 2, 5		1.9	5	10	10	Yes
			Pulp: 0.34, 0.4, 0.4, 0.4, 0.7, 0.9		0.40	0.9	-	-	-
		S-EU outside	1.395, 1.605, 2.405, 2.63, 3.125, 3.765	0.51 – 1.44					

* Source of EU MRL: Reg (EC) 149/2018 2008

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available EU data, the intended uses on grapes (table and wine), ~~tomato~~, ~~eggplant~~, potato, and pome fruits are considered acceptable, ~~either for both indoor and~~ outdoor use according to each intended use.

According to appendix D of EU guidelines, extrapolation to solanaceous eggplants, are possible with all trials on tomato.

The data submitted show that no exceedance of the MRL will occur.

~~Additional trials on pome fruits are on going.~~

The uses on grapes (table and wine), ~~tomato~~, ~~eggplant,~~ potato, and pome fruits are considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Table 7.2-5: Input values for the dietary burden calculation (considering the uses authorized in the country of the zRMS/authorized within the zone/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	0.87	STMR	0.87	STMR
Potato, culls	1.30	STMR	1.30	STMR
Swede	0.95	Background data (EFSA,2018)	0.95	Background data (EFSA,2018)
Turnip	0.95	Background data (EFSA,2018)	0.95	Background data (EFSA,2018)
Barley, grain	4.09	Monitoring data (EFSA,2018)	4.09	Monitoring data (EFSA,2018)

Feed Commodity	**Median dietary burden**		**Maximum dietary burden**	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
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	1.28	STMR	1.28	STMR
Beet, sugar	1.40	STMR	1.40	STMR
Citrus	0.80	STMR (oranges)	0.80	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)
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 7.2-6: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Copper					
Beef cattle*	3.0206	3.021	Potato	40	Y
Dairy cattle*	4.6693	4.669	Potato	30	Y
Ram/ewe	4.2085	4.209	Potato	40	Y
Lamb	3.5815	3.582	Potato	20	Y
Breeding swine	1.531	1.531	Potato	20	Y
Finishing swine*	0.715	0.715	Soybean	10	Y
Broiler poultry	1.098	1.098	Potato	20	Y
Layer poultry*	1.518	1.518	Beet, sugar	5	Y
Turkey	0.782	0.782	Soybean	45	Y

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

zRMS comment:
A dietary burden calculation has been performed by EFSA during the review of existing MRLs for copper compounds (EFSA Journal 2018;16(3):5212). Authorised uses, background residue levels and monitoring data were considered in this assessment. The dietary burdens calculated for all groups of livestock were found to highly exceed the trigger value of 0.004 mg/kg bw/d.
The dietary burdens calculated for all groups of livestock were found to highly exceed the trigger value of 0.1 mg/kg dry matter (DM). The calculated dietary burdens range between 19.1 mg/kg DM (poultry layer) to 147.6 mg/kg DM (cattle). For information purpose, EFSA also assessed the theoretical dietary burdens which would result from the authorised uses only, meaning without consideration of the background levels and monitoring data. The dietary burdens hereby calculated would range between 14.8 and 138.7 mg/kg DM, which is in the same range than the overall dietary burdens resulting from the above mentioned calculation. As this calculation is just theoretical, it was not reported in the list of end points of the present opinion. However, this result just shows that the residues arising from the direct authorised pesticide uses (in particular potatoes and by-products of potato industry) are the main drivers of the dietary burden compared to the background levels of copper.

Input Values: EFSA Journal 2018;16(3):5212

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Max dietary burden (mg/kg DM)	Highest contributing commodity[(a)]	Trigger exceeded (Y/N)
	Risk assessment residue definition: total copper				
Cattle (all diets)	4.13	4.39	147.6[b]	Potatoes (process waste)	Y
Cattle (dairy only)	4.13	4.39	114.1	Potatoes (process waste)	Y
Sheep (all diets)	4.62	4.80	143.9	Potatoes (process waste)	Y
Sheep (ewe only)	4.62	4.80	143.9	Potatoes (process waste)	Y

Animal species	**Median dietary burden (mg/kg bw/d)**	**Maximum dietary burden (mg/kg bw/d)**	**Max dietary burden (mg/kg DM)**	**Highest contributing commodity[(a)]**	**Trigger exceeded (Y/N)**
Swine (all diets)	1.73	1.88	81.4	Potatoes (process waste)	Y
Poultry (all diets)	1.53	1.58	22.5	Potatoes (dried pulp)	Y
Poultry (layer only)	1.20	1.31	19.1	Potatoes (dried pulp)	Y

bw: body weight
a) For the maximum dietary burden.
b) The highest dietary burdens expressed in mg/kg DM results from beef cattle.

Additional calculations are not required.

Applicant is asked to explain the presented in this point data (see Reporting Table, DE comment No 5).

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 summarised 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)	**3.021**	**4.669**	**4.209**	**3.582**	**1.534**	**0.715**	**1.098**	**1.518**	**0.782**
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 calculated under Section 7.2.4.1 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(s) and were considered acceptable. No further studies have been performed.

7.2.5.1 Available data for all crops under consideration

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

Table 7.2-7: Overview of the available processing studies

Processed commodity	Number of studies[(a)]	Median PF *	Median CF **	Comments	Reference
EU data					
Copper					
Table grapes, dried (raisins)	9	2.60			EFSA 2018
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					
Indicative processing faactors (limited dataset)					
Apples, wet pomace	2	0.73			EFSA 2018
Applicant data, used in risk assessment (previously assessed at EU level)					
Tomatoes, washed fruit	10	0.6			EFSA 2008
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) PF for wine is derived from a combined dataset of red and white wine studies

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.

Grapes:

A total of 24 trials were carried out in wine and table grapes in southern and northern EU countries over four seasons.

Samples of treated and untreated fruit were taken at normal harvest (PHI 21 days or later) and processed into fractions following the production of juice, wine and raisins.

In balance studies, residues of copper were determined in all processed fractions including the by-products and waster products. In follow-up studies, residues were determined in by-products and edible commodities only (i.e. must, juice, wine, wet pomace and raisins) and transfer factors were determined.

In wine grapes, residues of copper in the treated must and pomace were higher than in the corresponding unprocessed fruit and the mean transfer factors for these two commodities were 1.9 and 2.8, respectively. Residues of copper in treated juice and wine were lower than in the corresponding unprocessed fruit and the mean transfer factors for these two commodities were 0.4 and 0.07, respectively. The mean residue for copper in wine was 0.4 mg/kg.

Levels of copper in untreated commodities were higher than the untreated unprocessed fruit in juice (transfer factor 1.5), wet pomace (transfer factor 3.5) and lower than untreated fruit in must (transfer factor 0.7) and wine (transfer factor 0.11).

In table grapes, residues of copper in the treated raisins were higher than in the corresponding unprocessed fruit (mean transfer factor 2.7). Levels of copper in the untreated raisins were also higher than in the corresponding unprocessed fruit (mean transfer factor 4.7).

7.2.6 Magnitude of residues in representative succeeding crops

See Chapter 7.2.2.2.

On crop under evaluation (grapevine and pome fruits) is not expected to be grown in rotation. Further investigation of residues in rotational crop is therefore not required. Other crops under consideration (tomato, eggplants, potato) can be grown in rotation. Considering available data dealing with nature of residues, no study dealing with magnitude of residues in succeeding crops is needed.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.

Conclusion on rotational crops studies

No studies were required/relevant. It has been estimated that concentrations of Copper hitting the ground during application were found insignificant compared to the concentration of Copper naturally present in soil (EFSA, 2008).

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

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of COPPER HYDROXIDE 50 WP. 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. Also, the bees are not attracted to the flowers from tomato and grapes crops.
A survey of recent peer-reviewed literature revealed that levels of copper broadly vary between 0.11-15.5 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 characterisation of artisanal honey produced on the island of Ireland by palynological and physico-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 producted 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). 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. **Błąd! Nie można odnaleźć źródła odwołania.**

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 7.2-8: 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 1)	Back-ground mg/kg 2)	Monitoring mg/kg 2)	PRIMo Input mg/kg	Comment / Refer-ence
1	FRUIT (FRESH OR FROZEN)										
	Citrus fruit	20	SEU								
	Grapefruit		SEU					0.44	0.49	0.80	STMR Oranges (Pulp)
4	Oranges		SEU	Pulp (BBCH≥84): 0.51, 0.54, 0.56, 0.68, 0.71, 0.8, 0.9, 1.075, 1.28, 1.42, 1.87	0.80	1.9		0.44	0.51	0.80	STMR Oranges (pulp) with BBCH≥84
4	Lemons		SEU					0.44	0.53	0.62	STMR Mandarin (Pulp)
4	Limes		SEU					0.44	-	0.62	STMR Mandarin (Pulp)
4	Mandarins		SEU	Pulp (BBCH≥84): 0.41, 0.42, 0.49, 0.62 0.78, 1.20, 1.62	0.62	1.6	0.48 – 0.70	0.44	0.59	0.62	STMR Mandarins (pulp) with BBCH≥84
4	Other citrus fruits		SEU						-	0.80	STMR Oranges (Pulp)
2	Tree nuts (shelled or unshelled)	30	SEU	Almond: 6.735, 10.20, 11.105 Walnuts: 10.63, 12.00, 8.045, 10.615, 14.40	10.6	14.4	7.27-18.3	4.5-13.3	12.64-18.92	10.62	STMR Al-mond/walnut
	Almonds							10.7	-	10.62	STMR Al-mond/walnut
	Brazil nuts							10.7	18.92	10.62	Extrapolation from Al-mond/walnut (STMR)
	Cashew nuts							13.3	-	13.3	Background data (EFSA, 2018)
	Chestnuts							10.7	-	10.62	Extrapolation

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 1)	Back-ground mg/kg 2)	Monitoring mg/kg 2)	PRIMo Input mg/kg	Comment / Refer-ence
											from Al-mond/walnut (STMR)
	Coconuts							4.5	-	4.5	Background data (EFSA, 2018)
	Hazelnuts/cobnuts							10.7	15.13	10.62	Extrapolation from Al-mond/walnut (STMR)
	Macadamia							10.7	-	10.62	Extrapolation from Al-mond/walnut (STMR)
	Pecans							10.7	-	10.62	Extrapolation from Al-mond/walnut (STMR)
	Pine nut kernels							13.3	15.96 (n=103)	15.96	Monitoring data (EFSA, 2018)
	Pistachios							13.3	-	10.62	Extrapolation from Al-mond/walnut (STMR)
	Walnuts							10.7	12.64	10.62	Extrapolation from Al-mond/walnut (STMR)
	Other tree nuts									10.62	Extrapolation from Al-mond/walnut (STMR)

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 1)	Back-ground mg/kg 2)	Monitoring mg/kg 2)	PRIMo Input mg/kg	Comment / Refer-ence
2	Pome fruit	5	SEU								
	Apples		SEU	0.98, 1.09, 1.10, 1.24, 1.33, 1.34, 2.24, 2.63	1.28	2.63	0.39 – 0.67	0.77	0.5 (n=128)	Tier I: 1.28 Tier II: 0.5	Tier I: STMR Apples Tier II: Monitoring data (EFSA, 2018)
4	Pears		SEU					0.77	0.8	1.28	STMR Apples (post-flowering)
4	Quinces		SEU					0.77	<2	1.28	STMR Apples (post-flowering)
4	Medlar		SEU					0.77	-	1.28	STMR Apples (post-flowering)
	Loquat		SEU					0.77	-	1.28	STMR Apples (post-flowering)
4	Other pome fruits		SEU							1.28	STMR Apples (post-flowering)
2	Stone fruit	5	SEU								
	Apricots		SEU					1.02	0.76	2.36	STMR peaches (pulp)
4	Cherries		N/SEU	Pulp: 1.355, 1.77, 2.735, 4.01, 3.315, 4.15, 4.765	3.32	4.76		1.02	0.77	3.32	STMR cherries N+S pulp
4	Peaches		SEU	Pulp: 1.405, 2.135, 2.275, 2.33, 2.39, 3.29, 3.36, 4.09	2.36	4.09	0.29 – 1.32	1.02	0.89	2.36	STMR peaches (pulp)
4	Plums		SEU	0.72, 0.75, 1.45, 1.86	1.10	1.86	-	1.02	0.62	1.10	STMR plum (pulp)
4	Other stone fruits		SEU					1.02		1.28	STMR Apples (post-flowering)
2	Berries & small fruits										

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 1)	Back-ground mg/kg 2)	Monitoring mg/kg 2)	PRIMo Input mg/kg	Comment / Refer-ence
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	All	0.47, 0.47, 0.51, 0.70, 0.81, 0.87, 0.94, 0.97, 1.08, 1.18, 1.20, 1.36, 1.43, 1.75, 1.76, 2.43, 2.69, 2.94, 3.12, 3.28, 3.28, 3.57, 4.37, 5.16, 5.95	1.36	5.95	0.14 – 1.23	0.43	0.37 (n=193)	Tier I: 1.36 Tier II: 0.37	Tier I: STMR all regions Tier II: Monitoring data (EFSA, 2018)
4	Blackberries							1.4	0.95	1.00	Extrapolation rasp-berries/currant STMR
4	Dewberries							1.4	0.79	1.00	Extrapolation rasp-berries/currant STMR
4	Raspberries	3	SEU	0.77, 0.95, 1.04, 1.08	1.00	1.08	0.7 – 1.22	1.4	0.61	1.00	STMR raspber-ries/currant
4	Other Cane fruits									1.00	Extrapolation rasp-berries/currant STMR
3	Other small fruits & berries	5									

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 1)	Back-ground mg/kg 2)	Monitoring mg/kg 2)	PRIMo Input mg/kg	Comment / Refer-ence
4	Blueberries							1.4	0.6	1.00	Extrapolation rasp-berries/currant STMR
4	Cranberries							1.4	<2	1.00	Extrapolation rasp-berries/currant STMR
4	Currants (red, black, white)	3	SEU	0.77, 0.95, 1.04, 1.08	1.00	1.08	0.62 – 0.91	1.4	0.78	1.00	STMR raspber-ries/currant
4	Gooseberries							1.4	0.77	1.00	Extrapolation rasp-berries/currant STMR
4	Rose hips							1.4	-	1.00	Extrapolation rasp-berries/currant STMR
4	Mulberries							1.4	-	1.00	Extrapolation rasp-berries/currant STMR
4	Azarole							1.4	-	1.00	Extrapolation rasp-berries/currant STMR
4	Elderberries							1.4	-	1.00	Extrapolation rasp-berries/currant STMR
4	Other small fruits & berries								-	1.00	Extrapolation rasp-berries/currant STMR
2	Miscellaneous fruit										
3	Miscellaneous fruit (edible peel)	20									
4	Dates							0.86	1.73	0.86	Background data

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 1)	Back-ground mg/kg 2)	Monitoring mg/kg 2)	PRIMo Input mg/kg	Comment / Refer-ence
											(EFSA, 2018)
4	Figs							0.86	7.85	7.85	Monitoring data (EFSA, 2018)
4	Table olives		SEU	Pulp 2.60, 4.83, 5.05, 5.10, 5.12, 5.28, 5.45, 5.92, 6.37, 6.67, 7.82, 8.91, 9.63, 10.81, 11.21, 19.11	6.143	19	2.15-4.61	2.28	2.95	6.143	STMR olive (pulp)
4	Kumquats							0.86	<2	0.86	Background data (EFSA, 2018)
4	Carambola							0.86	-	0.86	Background data (EFSA, 2018)
4	Persimmon							0.86	0.22	0.86	Background data (EFSA, 2018)
4	Jambolan (java plum)							0.86	-	0.86	Background data (EFSA, 2018)
4	Other misc. fruits (edible peel)							0.86	-	0.86	Background data (EFSA, 2018)
3	Miscellaneous fruit (inedible peel, small)	20									
4	Kiwi			Whole fruit 5.470, 7.016, 6.871, 11.235 Pulp: 1.67, 1.73, 3.03, 3.05, 3.09	3.04	3.09	1.18-2.27	1.48	1.54	3.04	STMR Kiwi (pulp)
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 (cac-tus fruit)							1.48	-	1.48	Background data (EFSA, 2018)

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 1)	Back-ground mg/kg 2)	Monitoring mg/kg 2)	PRIMo Input mg/kg	Comment / Refer-ence
4	Star apple							1.48	-	1.48	Background data (EFSA, 2018)
4	American persim-mon							1.48	-	1.48	Background data (EFSA, 2018)
4	Other misc. fruit (inedible peel, small										
3	Miscellaneous fruit (inedible peel, large)										
4	Avocados							0.96	2.9	0.96	Background data (EFSA, 2018)
4	Bananas							0.96	1.08	0.96	Background data (EFSA, 2018)
4	Mangoes							0.96	0.6	0.96	Background data (EFSA, 2018)
4	Papaya							0.96	0.39	0.96	Background data (EFSA, 2018)
4	Pomegranate							0.96	1.44	0.96	Background data (EFSA, 2018)
4	Cherimoya							0.96	-	0.96	Background data (EFSA, 2018)
4	Guava							0.96	0.74	0.96	Background data (EFSA, 2018)
4	Pineapple							0.96	0.88	0.96	Background data (EFSA, 2018)
4	Bread fruit							0.96	-	0.96	Background data (EFSA, 2018)
4	Durian							0.96	-	0.96	Background data (EFSA, 2018)

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 1)	Back-ground mg/kg 2)	Monitoring mg/kg 2)	PRIMo Input mg/kg	Comment / Reference
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	NEU	0.94, 0.54, 1.20, 1.00, 1.10, 1.00, 2.20, 0.90, 1.40, 1.60, 2.00, 2.30, 1.40, 1.10, 1.60, 1.30, 2.40, 3.10	1.30	4.3	0.08 – 3.8	1.06	0.86 (n=572)	Tier I: 1.30 Tier II: 0.86	Tier I: STMR tubers, NEU+SEU combined Tier II: Monitoring data (EFSA, 2018)
			SEU	1.52, 4.30, 3.10, 1.87, 3.30, 0.75, 1.70, 0.87, 1.00, 1.30, 2.80, 1.30, 1.20, 1.00, 1.80, 0.60, 1.60, 1.10, 1.66, 1.74, 6×<2.00, 1.2							
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							1.51	-	1.51	Background data

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 1)	Back-ground mg/kg 2)	Monitoring mg/kg 2)	PRIMo Input mg/kg	Comment / Refer-ence
	and tuber vegeta-bles										(EFSA, 2018)
4	Beetroot							0.95	0.77	0.95	Background data (EFSA, 2018)
4	Carrots	3	NEU/SEU	0.55, 1.215, 0.87, 0.485, 0.87, 2.14, 0.82, 0.86, 1.48, 1.44	0.87	2.14	0.29 – 1.99	0.95	0.46 (n=125)	Tier I: 0.87 Tier II: 0.46	Tier I: STMR Carrot Tier II: 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 arti-chokes							0.95	-	0.95	Background data (EFSA, 2018)
4	Parsnips							0.95	1.02	0.95	Background data (EFSA, 2018)
4	Parsley root							0.95	1.46	0.95	Background data (EFSA, 2018)
4	Radishes							0.95	0.17 (n=76)	0.17	Monitoring data (EFSA, 2018
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

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 1)	Back-ground mg/kg 2)	Monitoring mg/kg 2)	PRIMo Input mg/kg	Comment / Refer-ence
											(EFSA, 2018)
4	Onions		NEU SEU	0.455, 0.49, 0.53, 0.53, 0.565, 0.625, 0.74, 0.37, 0.46, 0.615, 0.81	0.53	0.81	0.37-0.8	0.56	0.55	0.53	STMR Onion NEU+SEU
4	Shallots									0.53	STMR onion
	Spring onions							0.83	0.51	0.83	Background data (EFSA, 2018)
4	Other bulb vegeta-bles									0.83	Background data (EFSA, 2018)
2	Fruiting vegetables										
3	Solanacea	5									
4	Tomatoes		SEU	PHI3: 1.8, 2.0, 2.9, 1.7, 1.5, 2.2, 1.5, 1.9, 2.4, 1.0, 1.0, 0.92, 1.0, 2.0, 2.0, 1.6, 2.0 PHI10 (PROC): 2.4, 2.2, 1.8, 1.5, 2.0, 2.3, 2.2, 1.4, 3.7, 2,2, 2.0, 2.2, 2.4, 1.4, 1.6, 1.7, 2.2, 2.1, 2.1	2.0	3.7	0.47-1.2	0.75	0.37	2.0	STMR SEU PHI 3+10
	Peppers		NEU SEU GH	2.20, 3.07, 1.465, 1.25, 1.58, 2.97, 2.855, 2.22, 2.585, 3.37, 4.68, 1.27, 1.345, 1.985, 2.875, 2.96, 0.985, 1.315, 3.175, 3.405	2.59	4.68	0.14-0.81	0.75	0.56	2.59	STMR NEU+SEU+GH
4	Aubergines (egg-plant)							0.75	0.46	2.59	Extrapolation from Pepper (STMR)
4	Okra, lady’s fin-gers							0.94	-	0.94	Background data (EFS, 2018)
4	Other solanacea								-	0.94	Extrapolation from

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 1)	Back-ground mg/kg 2)	Monitoring mg/kg 2)	PRIMo Input mg/kg	Comment / Refer-ence
											Okra
3	Cucurbits (edible peel)	5									
4	Cucumbers		NEU SEU GH	0.37, 0.51, 0.515, 0.63, 0.745, 0.955, 1.24, 1.35, 0.61, 0.495, 0.425, 0.465, 0.87, 0.76, 0.59, 0.625, 0.35, 0.54, 0.545, 0.635, 0.67, 0.93, 1.255, 1.775	0.63	1.78	0.21-0.58	0.37	0.31	0.63	STMR NEU+SEU+GH
4	Gherkins									0.63	Extrapolation from cucumber (STMR)
4	Courgettes									0.63	Extrapolation from cucumber (STMR)
4	Other cucurbits (edible peel)									0.63	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	0.405	5		0.42	0.47	0.405	STMR SEU+GH Pulp
			GH	Whole fruits: 0.79, 1.2, 1.8, 2, 2, 5 Pulp: 0.34, 0.4, 0.4, 0.4, 0.7, 0.9							
4	Pumpkin									0.405	Extrapolation from melon (STMR Pulp)

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 1)	Back-ground mg/kg 2)	Monitoring mg/kg 2)	PRIMo Input mg/kg	Comment / Refer-ence
4	Watermelon									0.405	Extrapolation from melon (STMR Pulp)
4	Other cucurbits (inedible peel)									0.405	Extrapolation from melon (STMR Pulp)
3	Sweet corn	10						0.48	0.88 (n=84)	0.88	Monitoring data (EFSA, 2018)
3	Other fruiting veg-etables	5									
2	Brassica vegeta-bles	20									
3	Flowering brassica										
4	Broccoli		SEU	0.86, 0.92, 1.11, 1.92	1.01	1.92	0.26-0.54	0.41	0.52	1.01	STMR
4	Cauliflower		SEU	0.23, 0.35, 0.37, 2.79	0.36	2.79	0.25-0.34	0.41	0.28	0.36	STMR
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 brassi-ca									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 brassi-									1.24	Monitoring data

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 1)	Back-ground mg/kg 2)	Monitoring mg/kg 2)	PRIMo Input mg/kg	Comment / Refer-ence
	ca										(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 let-tuce
4	Lettuce		GH	36.0, 20.2, 64.6, 35.4, 17.5, 16.3, 25.3, 34.2	22.75	64.6		0.83	2.57 (n=166)	Tier I: 22.75 Tier II: 2.57	Tier I: STMR GH+SEU Tier II: Monitoring data (EFSA, 2018)
			SEU	53.95, 43.2, 7.09, 20.2, 31.05, 11.3, 3.22, 2.03							
4	Escarole (broad-leave endive)							0.56	0.44	Tier I: 22.75 Tier II: 2.57	Extrapolation let-tuce
4	Cress							0.83	-	Tier I: 22.75 Tier II: 2.57	Extrapolation let-tuce
4	Land cress							0.83	-	Tier I: 22.75 Tier II: 2.57	Extrapolation let-tuce
4	Rocket, Rucola							0.83	0.81 (n=61)	0.81	Monitoring data (EFSA, 2018)

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 1)	Back-ground mg/kg 2)	Monitoring mg/kg 2)	PRIMo Input mg/kg	Comment / Refer-ence
4	Red mustard							0.83	-	Tier I: 22.75 Tier II: 2.57	Extrapolation let-tuce
4	Leaves and sprouts of Brassica spp							0.56	-	Tier I: 22.75 Tier II: 2.57	Extrapolation let-tuce
4	Other lettuce and other salad plants									Tier I: 22.75 Tier II: 2.57	Extrapolation let-tuce
2	Leaf vegetables & fresh herbs										
3	Spinach & similar (leaves)	20									
4	Spinach							0.83	1.59	1 Tier I: 22.75 Tier II: 2.57	Extrapolation let-tuce
4	Purslane							0.83	-	0.83	Extrapolation let-tuce
4	Beet leaves							0.83	<2	0.83	Extrapolation let-tuce
4	Other spinach and similar						1.1	0.83	-	0.83	Extrapolation let-tuce
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

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 1)	Back-ground mg/kg 2)	Monitoring mg/kg 2)	PRIMo Input mg/kg	Comment / Refer-ence
											(EFSA, 2018)
3	Herbs						4.2	1.20	1.85 (n=530)	1.85	Monitoring data (EFSA, 2018)
2	Legume vegeta-bles (fresh)	20									
4	Beans (whole pods)		NEU	1.76, 1.84, 2.26, 3.27, 3.29, 3.66	2.52	3.77	0.38-1.44	0.48	0.78	2.52	STMR NEU+SEU
			SEU	1.395, 1.605, 2.405, 2.63, 3.125, 3.765							
	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)		SEU/ NEU	1.495, 1.79, 2.03, 2.44, 2.445, 2.585, 1.55, 1.97, 2.47	2.03	2.59	1.18-1.88	1.76	1.42	2.03	STMR NEU+SEU
4	Lentils (fresh)									3.18	Background data (EFSA, 2018)
4	Other legume veg-etables (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	SEU	3.84, 4.73, 8,25, 11.31	6.49	11.31	0.66-	0.65	-	6.49	STMR

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 1)	Back-ground mg/kg 2)	Monitoring mg/kg 2)	PRIMo Input mg/kg	Comment / Refer-ence
							1.53				
4	Leek	20	SEU	3.94, 7.75, 14.2, 25.25	10.98	25.25	0.49-2.8	0.65	0.38	10.98	STMR
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										

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 1)	Back-ground mg/kg 2)	Monitoring mg/kg 2)	PRIMo Input mg/kg	Comment / Refer-ence
4	Linseeds	30						12.0	12.96 (n=96)	12.96	Monitoring data (EFSA, 2018)
4	Peanuts	30						12.0	-	12	Background data (EFSA, 2018)
4	Poppy seeds	30						12.0	16.05 (n=80)	16.05	Monitoring data (EFSA, 2018)
4	Sesame seed	30						12.0	16.11	12	Background data (EFSA, 2018)
4	Sunflower seed	40						12.0	18.41 (n=101)	18.41	Monitoring data (EFSA, 2018)
4	Rape seed	30						12.0	-	1.2	12.0 (x PF oil)
4	Soya bean	40						12.0	-	12	Background data (EFSA, 2018)
4	Mustard seed	30						12.0	6.17	12	Background data (EFSA, 2018)
4	Cotton seed	30						12.0	-	12	Background data (EFSA, 2018)
4	Pumpkin seed	30						12.0	11.35	12	Background data (EFSA, 2018)
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

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 1)	Back-ground mg/kg 2)	Monitoring mg/kg 2)	PRIMo Input mg/kg	Comment / Refer-ence
											Linseed
2	Oil fruits	30									
4	Olives for oil pro-duction			See table olives	6.1	19		2.28	-	0.61	STMR * PF (0.1)
1	Palm nuts (palmoil kernels)	30								4.54	From literature 3)
4	Palmfruit	30								3.34	From literature 4)
4	Kapok	30								4.54	Extrapolation from Palm nuts
4	Other oil fruits									4.54	Extrapolation from Palm nuts
1	CEREALS	10									
4	Barley							4.15	4.09 (n=83)	4.09	Monitoring data (EFSA, 2018)
4	Buckwheat							8.42	6.68	8.42	Background data (EFSA, 2018)
4	Maize							4.15	2.4	2.4	Median monitoring data (EFSA, 2018)
4	Millet							4.15	6.73	4.15	Background data (EFSA, 2018)
4	Oats							4.15	5.09	4.15	Background data (EFSA, 2018)
4	Rice							4.15	2.54 (n=264)	2.54	Monitoring data (EFSA, 2018)
4	Rye							4.15	3.57 (n=157)	3.57	Monitoring data (EFSA, 2018)
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

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 1)	Back-ground mg/kg 2)	Monitoring mg/kg 2)	PRIMo Input mg/kg	Comment / Refer-ence
											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		163, 178, 192, 250	184.86	249.5	6.3-56.4	-	149.8 (n=8)	184.86	STMR
1	SPICES	40								11.3	Background (EFSA, 2018)
1	SUGAR PLANTS	5									
4	Sugar beet (root)		NEU/ SEU	0.785, 1.905, 1.82, 1.20, 1.145, 1.125, 1.66, 1.60	1.4	1.91	0.48-1.36	1.25	-	1.4	STMR NEU+SEU
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									1.4	Extrapolation from Sugar beet
1	PRODUCT OF ANIMAL ORIGIN										
2	MEAT, etc.										
3	SWINE										

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 1)	Back-ground mg/kg 2)	Monitoring mg/kg 2)	PRIMo Input mg/kg	Comment / Refer-ence
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)
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						-		-	

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 1)	Back-ground mg/kg 2)	Monitoring mg/kg 2)	PRIMo Input mg/kg	Comment / Refer-ence
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. HIN-NIES										
4	Meat	5						0.9	2.1	0.9	Background data (EFSA, 2018)
4	Fat	5						0.39		0.39	Background data (EFSA, 2018)
4	Liver	30						64.3		64.3	Background data (EFSA, 2018)
4	Kidney	30						4.61		4.61	Background data (EFSA, 2018)
4	Edible offal	30								-	
4	Other products	5								-	
3	POULTRY										
4	Meat	5						0.65	3.47 (n=144)	3.47	Monitoring data (EFSA, 2018)
4	Fat	5						0	3.2	0	Background data (EFSA, 2018)
4	Liver	30						6.9	-	6.9	Background data

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 1)	Back-ground mg/kg 2)	Monitoring mg/kg 2)	PRIMo Input mg/kg	Comment / Refer-ence
											(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	0.58	Monitoring data

Level	RAC	tMRL	Region	Individual trial results mg/kg	Median STMR mg/kg	Highest residue mg/kg	Control mg/kg 1)	Back-ground mg/kg 2)	Monitoring mg/kg 2)	PRIMo Input mg/kg	Comment / Refer-ence
									(n=145)		(EFSA, 2018)
4	Qual							0.62	0.58 (n=145)	0.58	Monitoring data (EFSA, 2018)
4	Other eggs							0.62	0.58 (n=145)	0.58	Monitoring data (EFSA, 2018)
2	Honey									0.53	ANSES back-ground values
2	Amphibian and Rep.									2.5	ANSES back-ground values
2	Other terr.									4.00	ANSES back-ground 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

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 118% of ADI. For this diet, the highest contributor is natural copper background in maize with 11% of ADI. It should be noted that the biggest contributor (cereal) is not a supported use for copper compounds.The second highest TMDI for copper is the "GEMS/Food G11" with 81% of ADI where soyabean is the major contributor with 30% of the ADI.

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 92% of ADI. For this diet, the highest contributor is natural copper background in maize with 11% of ADI.

In private communication with EFSA4, the input values for maize consumption in the "NL Toddler" diet in the PRIMo Rev 3 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 (See Appendix 3 A 3.3).

Copper levels in drinking water5,6 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.

Dietary surveys

Model calculations as estimated above, based on STMR residue values are typically worst-case as they assume that all of the food commodity contains residues. Even with this assumption, the intakes of copper found on treated commodities are within the ADI of 0.15 mg/kg bw/day. The standard model (PRIMo) estimates that the highest dietary intake for copper is for the "NL Toddler" at 92% 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 7.2-9 below. These surveys indicate that the European median intakes of copper via the diet are in fact in the range of 0.39 – 1.46 mg/day across different age groups for both males and females. This is a more realistic estimate of copper intake levels.
Therefore, it can be concluded that the risk to consumers from the use of copper as a plant protection product is acceptable.

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

Table 7.2-9: 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.
EFSA11 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 are 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 funcigide 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

Extensive calculation sheets are presented in Appendix 3.

The TMDI estimates for the various diets were found 92-6% of ADI. The highest TMDI was calculated for the NL Toddler. For this diet, maize and wheat were the highest contributors to the residue intake, representing 11% of ADI and 11% of ADI, respectively. It should be noted that the biggest contributors

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

(cereal) are not supported uses for copper compounds.

The NESTI was not calculated as no ARfD was set.

Table 7.2-10: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	92% (NL Toddler Diet)
IEDI (% ADI) according to EFSA PRIMo	Not calculated
IESTI (% ARfD) according to EFSA PRIMo*	Not calculated

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

The proposed uses of copper in the formulation SHA 9100A 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

Aigberua, A.O., Ovuru, K.F. and Izah, S.C., Evaluation of Heavy Metals in Palm Oil Sold in Some Markets in Yenagoa Metropolis, Bayelsa State, Negeria, E C Nutrition 11.6(2017):244-252

Akpakpan, A.E., Eduok, U.M., Udiong, D.S., Udo, I.E. and Ntukuyoh, A.I., Level of Metals in Kernels and Shells of Oil Palm and Coconut Fruits, International Journal of Modern Chemistry, 2012, 2(1): 20-27

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.

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

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

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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
KCP 8.3.1.1	G. XXX	2020	Determination of the residues of copper hydroxide in/on potato after four applications of Copper hydroxide 50% WP in Northern Europe – Hungary in 2019. Report No. 034SRHU19R48 – field phase. GLP Unpublished	N	Sharda
KCP 8.3.1.2	J. XXX	2020	Quantitative analysis of copper residue in potato in field conditions (Raw Agricultural Commodity) after two application of Copper hydroxide 50% WP. Report No. PB-2020-06 – analytical phase. GLP Unpublished	N	Sharda
KCP 8.3.1.3	R. XXX	2020	Magnitude of the residue of copper hydroxide in potato (Raw Agricultural Commodity – RAC) grown in open field conditions after four applications of formulated product Copper hydroxide 50% WP – two harvest and two decline curve trials in Northern Europe – Poland (2019). Report No. D-2019-5 – field phase. GLP Unpublished	N	Sharda
KCP 8.3.1.4	J. XXX	2020	Quantitative analysis of copper residue in potato in field conditions (Raw Agricultural Commodity) after two applications of Copper hydroxide 50% WP Report No. PB-2020-05 – analytical phase. GLP	N	Sharda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 8.3.2.1	G. XXX	2019	Determination of the residues of copper hydroxide in/on apple after three applications of Copper Hydroxide 50% WP in Northern Europe – Hungary in 2019. G. Report No. 034SRHU19R49 – field phase. GLP Unpublished	N	Sharda
KCP 8.3.2.2	J. XXX	2020	Quantitative analysis of copper residue in apple in field conditions (Raw Agricultural Commodity) after two application of Copper hydroxide 50% WP. Report No. PB-2020-1 – analytical phase. GLP Unpublished	N	Sharda
KCP 8.3.2.3	R. XXX	2019	Magnitude of the residue of copper hydroxide in pome fruits (Raw Agricultural Commodity – RAC) grown in open field conditions after three applications of formulated product Copper hydroxide 50% WP – two harvest and two decline curve trials in Northern Europe – Poland (2019). Report No. D-2019-06 – field phase GLP Unpublished	N	Sharda
KCP 8.3.2.4	O. XXX	2020	Quantitative analysis of copper residue in apple in field conditions (Raw Agricultural Commodity) after two application of Copper hydroxide 50% WP. Report No. PB-2019-09 – field phase GLP Unpublished	N	Sharda

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

Please note that all data mentioned as part of Monograph, DAR, RAR, or EFSA journals are considered as relied on.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
CA 6.3.1-01	XXX, P.	1999	Generation of wine grape fruits and processed samples, suitable for residue analysis of copper, cymoxanil and folpet. 9801AGT Viti R&D, Y N	N	EuCuTF*
CA 6.3.1-02	XXX, R.	2003a	Copper: Residue levels in wine grape and processed fractions from trials conducted in France, Spain and Italy during 2001. AF/5989/CU. Agrisearch Y N	N	EuCuTF
CA 6.3.1-03	XXX, C.	2003a	Copper: Residue levels in wine grapes from trials conducted in southern France, Italy and southern Spain during 2002., AF/6891/CU. Agrisearch Y N	N	EuCuTF
CA 6.3.1-04	XXX, R.	2003b	Copper: Residue levels in wine grape and processed fractions from trials conducted in northern France and Ger-many during 2001 AF/5991/CU. Agrisearch GLP, Unpublished.	N	EuCuTF
K-CA 6.3.1-05	XXX, C.	2003b	Copper: Residue levels in wine grapes from trials conducted in Northern France and Germany during 2002 AF/6890/CU Agrisearch Y N	N	EuCuTF

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
K-CA 6.3.1-06	XXX, R.	2003c	Copper: Residue levels in wine grapes from a single trial conducted in northern France during 2002. AF/6842/CU. Agrisearch Y N	N	EuCuTF
K-CA 6.3.1-07	XXX, A	1998a	Determinazione dei residui di rame in uva a seguito di trattamenti per la difes della vite con I formulate pasta caffaro e cuprocaffaro 255 CER/RES (11/98) Industrie Chimiche Caffaro Y N	N	EuCuTF*
K-CA 6.3.1-08	XXX & XXX	1999a	Mesure du niveau de résidus de cuivre de l'hydroxyde de cuivre sur vigne. Ministère de l'agriculture et de la pêche, RVVIXX198/43 Y N	N	EuCuTF*
K-CA 6.3.1-09	XXX, A	1998b	Determinazione dei residui di rame in uva e vino 252 CER/RES (8/98) Industrie Chimiche Caffaro, Y N	N	EuCuTF*
CA 6.3.1-10	XXX, R	2003d	Copper: Residue levels in table grape and processed fractions from trials conducted in Spain and Italy during 2001. AF/5990/CU Agrisearch, Y N	N	EuCuTF
CA 6.3.1-11	XXX, R	2003e	Copper: Residue levels in table grape from a single trial conducted in Spain during 2002. AF/6550/CU.	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
			Agrisearch Y N		
CA 6.3.2-01	XXX, C	2003c	Copper: Residue levels in tomato (outdoor - industrial for processing) from trials conducted in France, Spain and Italy during 2002. AF/6548/CU. Agrisearch Y N	N	EuCuTF
CA 6.3.2-02	XXX, J C & XXX, L	1999b	*n.b. This reference is comprised of three separate reports in one pdf document…* 1. Mesure du niveau de résidus de cuivre sur tomate. RLTOXX197/30 Ministère de l'agriculture et de la pêche Y N 2. Mesure du niveau de résidus de cuivre de l'hydroxyde de cuivre sur tomate RLTOXX198/42 Ministère de l'agriculture et de la pêche Y N 3. Mesure du niveau de résidus de cuivre de l'hydroxyde de cuivre sur tomate RLTOXX199/43 Ministère de l'agriculture et de la pêche Y N	N	EuCuTF*
CA 6.3.2-03	XXX, R	2003f	Copper: Residue levels in tomato (outdoor - industrial for processing) from trials conducted in France, Spain and Italy during 2001. AF/5987/CU. Agrisearch, Y N	N	EuCuTF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
CA 6.3.2-04	XXX, C.	2003d	Copper: Residue levels in tomato (outdoor - for fresh consumption) from trials conducted in France, Spain and Italy during 2002. AF/6547/CU Agrisearch, Y N	N	EuCuTF
CA 6.3.2-05	XXX, R.	2003g	Copper: Residue levels in tomato (outdoor - for fresh consumption) from trials conducted in France, Spain and Italy during 2001. AF/5986/CU. Agrisearch Y N	N	EuCuTF
CA 6.3.2-06	XXX, C.	2003e	Copper: Residue levels in tomato (outdoor - for fresh consumption) from trials conducted in France, Spain and Italy during 2002. AF/6547/CU Agrisearch, Y N	N	EuCuTF
CA 6.3.3-01	XXX, 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	XXX, 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

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 6.3.4-01	XXX, N.	2009a	Determination of residues of copper in cucumber (RAC fruit) following four treatments with different copper formulations under open field conditions in northern and southern Europe in 2009 C 48132 Harlan laboratories Y N	N	EuCuTF*
CA 6.3.4-02	XXX, N.	2010a	Determination of residues of copper in cucumber (RAC fruit) following four treatments with different copper formulations under open field conditions in northern and southern Europe in 2010 C 91095 Harlan laboratories Y N	N	EuCuTF*
CA 6.3.4-03	XXX, N.	2011	Determination of residues of copper in cucumber (RAC fruit) following four treatments with different copper formulations under open field conditions in northern Europe in 2011 D35555 Harlan laboratories Y N	N	EuCuTF*
CA 6.3.5-01	XXX, N.	2009b	Determination of residues of copper in greenhouse cucumber (RAC fruit) following four treatments with different copper formulations in northern and southern Europe in 2009 C48121 Harlan laboratories Yes No	N	EuCuTF*
CA 6.3.5-02	XXX, N.	2010b	Determination of residues of copper in greenhouse cucumber (RAC fruit) following four treatments with different copper formulations in greenhouse in northern and southern Europe in 2010 C91084 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 6.3.6-01~~	~~XXX, A.C.~~	~~2006a~~	~~Magnitude of residues of copper and cymoxanil in field melons (fruiting vegetables) following applications of metallic copper (as copper oxychloride)/cymoxanil (DPX-KK807) 44WG (9.5:1) under maximum label rates – southern Europe, 2004~~ ~~DuPont-14542, Revision No. 1~~ ~~Charles River Laboratories (UK)~~ ~~Y~~ ~~N~~	~~N~~	~~EuCuTF*~~
~~CA 6.3.6-02~~	~~XXX, A.C.~~	~~2006b~~	~~Magnitude of residues of copper and cymoxanil in field melons (fruiting vegetables) following applications of metallic copper (as copper oxychloride)/cymoxanil (DPX-KK807) 44WG (9.5:1) under maximum label rates – southern Europe, season 2005~~ ~~DuPont-16970~~ ~~Charles River Laboratories (UK)~~ ~~Y~~ ~~N~~	~~N~~	~~EuCuTF*~~
~~CA 6.3.6-03~~	~~XXX, R.J.~~	~~2008a~~	~~Magnitude of residues of copper in field melons (cucurbits-inedible peel) following applications of metallic copper (as copper oxychloride)/Cymoxanil (DPX-KK807) 44WP (9.5:1)-southern Europe, season 2007~~ ~~DuPont-22565~~ ~~Charles River Laboratories (UK)~~ ~~Y~~ ~~N~~	~~N~~	~~EuCuTF*~~
~~CA 6.3.6-04~~	~~XXX, O~~	~~2005~~	~~Residue determination of copper in melon after 6 applications of ATOFAP02 (WG 20%) or ATOFAP17NC (WG 40%)~~ ~~B_05RFLME01~~ ~~Staphyt~~ ~~Yes~~ ~~No~~	~~N~~	~~EuCuTF*~~
~~CA 6.3.6-~~	~~XXX, O~~	~~2006~~	~~Residue determination of copper in melon after 6 applications of ATOFAP02 (Copper – 20% WG) or~~	~~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
05			ATOFAP17NC (Copper - 40% WG) B_06RFLME01 Y N		
CA 6.3.7-01	XXX, 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	XXX, 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*
CA 6.5.3/01:	XXX, R.	2003h	Copper: Residue levels in tomato (outdoor - industrial for processing) from trials conducted in France, Spain and Italy during 2001 AF/5987/CU Agrisearch Y N	N	EuCuTF
CA 6.5.3/02:	XXX, C.	2003g	Copper: Residue levels in tomato (outdoor - industrial for processing) from trials conducted in France, Spain and Italy during 2002. AF/6548/CU Agrisearch Y N	N	EuCuTF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
CA 6.5.3/03	XXX, P.	1999	Generation of wine grape fruits and processed samples, suitable for residue analysis of copper, cymoxanil and folpet 9801AGT, Processing phase 9801ATV. Viti R&D Y N	N	EuCuTF*
CA 6.5.3/03	XXX, C.	1999a	Analyses de résidus de cuivre sur raisin, vin, marc et mout. 981218 Lara Laboratoire Y N	N	EuCuTF*
CA 6.5.3/03	XXX, C.	2003a	Analyses de résidus de cuivre et cymoxanil sur raisin, vin. 981219. Lara Laboratoire Y N	N	EuCuTF*
CA 6.5.3/03	XXX, C.	2003b	Analyses de résidus de cuivre, cymoxanil et folpel sur raisin et vin. 981220. Lara Laboratoire Y N	N	EuCuTF*
CA 6.5.3/03	XXX, C.	1999b	Analyses de résidus de cuivre sur raisin. Lara Laboratoire, 990723. Y N	N	EuCuTF*
CA 6.5.3/04:	XXX, A.	1998b	Determinazione dei residui di rame in uva e vino 252 CER/RES (8/98) Industrie Chimiche Caffaro, Y	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
			N		
CA 6.5.3/05:	XXX, A.	1999	Determination of copper residues in grape raw agricultural commodity, and in must and wine following treatments with the preparation Bouillie Bordelaise RSR under field conditions in France in 1998. R 8031	N	UPL
CA 6.5.3/06:	XXX, R..	2003i	Copper: Residue levels in wine grape and processed fractions from trials conducted in France, Spain and Italy during 2001. AF/5989/CU	N	EuCuTF
CA 6.5.3/07	XXX, R.	2003j	Copper: Residue levels in wine grape and processed fractions from trials conducted in northern France and Germany during 2001 AF/5991/CU	N	EuCuTF
CA 6.5.3/08	XXX, R.	2003k	Copper: Residue levels in table grape and processed fractions from trials conducted in Spain and Italy during 2001. AF/5990/CU. Agrisearch Y N	N	EuCuTF
CA 6.5.3/09	Anon	1992	Cuprasol (49.9% copper as copper oxychloride) SPI 12827	N	EuCuTF
CA 6.5.3/10	Anon	1992	Wacker 83 v (24.8% copper as copper oxychloride) SPI 12828	N	EuCuTF
CA 6.5.3/11	Anon	1992	Fitoran grün (42.8% copper as copper oxychloride) SPI 12828	N	EuCuTF

* Owned by some members of the Task Force

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

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

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

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

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

List of data relied on and not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	EFSA	2018	Review if the existing maximum residue levels for copper compounds according to Article 12 of Regualtion (EC) 396/2005 - EFSA Journal 2018;16(3):5212 N Y	N	-

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Copper Hydroxide

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

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

A 2.1.1.1.2 Storage stability of residues in animal products

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

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

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

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

A 2.1.2.1.2 Nature of residue in rotational crops

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

A 2.1.2.1.3 Nature of residues in processed commodities

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

A 2.1.2.2 Nature of residues in livestock

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

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Potato

A 2.1.3.1.1 Study

Comments of zRMS:	Study is accepted

Reference:	KCP 8.3.1.1
Report	Determination of the residues of copper hydroxide in/on potato after four applications of Copper hydroxide 50% WP in Northern Europe – Hungary in 2019. G. XXX, 2020, Report No. 034SRHU19R48 – field phase.
Guideline(s):	Commission Regulation (EU) no 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) no 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to provide results from the magnitude of residues of copper hydroxide in/on potato, grown in open field conditions, in order to support the registration of the plant protection product applied according Good Laboratory Practice (GLP).

Four trials were conducted in Hungary in 2019. The field phase was performed in Vép (SRHU19-361-034FR), in Bocfölde (SRHU19-362-034FR), in Kőszeg (SRHU19-363-034FR), in Zalalövő (SRHU19-364-034FR).
Four applications (7 days interval) of the formulated product Copper hydroxide 50% WP were applied at a target rate of 2.4 kg formulated product/ha (1200 g active ingredient/ha) to potato, using conventional sprayer equipment, under open field condition, with the last application done 14 days before commercial harvest.

Specimens (tubers) were collected at 0, 3, 7, and 14 DALA in decline trial and at 14 DALA in harvest trial, frozen and shipped deep frozen to analytical facility of Fertico for residue analysis.

Comments of zRMS:	Study is accepted

Reference:	KCP 8.3.1.2
Report	Quantitative analysis of copper residue in potato in field conditions (Raw Agricultural Commodity) after two application of Copper hydroxide 50% WP. J. XXX, 2020, Report No. PB-2020-06 – analytical phase.
Guideline(s):	SANCO/825/00 rev. 8.1 SANCO/3029/99 rev. 4
Deviations:	No
GLP:	Yes

Acceptability: Yes

The study of copper residue in the potato sample was based on the analysis of total copper content by ICP-MS technique in a sample treated with a.s. and untreated a.s.

Frozen samples were homogenized inside knife mill (steel bowl) with use of liquid nitrogen.

Preparation of Stock Standard Solution

Prepare an intermediate solution of 10 ppm.

In a volumetric flask with a capacity of 100ml add 50 ml of water to half of the flask capacity. Add 10ml of nitric acid and 100 µl of the certified standard (VHG-TCUN-100), respectively, and fill up to the mark with water. Prepare a series of standards for the curve from this solution.

Homogenized samples were weighted (0,4-0,6 g) and put into TFM vessels used for mineralization process. 10 ml of nitric acid was added. Samples were mineralized on the FOOD Programe at Mars 6. FOOD program parameters:

- Stages: 1
- Power: 290 — 1800
- Ramp Time 20:00 minutes
- Hold Time 15:00 minutes
- Temperature: 210
- TempGuard: OFF
- Method Created by: CEM
- Control Style: One Touch
- Sample type: Organic
- Sample preparation notes: 0.5 g (wet weight), 10 mL HNO_3, allow samples to predigest by standing open for minimum 15 minutes before sealing vessels.

Sample after mineralization were transferred into 50 ml single-graduated flasks. If sample were fortified, it was necessary to add aliquot volume of analitycal standard and fill up to the mark with water.

Sample preparated this way was analyzed on ICP-MS.

POTATO samples: untreated (U) no. 4938-4943 and treated (T) no .4944-4953. Portion A was taken for preparation in treated and untreated samples. Analytical samples were prepared for the determination copper content in them by ICP-MS 7800 mass spectrometer. Three test untreated samples (U1, U2, U3), and three treated samples (T1, T2, T3) two fortified samples O1 and O2 (O1 for untreated and O2 for treated). Additional CRM1 was prepared with the tested samples. CRM and fortified samples were preparing the same as other samples. After weighing of samples, calibration standard were added to prepare fortified samples. Method of preparing samples:

- **Weighing**

Samples were mixed and weighed into 150 ml TFM vessels in a weighing room, using a scale Radwag PS 1000.X2 (Laboratory barcode: 33000000053). Weighing 0.400 g - 0.600 g of a homogeneous sample; read the result on the balance with an accuracy of verification scale ± 0.001 g

It is necessary, to add calibration standard after weighing fortified samples.

- **Addition of nitric acid**

To each sample, 10 ml of concentrated nitric acid was added using a 10 ml measuring cylinder. Sample were left for 15 minutes before closing the digestating vessels.

- **Microwave pressure digestion**

Microwave pressure digestion was conducted using Mars 6.0 The *Food* program was chosen in accordance with parameters mentioned in 3.2.1

- **Quantitatively sample transfer**

Digested samples were left 30 minutes in the rotor for cooling. Samples were quantitatively transferred to 50 ml single-graduated flasks and top up to 50 ml with water. Samples were transferred to 14 ml disposable PP tubes. Samples prepared in this way are ready for testing.

Table A 1: Summary of trials

Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (c)	**Growth stage at last treatment or date**	**Portion analyzed**	**Residues (mg/kg)**	**PHI (days)** (d)	**Details on trial** (e)
			g a.s./ ha	**Water (l/ha)**	**g a.s./hl**				**Copper content**		
SRHU19-361-034FR/N-EU/Hungary/2019	Potato/Desiree	26/04/2019 July 2019 08/2019	1299 1208 1300 1183	812 755 813 739	-	17/04/2019 24/07/2019 31/07/2019 07/04/2019	BBCH 69 BBCH 71 BBCH 75 BBCH 85	Tuber	n.d.	14	Analytical phase: PB-2020-06 LOQ: 3.7 mg/kg LOD: 1.1 mg/kg
SRHU19-362-034FR/N-EU/Hungary/2019	Potato/Desiree	18/04/2019 July 2019 082019	1238 1265 1090 1285	774 791 681 803	-	15/07/2019 22/07/2019 29/07/2019 05/08/2019	BBCH 69 BBCH 75 BBCH 81 BBCH 85	Tuber	n.d.	14	Analytical phase: PB-2020-06 LOQ: 3.7 mg/kg LOD: 1.1 mg/kg
SRHU19-363-034FR/N-EU/Hungary/2019	Potato/Agria	03/04/2019 July 2019 08/2019	1296 1267 1180 1263	810 792 738 789		15/07/2019 22/07/2019 29/07/2019 05/08/2019	BBCH 69 BBCH 71 BBCH 81 BBCH 85	Tuber Tuber Tuber Tuber	<LOQ (1.423) n.d. n.d. <LOQ (1.224)	0 3 7 14	Analytical phase: PB-2020-06 LOQ: 3.7 mg/kg LOD: 1.1 mg/kg
SRHU19-364-034FR/N-EU/Hungary/2019	Potato/Agria	20/04/2019 July 2019 08/2019	1116 1184 2303 1214	698 740 815 759		17/04/2019 24/07/2019 31/07/2019 07/04/2019	BBCH 69 BBCH 71 BBCH 75 BBCH 85	Tuber Tuber Tuber Tuber	n.d. n.d. n.d. n.d.	0 3 7 14	Analytical phase: PB-2020-06 LOQ: 3.7 mg/kg LOD: 1.1 mg/kg

A 2.1.3.1.2 Study

Comments of zRMS:	Study is accepted

Reference:	KCP 8.3.1.3
Report	Magnitude of the residue of copper hydroxide in potato (Raw Agricultural Commodity – RAC) grown in open field conditions after four applications of formulated product Copper hydroxide 50% WP – two harvest and two decline curve trials in Northern Europe – Poland (2019). R. XXX, 2020, Report No. D-2019-5 – field phase.
Guideline(s):	Commission Regulation (EU) no 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) no 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

A study on the magnitude of the residue of copper hydroxide in potatoes Raw Agricultural Commodity (RAC) was conducted in Poland following four foliar applications of formulated product Copper hydroxide 50% WP containing 500 g*kg^{-1} of copper hydroxide.

Two harvest trials and two decline curve trials were set up on potatoes in Poland. Trials consisted of one untreated plot U and one treated plot T. Foliar applications of Copper hydroxide 50% WP were performed on the treated plot at the target dose rate of 2,4 kg*ha^{-1} FP (equivalent to 1200 g a.s.*ha^{-1} of copper hydroxide). The target spray of water volume was 500-1000 litres per hectare according to Good Agricultural Practices.

Applications were performed following the target schedule:

- 1st foliar application performed at 35±2 days before normal commercial harvest,
- 2nd foliar application performed at 28±2 days before normal commercial harvest,,
- 3rd foliar application performed at 21±1 days before normal commercial harvest,
- 4rd foliar application performed at 14±1 days before normal commercial harvest.

All applications were conducted at BBCH 15-85.

In HS trials, RAC specimens for analyses (tubers) were collected at normal commercial harvest. In DCS trials, RAC specimens for analysis (tubers) were collected following the target schedule below:

- at 0 days after application just after application,
- at 3±1 days after application (U+T),
- at 7±1 days after application (only T),
- at 14±1 days after application (U+T)

Comments of zRMS:	Study is accepted

Reference:	KCP 8.3.1.4
Report	Quantitative analysis of copper residue in potato in field conditions (Raw Agricultural Commodity) after two applications of Copper hydroxide 50% WP. J. XXX, 2020, Report No. PB-2020-05 – analytical phase.
Guideline(s):	SANCO/825/00 rev. 8.1 SANCO/3029/99 rev. 4
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The study of copper residue in the potato sample was based on the analysis of total copper content by ICP-MS technique in a sample treated with a.s. and untreated a.s.

Frozen samples were homogenized inside knife mill (steel bowl) with use of liquid nitrogen.

Preparation of Stock Standard Solution

Prepare an intermediate solution of 10 ppm.

In a volumetric flask with a capacity of 100ml add 50 ml of water to half of the flask capacity. Add 10ml of nitric acid and 100 µl of the certified standard (VHG-TCUN-100), respectively, and fill up to the mark with water. Prepare a series of standards for the curve from this solution.

Homogenized samples were weighted (0,4-0,6 g) and put into TFM vessels used for mineralization process. 10 ml of nitric acid was added. Samples were mineralized on the FOOD Programe at Mars 6. FOOD program parameters:

- Stages: 1
- Power: 290 — 1800
- Ramp Time 20:00 minutes
- Hold Time 15:00 minutes
- Temperature: 210
- TempGuard: OFF
- Method Created by: CEM
- Control Style: One Touch
- Sample type: Organic
- Sample preparation notes: 0.5 g (wet weight), 10 mL HNO_3, allow samples to predigest by standing open for minimum 15 minutes before sealing vessels.

Sample after mineralization were transferred into 50 ml single-graduated flasks. If sample were fortified, it was necessary to add aliquot volume of analitycal standard and fill up to the mark with water.

Sample preparated this way was analyzed on ICP-MS.

POTATO samples: untreated (U) no. 4656,-4661 and treated (T) no .4662-4671. Portion A was taken for preparation in treated and untreated samples. Analytical samples were prepared for the determination copper content in them by ICP-MS 7800 mass spectrometer. Three test untreated samples (U1, U2, U3), and three treated samples (T1, T2, T3) two fortified samples O1 and O2 (O1 for untreated and O2 for treated). Additional CRM1 was prepared with the tested samples. CRM and fortified samples were preparing the same as other samples. After weighing of samples, calibration standard were added to prepare fortified samples. Method of preparing samples:

- **Weighing**

Samples were mixed and weighed into 150 ml TFM vessels in a weighing room, using a scale Radwag PS 1000.X2 (Laboratory barcode: 33000000053). Weighing 0.400 g - 0.600 g of a homogeneous sample; read the result on the balance with an accuracy of verification scale ± 0.001 g

It is necessary, to add calibration standard after weighing fortified samples.

- **Addition of nitric acid**

To each sample, 10 ml of concentrated nitric acid was added using a 10 ml measuring cylinder. Sample were left for 15 minutes before closing the digestating vessels.

- **Microwave pressure digestion**

Microwave pressure digestion was conducted using Mars 6.0 The *Food* program was chosen in accordance with parameters mentioned in 3.2.1

- **Quantitatively sample transfer**

Digested samples were left 30 minutes in the rotor for cooling. Samples were quantitatively transferred to 50 ml single-graduated flasks and top up to 50 ml with water. Samples were transferred to 14 ml disposable PP tubes. Samples prepared in this way are ready for testing.

Table A 2 Summary of trials

Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (c)	**Growth stage at last treatment or date**	**Portion analyzed**	**Residues (mg/kg)**	**PHI (days)** (d)	**Details on trial** (e)
			g a.s./ ha	**Water (l/ha)**	**g a.s./hl**				**Copper content**		
D-2019-05-F01/N-EU/Poland/2019	Potato/Lord	26/03/2918 24/06- 14/07/2019 21/07/2019	1155 1190 1235 1225	773 797 823 816	-	11/06/2019 17/06/2019 25/06/2019 02/07/2019	BBCH 42 BBCH 43 BBCH 44 BBCH 47	Tuber	n.d.	13	Analytical phase: PB-2020-06 LOQ: 3.7 mg/kg LOD: 1.1 mg/kg
D-2019-05-F02/N-EU/Poland/2019	Potato/Brooke	22/04/2019 28/06- 19/07/2019 15/08/2019	1191 1240 1150 1178	794 826 766 785	-	03/07/2019 11/07/2019 17/07/2019 24/07/2019	BBCH 42 BBCH 43 BBCH 45 BBCH 46	Tuber	n.d.	14	Analytical phase: PB-2020-06 LOQ: 3.7 mg/kg LOD: 1.1 mg/kg
D-2019-05-F03/N-EU/Poland/2019	Potato/Irga	24/04/2019 13/06- 06/07/2019 07/09/2019	1182 1223 1166 1173	788 816 777 782		03/07/2019 11/07/2019 17/07/2019 24.07/2019	BBCH 43 BBCH 44 BBCH 46 BBCH 46	Tuber Tuber Tuber Tuber	n.d. <LOQ (1.212) n.d. n.d.	0 2 7 14	Analytical phase: PB-2020-06 LOQ: 3.7 mg/kg LOD: 1.1 mg/kg
D-2019-05-F04/N-EU/Poland/2019	Potato/Tajfun	18/04/2019 01- 24/07/2019 07/09/2019	1224 1156 1203 1157	816 770 802 772		03/07/2019 11/07/2019 17/07/2019 24/07/2019	BBCH 42 BBCH 43 BBCH 45 BBCH 48	Tuber Tuber Tuber Tuber	n.d. n.d. n.d. n.d.	0 2 7 14	Analytical phase: PB-2020-06 LOQ: 3.7 mg/kg LOD: 1.1 mg/kg

A 2.1.3.2 Apple

A 2.1.3.2.1 Study

Comments of zRMS:	Study is accepted

Reference:	KCP 8.3.2.1
Report	Determination of the residues of copper hydroxide in/on apple after three applications of Copper Hydroxide 50% WP in Northern Europe – Hungary in 2019. G. XXX, 2019, Report No. 034SRHU19R49 – field phase.
Guideline(s):	Commission Regulation (EU) no 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) no 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to provide results from the magnitude of residues of copper hydroxide in/on apple, grown in open field conditions, in order to support the registration of the plant protection product applied according Good Laboratory Practice (GLP).

Four trials were conducted in Hungary in 2019. The field phase was performed in Veszprém (SRHU19-365-034FR), Sótony (SRHU19-366-034FR), Kőszeg (SRHU19-367-034FR) and Sé (SRHU19-368-034FR).

Three applications (10 days interval) of the formulated product Copper hydroxide 50% WP were applied at a target rate of 2.4 kg / ha to apple, using conventional sprayer equipment, under open field condition, with the last application done 21 days before commercial harvest.

Specimens (fruit) were collected at at 0, 3, 7, 14 and 21 DALA (days after last application) in decline trial and at 21 DALA (at normal harvest day) in harvest trial. Frozen and shipped deep frozen to analytical facility.

Comments of zRMS:	Study is accepted

Reference:	KCP 8.3.2.2
Report	Quantitative analysis of copper residue in apple in field conditions (Raw Agricultural Commodity) after two application of Copper hydroxide 50% WP. J. XXX, 2020, Report No. PB-2020-10 – analytical phase.
Guideline(s):	SANCO/825/00 rev. 8.1 SANCO/3029/99 rev. 4
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The study of copper residue in the apple sample was based on the analysis of total copper content by ICP-MS technique in a sample treated with a.s. and untreated a.s.

Frozen samples were homogenized inside knife mill (steel bowl) with use of liquid nitrogen.

Preparation of Stock Standard Solution

Prepare an intermediate solution of 10 ppm.

In a volumetric flask with a capacity of 100ml add 50 ml of water to half of the flask capacity. Add 10ml of nitric acid and 100 µl of the certified standard (VHG-TCUN-100), respectively, and fill up to the mark with water. Prepare a series of standards for the curve from this solution.

Homogenized samples were weighted (0,4-0,6 g) and put into TFM vessels used for mineralization process. 10 ml of nitric acid was added. Samples were mineralized on the FOOD Programe at Mars 6. FOOD program parameters:

- Stages: 1
- Power: 290 — 1800
- Ramp Time 20:00 minutes
- Hold Time 15:00 minutes
- Temperature: 210
- TempGuard: OFF
- Method Created by: CEM
- Control Style: One Touch
- Sample type: Organic
- Sample preparation notes: 0.5 g (wet weight), 10 mL HNO_3, allow samples to predigest by standing open for minimum 15 minutes before sealing vessels.

Sample after mineralization were transferred into 50 ml single-graduated flasks. If sample were fortified, it was necessary to add aliquot volume of analitycal standard and fill up to the mark with water.

Sample preparated this way was analyzed on ICP-MS.

Apple samples: untreated (U) no. 4611, 4612, 4613, 4618, 4620, 4622, and treated (T) no. 4614, 4615, 4616, 4617, 4619, 4621, 4623, 4828, 4829, 4830, 4831, 4832. Portion A was taken for preparation in treated and untreated samples. Analytical samples were prepared for the determination copper content in them by ICP-MS 7800 mass spectrometer. Three test untreated samples (U1, U2, U3), and three treated samples (T1, T2, T3) two fortified samples O1 and O2 (O1 for untreated and O2 for treated). Additional CRM1 was prepared with the tested samples. CRM and fortified samples were preparing the same as other samples. After weighing of samples, calibration standard were added to prepare fortified samples. Method of preparing

- **Weighing**

Samples were mixed and weighed into 150 ml TFM vessels in a weighing room, using a scale Radwag PS 1000.X2 (Laboratory barcode: 33000000053). Weighing 0.400 g - 0.600 g of a homogeneous sample; read the result on the balance with an accuracy of verification scale ± 0.001 g

It is necessary, to add calibration standard after weighing fortified samples.

- **Addition of nitric acid**

To each sample, 10 ml of concentrated nitric acid was added using a 10 ml measuring cylinder. Sample were left for 15 minutes before closing the digestating vessels.

- **Microwave pressure digestion**

Microwave pressure digestion was conducted using Mars 6.0 The *Food* program was chosen in accordance with parameters mentioned in 3.2.1

- **Quantitatively sample transfer**

Digested samples were left 30 minutes in the rotor for cooling. Samples were quantitatively transferred to 50 ml single-graduated flasks and top up to 50 ml with water. Samples were transferred to 14 ml disposable PP tubes. Samples prepared in this way are ready for testing.

Table A 5: Summary of trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treat-ment or date	Portion ana-lyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ha	Water (l/ha)	g a.s./hl				Copper content		
SRHU19-365-034F/N-EU/Hungary/2019	Apple/Jonathan	15/10/2009 04/2019 25/08/2019	1168 1262 1277	779 841 851	-	15/07/2019 25/07/2019 04/08/2019	BBCH 79 BBCH 82 BBCH 83	Fruit	<LOQ (0.17)	21	Analytical phase: PB-2020-06 LOQ: 1.0 mg/kg LOD: 0.25 mg/kg
SRHU19-366-034F/N-EU/Hungary/2019	Apple/Eva	2015 04/2019 25/08/2019	1259 1185 1153	839 790 769	-	15/07/2019 25/07/2019 04/08/2019	BBCH 79 BBCH 82 BBCH 83	Fruit	<LOQ (0.917)	21	Analytical phase: PB-2020-06 LOQ: 1.0 mg/kg LOD: 0.25 mg/kg
SRHU19-367-034F/N-EU/Hungary/2019	Apple/Teliarany	2010 04/2019 25/08/2019	1161 1177 1174	774 784 783		15/07/2019 25/07/2019 04/08/2019	BBCH 79 BBCH 82 BBCH 83	Fruit Fruit Fruit Fruit Fruit	1.341 1.777 <LOQ (0.775) 1.147 1.535	0 3 7 14 21	Analytical phase: PB-2020-06 LOQ: 1.0 mg/kg LOD: 0.25 mg/kg
SRHU19-368-034F/N-EU/Hungary/2019	Apple/Gala	2005 04/2019 25/08/2019	1179 1148 1226	786 765 818		15/07/2019 25/07/2019 04/08/2019	BBCH 79 BBCH 82 BBCH 83	Fruit Fruit Fruit Fruit Fruit	1.081 1.144 1.788 <LOQ (0.724) <LOQ (0.535)	0 3 7 14 21	Analytical phase: PB-2020-06 LOQ: 1.0 mg/kg LOD: 0.25 mg/kg

A 2.1.3.2.2 Study

Comments of zRMS:	Study is accepted

Reference:	KCP 8.3.2.3
Report	Magnitude of the residue of copper hydroxide in pome fruits (Raw Agricultural Commodity – RAC) grown in open field conditions after three applications of formulated product Copper hydroxide 50% WP – two harvest and two decline curve trials in Northern Europe – Poland (2019). R. XXX, 2019, Report No. D-2019-06 – field phase.
Guideline(s):	Commission Regulation (EU) no 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) no 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Reference:	KCP 8.3.2.4
Report	Quantitative analysis of copper residue in apple in field conditions (Raw Agricultural Commodity) after two application of Copper hydroxide 50% WP. O. XXX, 2020, Report No. PB-2020-09 – analytical phase phase.
Guideline(s):	SANCO/825/00, rev. 8.1 and SANCO/3029/99, rev 4
Deviations:	No
GLP:	Yes
Acceptability:	Yes

A study on the magnitude of the residue of copper hydroxide in pome fruits Raw Agricultural Commodity (RAC) was conducted in Poland following three foliar applications of formulated product Copper hydroxide 50% WP containing 500 g*kg^{-1} of copper hydroxide.

Two harvest trials and two decline curve trials were set up on apples in Poland. Trials consisted of one untreated plot U and one treated plot T. Foliar applications of Copper hydroxide 50% WP were performed on the treated plot at the target dose rate of 2,4 kg*ha^{-1} FP (equivalent to 1200 g a.s.*ha^{-1} of copper hydroxide). The target spray of water volume was 800-1000 litres per hectare according to Good Agricultural Practices.

Applications were performed following the target schedule:

- 1st foliar application performed at 10±1 days before application A2,
- 2nd foliar application performed at 10±1 days before application A3,
- 3rd foliar application performed at 21±1 days before normal commercial harvest.

All applications were conducted at BBCH 15-85.

In HS trials, RAC specimens for analyses (fruit) were collected at normal commercial harvest. In DCS trials, RAC specimens for analysis (fruit) were collected following the target schedule below:

- at 0 days after application just after application,
- at 3±1 days after application (U+T),
- at 7±1 days after application (only T),
- at 14±1 days after application (only T),
- at 21±1 days after application (U+T).

Table A 6: Summary of trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Copper content		
D-2019-06-F01/N-EU/Poland/2019	Apple/Cortland	2000 20/04-05/05/2019 04/10/2019	1180 1226 1237	983 1021 1031	-	22/08/2019 02/09/2019 13/09/2019	BBCH 76 BBCH 77 BBCH 81	Fruit	1.185	21	
D-2019-06-F02/N-EU/Poland/2019	Apple/Idared	09/1995 23/04/2019-14/05/2019 18/10/2019	1211 1155 1207	815 770 804	-	05/09/2019 16/09/2019 27/09/2019	BBCH 77 BBCH 79 BBCH 81	Fruit	1.421	22	
D-2019-06-F03/N-EU/Poland/2019	Apple/Red Jonaprince	2014 - 03/10/2019	1156 1256 1239	963 1047 1032		22/08/2019 02/09/2019 13/09/2019	BBCH 77 BBCH 78 BBCH 81	Fruit	1.414 1.380 1.349 <LOQ (0.977) <LOQ (0.920)	0 3 7 14 21	
D-2019-06-F04/N-EU/Poland/2019	Apple/Champion	06/04/2019 12/05/2019 30/09/2019	1173 1142 1170	978 951 975		20/08/2019 30/08/2019 09/09/2019	BBCH 78 BBCH 79 BBCH 81	Fruit	4.798 4.414 3.631 3.112 2.964	0 3 8 14 21	

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

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

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

A 2.1.5.1 Distribution of the residue in peel/pulp

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

A 2.1.5.2 Processing studies on a core set of representative processes

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

A 2.1.6 Magnitude of residues in representative succeeding crops

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

A 2.1.7 Other/Special Studies

No new data were submitted in the framework of this application.
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Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations Copper (all crops) – Tier I

European Food Safety Authority

EFSA PRIMo revision 3.0; 2017/12/11

Copper

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day): **0.15** ARfD (mg/kg bw): **not necessary'**

Source of ADI: Source of ARfD:

Year of evaluation: Year of evaluation:

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 1

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
118%	NL toddler	177.56	11%	Maize/corn	11%	Spinaches	11%	Wheat		118%
81%	GEMS/Food G11	121.30	30%	Soyabeans	10%	Wheat	3%	Coffee beans		81%
79%	GEMS/Food G10	118.97	26%	Soyabeans	11%	Wheat	5%	Lettuces		79%
76%	GEMS/Food G06	113.98	20%	Wheat	10%	Soyabeans	5%	Table grapes		76%
75%	GEMS/Food G07	111.77	14%	Soyabeans	12%	Wheat	8%	Bovine: Liver		75%
73%	NL child	109.53	11%	Wheat	8%	Sugar beet roots	5%	Apples		73%
70%	GEMS/Food G08	104.70	16%	Soyabeans	11%	Wheat	6%	Sunflower seeds		70%
67%	GEMS/Food G15	100.17	14%	Soyabeans	13%	Wheat	7%	Sunflower seeds		67%
64%	FI adult	95.28	52%	Coffee beans	2%	Lettuces	2%	Rye		64%
63%	DE child	94.30	12%	Wheat	11%	Apples	7%	Table grapes		63%
58%	IE adult	87.41	14%	Sheep: Liver	6%	Wheat	4%	Sweet potatoes		58%
53%	FR child 3 15 yr	79.99	13%	Wheat	4%	Milk: Cattle	3%	Sugar beet roots		53%
47%	DK child	71.04	13%	Rye	12%	Wheat	2%	Lettuces		47%
44%	FR toddler 2 3 yr	66.01	8%	Wheat	5%	Milk: Cattle	3%	Apples		44%
44%	ES child	65.40	12%	Wheat	6%	Lettuces	3%	Poultry: Muscle/meat		44%
43%	RO general	65.20	14%	Wheat	8%	Sunflower seeds	3%	Potatoes		43%
39%	IT toddler	58.89	18%	Wheat	4%	Lettuces	4%	Other cereals		39%
39%	NL general	58.29	5%	Wheat	3%	Sugar beet roots	3%	Coffee beans		39%
38%	UK infant	57.04	7%	Wheat	6%	Milk: Cattle	5%	Bovine: Liver		38%
37%	UK toddler	56.22	11%	Wheat	4%	Beans	3%	Milk: Cattle		37%
36%	DE women 14-50 yr	53.84	6%	Wheat	4%	Sugar beet roots	4%	Coffee beans		36%
35%	DE general	53.21	5%	Wheat	4%	Coffee beans	4%	Sugar beet roots		35%
35%	PT general	53.19	11%	Wheat	5%	Potatoes	4%	Sunflower seeds		35%
35%	SE general	52.00	9%	Wheat	6%	Lettuces	4%	Potatoes		35%
32%	ES adult	47.83	8%	Lettuces	6%	Wheat	1%	Poultry: Muscle/meat		32%
32%	IT adult	47.51	11%	Wheat	6%	Lettuces	2%	Other lettuce and other salad plan		32%
29%	FR adult	43.25	6%	Wheat	4%	Coffee beans	2%	Other lettuce and other salad plan		29%
23%	FI 3 yr	33.80	4%	Potatoes	3%	Wheat	2%	Oat		23%
22%	FR infant	32.64	4%	Spinaches	3%	Milk: Cattle	2%	Wheat		22%
19%	UK vegetarian	28.91	6%	Wheat	2%	Lettuces	2%	Beans		19%
19%	FI 6 yr	28.82	3%	Potatoes	3%	Wheat	1%	Rye		19%
19%	LT adult	27.90	3%	Wheat	3%	Potatoes	3%	Rye		19%
17%	UK adult	26.20	5%	Wheat	2%	Lettuces	1%	Potatoes		17%
16%	DK adult	23.33	3%	Wheat	1%	Lettuces	1%	Rye		16%
11%	PL general	15.98	3%	Potatoes	2%	Apples	2%	Table grapes		11%
7%	IE child	10.70	3%	Wheat	0.6%	Milk: Cattle	0.5%	Potatoes		7%

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 118.4 % of the ADI.
For 1 diet(s) the ADI is exceeded.

A 3.2 TMDI calculations Copper (all crops) – Tier II

European Food Safety Authority

EFSA PRIMo revision 3.0; 2017/12/11

Copper

LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	**0.15**	ARfD (mg/kg bw):	**not necessary'**
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
92%	NL toddler	137.78	11%	Maize/corn	11%	Wheat	10%	Milk: Cattle		92%
73%	GEMS/Food G11	109.52	30%	Soyabeans	10%	Wheat	3%	Coffee beans		73%
71%	GEMS/Food G10	106.11	26%	Soyabeans	11%	Wheat	3%	Poultry: Muscle/meat		71%
68%	GEMS/Food G06	102.52	20%	Wheat	10%	Soyabeans	5%	Tomatoes		68%
67%	GEMS/Food G07	100.93	14%	Soyabeans	12%	Wheat	8%	Bovine: Liver		67%
62%	GEMS/Food G08	93.51	16%	Soyabeans	11%	Wheat	6%	Sunflower seeds		62%
62%	GEMS/Food G15	92.99	14%	Soyabeans	13%	Wheat	7%	Sunflower seeds		62%
60%	FI adult	90.43	52%	Coffee beans	2%	Rye	0.9%	Wheat		60%
59%	NL child	88.47	11%	Wheat	8%	Sugar beet roots	5%	Sunflower seeds		59%
53%	IE adult	79.77	14%	Sheep: Liver	6%	Wheat	4%	Sweet potatoes		53%
47%	FR child 3 15 yr	70.92	13%	Wheat	4%	Milk: Cattle	3%	Sugar beet roots		47%
45%	DE child	68.20	12%	Wheat	4%	Apples	3%	Milk: Cattle		45%
42%	DK child	63.53	13%	Rye	12%	Wheat	2%	Milk: Cattle		42%
41%	RO general	61.14	14%	Wheat	8%	Sunflower seeds	3%	Tomatoes		41%
39%	FR toddler 2 3 yr	58.26	8%	Wheat	5%	Milk: Cattle	3%	Sugar beet roots		39%
36%	ES child	53.29	12%	Wheat	3%	Poultry: Muscle/meat	2%	Milk: Cattle		36%
36%	UK infant	53.26	7%	Wheat	6%	Milk: Cattle	5%	Bovine: Liver		36%
34%	UK toddler	50.53	11%	Wheat	4%	Beans	3%	Milk: Cattle		34%
32%	IT toddler	47.50	18%	Wheat	4%	Other cereals	2%	Tomatoes		32%
32%	NL general	47.47	5%	Wheat	3%	Sugar beet roots	3%	Coffee beans		32%
31%	PT general	45.96	11%	Wheat	4%	Sunflower seeds	3%	Potatoes		31%
31%	DE general	45.76	5%	Wheat	4%	Coffee beans	4%	Sugar beet roots		31%
30%	DE women 14-50 yr	45.55	6%	Wheat	4%	Sugar beet roots	4%	Coffee beans		30%
26%	SE general	39.36	9%	Wheat	3%	Bovine: Muscle/meat	2%	Potatoes		26%
25%	FR adult	36.84	6%	Wheat	4%	Coffee beans	1%	Sunflower seeds		25%
23%	ES adult	34.14	6%	Wheat	1%	Poultry: Muscle/meat	1%	Barley		23%
22%	IT adult	32.56	11%	Wheat	2%	Other cereals	2%	Tomatoes		22%
18%	FI 3 yr	26.89	3%	Wheat	3%	Potatoes	2%	Oat		18%
16%	FR infant	24.45	3%	Milk: Cattle	2%	Wheat	2%	Leeks		16%
16%	UK vegetarian	23.66	6%	Wheat	2%	Beans	0.8%	Tomatoes		16%
16%	LT adult	23.58	3%	Wheat	3%	Rye	2%	Potatoes		16%
15%	FI 6 yr	22.29	3%	Wheat	2%	Potatoes	1%	Rye		15%
15%	UK adult	22.12	5%	Wheat	1%	Beans	1.0%	Poultry: Muscle/meat		15%
12%	DK adult	18.68	3%	Wheat	1%	Rye	0.8%	Milk: Cattle		12%
7%	PL general	10.52	2%	Potatoes	1%	Tomatoes	0.7%	Apples		7%
6%	IE child	9.52	3%	Wheat	0.6%	Milk: Cattle	0.5%	Rice		6%

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

A 3.3 TMDI calculations Copper (all crops) – Maize consumption refinement for "NL Toddler" Diet

European Food Safety Authority

EFSA PRIMo revision 3.0; 2017/12/11

Copper			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	0.15	ARfD (mg/kg bw):	not necessary'
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
81%	NL toddler	121.54	11%	Wheat	10%	Milk: Cattle	8%	Bovine: Liver		81%
73%	GEMS/Food G11	109.52	30%	Soyabeans	10%	Wheat	3%	Coffee beans		73%
71%	GEMS/Food G10	106.11	26%	Soyabeans	11%	Wheat	3%	Poultry: Muscle/meat		71%
68%	GEMS/Food G06	102.52	20%	Wheat	10%	Soyabeans	5%	Tomatoes		68%
67%	GEMS/Food G07	100.93	14%	Soyabeans	12%	Wheat	8%	Bovine: Liver		67%
62%	GEMS/Food G08	93.51	16%	Soyabeans	11%	Wheat	6%	Sunflower seeds		62%
62%	GEMS/Food G15	92.99	14%	Soyabeans	13%	Wheat	7%	Sunflower seeds		62%
60%	FI adult	90.43	52%	Coffee beans	2%	Rye	0.9%	Wheat		60%
59%	NL child	88.47	11%	Wheat	8%	Sugar beet roots	5%	Sunflower seeds		59%
53%	IE adult	79.77	14%	Sheep: Liver	6%	Wheat	4%	Sweet potatoes		53%
47%	FR child 3 15 yr	70.92	13%	Wheat	4%	Milk: Cattle	3%	Sugar beet roots		47%
45%	DE child	68.20	12%	Wheat	4%	Apples	3%	Milk: Cattle		45%
42%	DK child	63.53	13%	Rye	12%	Wheat	2%	Milk: Cattle		42%
41%	RO general	61.14	14%	Wheat	8%	Sunflower seeds	3%	Tomatoes		41%
39%	FR toddler 2 3 yr	58.26	8%	Wheat	5%	Milk: Cattle	3%	Sugar beet roots		39%
36%	ES child	53.29	12%	Wheat	3%	Poultry: Muscle/meat	2%	Milk: Cattle		36%
36%	UK infant	53.26	7%	Wheat	6%	Milk: Cattle	5%	Bovine: Liver		36%
34%	UK toddler	50.53	11%	Wheat	4%	Beans	3%	Milk: Cattle		34%
32%	IT toddler	47.50	18%	Wheat	4%	Other cereals	2%	Tomatoes		32%
32%	NL general	47.47	5%	Wheat	3%	Sugar beet roots	3%	Coffee beans		32%
31%	PT general	45.96	11%	Wheat	4%	Sunflower seeds	3%	Potatoes		31%
31%	DE general	45.76	5%	Wheat	4%	Coffee beans	4%	Sugar beet roots		31%
30%	DE women 14-50 yr	45.55	6%	Wheat	4%	Sugar beet roots	4%	Coffee beans		30%
26%	SE general	39.36	9%	Wheat	3%	Bovine: Muscle/meat	2%	Potatoes		26%
25%	FR adult	36.84	6%	Wheat	4%	Coffee beans	1%	Sunflower seeds		25%
23%	ES adult	34.14	6%	Wheat	1%	Poultry: Muscle/meat	1%	Barley		23%
22%	IT adult	32.56	11%	Wheat	2%	Other cereals	2%	Tomatoes		22%
18%	FI 3 yr	26.89	3%	Wheat	3%	Potatoes	2%	Oat		18%
16%	FR infant	24.45	3%	Milk: Cattle	2%	Wheat	2%	Leeks		16%
16%	UK vegetarian	23.66	6%	Wheat	2%	Beans	0.8%	Tomatoes		16%
16%	LT adult	23.58	3%	Wheat	3%	Rye	2%	Potatoes		16%
15%	FI 6 yr	22.29	3%	Wheat	2%	Potatoes	1%	Rye		15%
15%	UK adult	22.12	5%	Wheat	1%	Beans	1.0%	Poultry: Muscle/meat		15%
12%	DK adult	18.68	3%	Wheat	1%	Rye	0.8%	Milk: Cattle		12%
7%	PL general	10.52	2%	Potatoes	1%	Tomatoes	0.7%	Apples		7%
6%	IE child	9.52	3%	Wheat	0.6%	Milk: Cattle	0.5%	Rice		6%

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

IEDI calculations

Not required as the TMDI does not exceed the ADI

zRMS comment

TMDI calculations Copper (all crops) – Tier I PRIMo rev.31

Input values: *EFSA Journal 2018;16(3):5212; Table D.2. Consumer risk assessment*

TMDI (% ADI) according to EFSA PRIMo rev.3.1 max. 165% (NL Toddler Diet); Highest contributor: 19 % maize corn.
Accepted uses:
Wine grapes: 4.23%, PT general
Potato: 7.11%, PT general
Pome fruit:
Apples: 11.73% DE child
Pears: 4.08% NL toddler
Quinces: 0.03% RO general
Medlar: 0.08% GEMS/Food G15
Loquats/Japanese medlars: 0.06% GEMS/Food G10

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Copper compounds

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:	Reg. (EU)	Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 1

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
165%	NL toddler	247,75	19%	Maize/corn	17%	Spinaches	12%	Oil palm kernels		
98%	GEMS/Food G06	147,18	20%	Wheat	10%	Soyabeans	6%	Table grapes		
98%	NL child	147,17	16%	Oil palm fruits	11%	Wheat	7%	Sugar beet roots		
96%	GEMS/Food G11	143,52	30%	Soyabeans	10%	Wheat	5%	Potatoes		
95%	GEMS/Food G10	142,76	26%	Soyabeans	11%	Wheat	7%	Lettuces		
90%	GEMS/Food G07	135,20	14%	Soyabeans	12%	Wheat	8%	Bovine: Liver		
84%	GEMS/Food G08	125,33	16%	Soyabeans	11%	Wheat	6%	Sunflower seeds		
79%	GEMS/Food G15	118,26	14%	Soyabeans	13%	Wheat	7%	Sunflower seeds		
77%	DE child	115,59	12%	Apples	12%	Wheat	8%	Table grapes		
75%	FI adult	112,54	61%	Coffee beans	3%	Lettuces	2%	Rye		
72%	IE adult	107,38	14%	Sheep: Liver	6%	Wheat	3%	Sweet potatoes		
57%	FR child 3 15 yr	85,14	13%	Wheat	4%	Milk: Cattle	3%	Sugar beet roots		
56%	NL general	83,85	9%	Oil palm fruits	5%	Wheat	4%	Spinaches		
56%	DK child	83,61	15%	Rye	12%	Wheat	3%	Lettuces		
54%	ES child	80,60	12%	Wheat	10%	Lettuces	3%	Poultry: Muscle/meat		
52%	RO general	77,96	14%	Wheat	8%	Sunflower seeds	5%	Potatoes		
49%	FR toddler 2 3 yr	72,87	9%	Wheat	5%	Milk: Cattle	4%	Spinaches		
45%	PT general	67,63	11%	Wheat	7%	Potatoes	4%	Wine grapes		
45%	SE general	66,77	9%	Lettuces	9%	Wheat	6%	Potatoes		
44%	DE women 14-50 yr	65,30	6%	Wheat	5%	Coffee beans	4%	Sugar beet roots		
43%	UK infant	64,88	7%	Wheat	6%	Milk: Cattle	5%	Bovine: Liver		
43%	DE general	64,70	5%	Wheat	5%	Coffee beans	4%	Sugar beet roots		
42%	ES adult	63,39	12%	Lettuces	6%	Wheat	2%	Chards/beet leaves		
42%	UK toddler	63,32	11%	Wheat	5%	Potatoes	4%	Beans		
40%	IT toddler	59,67	18%	Wheat	7%	Lettuces	2%	Tomatoes		
35%	FR adult	52,71	6%	Wheat	4%	Coffee beans	4%	Wine grapes		
35%	IT adult	52,20	11%	Wheat	9%	Lettuces	2%	Spinaches		
29%	FI 3 yr	43,32	6%	Potatoes	3%	Wheat	2%	Rye		
28%	FR infant	41,47	6%	Spinaches	3%	Milk: Cattle	3%	Potatoes		
26%	UK vegetarian	38,49	6%	Wheat	3%	Lettuces	2%	Potatoes		
25%	FI 6 yr	37,06	5%	Potatoes	3%	Wheat	2%	Lettuces		
24%	UK adult	35,50	5%	Wheat	3%	Lettuces	2%	Potatoes		
22%	LT adult	33,15	4%	Potatoes	3%	Rye	3%	Wheat		
20%	DK adult	30,66	3%	Wheat	2%	Lettuces	2%	Potatoes		
14%	PL general	21,02	5%	Potatoes	2%	Apples	2%	Table grapes		
8%	IE child	12,29	3%	Wheat	0,8%	Rice	0,8%	Potatoes		

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 165,2 % of the ADI.
For 1 diet(s) the ADI is exceeded.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

Not needed.